

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

SOLMETEX, LLC,	)	Case No. 1:24-cv-00954-RJJ-MV
	)	
	)	Hon. Robert J. Jonker
Solmetex, Counter-Defendant	)	Hon. Judge Maarten Vermaat, Magistrate
	)	
v.	)	
	)	
	)	
ASCENTCARE DENTAL PRODUCTS,	)	
INC.,	)	
	)	
	)	
Defendant, Counter-Solmetex.	)	

**DECLARATION OF DR. I-YEU (“STEPHEN”) SHEN IN SUPPORT OF
DEFENDANT’S OPENING CLAIM CONSTRUCTION BRIEF**

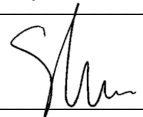
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I, Dr. I-Yeu (“Stephen”) Shen, make this declaration as an independent expert retained by Defendant Ascentcare Dental Products, Inc. (“Ascentcare”) in its lawsuit against Plaintiff Solmetex, LLC (“Solmetex”) to provide my expert opinion as to how a Person Having Ordinary Skill in the Art (“PHOSITA”) would understand certain terms the parties have identified as of the filing date of the applicable patent. I make this declaration either from my own personal knowledge, from documents produced by the parties, from the files of Miller Johnson kept in the ordinary course of business, or from publicly available documents, with which I am familiar, as should be apparent from the context of my statements. I declare under penalty of perjury under the laws of the United States of America that the following is true and correct.

Dated: September 16, 2025



Dr. I-Yeu (“Stephen”) Shen

I. BACKGROUND AND QUALIFICATIONS

1. My qualifications generally are set forth in my Curriculum Vitae, which is attached as **Appendix A**. Appendix A also includes a list of the publications I have authored and a list of the other cases in which I have testified during the last four years. I have extensive experience in this area as evidenced in my CV. I highlight some of this experience below.

2. I have done research and development in the areas of data storage systems, precision machines, sensors, actuators, and medical/dental devices for more than 40 years in the capacity as a scholar, professor, reviewer, author, editor, speaker, conference chair, professional community leader, consultant, inventor, mentor, advisory board member, and entrepreneur. Since I have broad expertise, I will only explain below my experience and qualification relevant to dental devices and equipment, which is the core of the dispute I address below.

3. I received my PhD in Mechanical Engineering in 1991 from the University of California, Berkeley. I was an Assistant Professor in the Department of Engineering Mechanics at the University of Nebraska-Lincoln from 1991 to 1993. I joined the University of Washington in 1993 as an Assistant Professor. I am currently a Professor in Mechanical Engineering at the University of Washington.

4. I have conducted research and development on dental equipment and devices since 2015. My research and development experience encompasses common devices used in general dentistry (e.g., handpieces and ultrasound scalers) to specialized devices in implant dentistry (e.g., implant stability analyzers).

5. Starting in 2015, I have conducted research with a group of professors, dentists, students, and researchers from the School of Dentistry at the University of Washington to evaluate osseointegration between an implant and its surrounding bone by measuring stability (i.e., immobility) of the implant. A dental implant stability analyzer with high precision and accuracy was conceptualized. Simulations were performed, prototypes were made, and calibrated tests were conducted to prove the concept. This research effort led to 5 papers published in peer-reviewed archival journals as well as 2 U.S. patents and 4 international patents. Three of the five papers were published in a prestigious dentistry journal, while other two papers were published in reputable engineering journals.

6. In 2021, I spun off the research from the University of Washington to form a start-up company Quiver Dental, Inc., which is registered in the State of Delaware as a C-Corp. The mission of Quiver Dental, Inc. is to commercialize the implant stability analyzer and bring it to the market in a timely manner. I am currently serving as the Executive Chairman of Quiver Dental, Inc.

7. From 2016 to 2020, I was also a consultant to Nakanishi Inc. (NSK), Japan. NSK is a leading global company focusing on dental equipment and devices, with products including handpieces (e.g., air turbines and contra-angles), oral hygiene (e.g., ultrasonic scalers and lubrication systems), dental lab equipment (e.g., micromotors), endodontics, and surgical equipment (e.g., dental implant stability analyzer and ultrasonic scalpels). During my consultancy, I went to NSK's research center at Kanuma, Japan every quarter to advise its engineers to improve its products. I reported directly to the CEO and CTO of NSK.

II. SUMMARY OF OPINIONS

8. I understand that Solmetex currently asserts seven utility patents: 11,589,969 ("the '969 Patent"), 11,589,970 ("the '970 Patent"), 11,744,686 ("the '686 Patent"), 11,826,217 ("the '217 Patent"), 12,011,329 ("the '329 Patent"), 12,167,948 ("the '948 Patent"), and 12,290,418 ("the '418 Patent"). I refer to these patents collectively as the "Asserted Patents."

9. The '969 Patent, the '970 Patent, the '686 Patent, the '329 Patent, and the '418 Patent are related. Each patent lists two inventors: Tam Thanh Pham and Thien Nguyen. The '969 Patent, the '970 Patent, the '686 Patent, the '329 Patent, and the '418 Patent are all continuations applications claiming priority to U.S. Application No. 14/100,323, now U.S. Patent No. 8,911,232, which is not asserted in the case. Each of these patents shares a specification and relates to a dental isolation mouthpiece with enclosing sidewalls. I refer to these patents as the "First Family". I note that the First Family all have similar specifications. I understand the parties identified various terms for construction from the First Family, which I discuss below.

10. The '217 Patent and the '948 Patent are also related to one another. Each one lists four inventors: Tam Thanh Pham, Thien Nguyen, Ethan Nguyen, and Lauren Nguyen. The '217 Patent and the '948 Patent both claim priority to U.S. Provisional Application No. 62/846,353, and the '948 Patent is a continuation of the '217 Patent. Each of these patents shares a specification

and relates to a dental isolation mouthpiece with two intervening sidewalls on each side. I refer to these patents as the “Second Family”. I understand the parties identified various terms for construction from the Second Family, which I discuss below.

11. I have been asked to review the terms the parties have identified as requiring construction at this stage of the litigation, the construction Ascentcare proposes, the claims, specifications, and prosecution histories of the Asserted Patents, and the additional evidence Ascentcare has identified as supporting its constructions. It is my opinion the constructions Defendant proposes are supported by the claims and intrinsic evidence, as well as my knowledge and experience as a person having ordinary skill in the art (“PHOSITA”). In contrast, the implied constructions Solmetex proposes based on its infringement contentions exceed the boundaries of the specification and are incorrect.

12. I note that Ascentcare also filed several petitions for *Inter Partes* Review, and those petitions were supported by Dr. Brian P. Black. He separately authored several declarations in support of Defendant Ascentcare’s petitions for *Inter Partes* Review of the Asserted Patents. In these declarations, he opined the “plain and ordinary meaning” of the patent terms was sufficient for purposes of the petition. For example, in his declaration supporting *Inter Partes* Review of the ’969 Patent, he stated:

I believe that all terms, *for the purposes of inter partes review*, can be given *their plain and ordinary meaning in view of the specification*. Also, to the extent there is any dispute regarding claim scope, *I am applying Patent Owner’s implied construction in view of the infringement contentions supplied*. To the extent that the parties have disputes as to claim interpretation, they are irrelevant to the validity of the ’969 Patent because it is my opinion that all of the claims

are clearly invalid as anticipated or obvious based on the prior art I have considered and my experience in the dental isolation mouthpiece field. In Ground 1, applying my patent to claim 19, I apply all of Patent Owner's implied claim constructions from their infringement contentions. For example, while I do not agree that significantly different sized walls can be "corresponding" under the claim language because walls of differing size would not be able to form an acceptable connecting wall that connects the "corresponding edges", I nevertheless apply Patent Owner's implied construction here. I note that Patent Owner asserts that Petitioner's device, which has a much larger posterior wall than the anterior wall is "corresponding". EX1011, p. 5. While I do not agree with this construction, I apply it in Ground 1 to show that Patent Owner's constructions result in invalidity of at least claim 19. The same can be said of terms like "end", "edge", and "side". Patent Owner seems to conflate these words, despite using different terminology to define their invention. EX1011, p. 7. The same is true of "connecting wall". *Id.* Importantly, Ground 2 shows invalidity of '969 Patent in view of either Petitioner's or Patent Owner's construction. So, again, claim construction is not an issue the Board must resolve to find invalidity.

SOLMETEX_0011389-90, ¶¶ 52-55 (emphasis added).

13. This statement—or similar statement in the other declarations he authored in support of Ascentcare's petitions for *Inter Partes* Review—does not mean it is my opinion that the terms the parties have identified in the district court litigation do not need construction. Rather, as he expressly stated in the quoted text above, it was Dr. Black's opinion that the Board need not

construe the claims because the claims are invalid under either party's construction. In other words, regardless of whether the USPTO Patent Trial and Appeal Board accepts Solmetex's construction or adopts the construction I, and Ascentcare, propose herein—the patents are invalid as anticipated and/or rendered obvious because the prior art identified in the petitions reads on either interpretation. To be clear, I am not opining the terms should be given different meanings for purposes of invalidity than infringement.

14. In this litigation, however, we are concerned with more than the question of whether the Asserted Patents are invalid as obvious and/or anticipated. We must also consider questions of infringement, as well as invalidity under the doctrines of written description and indefiniteness, legal considerations that are expressly excluded from *inter partes* review challenges. Here, properly construing the claim terms greatly matters. For example, Solmetex contends the “third wall” encompasses a central spine, despite differentiating spines during prosecution. SOLMETEX_0000985. The specification of the First Family, however, describes only sidewalls that connect edges of the anterior and posterior walls as supporting the recited “third wall.” See SOLMETEX_0001219. Thus, if the Court construes the term “third wall” to be broad enough to include a central spine, as advocated by Solmetex (Solmetex Infringement Contentions, Appendix 10, p. 10-10), the parties must address whether the term is invalid because it lacks sufficient written description. This was not at issue in the petitions for *Inter Partes* Review.

15. Moreover, Dr. Black correctly noted that the terms should be given their plain and ordinary meaning *in view of the specification*, which I have been informed by counsel is the correct standard for claim construction. The specification simply does not support the constructions implied by some of Solmetex's infringement contentions. For example, Solmetex points to a bite block on the VacuLUX mouthpiece as the claimed “connecting wall” that connects an “edge” of

an anterior wall to a corresponding edge of the superior wall (Solmetex Infringement Contentions, Appendix 2, p. 2-9), but the specification does not support an integral mouth prop. Instead, the specification only describes a *detachable* mouth prop. '970 Patent, 5:48-50. A mouth prop cannot be both detachable and a permanent wall that connects edges of the anterior and posterior wall, particularly for an injection molded silicone mouthpiece. Thus, the specification does not support the position taken by Solmetex in asserting infringement, and Solmetex's broad construction would violate the written description requirement, rendering the claims invalid.

16. Further still, the parties clearly have a dispute over claim scope over simpler terms like "a main body portion" and "interior surface". As an example, the claims and the specification clearly delineate between the main body portion, the cheek retractor portion, the suction connector portion, and the mouth prop. The claims specify that the "connecting wall..." is part of the main body portion. Yet, as discussed above, Solmetex points to the mouth prop, a separate, detachable component from the main body, as the claimed "connecting wall". Here, Ascentcare, correctly, proposes that a bite block cannot be part of the recited "main body portion", while Solmetex, incorrectly, contends it can. So, there is a clear dispute over claim scope.

III. MATERIALS CONSIDERED

17. In forming my opinions below, I have considered and relied upon the use of the identified terms in the context of the claims, their use in the specification, and the prosecution history. Secondly, I have considered additional information, such as dictionary definitions. In each instance wherein I rely on this additional information, I have identified the information in the paragraphs below. In forming my opinions, I have examined these materials from the perspective of a PHOSITA, which I consider myself.

Materials Considered	
U.S. Patent No. 11,589,969 ("the '969 Patent")	U.S. Patent No. 8,911,232 ("the '232 Patent")

	Patent”)
U.S. Patent No. 11,589,970 (“the ’970 Patent”)	U.S. Patent No. 9,788,924 (“the ’924 Patent”)
U.S. Patent No. 11,744,686 (“the ’686 Patent”)	U.S. Patent No. 11,576,764 (“the ’764 Patent”)
U.S. Patent No. 11,826,217 (“the ’217 Patent”)	Prosecution History of the ’232 Patent
U.S. Patent No. 12,011,329 (“the ’329 Patent”)	Prosecution History of the ’924 Patent
U.S. Patent No. 12,167,948 (“the ’948 Patent”)	Prosecution History of the ’764 Patent
U.S. Patent No. 12,290,418 (“the ’418 Patent”)	Expert Declaration of Dr. Brian P. Black supporting <i>Inter Partes Review</i> Petition of the ’969 Patent
Prosecution History of the ’969 Patent	Solmetex’s Proposed Terms for Construction
Prosecution History of the ’970 Patent	Ascentcare’s Proposed Terms for Construction
Prosecution History of the ’686 Patent	Solmetex’s Initial Infringement Contentions
Prosecution History of the ’217 Patent	Korean Patent No. 10-1082826 (“Park”)
Prosecution History of the ’329 Patent	Isolite Product
Prosecution History of the ’948 Patent	First VacuLUX mouthpiece product
Prosecution History of the ’418 Patent	Second VacuLUX mouthpiece product
U.S. Patent No. 6,974,321 (“Hirsch”)	Solmetex’s Autoclavable Product
U.S. Patent No. 8,029,280 (“Black”)	https://solmetex.com/product/autoclavable-mouthpiece/ .
U.S. Patent No. 9,532,858 (“Hirsch2”)	Solmetex’s Single Use mouthpiece product
U.S. Patent No. 4,024,642 (“Zorovich”)	European Patent No. EP3184076
U.S. Patent No. 3,802,081 to Rogers (“Rogers”)	Prosecution History of EP3184076
Australian Patent No. AU2014202637B2	European Patent No. EP2903557B1
Prosecution History of Prosecution History of AU201600275A1	Prosecution History of EP2903557B1
Brazilian Patent No. BR112014011637B1	Canadian Patent No. CA2851861C
Canadian Patent No. CA2919142C	Chinese Patent No. CN105578986B
Spanish Patent No. ES2622169T3	Japanese Patent No. JP5961328B1
Japanese Patent No. JP6349350B2	Korean Patent No. KR101730509B1
Mexican Patent No. MX354381B	New Zealand Patent No. NZ718848A
Philippines Patent No. PH12016500682B1	Russian Patent No. RU2659012C1
PCT Publication No. WO2015088577A1	Prosecution History of CA2919142C
Prosecution History of CA2919142C	

IV. LEGAL STANDARDS

18. I am not an attorney and will not offer opinions on the law. I have been informed by counsel of at least some of the legal standards for claim construction, identified below, which I have employed in forming my opinions that are recited in this declaration.

19. I have been informed by counsel that infringement is a two-step inquiry: first the meaning of the terms and scope of the patent must be determined, and only then can a factfinder apply the construed claims to the accused device or system. Counsel has also explained to me that the objective in claim construction is to determine what a given claim term would mean to a person of ordinary skill in the field at the time of the patent's earliest priority date. I have also been informed that, if a claim term has a commonly understood meaning to those in the field, then that plain meaning is how the claim term should be construed in the absence of evidence to the contrary.

20. I have been informed by counsel that evidence to the contrary may be either intrinsic evidence (evidence contained within the prosecution history or the patent itself) or extrinsic evidence (everything else, such as dictionary definitions). I have been informed that the strongest evidence of a claim term's meaning is the words of the claim itself, followed by any definition or explanation given in the patent's specification, followed by any definition or explanation given in the patent's prosecution history. I have been informed that other claims, either asserted or unasserted, can also be valuable sources for claim construction. For example, differences among claims can be a useful guide in understanding a claim term's meaning.

21. I have been informed by counsel that extrinsic evidence is evidence from outside the patent's prosecution history, which may include expert testimony, other literature defining the term or terms, and the like. I have been informed by counsel that dictionary definitions are also extrinsic evidence, although they may be used to inform what the plain and ordinary meaning of a claim term is.

22. I have been informed by counsel that a continuation application may not add new matter not disclosed in the original specification. I have also been informed by counsel that disclosure of a species in a parent application cannot always provide adequate written description

support for claims to the genus in a child application.

23. I have been informed by counsel that a patent specification must conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Solmetex regards as its invention. To be definite, the boundaries of the claim, as construed by the court, must inform with “reasonable certainty” a PHOSITA about the scope of the invention, based on the language of the claim, the specification, and the prosecution history, as well as the PHOSITA’s knowledge of the relevant field of art. If the meaning of a claim is discernable, even where reasonable persons may disagree, the claim is sufficiently clear to be definite. I have been advised that it is among the duties of a Patent Examiner at the U.S. Patent and Trademark Office to examine the claims of patent applications for compliance with the requirement of definiteness

V. PERSON OF ORDINARY SKILL IN THE ART

24. As noted above, I have reviewed the Asserted Patents, their prosecution history, and the other materials identified in the Materials Considered from the perspective of a PHOSITA.

25. I have been informed that the following five factors inform the analysis for determining the level of ordinary skill in the art: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. I apply these factors in the section below in providing my opinion as to the level of one having ordinary skill in the art.

26. I reviewed and agree with Dr. Black’s analysis in paragraphs 41-50 of his declaration supporting the ’969 IPR petition. As such, I adopt his analysis herein. SOLMETEX_0011385-89.

27. Using these factors, it is my opinion that a PHOSITA during the time of the filing of the patent applications (March 2002 being the filing of the earliest application) would be a

person having at least a B.S. degree in mechanical engineering or a related field or a dental degree, with at least two (2) years' experience designing dental apparatuses. If the person has a higher level of education, such as a Masters' degree, less work experience could be acceptable, and vice versa. It is my opinion that a PHOSITA would be the same for each of the Asserted Patents.

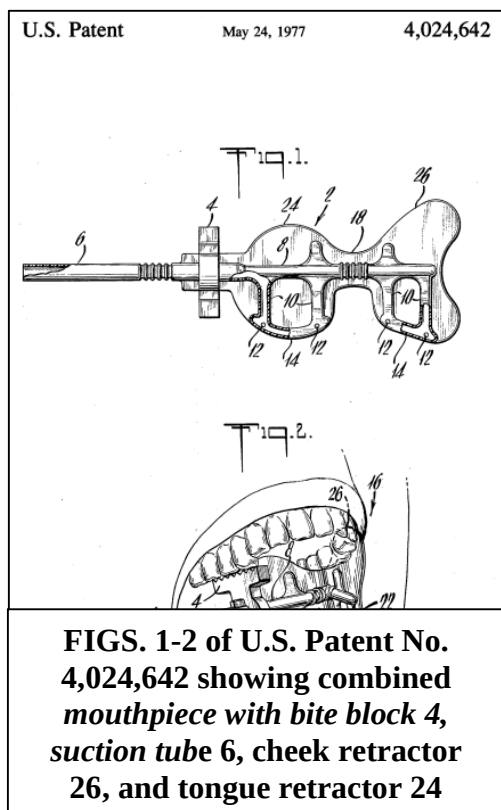
28. I have knowledge relevant to what a person having ordinary skill in the art at the time of the invention would understand and do. In late 2012, at the priority date of the First Family, which have the earliest priority date of any of the Asserted Patents, I had more than 20 years of experience in this field and was a PHOSITA.

VI. THE FIRST FAMILY

29. I understand that the parties have identified the several terms for construction, which I analyze individually below.

a. Overview of the First Family

30. As discussed above, the specifications of the '969 Patent, the '970 Patent, the '686

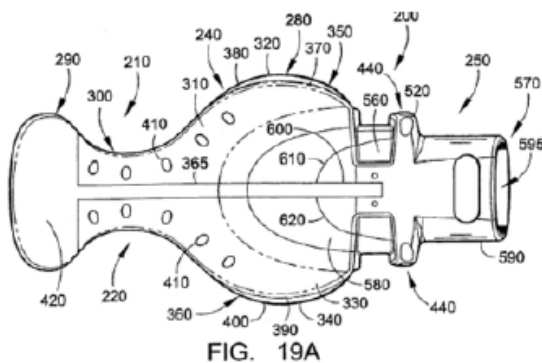


Patent, the '329 Patent, and the '418 Patent are similar. Thus, for the sake of simplicity, I cite only to the '970 Patent in this section, unless otherwise noted.

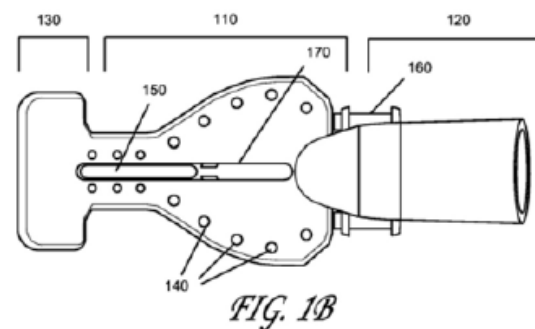
31. The First Family is directed to “a mouthpiece that may be attached to a high-suction dental adapter for the purposes of assisting the dental staff during dental procedures through chair-side, hands-free suction, and isolation.” '970 Patent, 1:45-49. The First Family explains that before isolation mouthpieces, which were first disclosed in 1977 by Dan Zorovich of Johnson and Johnson (U.S. Patent No. 4,024,642, see left,

SOLMETEX_0011864-67), dental treatment involved “many different types of dental equipment and materials” including “an intraoral mirror, a bite block, a slow speed suction ejector, a high speed suction ejector, gauzes, cotton rolls, and dry angles.” ’970 Patent, 1:25-30. A PHOSITA would know that isolation mouthpieces were well-known by 2012 to combine many of these items together (as seen in U.S. Patent No. 4,024,642, illustrated above), and a PHOSITA would know that an isolation mouthpiece includes a bite block (sometimes called a mouth prop) to passively keep a patient’s mouth open without fatiguing the patient’s jaw muscles, suction to remove liquid or other debris in the oral cavity, patient tongue retraction to prevent tongue tissue from interfering during a dental operation, and patient cheek retraction to isolate cheek tissue from the operating area. By combining all these features into one device, a dental assistant’s or dental hygienist’s presence may not be necessary during a dental procedure.

32. Solmetex did not invent a one-piece, all-in-one isolation mouthpiece, as products like Isolite and Mr. Thirsty both existed in late 2012, when Solmetex filed its provisional application related to the First Family Patents.

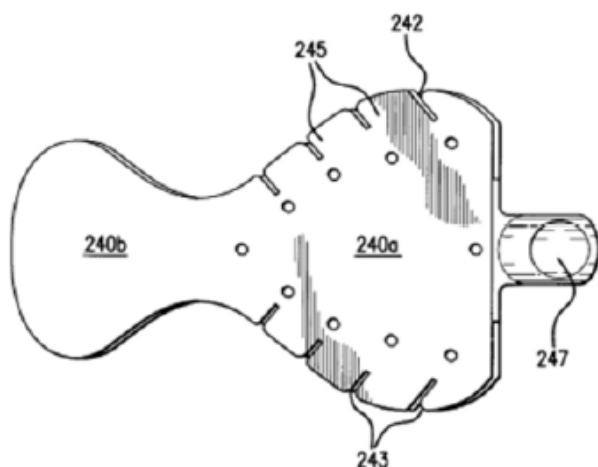


“Hirsch/Isolite¹”

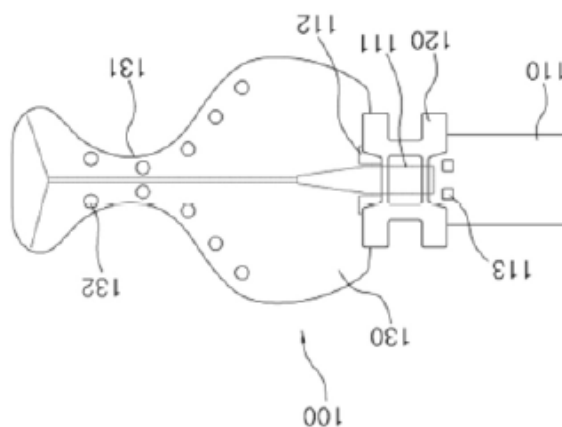


“Solmetex’s First Family”

¹ Associated with at least U.S. Patent No. 6,974,321 (hereinafter “Hirsch”), Ascentcare 00006100-6122



“Black²/Mr. Thirsty/Airbug”

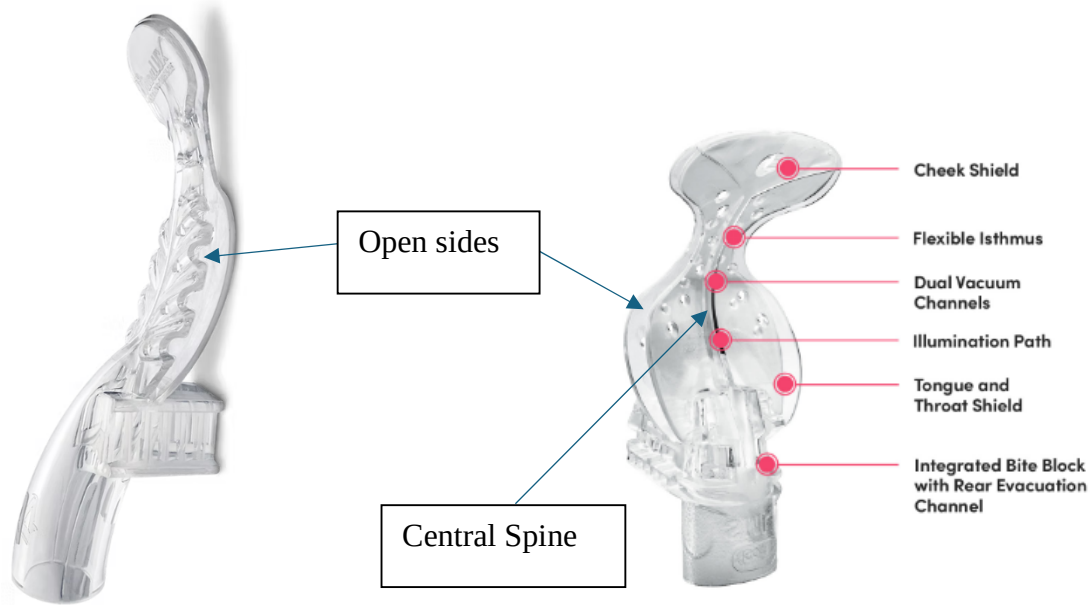


“Park”³

Solmetex’s contribution to this field is much more limited in that it disclosed an enclosed mouthpiece with sidewalls, forming a pocket, *without* a central spine. Isolite, Mr. Thirsty (and the Ascentcare VacuLUX for that matter) are open-sided mouthpieces, and the Isolite and VacuLUX mouthpieces have a central spine, different from the mouthpieces disclosed by the First Family.

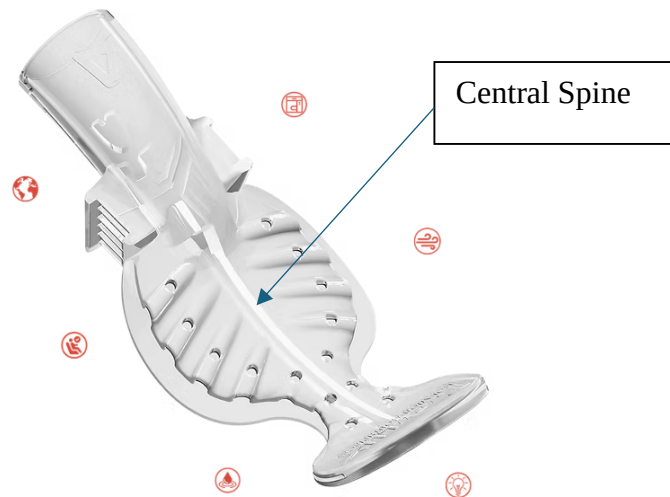
² Associated with at least U.S. Patent No. 8,029,280 (hereinafter “Black”), SOLMETEX_0011460-520

³ Korean Patent No. 10-1082826 (hereinafter “Park”), SOLMETEX_0011521-41



VacuLUX (Accused Product)

“Isolite”



VacuLUX (Accused Product)

33. From reading the “Description of the Related Art” section, it is not immediately clear to me what problem Solmetex was attempting to solve. This section describes a two-person team for certain dental procedures and the need for numerous pieces of dental equipment to perform the dental procedures. The specification then says:

There is, therefore, 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.

Id. at 1:39-41. This language would appear to suggest the First Family was trying to solve the problem of creating a comfortable, safe, and all-in-one mouthpiece. However, as discussed above, an all-in-one mouthpiece already existed for decades. Looking at the European prosecution of a European sister application, the European examiner framed the problem to be solved like this:

The problem to be solved by the present invention may therefore be regarded as maintaining the anterior and posterior walls separate from each other during operation when suction is applied to the system.

Ascentcare 00006660. The European Examiner noted that Black uses transverse walls to solve this exact problem. Ascentcare 00006660-61. Meanwhile, Hirsch uses a central spine. Hirsch, 11:59-64. Alternatively, the First Family uses a bridge structure. '970 Patent, 4:48-65. A PHOSITA would understand that the First Family did not solve the problem of a dental operation needing numerous different pieces of dental equipment⁴; either Zorovich or Hirsch solved that problem. Instead, the First Family presented an alternative to Hirsch's spine and Black's transverse walls (see Black, 14:21-47), which Solmetex argued was more comfortable. Ascentcare 00006641-42.

34. Isolation mouthpieces, including the mouthpiece disclosed by the First Family of Patents, are positioned in a patient's mouth such that "the suction connector portion may protrude from one side of the patient's mouth, while the main body lies against the back of the patient's mouth, and the cheek retractor presses against the patient's cheek on the opposite side of the patient's mouth." '970 Patent, 2:9-14. Typically, isolation mouthpieces are bent slightly during

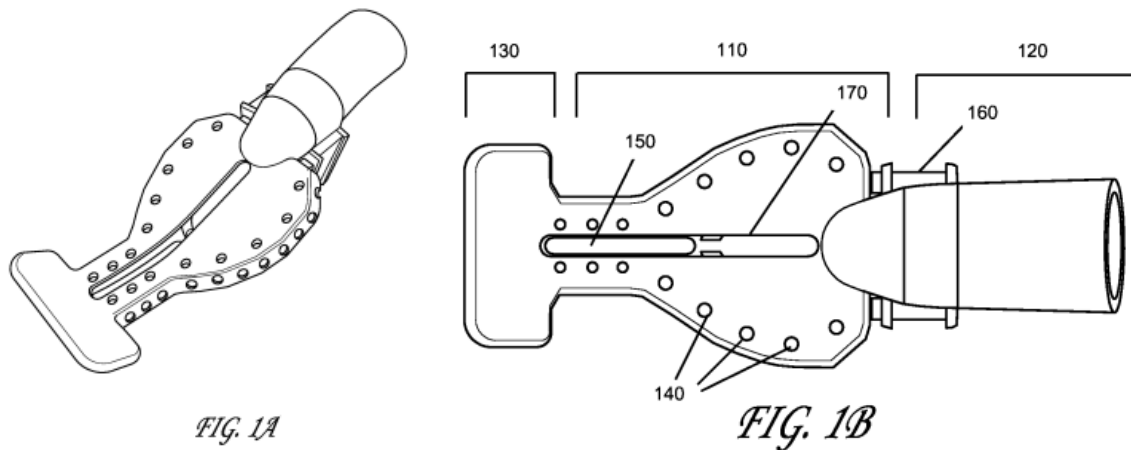
⁴ Notably, the Australian Examiner said, "the present invention seeks to solve the problem of a dental technician needing to handle multiple tools at the same time. D3 (Black) is considered to solve this problem by providing an integrated mouthpiece and suction device." AU2016200275, Examination Report dated May 29, 2018, p. 3-4. Here, the Examiner agrees with me that the prior art already solved the problem of an all-in-one isolation mouthpiece.

use and once positioned. The bending occurs both latitudinally (causing the mouthpiece to curl) and longitudinally due to pressure from the roof and floor of the patient's mouth. '970 Patent, 2:5-14, 3:39-44. The figure below depicts an isolation mouthpiece positioned in a patient's mouth during a dental operation and the bending that occurs.



As can be seen, the suction connector is protruding out the right side of a patient's mouth, the narrow neck wraps behind the patient's left-side molars, and the cheek retractor retracts the patient's left cheek tissue. Meanwhile, the majority of the mouthpiece acts as a tongue retractor preventing the tongue from interfering with the dental operation occurring on the patient's left-side teeth.

35. According to the First Family, the "mouthpiece" includes a "suction connector portion 120", a "main body portion 110", and a "cheek retractor portion 130".



'970 Patent, 1:49-51, 2:8-10, 3:24-26. According to the specification, the "mouthpiece" is used **"with a detachable mouth prop"**. '970 Patent, 2:27-40 (emphasis added). FIGs. 1A-1E illustrate the mouthpiece with the detachable mouth prop, and FIGs. 2A-2E illustrate the mouthpiece "where the detachable mouth prop has been detached." '970 Patent, 2:38-40, 3:20-26. The specification consistently describes the mouthpiece and mouth prop as separate components. Indeed, when describing injecting molding to form a singular apparatus, the specification specifically says, "the main body portion, cheek retractor portion, and suction connector portion (and sub-portions thereof) may be *molded in one piece, preferably by injection molding*." '970 Patent, 1:51-54, 3:10-14. Separately, the specification says, "[t]he mouth prop 160 may be made of thickened silicone material *injected molded in a single piece* with an elastic strap corresponding to the circumference of the suction connector portion." '970 Patent, 5:40-43. In other words, each of the "mouthpiece" and the "mouth prop" may be separately injection molded, but the specification never describes them as injection molded *together* as one piece. Indeed, the specification never describes any embodiment where the main body portion, cheek retractor portion, suction connector portion, *and mouth prop* are molded in one piece because the mouth prop is exclusively described as removable.

36. Some of the asserted claims recite that the mouth prop is a part of the "mouthpiece"

or specifically part of the suction connector portion. (e.g., claim 19 of the '970 Patent recites, “A mouthpiece comprising: a main body portion...; a mouth prop”). However, the specification says, “the mouthpiece may be **used with** a mouth prop 160”. '970 Patent, 5:21. Thus, there is some confusion as to whether a “mouthpiece” only includes the main body portion, cheek retractor portion, suction connector portion, or whether the “mouthpiece” can also include the removable mouth prop. Either way, the specification never describes an integral mouth prop formed as one piece with the cheek retractor portion 120, the main body portion 110, and a cheek retractor portion 130. In fact, the specification very clearly says, “Because the mouth prop and mouthpiece **are detachable** from each other, different sizes of each may be mixed and matched as needed for a particular patient's mouth.” '970 Patent, 5:48-50 (emphasis added). Notably, this sentence lacks any permissive language (e.g., “may be detachable” or “can be detachable”), which is pervasive throughout the rest of the specification, leading a PHOSITA to understand that the removable mouthpiece is not optional or simply one exemplary embodiment. In fact, an isolation mouthpiece having an integral mouth prop/bite block was not disclosed until the Second Family. '217 Patent, 2:61-65 (“A bite block 101 may also be **integrated to the suction connector portion 108** near the first end 104 of the main body portion 102, though the bite block 101 may be positioned anywhere on the suction connector portion 108.” (emphasis added); *see also Id.* at 3:8-10, “the suction connector portion 108, the cheek retractor portion 110, the bite block 101, and the main body portion 102 are constructed as one piece.”).

37. I note that Solmetex’s autoclavable product, which looks identical to the drawings in the First Family, includes a removable bite block and is only available for purchase with a removable bite block.



Autoclavable Mouthpiece



DryShield mouthpieces are made of a soft, flexible silicone material designed to fit comfortably in the patient's mouth.

- Autoclavable
- Interchangeable bite block
- Tongue and oral pathway shield
- Airway protection
- Cheek retractor

<https://solmetex.com/product/autoclavable-mouthpiece/>.



Solmetex explained that this removable bite block is a feature allowing a first sized mouth prop (e.g., medium) to be swapped out for a different sized mouth prop (e.g., large) to accommodate different patient mouth sizes. '970 Patent, 5:46-50.

38. The lack of permissive language is also notably absent when describing how the

detachable mouth prop attaches to the suction connector. The specification says, “The mouth prop 160 **has** an internal, rectangular-shaped female slot designed to fit snugly with the external, rectangular-shaped male plug 220 of the suction connector portion 120 of the mouthpiece.” ’970 Patent, 5:43-46 (emphasis added). Again, the specification usually uses permissive language, but in multiple places specifically describing the detachability of the mouth prop, the specification suspends use of permissive language. This consistency in mandatory language to this specific feature demonstrates to a PHOSITA that the inventors only envisioned a mouthpiece with a detachable mouth prop. At the very least, a PHOSITA would understand the claims, in view of this disclosure, as supporting an embodiment where the mouth prop could be removable, and a mouth prop that serves as a permanent wall that connects the anterior wall to the posterior wall would be outside that scope because that connection would prevent any detachability.

39. In addition to a removable bite block, the First Family of Patents only describes an *enclosed* “main body portion 110” formed as an “enclosed pocket”. ’970 Patent, 1:61-63, 3:48-50, 3:51-60, 5:59-62. As both shown and described in the First Family of Patents, the main body portion includes four walls: an anterior wall, a posterior wall, a superior sidewall, and an inferior

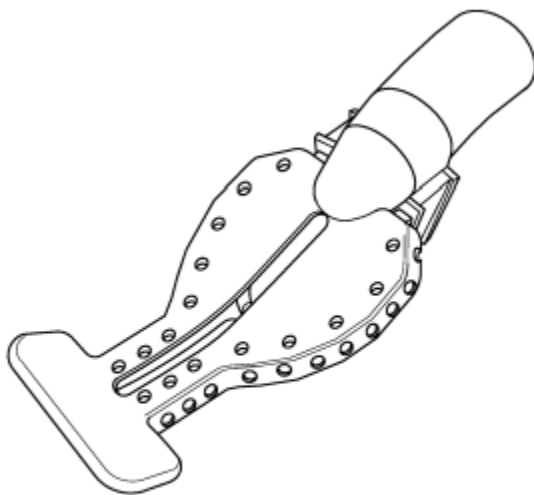


FIG. 1A

sidewall. Anterior means “facing the front of the mouth”; posterior means “facing the back of the mouth”, superior means “the side that rests against the roof of a patient’s mouth when placed”, and inferior means “the side that rests against the floor of the patient’s mouth.” ’970 Patent, 3:45-58. The anterior and posterior walls never change in definition, but the inferior and

superior sides can flip because the mouthpiece is formed symmetrically allowing for a change in orientation. *Id.* In other words, the suction connector can extend out of either the left or right side of a patient's mouth, so the inferior and superior walls swap based on which side of a patient's mouth the suction connector is placed.

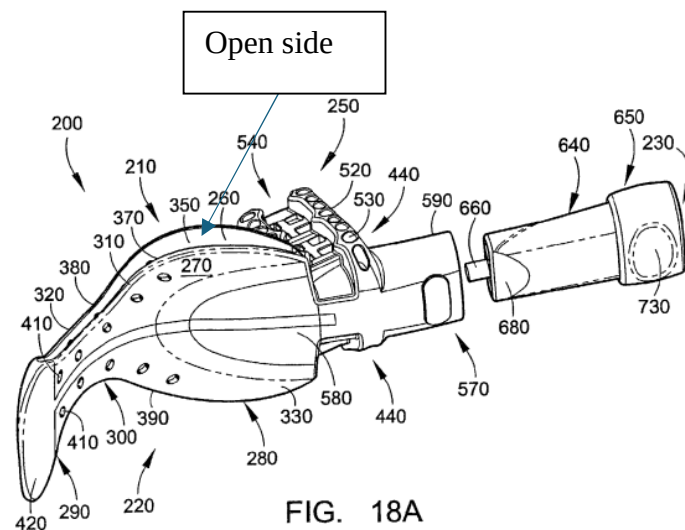
40. Regardless, the specification never describes an embodiment without inferior/superior sidewalls. The specification describes the main body portion like this:

An exemplary main body portion **110**, when placed in a mouth, 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. The two walls may connect at a superior wall and an inferior wall forming a body that is at least partially enclosed. Superior may be used herein to refer to the side that rests against a roof of a patient's mouth when placed therein, and inferior may be used to refer to the side that rests against the floor of the patient's mouth. The superior and inferior sides may be formed identically, which may allow for the mouthpiece to change orientation such that the superior side may appear as the inferior side and vice versa, in the new orientation. When in use, the respective sides of the main body portion **110** may serve to protect and separate the top of the mouth and the bottom of the mouth/tongue. In addition, the main body portion **110** may also serve to protect the back of the mouth (e.g., throat and airway) from falling debris.

'970 Patent, 3:45-63.

41. In fact, during prosecution, Solmetex explained that the sidewalls are necessary, saying "The [anterior, posterior, inferior, and superior] 'walls' therefore enclose an interior space through which suction can be applied consistently throughout, while maintaining the structural integrity of the main body shape and enclosed interior space during suction." SOLMETEX_0000985. In other words, a PHOSITA would understand Solmetex's argument to mean that the sidewalls provide anti-collapse features ("structural integrity") at the edges during suction, and by *enclosing* the interior space, suction pressure is relatively consistent throughout the enclosed interior space formed by those four walls. Solmetex specifically contrasted the disclosed, enclosed, pocket-formed main body portion of the First Family with an open-sided

mouthpiece having a central spine (Hirsch). *Id.* Hirsch's mouthpiece having a central spine does not have anti-collapse features at the side edges of the mouthpiece, and Hirsch's mouthpiece was known to seal at the edges because of the lack of anti-collapse structure formed on the edges. U.S. Patent No. 9,532,858 (Hereinafter "Hirsch2", SOLMETEX_0011886-901), 4:67-5:8.



Moreover, suction in an open-sided mouthpiece, like Hirsch shown above (or the Accused Products) would not be “consistent” in all areas of the wider tongue retractor portion as mandated by fundamental principals in fluid mechanics. Fluid entering the open sides forms a converging flow pattern accelerating the fluid particles toward the spine and the suction tube. As the fluid accelerates toward the spine and the suction tube, suction pressure increases to sustain the acceleration. Therefore, suction pressure at the open sides would be lower than the suction pressure near the suction tube, and the suction pressure is not consistent throughout the mouthpiece. Such is not the case in an enclosed mouthpiece where fluid flows into the enclosure primarily in the normal direction (e.g., through the slit or perforations). The enclosure serves as a reservoir where fluid is collected and subsequently transferred to the suction tube. The flow inside the enclosure is more stagnant and uniform; therefore, the suction pressure can be consistent throughout due to the enclosure. Thus, Solmetex differentiated from open-sided, subdivided (having a central spine)

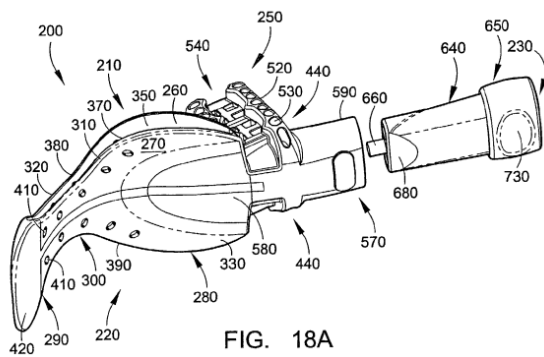
mouthpieces, meaning that Solmetex argued during prosecution that its mouthpiece is limited to an enclosed main body portion with closed sidewalls and lacking a central spine.

42. Solmetex contrasted its mouthpiece with the four-flapped, central spine mouthpiece of Hirsch multiple times. For example, during prosecution of an unasserted, sister patent (U.S. Patent No. 11,576,764), Solmetex said the following:

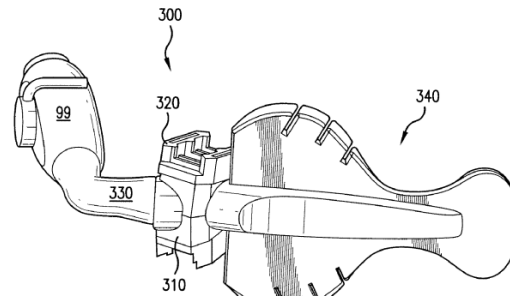
Hirsch similarly fails to disclose the claimed ‘bridge structure.’ *Hirsch* only discusses “the flaps 320, 33, 340, 350” that “all extend from and share a common, central spine 365” as illustrated in FIG. 19B below. *Hirsch*, [0082], FIG. 19B. Such “central spine 365” of *Hirsch* “extends longitudinally a majority of the length of the retractor 240 and divides the upper half 210 from the lower half 220 of the intraoral device 200,” to attach “upper front flap 310,” “upper rear flap 320,” “lower front flap 330,” and “lower rear flap 340.” *Id.* In contrast, the claim recites that the ‘bridge structure’ only protrudes from ‘an interior surface of the second wall’ and ‘not attached to the first wall.’

Ascentcare 00004767.

43. It’s important to recognize the role of the prior art in Solmetex’s specification and prosecution history. As mentioned, at least two isolation mouthpieces (Mr. Thirsty/Air Bug related to U.S. Patent No. 8,029,280 to Brian P. Black (“Black”) and Isolite related to at least U.S. Patent No. 6,974,321 to James Hirsch (“Hirsch”)) existed in late 2012, which Solmetex asserts is the priority date of the First Family. As seen below, both Black and Hirsch disclose mouthpieces comprising a bite block, a suction connector, a wider tongue retractor, and a cheek retractor having very similar shapes to the mouthpiece disclosed by the First Family

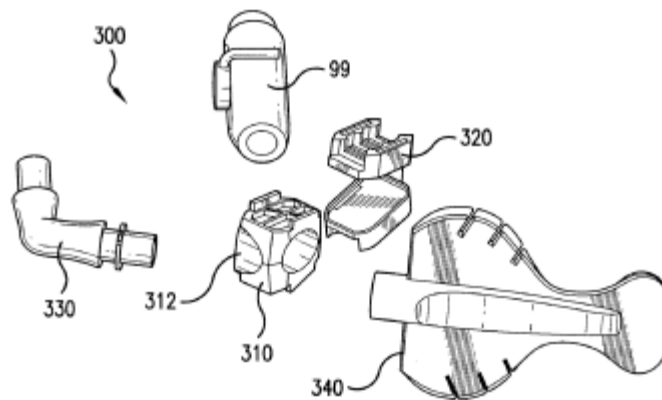


Hirsch/Isolite



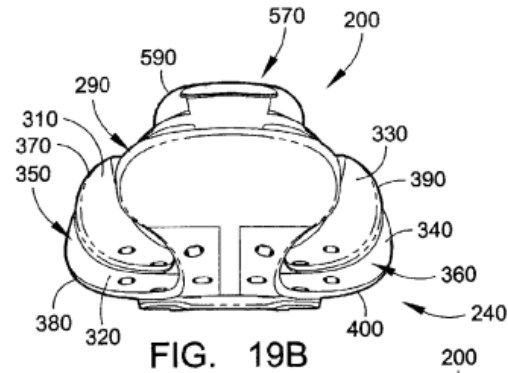
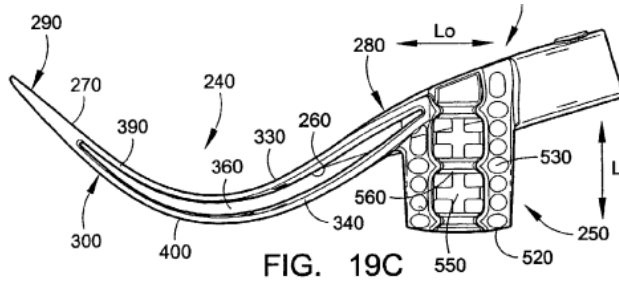
Black/Mr. Thirsty

Black even disclosed a removable bite block, as seen below.



Hirsch, importantly, described a mouthpiece having a central spine with four flaps (two anterior, two posterior) extending therefrom.⁵

⁵ I note that Ascentcare's VacuLUX mouthpiece follows a similar central spine and four-flap configuration.



Hirsch, with central spine 365, and flaps 310, 320, 330, 340

A central spine offers several advantages: (1) increased cheek retraction force due to a thicker material formed at the narrow “neck” part of the mouthpiece (which wraps around a patient’s molars when positioned), (2) light transmission to light up the patient’s mouth during an operation, and (3) anti-collapse structure down the central line of the mouthpiece maintaining a suction channel near the spine. By anti-collapse structure, I mean a mechanical structure that prevents the posterior flap and anterior flap from coming together under suction (i.e., collapsing), which would block suction or significantly limit suction pressure. Hirsch claimed such a central spine (e.g., U.S. 6,974,321, claim 1), and PHOSITAs knew that they had to design an isolation mouthpiece without a central spine during the lifetime of Hirsch, which I am informed by counsel ended in 2019.

44. Based on the disclosure of Hirsch’s patent, Solmetex appears to have designed around an isolation mouthpiece with a central spine to avoid infringing Hirsch’s patent. Solmetex was clearly aware of Hirsch and his patent rights. Indeed, Solmetex exclusively cited Hirsch references in its first Information Disclosure Statement to the Patent Office. SOLMETEX_0011710.

45. As I mentioned above, a spine offers three benefits (light transmission, anti-collapse, and cheek retraction force). The First Family described two separate features intended to emulate two of those benefits of a central spine. First, to replace the spine’s cheek retraction force,

the First Family disclosed a “stability bar 150” that “reinforces the stability of the rectangular portion and assist [sic] in shaping this region to the intraoral posterior shape of the patient’s mouth” ’970 Patent, 4:22-25. This description is confusingly worded, but claim 10 of the ’969 Patent clarifies my point, namely that the stability bar is a thickening of material to increase cheek tissue retraction force. (“wherein a thickness of the stability bar corresponds to resilience by which the cheek retractor portion applies pressure during bending.”). Moreover, the specification sometimes calls the “stability bar” a “reinforcing bar”. ’970 Patent, 2:64-67. Specifically to avoid being called a spine, the First Family carefully discloses that the stability bar 150 only protrudes from and connects to the posterior wall but does not connect to both the anterior and posterior wall within the interior space of the pocket. ’970 Patent, 4:30-34, FIG. 6B. Again, this stands in stark contrast to the Second Family specification that describes the stability bar like this: “The stability bar 143 may protrude from the interior surface 135 of the posterior wall 114 towards the interior surface 113 of the anterior wall 112. The stability bar 143 may be of **any height** ranging from the height of the interior space 126 or any height less than the interior space 126.” ’217 Patent, 5:58-61 (emphasis added). Of course, in 2019, the priority date of the Second Family of Patents, the Hirsch patent was expiring, so infringing Hirsch’s patent was no longer a concern.

46. In addition to the stability bar, the specification discloses a “bridge structure 180” formed on “an interior surface to ensure that the anterior and posterior surfaces remain separated during suction”. ’970 Patent, 4:48-51. In other words, the bridge structure 180 provides the anti-collapse structure necessary due to the absence of a spine. Therefore, Solmetex described a spineless, isolation mouthpiece with sidewalls, a bridge structure, and a stability bar that collectively replace most of the features of a spine.

47. Finally, regarding the anti-collapse bridge structure 180, because the specification

described an enclosed pocket with sidewalls, the specification consistently describes the bridge structure as “internal”, which a PHOSITA would understand because the sidewalls themselves would provide anti-collapse structure on the edges, and the anti-collapse benefits of the bridge structure would be necessary at other locations, like centrally within the pocket, which is exactly where the bridge structure is described. ’970 Patent, 4:59-61. In fact, the specification calls the bridge structure “internal” at three different locations. ’970 Patent, 2:62-63, 3:27-29, 4:30-34. Indeed, the specification explains that the *internal* bridge structure 180 is only visible “without the *surrounding* walls”. ’970 Patent, 4:53-54, FIG. 5 (emphasis added). FIG. 1E and 2E confirm that the bridge structure is only fully visible by removing sidewalls via cross-sections. ’970 Patent, 2:35-36, 2:47-48. Just like the “internal” stability bar, the internal bridge structure is described as a protrusion formed on an “interior surface”, which a PHOSITA would understand to be a surface inside the pocket formed by the anterior wall, posterior wall, and sidewall. ’970 Patent, 4:30-34.

48. In a similar vein, the specification describes the bridge structure as being formed on or protruding from an *interior* surface an additional three times. ’970 Patent, 2:15-18, 4:48-51. The specification even explains and illustrates that the bridge structure 180 is “centrally located” within the main body portion of the mouthpiece. ’970 Patent, 4:59-61, FIG. 5.

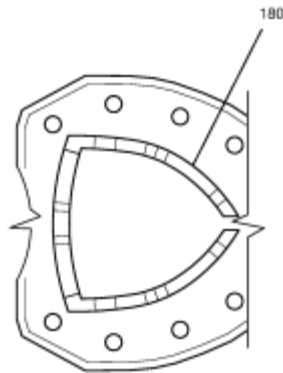


FIG. 5

'970 Patent, FIG. 5

49. A PHOSITA would understand that the bridge structure would exist in the central part of the enclosed pocket, where collapse would most likely occur. And that central section is exactly where the specification describes the internal bridge structure 180. '970 Patent, 4:30-34, 4:59-61, FIG. 5. Because of the disclosed sidewalls, a PHOSITA would not understand the disclosed bridge structure as being formed on edges of the mouthpiece.

50. The specifications for the First Family of Patents thus inform a PHOSITA that the claimed dental isolation mouthpiece is an enclosed pocket with an anterior wall, a posterior wall, and sidewalls and an internal, anti-collapse bridge structure formed centrally within the interior space of the pocket defined by the walls. A PHOSITA would further understand that this combination of elements (sidewalls, pocket, internal bridge structure) result in a dental isolation mouthpiece without a spine. These small differences differentiate the First Family of Patents from Hirsch and Black, which are both open-sided isolation mouthpieces, with Hirsch having a spine.

51. I understand that Solmetex has other patents, not asserted in this litigation but to which all the First Family of Patents claim priority. '232 Patent, claim 1 ("wherein the anterior

wall, the posterior wall, and the side wall define an interior portion of the defined pocket”). The original claims examined by the United States Patent and Trademark Office in the First Family recited sidewalls. SOLMETEX_0011676, SOLMETEX_0011701.

52. I note that every Solmetex international patent reviewed on Espacenet in the First Family of Patents also recites sidewalls.⁶ (AU2014202637B2, “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”; BR112014011637B1; CA2851861C, “wherein the anterior wall, the posterior wall, and the side wall define an interior portion of the defined pocket”; CA2919142C, “a side wall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall, and wherein at least part of the side wall comprises a plurality of perforations”; CN105578986B, “wherein the front wall, the rear wall, and the sidewall define an interior portion defining the cavity”; EP2903557B1, “wherein the anterior wall, the posterior wall, and the side wall define an interior portion of the defined pocket”; EP3184076B1, “a main body portion (110) comprising a defined pocket having an anterior wall, a posterior wall, 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”; ES2622169T3, “a defined compartment having a front wall, a back wall, and a side wall between the front wall and the back wall, and the front wall, the back wall and the sidewall define An inner part of the defined compartment”, JP5961328B1, “A front wall, a rear wall outside the curved surface, and a predetermined pocket having a side wall between the front wall and the rear wall, the front wall, the rear wall, and the

⁶ I reproduced only the international claim language having an English or a trusted machine translation from Espacenet.

side wall being of the predetermined pocket”; JP6349350B2; KR101730509B1, “wherein said front wall, said rear wall and said side wall define an interior of said defined pocket”; MX354381B; NZ718848A; PH12016500682B1; RU2659012C1, “a main body portion comprising a formed pocket with a front wall, a rear wall and a side wall between the front wall and the rear wall, wherein the front wall, the rear wall and the side wall define the inside of the formed pocket”); WO2015/088577

53. In fact, for over seven years, the claims of the '969, '970, and '686 Patents recited sidewalls, with the '969 Patent going so far as reciting four sidewalls for a time. SOLMETEX_0000183, SOLMETEX_0000242, SOLMETEX_0000983; SOLMETEX_0001724, SOLMETEX_0001772, SOLMETEX_0002514; SOLMETEX_0003177, SOLMETEX_0003236, SOLMETEX_0003955. After nearly seven years of consistently claiming sidewalls, in January 2021, Solmetex amended its claim language in at least four patent applications, all in the same way, by removing any recitation of a sidewall. SOLMETEX_0001061-62; SOLMETEX_0002613; SOLMETEX_0004003-07. The timing of these shifts in claim language is conspicuous, given that, as I have been informed by counsel, Ascentcare announced the release of a competing isolation mouthpiece in December 2020, just a month prior to this sudden and unexplained change in patent application strategy. While Solmetex now used different words for the same idea, the Examiner rejected these new words as indefinite unless the claims made it clear that the wall connected “edges” of the anterior and posterior walls. SOLMETEX_0001217-19; SOLMETEX_0002625-26; SOLMETEX_0004033-34, SOLMETEX_0004105-06. In other words, the Examiner understood Solmetex’s specification to be limited to an isolation mouthpiece with sidewalls formed at and connecting edges of the anterior and posterior walls. Solmetex was forced to add limitations specifying that an edge of the anterior wall was connected to an edge of

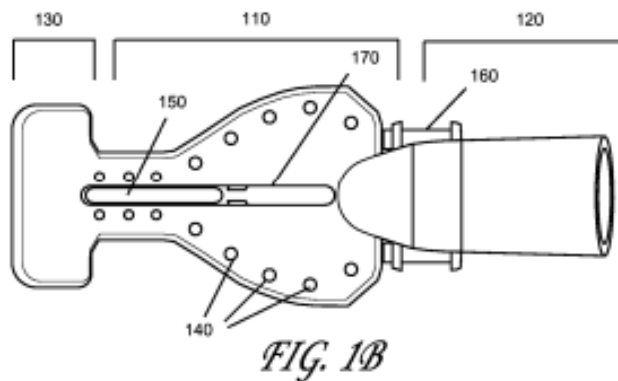
the posterior wall in response to the Examiner's rejections. SOLMETEX_0001454-56; SOLMETEX_0002694; SOLMETEX_0004033-34, SOLMETEX_0004359. Solmetex also received the '329 Patent and '418 Patent from a different examiner without these essential elements.

54. As I discuss below in more detail, Solmetex's infringement contentions are based on unreasonably broad interpretation of claim language, divorced from the specification. A PHOSITA would never understand the First Family of Patents as Solmetex suggests in its infringement contentions. Due to these positions, there is a clear claim scope dispute on many claim terms, meaning that several claim terms that would typically be clear in language require construction.

b. "Main body" and "Main body portion"

55. It is my opinion that a PHOSITA would understand the term "main body portion" to mean "the portion of the mouthpiece between, but not including, the cheek retractor and the suction connector and mouth prop, if present."

56. As I explained above, the first step in understanding claim term scope and construction is to look at the claim language itself. In, for example, claim 19 of the '969 Patent, the claim language says, "A dental mouthpiece comprising: a main body portion... a suction connector portion, and a cheek retractor...". That is, a PHOSITA would understand that the claim language recites the three "portions" (reference numbers 110, 120, 130 below) of the mouthpiece described by the specification.

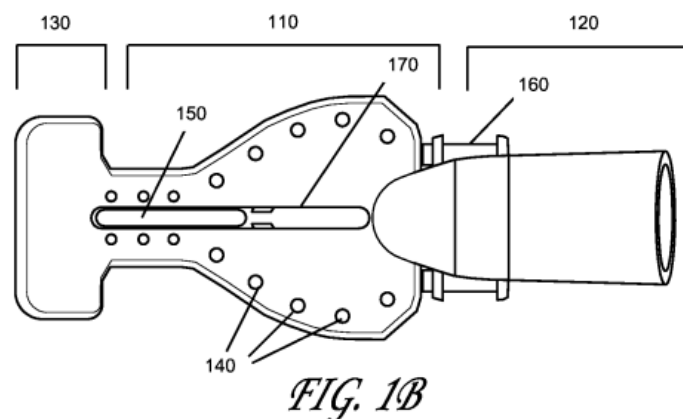


The claim is even more specific, explaining that the suction connector portion is “connected to a first *end* of the main body portion”, and the cheek retractor is “connected to a second *end* of the main body portion.” Since the cheek retractor and suction connector portion connect where the main body portion *ends*, then a PHOSITA would understand that the main body portion is distinct from the suction connector portion and cheek retractor portion.

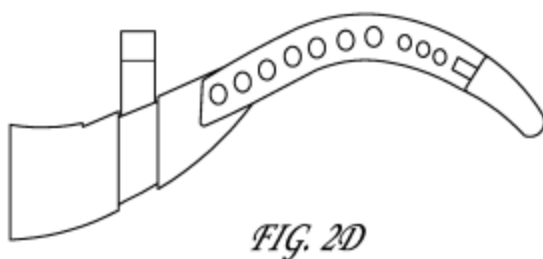
57. Claim 18 of the '970 Patent is similar. However, in the '970 Patent, claim 18 further recites a mouth prop. For example, claim 18 of the '970 Patent recites “A mouthpiece comprising: a main body portion... a mouth prop... and a suction connector...” Like the '969 Patent, the mouth prop is “located at the first *end* of the main body portion.” Again, the claims recite that the main body portion is a separate element from the other three major components of the mouthpiece (the suction connector, the cheek retractor, and the mouth prop). All other claims of the '969, '970, '686, '329, and '418 Patents are recited similarly. The claims never recite, for example, “a main body portion comprising a mouth prop” or “a main body portion comprising a suction connector portion”. Rather, these are always recited as separate and distinct elements of the mouthpiece.

58. A PHOSITA would understand the specification as confirming this understanding of the “main body portion”. First, the specification defines the main body portion as one of the three main elements of the mouthpiece. (“Such a mouthpiece may comprise a main body portion,

a cheek retractor portion, and a suction connector portion.” ’970 Patent, 1:49-51, 3:8-10). When describing the main body portion itself, the specification explains that the main body portion includes “mesh or perforations 140, a stability bar, 150, an open slit 170, and an internal bridge 180.” *Id.* at 3:27-29. Again, the suction connector portion, the cheek retractor portion, and the mouth prop are not described as being included in or associated with the “main body portion”. Like the claim language, the suction connector and cheek retractor are described as being connected at the “ends” of the main body portion. *Id.* at 3:29-31, 4:14-16. Even FIG. 1B illustrates the portions 110, 120, 130 as lacking any overlap between the main body portion 110, the suction connector portion 120, and the cheek retractor 130.



59. Solmetex may point to this figure as supposed support for the idea that a section of the mouth prop 160 facing the main body portion 110 can fit within the “main body portion” because the bracket 110 ambiguously might extend a bit into the mouth prop 160. However, the brackets included in FIG. 1B are not perfectly placed and do not account for the curved nature of



the mouthpiece. *See e.g., Id.* at FIG. 2D (showing curved mouthpiece). Indeed, according to this logic (that the side of the mouth prop is in the 110 bracket) then the nose of the suction connector

120 is part of the main body portion, and there are two, sizable sections, between the three brackets, that are apparently neither suction connector nor main body portion nor cheek retractor. A PHOSITA would not interpret FIG. 1B so narrowly, and instead, a PHOSITA would look at FIG. 1B only as a guide in understanding the general locations of the three “portions” of the mouthpiece. Plus, it is important to remember that the mouthpiece is “formed on a curve”, so this section of the mouth prop that supposedly falls within the 110 bracket might just be a perspective issue due to the natural curvature of the mouthpiece. Indeed, a PHOSITA could map the labels 110, 120, and 130 to FIG. 2B, which shows the mouthpiece without the mouth prop. So, the mouth prop is under the main body portion 110, and is not part of the main body portion 110.

60. The specification further explains that the main body portion “comprises an enclosed pocket made up of an anterior wall, a posterior wall, and an exterior side wall connecting the edges of the anterior and posterior walls. *Id.* at 1:61-63. The Detailed Description is even more specific, explaining that the main body portion comprises four walls: an anterior wall, a posterior wall, an inferior side wall and a superior side wall. *Id.* at 3:45-50, FIGs. 1A-2E, 4. The specification never describes an embodiment of the main body portion without at least three walls, one of which being a side wall that connects edges of the anterior wall to edges of the posterior wall. As shown in FIGs. 2A-2E, where the detachable mouth prop is removed, the main body portion comprises those same walls even without the mouth prop present. Thus, the mouth prop’s presence cannot inform the structure of the main body portion if the mouth prop is to be detachable.

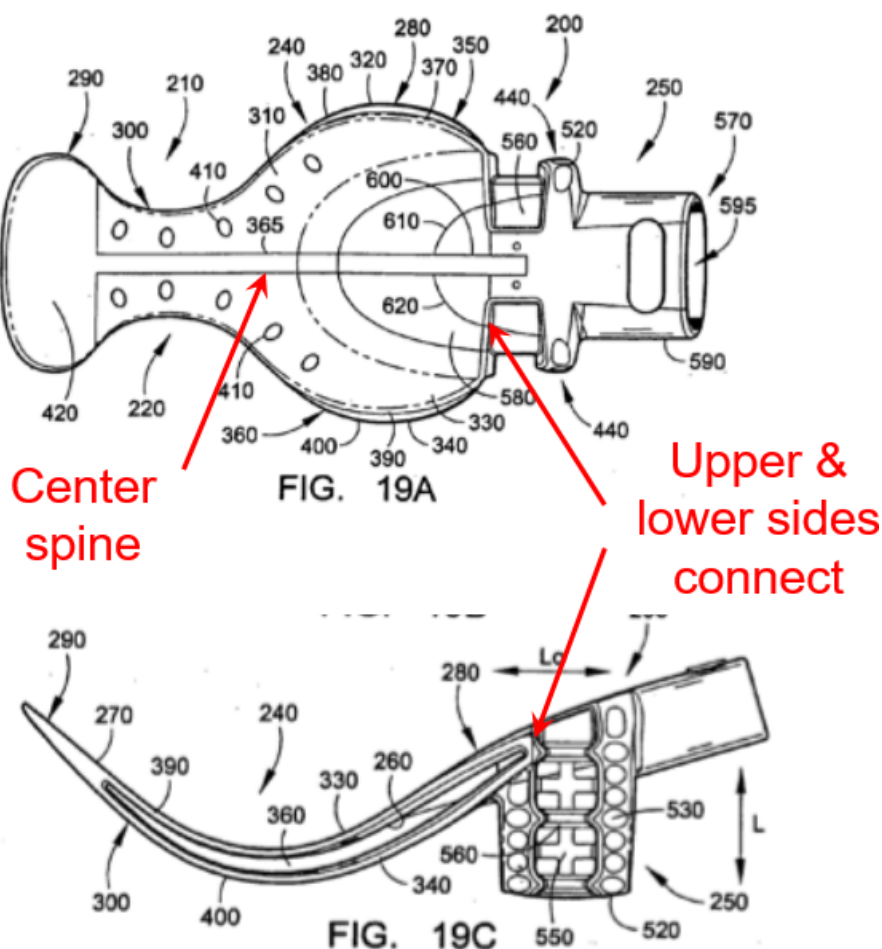
61. Indeed, the specification consistently describes a detachable mouth prop 160. By being detachable, the mouth prop cannot be part of or form a part of the main body portion. At no point does the specification describe or suggest an integrally formed mouth prop, which is in direct contrast to how Solmetex described an actually integral bite block in the Second Family. (*Compare*

'970 Patent, 5:43-50 ("The mouth prop 160 has an internal, rectangular-shaped female slot designed to fit snugly with the external, rectangular-shaped male plug 220 of the suction connector portion 120 of the mouthpiece. Mouth props may be made in different sizes for differently sized mouths. Because the mouth prop and mouthpiece are detachable from each other, different sizes of each may be mixed and matched as needed for a particular patient's mouth") with '217 Patent, 2:61-65 ("A bite block **101** may also be integrated to the suction connector portion **108** near the first end **104** of the main body portion **102**, though the bite block **101** may be positioned anywhere on the suction connector portion **108**.”).

62. During prosecution, the Examiner issued an indefiniteness rejection because he was unclear whether the mouth prop defines the main body portion or part of the mouthpiece. SOLMETEX_0002722-24. In response, Solmetex clarified that it is not part of the main body portion by amending the claims. SOLMETEX_0002958-59. Solmetex further clarified that the “main body portion” includes “‘a first wall extending from the first end to the second end’ and that ‘is narrower at the second end than at the first end,’ a corresponding ‘second wall located a distance from the first wall’ and likewise ‘extending from the first end to the second end’ and ‘narrower at the second end than at the first end,’ and a ‘connecting wall that connects one or more edges of the first wall to one or more corresponding edges of the second wall across the distance.’” SOLMETEX_0002958. Solmetex then further clarified that the “main body portion” also includes “a bridge structure”. SOLMETEX_0002959. Notably, Solmetex, during prosecution and in response to the Examiner’s confusion about whether the mouth prop could form part of the pocket, never asserted that the mouth prop was forming part of the pocket. Instead, Solmetex explained that the main body portion only includes a first wall, a second wall, a connecting wall, and a bridge structure, but it does not include the suction connector or the mouth prop, in accordance with the

specification. *Id.*

63. In another response to the United States Patent and Trademark Office, Solmetex differentiated from a mouthpiece (Hirsch) having an integral bite block. Specifically, Solmetex said, “The recited ‘walls’ therefore enclose an interior space through which suction can be applied consistently throughout, while maintaining the structural integrity of the man body shape and enclosed interior space during suction. In contrast, Hirsch includes subdivisions (e.g., via a spine) within its interior, as well as fails to teach any defined walls spanning across set distances as does the claimed superior and inferior walls.” SOLMETEX_0000985 (emphasis added). I show Hirsch below:



As can be seen by FIG. 19C, Hirsch has a connecting element on the “end” of the wider tongue

retractor area that connects the anterior flap to the posterior flap. This connecting element is integral with and part of the bite block 250. Despite this clear depiction, the Solmetex argued that Hirsch failed to teach “walls that enclose an interior space.” *Id.* Thus, a connecting wall cannot be formed at an “end” of the main body portion and cannot be part of the bite block, as clearly shown by Hirsch, because Solmetex argued that Hirsch’s mouthpiece is different from the claimed mouthpiece. *Id.* A PHOSITA would read this argument and understand that the claims are limited to sidewalls formed on the inferior and superior sides, as disclosed in the specification, and cannot be a wall formed at the end or as part of the bite block, as such a configuration is apparently not what was claimed or described by the patent.

64. Truthfully, this term should not need construction. However, Solmetex has pointed to the bite block of the VacuLUX mouthpiece as the recited “connecting wall” or “third wall” of the main body portion. *E.g.* Solmetex Infringement Contentions, Appendix 10, p. 10-10, Appendix 2, p. 2-9. Thus, Solmetex is impliedly taking the position that the plain and ordinary meaning of the term “main body portion” can include the bite block or portions of the bite block. Thus, there is a clear dispute over the scope of the term “main body portion” and whether any of the recited walls included in the main body portion can be a bite block.

65. As I explained above, the specification of the First Family of Patents only envisioned a *removable* bite block. The specification discloses sidewalls that must accommodate a removable mouth prop. Thus, the main body portion must have a sidewall/connecting wall/third wall independent of the mouth prop or else the mouth prop could not be removable. A PHOSITA would understand that, if the mouth prop acted as a connecting wall to the anterior and posterior walls, then the mouth prop would not be removable. Such a configuration (where the side of the mouth prop was a wall connecting the anterior and posterior walls) would defeat the purpose and

possibility of a removable bite block, which the specification clearly envisioned. Moreover, a PHOSITA would understand that sidewalls are necessary for functionality because the sidewalls prevent the side edges from collapsing under suction. In order to prevent collapse of the edges, the sidewalls must be formed at the edges of the anterior and posterior walls. As such, a PHOSITA would understand that the possibility of a detachable mouth prop must be preserved, which means that the connecting wall cannot be the mouth prop itself or any subsection of the mouth prop.

66. I have been informed by counsel, however, that claims should be construed to maintain the validity of the claims. I have also been informed by counsel that claims must be supported by the written description to be valid. Here, the written description does not support Solmetex's implied construction because the written description envisioned a removable bite block.

67. In fact, the specification affirmatively states that the "mouth prop and the mouthpiece **are** detachable". '970 Patent, 5:48. The specification goes further describing that the mouth prop "**has** an internal, rectangular-shaped female slot designed to fit snugly with the external, rectangular shaped male plug 220." *Id.* at 5:43-46. This language is not permissive or limited to some embodiments; it is mandatory language explaining how the mouthpiece *is*. The specification does not describe the detachability of the mouth prop as optional or limited to some of the envisioned embodiments. Instead, it is described as a feature on all embodiments, and a PHOSITA would understand the First Family of Patent to be limited to a mouthpiece with a detachable mouth prop, and not covering mouthpieces with an integral mouthpiece. *Compare* '970 Patent, 5:43-50 ("The mouth prop 160 **has** an internal, rectangular-shaped female slot designed to fit snugly with the external, rectangular-shaped male plug 220 of the suction connector portion 120 of the mouthpiece. Mouth props may be made in different sizes for differently sized mouths.

Because the mouth prop and mouthpiece are detachable from each other, different sizes of each may be mixed and matched as needed for a particular patient's mouth”) with ’217 Patent, 2:61-65 (“A bite block **101** may also be integrated to the suction connector portion **108** near the first end **104** of the main body portion **102**, though the bite block **101** may be positioned anywhere on the suction connector portion **108**.”)

68. During prosecution, Solmetex explained that the main body portion is “a partially enclosed pocket”. SOLMETEX_0000570. When discussing the limitation “a main body portion configured as a pocket having an interior defined by”, Solmetex pointed to FIG. 1B and specification section 3:45-50, which describes the four walls that define the partially enclosed body. *Id.* Solmetex then says, “as described and illustrated, the main body 110 is a *partially enclosed body (e.g., pocket) defined by several walls*”, as shown below. *Id.* Notably, Solmetex did not argue that the main body portion is defined by the mouth prop or portions of the mouth prop.

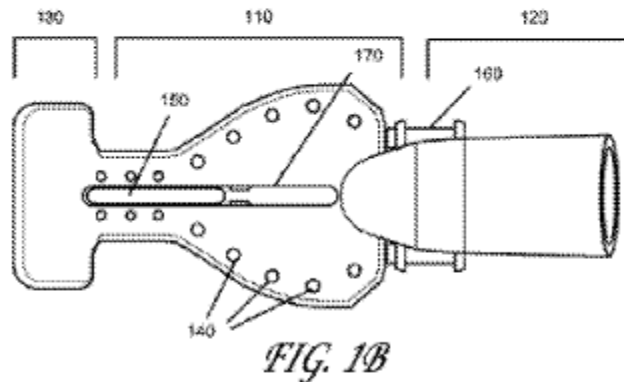
Specific elements of the independent claims are discussed below:

1. *'a main body portion configured as a pocket having an interior defined by:'*

The main body portion is described by the specification as follows:

An exemplary main body portion 110, when placed in a mouth, 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. The two walls may connect at a superior wall and an inferior wall forming a body that is at least partially enclosed.

Specification, [0035]; see also FIG. 1B (provided below)



As described and illustrated, main body portion 110 is a partially enclosed body (e.g., pocket) defined by several walls.

Id.

69. The specification never describes the mouth prop as a wall. Instead, the specification only describes the mouth prop as “a single piece with an elastic strap corresponding to the circumference of the suction connector portion”. ’970 Patent, 5:40-43. In other words, a PHOSITA would understand the specification to describe a detachable prop connectable to the suction connector using the strap. The only “walls” described by the specification are the anterior wall, the superior wall, the inferior sidewall, and the superior sidewall. *Id.* at 3:45-58. A PHOSITA

would not understand the side or any portion of the mouth prop to be a wall that connects the anterior and posterior walls. Indeed, the detachability of the mouth prop would dissuade a PHOSITA from understanding that a mouth prop could be considered a wall.

70. Finally, all the claims explain that the suction connector, when recited, is formed at one end of the main body portion and the cheek retractor, when recited, is formed at the opposite end. Thus, consistent with the prior art and the specification, the main body portion is always recited as sandwiched between the suction connector portion and cheek retractor portion. The specification only describes the mouth prop as being connected to the suction connector. In fact, the mouth prop *cannot* exist on the cheek retractor end because that is the set of teeth where the dental operation occurs. The bite block must engage the unoperated teeth, which must be the end opposite the cheek retractor. So, to allow a dentist to perform the dental operation, the suction connector and the mouth prop must be on the same side of a patient's mouth. Therefore, the main body portion is also necessarily sandwiched between the mouth prop and the cheek retractor.

71. As such, a PHOSITA would understand that the term "main body portion" requires a construction and means "the portion of the mouthpiece between, but not including, the cheek retractor and the suction connector and mouth prop, if present."

72. Finally, I recognize that some claims use the term "main body" rather than "main body portion". The specification uses these terms interchangeably (e.g., '970 Patent, 4:48-67, etc.), so it is my opinion that "main body" has the same plain meaning in view of the specification as "main body portion."

b. "pocket"

73. It is my opinion that a PHOSITA would understand the term "pocket" to mean "an enclosure without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall."

74. Starting with the claim language, the '969 and '970 Patents are the only two patents to use the word “pocket” in the claim language. In both claim 19 of the '969 Patent and claim 18 of the '970 Patent, the claims recite “a main body portion configured as a pocket at least partially enclosing an interior space.” Thus, the claims explain that a pocket “at least partially encloses an interior space.” Thus, this idea of an enclosure is supported by the claim language itself.

75. The specification also describes the main body portion of the mouthpiece as an enclosure and a pocket. (“The main body portion may comprise an enclosed pocket made up of an anterior wall, a posterior wall, and a side wall in between the anterior and posterior walls.” '970 Patent, 1:61-63, *see also* 4:16-21). The main body portion 110 is described as an enclosure with four walls. (“An exemplary main body portion **110**, when placed in a mouth, 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. ***The two walls may connect at a superior wall and an inferior wall forming a body that is at least partially enclosed.***” '970 Patent, 3:45-50). Indeed, the figures show a main body portion 110 enclosed by the anterior wall, the posterior wall, the inferior sidewall and the superior sidewall. FIGs. 1A-2E, 4. The specification never describes, illustrates, or suggests a mouthpiece without those four walls.

76. In addition, the specification describes the main body portion 110 as having a slit 170 that provides access “into the interior of the pocket of the main body portion”. '970 Patent, 4:16-21. The specification explains that the slit 170 is formed on the anterior wall, and the slit assists “in capture and suction of water, saliva, and debris, as well as assisting in cleaning and maintenance.” '970 Patent, 4:41-47. A PHOSITA would understand that the slit 170 for “cleaning and maintenance” and formed on the anterior wall is necessary particularly because the pocket is enclosed by the anterior wall, the posterior wall, and the inferior/superior sidewalls. In other words,

in the mouthpiece disclosed by the First Family, cleaning cannot occur through the open sides, so another cleaning opening was provided. Cleaning can occur through the open sides of open-sided mouthpieces, like Hirsch, Black, and Defendant's VacuLUX mouthpiece.

77. Further still, the specification describes an "internal bridge structure" 180 formed on an *interior surface* of the posterior wall that keeps the posterior wall and anterior wall separated under suction. '970 Patent, 4:48-51, 2:15-16. This internal, anti-collapse structure further confirms the enclosed nature of the pocket-configured mouthpiece. Indeed, a bridge structure 180 could not be "internal" unless it were enclosed by exterior walls that create the "interior space" or "inner cavity" claimed by the First Family. '970 Patent, 2:62-63, 3:27-29, 4:30-34.

78. So, the specification describes an "enclosed pocket" or "enclosed main body" (*Id.*, 1:61-63, 3:48-50, 5:59-62, FIGs. 1A-2E, 4); that the pocket encloses an interior space using four walls (*Id.*, 1:61-64, 3:45-63, 4:5-12, FIGs. 1A-2E, 4); that access to the enclosed space for cleaning the enclosed space is provided through a slit formed on the anterior wall (*Id.*, 4:16-21, 4:41-47, FIGs. 1A, 1B, 2A, 2B, 6B, 7A); and an internal bridge structure prevents collapse *inside* the pocket. (*Id.*, 2:62-63, 3:27-29, 4:30-34, FIGs. 1E, 2E, 5). A PHOSITA would understand that all these structures and features suggest an enclosed pocket having an enclosed sidewall, different from the open-sided prior art mouthpieces like Black and Hirsch.

79. Indeed, all the features of the main body portion (perforations, stability bar, open slit, and internal bridge (*Id.*, 3:27-29)) exist *because* the mouthpiece is an enclosure without a central spine. The perforations 140 exist to provide conduits for suction into the interior space created by the enclosure. *Id.*, 4:5-12, 1:63-2:5. The slit 170 provides an opening for cleaning (the slit also is another opening for suction) because no other ingress for cleaning exists. *Id.* 4:41-47, 1:66-2:5. The stability bar 150 reinforces the cheek retractor due to the lack of a central spine. *Id.*,

4:16-40. And the bridge structure 180 provides anti-collapse structure inside the pocket due to the lack of a central spine. *Id.* 4:48-51, 4:59-61, 2:15-18, FIG. 5. A PHOSITA, informed by this specification, would understand that the disclosed mouthpiece is an enclosed mouthpiece enclosed by an anterior wall, a posterior wall, and two sidewalls connecting edges of the anterior and posterior wall.

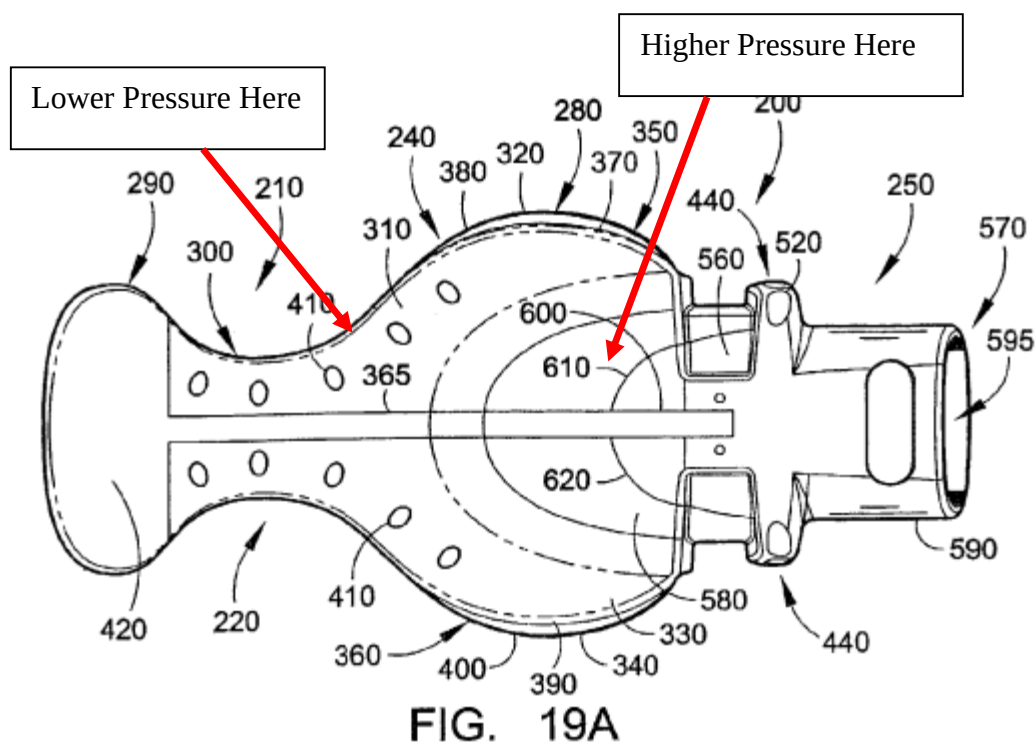
80. There is simply no open-sided mouthpiece embodiment described or even suggested by the First Family. Instead, the entire specification is focused on describing the enclosed pocket configuration the features that facilitate the enclosed pocket. Every Figure of the specification confirms this four-sided enclosure configuration. Thus, a PHOSITA would understand that the disclosed mouthpiece has an enclosure defined by four walls. While Solmetex included some boilerplate language suggesting the “descriptions are not intended to limit the scope of the invention to the particular forms set forth herein” (’970 Patent, 5:65-67), this language would not be interpreted by a PHOSITA as suggesting that the claimed “pocket” that “defines an interior space” could be anything other than a mouthpiece with four enclosing, exterior walls, two of which are sidewalls formed at edges of the anterior and posterior walls.

81. In addition, during prosecution, Solmetex differentiated from Hirsch, a prior art mouthpiece with a spine, meaning that the recited mouthpiece’s scope does not extend to subject matter given up during prosecution. For example, in an Interview Summary, Solmetex differentiated from the open-sided mouthpiece of Hirsch by noting the existence of the four walls that define pocket and enclose the interior space. Here, Solmetex said:

Hirsch fails to disclose ‘interior open space of the pocket’ that spans the inferior wall to superior wall. In particular, the claimed ‘main body portion’ has an ‘interior open space’ that is enclosed by and spans across the distance between anterior and

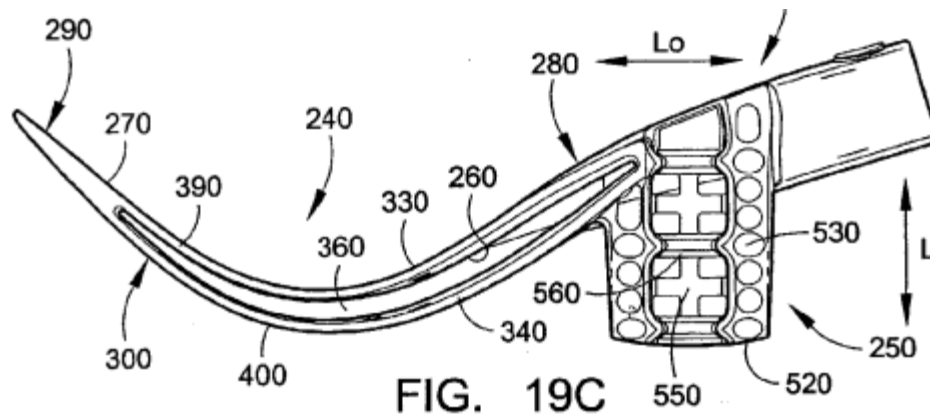
posterior walls, as well as spanning across the superior and inferior walls. The recited 'walls' therefore enclose an interior space through which suction can be applied consistently, with maintaining structural integrity of the main body shape and enclosed interior space during suction. In contrast, Hirsch includes subdivisions (e.g., via a spine) within its interior, as well as fails to teach any defined walls spanning across set distances as does the claimed superior and inferior walls.

SOLMETEX_0000985. By making this argument, Solmetex differentiated from prior art mouthpieces that include subdivisions, such as those having a central spine, like Hirsch. Exactly as taught by the specification, Solmetex argued that the interior open space of the pocket is defined by four walls, thereby creating an enclosure defined by four walls. Indeed, only a mouthpiece without subdivisions (i.e., without a central spine) and with enclosing walls could allow for consistently applied suction. From a physics standpoint, an open-sided mouthpiece (like Hirsch's shown below) would not consistently apply suction in all locations between an anterior flap and posterior flap. For example, suction pressure would be far lower at the edges of the flaps than it would be nearer to the suction connector entry port. Suction pressure would vary at edges of the flaps depending on the amount of fluid entering the edges.



Thus, according to Solmetex, mouthpieces with subdivisions within its interior is not an “interior open space” and not a “pocket”. This argument surrendered claim scope. Instead, the claims are limited to structures that enclose an interior open space *without subdivisions*, per Solmetex’s limiting arguments to the Examiner. Solmetex made this argument on more than one occasion. SOLMETEX_0000868-72, *see also* SOLMETEX_0000985-990. Solmetex had to make these arguments to overcome the prior art, particularly Hirsch. Solmetex cannot now recapture these broader concepts after arguing around those features to obtain a patent during prosecution.

82. Solmetex doubled down on differentiating between an interior space and open-sided mouthpieces. In the prosecution history of the ’969 Patent, Solmetex again differentiated over Hirsch saying that “‘open gaps’ further teach away from the claimed enclosed interior space.” SOLMETEX_0000986-89. As shown below, the Hirsch mouthpiece has open gaps 360 (i.e., open sides) on the sides of the mouthpiece.



The VacuLUX mouthpiece also has open gaps on the sides of a mouthpiece.



83. In fact, Solmetex very clearly relied on the specification to inform the Examiner what it meant by certain words, including pocket. In an Office Action Response, Solmetex walked the Examiner through each claim limitation and pointed to the specification and figures to “discuss” the specific elements claimed. SOLMETEX_0000570-72. When discussing the limitation “a main body portion configured as a pocket having an interior defined by:”, Solmetex pointed to FIG. 1B and the specification section 3:45-50, which describes the four walls that define the partially enclosed body. *Id.* Solmetex then says, “***as described and illustrated***, the main body 110 is a *partially enclosed body (e.g., pocket) defined by several walls.*” Solmetex provided these explanations in response to the Examiner taking the position that the open-sided mouthpiece of Black was a pocket. SOLMETEX_0000573. Solmetex again later argued that Black teaches a differently configured mouthpiece saying, “Nowhere does Black teach an interior open space

defined by a defined shape of an anterior wall, a corresponding shape of a posterior wall, a superior wall connecting an exterior edge of the anterior wall to a corresponding edge of the posterior wall, and an inferior wall connecting the exterior edge of the anterior wall to the corresponding edge of the posterior wall, and an interior open space of a pocket that extends into a rectangular portion.” SOLMETEX_0000871. In other words, Solmetex defined and specified what is a main body portion and a pocket, namely that it is a partially enclosed body defined by several walls. Solmetex went further saying the pocket lacks subdivisions thereby surrendering scope. Solmetex’s own words during prosecution, when explaining the disclosed mouthpiece, matches and clearly supports Ascentcare’s proposed construction.

84. The Examiner’s understanding that the pocket is an enclosure was confirmed when Solmetex tried to remove the sidewall limitations from the claim language. In January 2021, one month after Ascentcare launched the VacuLUX mouthpiece, Solmetex suddenly, after years of arguing for the patentability of a mouthpiece with sidewalls, removed the sidewall limitations from the claim language entirely. SOLMETEX_0001061-62; SOLMETEX_002613; SOLMETEX_0004003. The Examiner noticed this dramatic change and issued an indefiniteness rejection saying that the claim omitted essential elements. SOLMETEX_0001217-19; SOLMETEX_0002625-26 SOLMETEX_0004033-34, SOLMETEX_0004105-06. In other words, the Examiner found the enclosed nature of the main body portion/pocket to be “essential” to understanding the disclosed mouthpiece. Thus, the Examiner, an objective PHOSITA, found the pocket to be a partially enclosed body defined by several walls, including a sidewall formed at edges of the anterior wall and posterior wall. In fact, the Examiner said, “the omitted elements and structural cooperative relationships are: the first wall having an exterior edge, the second wall having an exterior edge corresponding to the exterior edge of the first wall, the connecting wall

connecting the first wall to the second wall along the exterior edges thereof, *defining said interior open space of the pocket*". *Id.* Solmetex tried to claim a mouthpiece without enclosing sidewalls to read on Ascentcare's product, but the Examiner did not allow claims directed to an open-sided mouthpiece because Solmetex did not invent an open-sided mouthpiece. *Id.*

85. Solmetex also made these same arguments in the '970 Patent. SOLMETEX_0013283. Solmetex is consistent that the pocket includes four walls that together enclose an interior open space.

86. In Australia, Solmetex faced the same prior art (Hirsch, which is called D2 below, and Black, which is called D3 below). In arguing around Hirsch and Black, Solmetex said the following:

D2

D2 does not disclose "a pocket having an interior defined by: an anterior wall...a posterior wall...and a side wall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall." The items 310, 320, 330, and 340 of D1 as purportedly showing a side wall are described as "[t]he front flaps 310, 330 and rear flaps 320, 340... separated by upper gap 350 and lower gap 360, respectively." As such, the items 310, 320, 330, and 340 cannot define "a pocket having an interior" or "a side wall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall."

AU2016200275, Examination Response dated April 23, 2018, p. 1. Thus, according to Solmetex, a mouthpiece with four flaps and open sides is not a pocket, does not have a wall connecting an exterior edge of the anterior wall to the exterior edge of the posterior wall, and does not have an interior. Regarding Black (called D3 below), Solmetex said the following:

D3

D3 does not disclose "a pocket having an interior defined by: an anterior wall...a posterior wall...and a side wall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall." As cited, [0005] of D3 describes a first layer and a second layer each having a posterior side and an anterior side and "the posterior side of the second layer is connected to the anterior side of the first layer by a plurality of walls." In other words, the exterior edges of the first layer and the second layer are not connected via a side wall; rather, the first layer and

the second layer are connected by a plurality of walls. Moreover, [0005] does not disclose a pocket having an interior. Fig. 4B of D3 also does not disclose a pocket having an interior; rather, a large gap between the walls is shown in Fig. 4B which does not constitute nor define a pocket having an interior.

Id. Again, Solmetex argues that an open sided mouthpiece with a gap between the anterior and posterior walls on the sides is not a pocket and does not have an interior.

87. While the specification is clear that the only embodiment clearly envisioned was a four-sided pocket, I note that the summary discusses a main body portion defined by the anterior wall, the posterior wall, and a sidewall. '970 Patent, 1:61-63. The claims also only recite three walls. It's not exactly clear to me how a three-sided, pocket-shaped mouthpiece would function in view of the First Family's disclosure, but it does appear that a mouthpiece with three exterior walls was at least contemplated. Nevertheless, the summary recites a sidewall, which a PHOSITA would understand to be an exterior wall. Thus, the pocket should be construed as being defined by at least three exterior walls.

88. Therefore, the specification only describes an enclosed mouthpiece that encloses an interior space defined by at least three exterior walls (anterior wall, posterior wall, sidewall). Moreover, Solmetex made numerous arguments during the pendency of several patent application specifying to the Examiner that the disclosed mouthpiece encloses an interior open space *without subdivisions*, such as a central spine. Thus, a PHOSITA informed by the specification and the prosecution histories of the '969 and 970 Patents would understand a pocket to mean "an enclosure

of a main body portion without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall.”

c. “Interior space”

89. It is my opinion that a PHOSITA would understand the term “interior space” to mean “an open space defined by the pocket” or, for the claims that do not recite a pocket, “an open space defined by an enclosure without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall”.

90. To begin, the concept of an interior open space and a pocket are integrally tied together. In paragraphs 73-88 above, I discussed how a PHOSITA would understand the term “pocket”. In that discussion, there is a great deal of discussion about the interior space and its relationship to the enclosure created by the main body portion or pocket. The analysis above applies here.

91. Beginning again with the claim language, claim 19 of the ’969 Patent recites “a main body portion configured as a pocket at least partially enclosing an interior space”. Here, the claim specifies that the pocket encloses the interior space. The claim goes on to explain the walls that define the pocket (first wall, second wall, connecting wall). Claim 19 of the ’969 Patent has further language about the interior space, saying “a first wall that includes one or more perforations in communication with the interior space of the pocket”. The second wall has similar language about perforations in communication with the interior space of the pocket. Claim 19 further adds, “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”. Again, the claim language relates the pocket, and its enclosing walls, with the interior space enclosed by those walls. Finally, the claim language of claim 19 says, “the suction connector configured to connect a vacuum source to the interior space of the pocket”. From this claim language, a PHOISTA would

understand that the interior space is created by the walls of the main body portion/pocket.

92. The other asserted independent claims are similar regarding the interior open space. In particular, claim 18 of the '970 Patent says, “a main body portion configured as a pocket at least partially enclosing an interior space that extends from a first end to a second end of the main body portion.” Claim 18 further recites that the first wall has an interior surface that faces the interior space of the pocket, and that the suction connector is in communication with the interior space. Again, the claim context suggests that the walls of the main body enclose and define the interior space.

93. Claim 12 of the '686 Patent confusingly uses the word “space” and “interior space” interchangeably. Claim 12 of the '686 Patent says, “a second wall having a plurality of second edges and located at a distance from the first wall, the distance corresponding to a space between the first wall and the second wall” and then later says “the bridge structure extending through the interior space towards the first wall.” The claim lacks proper antecedent basis for “interior space”. Hence, the claim is either indefinite or is referring to the previously introduced “space”. Here, the claim lacks the word “pocket”, but a PHOSITA would understand that for a space to be “interior” there must be some “exterior” boundaries, particularly when those boundaries (“first wall”, “second wall”, “connecting wall”) are expressly recited in the claim language. As such, I construe “space” and “interior space” the same. Like the '969 and '970 Patents, claim 12 of the '686 Patent also recites that the suction connector is in communication with the “space between the first and second wall”.

94. Claim 20 of the '418 Patent states, “wherein the first wall and the second wall define an interior space therebetween.” Dependent claim 21 adds that the suction connector is in communication with the interior space. The claim does recite a third wall that connects edges of

the first and second wall. A PHOSITA would understand that connecting edges would mean sidewalls (See Section VI.e), so again, the interior space is defined by at least three walls.

95. In all of the claims discussed above, the main body portion includes at least three walls: a first wall (anterior/posterior), a second wall (anterior/posterior), and a connecting wall (or third wall). While some of the claims only recite the interior space as existing between the first and second wall, it necessarily follows that the third wall also defines the interior space because the connecting/third wall is claimed as connecting edges of the first and second wall in all of the claims discussed above. It would be impossible and defy logic for the connecting/third wall to connect edges of the first wall and the second wall and not also define the interior space. By connecting edges, a PHOSITA would understand that the connecting wall/third wall is necessarily an exterior wall. Thus, a PHOSITA would understand that the interior space is defined at least by the three recited walls (and probably a fourth wall, given the limited specification disclosure).

96. The specification never uses the term “space” or “interior space”. It appears that the Solmetex only can rely on Figures to support this interior space. Solmetex appears to concede this point in the ’969 File History, saying that FIG. 2E and 7B show the interior space. SOLMETEX_0000870-71.

97. That said, the specification refers to an “interior portion”, an “interior surface”, “the interior of the pocket”, and an “interior side of the posterior surface of the main body”. ’970 Patent, 2:1-5, 2:15-18, 4:15-21, 4:30-34, 4:48-51. In each of these contexts, “interior” refers to a place inside the enclosed pocket disclosed by the specification. For example, the specification says, “The main body portion may comprise an enclosed pocket made up of an anterior wall, a posterior wall, and a side wall in between the anterior and posterior walls.” *Id.*, 1:61-63. The specification further adds, “Such openings (e.g., perforations and slit) allow for suction of air, fluids, and small debris

from the patient's mouth, through the openings into the interior portion, and into the suction connector portion towards a suction source.” A PHOSITA would understand that the perforations would extend through a wall defining a pocket into the “interior portion” created by the enclosed pocket. *Id.*, 4:5-12.

98. Later, the specification explains that the slit 170 in the anterior wall provides access “into the interior of the pocket”. *Id.* at 4:16-21. Again, the specification is describing an opening into an enclosed pocket, and the interior of the pocket is accessible for cleaning and maintenance through the slit opening. *Id.* at 4:44-47.

99. Finally, the specification describes the bridge structure as an internal structure formed on an “interior surface” of the posterior wall in numerous places. *Id.*, 2:62-63, 3:27-29, 4:30-34. FIGS. 5 and 2E show the bridge structure inside the pocket, and the bridge structure is only visible when the “surrounding walls” are not blocking the view of the internal bridge structure. ’970 Patent, 4:53-54, FIG, 5.

100. Throughout all these limited discussions of the interior, the specification consistently and only describes such an “interior” as a space created by the enclosure of numerous enclosing or surrounding walls. Moreover, as I discussed above in paragraph 81, Solmetex surrendered claim scope that includes a subdivided interior space by arguing around a mouthpiece with a central spine that subdivides. Consistent with a PHOSITA’s understanding, an “interior” must be defined by boundaries to separate the interior from the exterior. Thus, a PHOSITA would understand that an “interior space” would be a space defined by the pocket or defined by an enclosure without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall.

101. As I explained above, the pocket is an enclosure that defines the interior space.

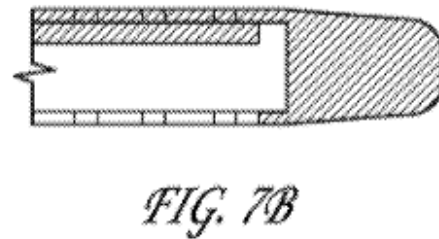
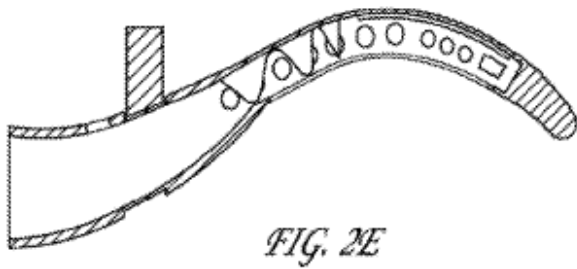
Even when the claims lack the specific term “pocket”, a PHOSITA would still understand the “interior space” to be the space defined by an enclosure that has exterior walls. Just logically, an “interior space” would be contrasted with an “exterior space”. There must be some structure that separates the exterior from the interior. An interior is often defined as something inside, and inside is defined as “situated within the boundaries or confines of”.

102. Solmetex recognized this and differentiated from mouthpieces that lack an “interior space”. Specifically, mouthpieces with open sides. When overcoming Hirsch, which has open sides, Solmetex said, “Hirsch fails to teach a ‘superior wall’ which has a ‘span less than a width of the anterior wall’ and define the shape of ‘the interior open space of the pocket’ along with anterior wall, posterior wall, and inferior wall’[sic]. *The specific teachings regarding open gaps* [i.e. open sides] *further teaches away from the claimed enclosed interior space.*” (emphasis added). SOLMETEX_0000988. As noted above, Hirsch’s open-sided mouthpiece has “gaps” on the sides rather than the enclosing sidewalls disclosed by the specification of the First Family. According to Solmetex, a mouthpiece with open sides cannot have an interior space. *Id.*

103. Solmetex also differentiated from Black’s open-sided mouthpiece, saying “Nowhere does Black teach an interior open space defined by [the walls of the main body portion]. SOLMETEX_0000871.

104. Solmetex even walked through the claim language and showed the Examiner what it intended regarding the claim language. SOLMETEX_0000570-72. When discussing the “main body portion”, Solmetex showed FIG. 1B and 3:45-50 of the specification, which describes the anterior wall, the posterior wall, and a superior wall and inferior wall. *Id.*

105. In addition, Solmetex pointed to FIG. 2E and 7B, and said:



As shown above, interior open space extends to each of the anterior wall, the posterior wall, the superior wall, and the inferior wall.

SOLMETEX_0000871. By saying “as shown above”, Solmetex limited themselves to the interior space illustrated by the figures. This statement was not made as mere “exemplary support”.

106. Solmetex’s international applications are also informative for how it used language to interpret and describe the disclosed mouthpiece. In Canada, the specification includes additional “Summary” paragraphs. SOLMETEX_0000486. The Summary paragraph says, “wherein the anterior wall, the posterior wall, and the side wall define an interior portion of the defined pocket.” *Id.* Again, Solmetex described an enclosed pocket that defines the interior space or “interior portion”, and the pocket comprises an anterior wall, a posterior wall, and a side wall. In fact, every international application I reviewed in the First Family, of which there are many (Canada, Europe, Korea, China, Japan, etc.), recite a sidewall. *See* paragraph 52 above. For example, EP3184076B1 recites, “a main body portion (110) comprising a defined pocket having an anterior wall, a posterior wall, 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.”

107. For all the reasons discussed above regarding pocket, it follows that the interior space is the space enclosed by the pocket. And, for claims that do not recite a pocket, it is my opinion that the interior space should be construed as “an open space defined by an enclosure

without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall.”

d. “inner cavity”

108. It is my opinion that “inner cavity” should be construed the same as “interior space.” Only claims 9 and 30 of the ’329 Patent use this language saying, “a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity”. The broad language of the claim merely suggests that the third wall has some involvement in defining this inner cavity.

109. The specification never uses the term inner cavity. The only “cavity” discussed in the specification is a patient’s oral cavity (i.e., mouth).

110. As discussed above in Sections VI.b-c, the specification only describes a close-sided, pocket-configured mouthpiece. Thus, the term “inner cavity” cannot have a different meaning than “interior space”. While different words are used, the specification only supports a space that is formed by an enclosure without subdivisions and that spanning between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall.

111. Like “interior space”, the term “inner cavity” suggests that there is an “outer” region, and a boundary must be drawn to define where that cavity becomes an “inner” cavity as opposed to an “outer” region. Referring to the specification, there can only be one conclusion: that the anterior wall, the posterior wall, and the sidewalls are exterior walls that define when a cavity becomes an “inner cavity” as opposed to an “outer” space. Thus, a PHOSITA would not understand “inner cavity” any differently than “interior space”.

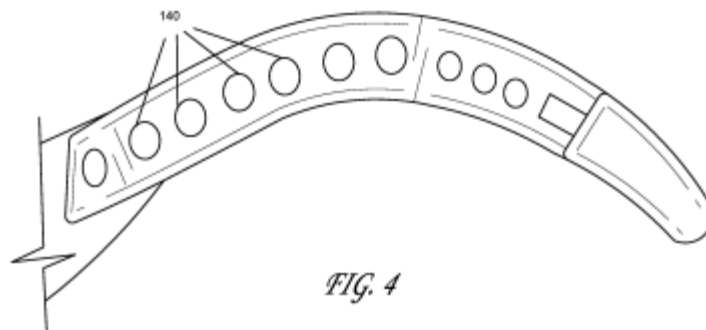
- e. “a connecting wall that connects the one or more edges of the first wall to the one or more corresponding edges of the second wall”; “a connecting wall that connects one or more edges of the first wall to one or more corresponding edges of the second wall”; “a third wall that connects one of the first edges of the first wall to one of the second edges of the second wall”**

112. It is my opinion that a PHOSITA would understand the term “connecting wall that connects the one or more edges of the first wall to the one or more corresponding edges of the second wall” (and other similar terms) to mean “a sidewall that connects either the inferior edge of the first wall to the inferior edge of the second wall or the superior edge of the first wall to the superior edge of the second wall”. The minor differences in claim language between these similar terms does not change the scope or understanding to a PHOSITA.

113. The claim language is specific in these three similar claim terms. The '970 Patent merely adds that the second wall's edge is “a corresponding edge” and the '418 Patent merely changes the term “connecting wall” to “third wall”, which has no effect on claim scope considering that the “third wall” claimed by claim 20 of the '418 Patent “connects” edges of the first and second wall. Thus, I will discuss these three terms, spanning four of the asserted independent claims together.

114. The claim language recites that the connecting/third wall is part of the main body portion. The claim language further explains that this recited wall connects *edges* of the first and second wall.

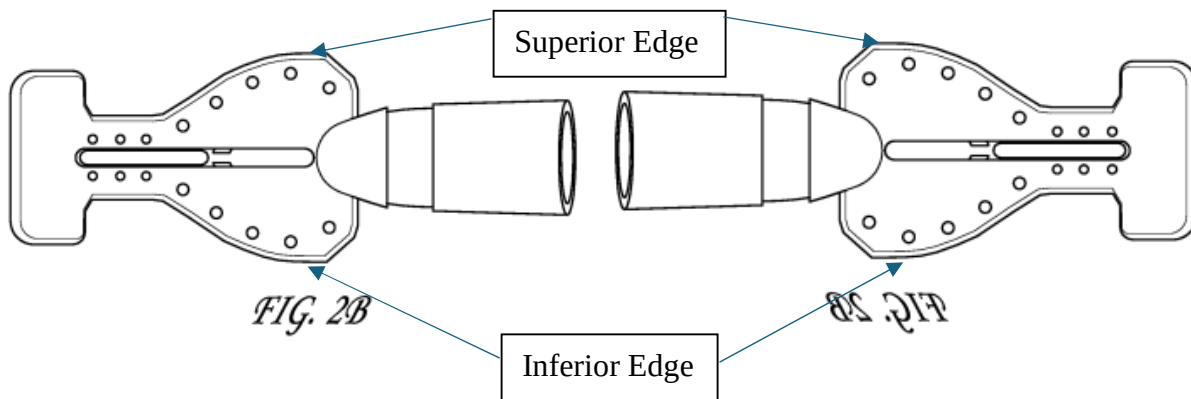
115. The specification only uses the term “edge” once saying, “In some embodiments, a set of holes may also form a mesh along the walls of the superior and inferior edges. FIG. 4 is a close-up view of an exemplary mesh wall in an exemplary mouthpiece.” '970 Patent, 4:9-12



Of note, FIG. 4 is described as showing “a close-up view of exemplary mesh sides in an exemplary mouthpiece.” *Id.*, 2:60-61. It should be noted that the specification expressly defines the terms “superior” and “inferior”, saying:

Superior may be used herein to refer to the side that rests against a roof of a patient's mouth when placed therein, and inferior may be used to refer to the side that rests against the floor of the patient's mouth.

'970 Patent, 3:51-54. Hence, the specification describes two “edges” of the mouthpiece: an inferior edge and a superior edge. The superior edge is the edge that rests against the roof of the patient's mouth, and the inferior edge is the edge that rests against the floor of the patient's mouth when in use. Depending on orientation, the superior and inferior sides can switch. *Id.*, 3:51-58.



The specification also uses this terminology to describe “sides” (“The superior and inferior sides may be formed identically...”). Thus, a PHOSITA would understand that the recited edges are boundaries formed on either the superior or inferior sides of the mouthpiece. The plain and ordinary meaning of an “edge” would be understood by PHOSITAs and laymen alike as an outer limit of an object. Here, as specifically recited by the claim language, the claim recites an edge as the external boundary of the anterior and posterior walls. (e.g., “a first wall having a plurality of first edges”)

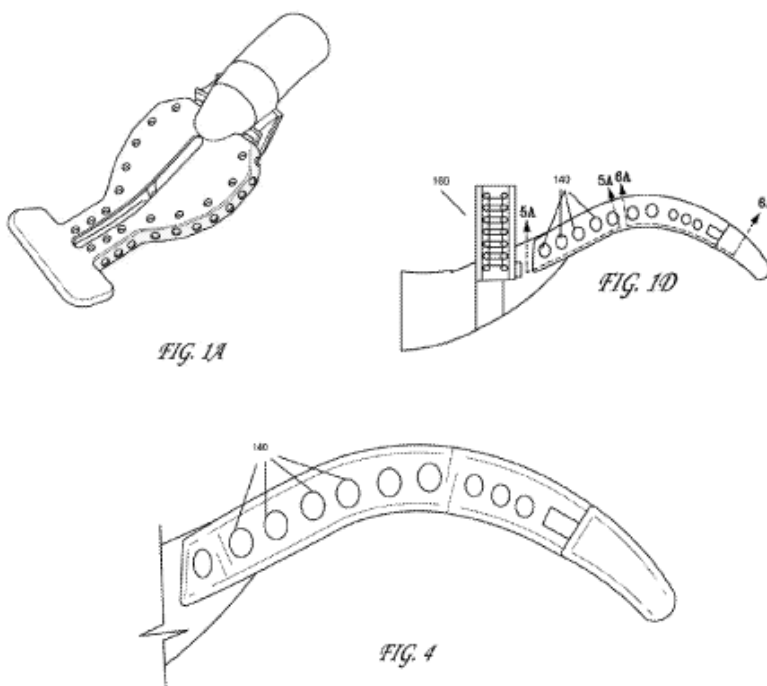
116. The Examiner agreed with my opinion. In the prosecution history of the '686 Patent, the Examiner said "the specification only describes that each of the first wall and the second wall includes superior and inferior edges (see [0035]). Therefore, the present application does not disclose the option of having a single or one edge on each of the first and second wall." SOLMETEX_0004546. Exactly as I said above, and exactly as the specification describes, a PHOSITA would understand the "edges" of the first wall and second wall to be either an inferior or superior edge. In other words, the outer limit of the anterior wall or the posterior wall is on the inferior and superior sides. Other boundaries are defined as "ends" according to both the claims and the specification. It should be noted that Solmetex disagreed with the Examiner's conclusions, and presented arguments why the Examiner's understanding of the edges was incorrect. SOLMETEX_0004515. However, the Examiner maintained the rejection, and Solmetex conceded by amending the claims to recite that the mouthpiece includes multiple edges. SOLMETEX_0004544-47 and SOLMETEX_0004567-69. Even when challenged, the Examiner's demonstrated that a PHOSITA would understand an edge to be either be an inferior or superior edge.

117. Knowing that an edge is either the inferior outer limit of the anterior/posterior wall (i.e., the inferior "edge" or the edge on the inferior "side") or the superior outer limit of the anterior/posterior wall (i.e., the superior "edge" or the edge on the superior "side"), a connecting wall that connects either the inferior edge or the superior edge would necessarily be a sidewall. That is, a PHOSITA would understand that a wall connecting either the inferior or superior edge of the anterior wall to the inferior or superior edge of the posterior wall is necessarily a sidewall. A PHOSITA would further arrive at this conclusion given that the specification never shows or describes anything but a mouthpiece with sidewalls. This understanding comports with the

discussion above regarding “pocket” and “interior space.”

118. Moreover, this sidewall was found by the Examiner to be an “essential element” of the claims. After Solmetex amended its claims one month after Ascentcare’s launch of the VacuLUX mouthpiece, the Examiner allowed the claims, but the Examiner *reinserted* the sidewall limitations after proposing an Examiner’s amendment. SOLMETEX_0001074-75, SOLMETEX_0001087. Solmetex wasn’t happy with that reinsertion or there was an apparent disagreement, and that is when the Examiner noted that the sidewall connecting edges of the anterior and posterior wall was essential subject matter. SOLMETEX_0001217-19.

119. At one point, Solmetex also walked the Examiner through the claims, including the limitation “a sidewall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall”. Solmetex explained to the examiner that, “The sidewall is illustrated in FIG. 1A, 1D, and 4 (provided below):”



Solmetex then added, “As can be seen from the illustrations provided, *the side wall connects the*

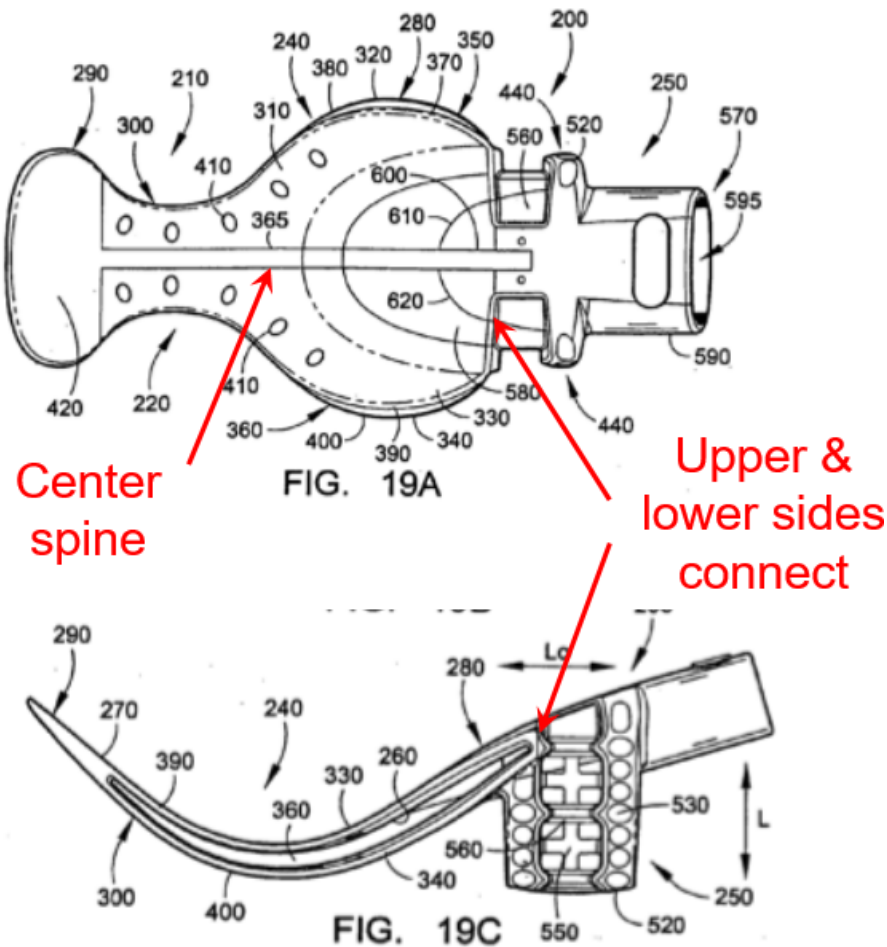
defined exterior edge of the anterior wall to the defined exterior edge of the posterior wall.”

SOLMETEX_0000571-2 (emphasis added). The claims may now recite a “connecting wall,” but the language regarding edges is nearly identical. A PHOSITA would know that a wall cannot connect an edge of the anterior wall to the edge of the posterior wall without being an exterior sidewall. Solmetex understood an edge to mean an exterior edge or peripheral edge at all times. See SOLMETEX_0005390 (“It is then further clarified by the attorney that “along the edge” refers to the peripheral edge and not the edge of the inner surface of the main wall”).

120. I should note that the sidewall limitation existed in the first patent issued. ’232 Patent, claim 1. It existed in the originally presented claims. *E.g.* SOLMETEX_0000183, SOLMETEX_0000242. Every international application that I reviewed in the First Family, of which there are many (Canada, Europe, Australia, etc.), recites a sidewall. See paragraph 52 above. The claims presented to the United States Patent Office in the ’969, ’970, and ’686 Patents recited at least one sidewall for nearly seven years of prosecution. SOLMETEX_0000183, SOLMETEX_0000242, SOLMETEX_0000983; SOLMETEX_0001724, SOLMETEX_0001772, SOLMETEX_0002514; SOLMETEX_0003177, SOLMETEX_0003236, SOLMETEX_0003955.

121. Solmetex also distinguished walls that do not connect inferior or superior edges, such as a wall that exists on an “end” of the main body portion near the bite block. In another response to the United States Patent and Trademark Office, Solmetex differentiated from a mouthpiece (Hirsch) having a wall formed at an end of a tongue retractor portion. Specifically, Solmetex said, “The recited ‘walls’ therefore enclose an interior space through which suction can be applied consistently throughout, while maintaining the structural integrity of the man body shape and enclosed interior space during suction. In contrast, Hirsch includes subdivisions (e.g., via a spine) within its interior, as well as fails to teach any defined walls spanning across set

distances as does the claimed superior and inferior walls.” SOLMETEX_0000985 (emphasis added). I show Hirsch below, which is from the reference Solmetex argued around



As can be seen by FIG. 19C, Hirsch has a wall on the “end” of the wider tongue retractor area that connects the anterior flap to the posterior flap. Despite this clear depiction, the Solmetex argued that Hirsch failed to teach “walls that enclose an interior space”. Thus, a PHOSITA would understand that a connecting wall cannot be formed at an “end” of the main body portion or as part of the bite block, as clearly shown by Hirsch, because Solmetex argued that Hirsch’s mouthpiece is different from the claimed mouthpiece. Indeed, a wall formed here would not connect either the inferior or superior edge. A PHOSITA would read this argument and understand that the claims are limited to sidewalls formed on the inferior and superior sides, as disclosed in the specification,

and cannot be a wall formed at the end or as part of the bite block, as such a configuration is apparently not what was claimed or described by the patent.

122. Finally, I note that the claims first examined by the Examiner are extremely similar to this language.

Claim Language – Preliminary Amendment	Final Claim Language
a side wall connecting the exterior edge of the anterior wall to the corresponding exterior edge of the posterior wall	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

Language in Blue is language very similar or identical across both instances of the claim. As seen in red, the only difference between the two versions of the claims is the recitation of “one or more” edges and changing “side” to “connecting”. This difference in nomenclature does not change the function of the recited wall or its structure or scope. The claim still recites an exterior wall connecting edges. As such, a connecting wall that connects edges as recited would be understood by a PHOSITA as a side wall.

123. Thus, for all these reasons, a “connecting wall” that connects edges of the anterior wall and posterior wall is necessarily a sidewall. Moreover, as the Examiner correctly noted, the specification only supports a mouthpiece with a superior edge and an inferior edge. Thus, the connecting wall connects either the inferior edge of the anterior wall formed on the inferior side of the mouthpiece to the inferior edge of the posterior wall or the superior edge of the anterior wall formed on the superior side of the mouthpiece to the superior edge of the posterior wall.

124. Once again, I note that my construction is the plain and ordinary meaning. However, Solmetex has taken the position that this connecting wall claim language is broad

enough to encompass an integral bite block formed at an end of a tongue retractor. Thus, there is a dispute regarding claim scope between the parties.

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

125. It is my opinion that a PHOSITA would understand the terms “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” / “wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall,” / “wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds in shape to the third edge of the second wall and the second edge of the first wall corresponds in shape to the fourth edge of the second wall; and wherein the first shape of the first wall corresponds to the second shape of the second wall” to mean “a second wall having a substantially identical shape to the shape of the first wall, such that the edges of the second wall are aligned with the edges of the first wall”. While these claims differ slightly in terminology, in view of the specification, they all describe the same concept, which is that the anterior wall and the posterior wall are substantially identical such that the edges of the anterior wall and posterior wall align. Indeed, the primary issue is understanding the word “correspond” or “corresponding”. As such, I discuss all three terms together.

126. Beginning again with the claim language, claim 19 of the '969 Patent recites “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”. Based on this language, a PHOSITA would understand that the second wall is at least similar in shape to the first wall, and the edges of the second wall are similar in location to the edges of the first wall. The claim goes further explaining that a connecting wall “connects the one or more edges of the first wall to the one or more edges of the second wall”. Thus, in view of the connecting wall language, a PHOSITA would understand that the correspondence in shape and edge locations must be close enough that they can be connected by a connecting wall. The shapes and sizes of the first and second wall may not need to be perfectly identical, but substantially identical so that the edges can be connected using a connecting wall.

127. The specification confirms this understanding. In fact, in the Figures, the anterior and posterior wall are illustrated as identical. ’970 Patent, FIG. 1B, 1C.

128. The specification never describes the anterior wall and posterior wall as “corresponding in shape”. Only the Figures support this concept, and the figures show identically sized and shaped anterior and posterior walls.

129. The concept of corresponding sizes/distances/shapes is described with regard to other features of the mouthpiece. For example, the specification explains that the “bridge structure 180 may be formed as an [sic] 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.” *Id.*, 4:53-59. Here, Solmetex specified that a “corresponding” distance can be within 1 mm of a second distance.

130. In other places of the specification, Solmetex used the word “corresponding” to mean something even more identical in size or shape than “within 1 mm”. For example, the

specification explains that the suction connector portion 120 has “an external, concave, notched region 210 that corresponds to a removable strap such that when the strap is in place, the external walls of the strap and the rest of the connector portion may be flush”, and the mouth prop strap corresponds to the circumference of the suction connector. *Id.*, 5:7-12, 5:38-42. The specification also explains that the suction connector portion 120 includes an external plug that “correspond[s] to and serve[s] to connect with an opening in the mouth prop 160”, and the mouth prop is described as fitting “snugly” within that opening. *Id.*, 5:25-29, 5:43-46. Lastly, the specification explains that the cutout 230 in the suction connector interlocks with a “corresponding protrusion”, and the specification explains that both the cutout and the protrusion have the exact same “shape as a logo”. *Id.*, 4:65-67, 5:35-39. In all of these instances, the specification is describing two interlocking elements that have identical or nearly identical respective dimensions.

131. So, the specification used the word “correspond” to describe identical shapes, a snug fit, a flush appearance, and within 1 mm. All of these uses of the term “correspond” suggest a *very* similar shape/size/proportion etc.

132. During prosecution, Solmetex confirmed its narrow usage of “corresponding”. In response to a rejection of Black, Solmetex walked the Examiner through every limitation, including the limitation “a posterior wall having a shape corresponding to the defined shape of the anterior wall, wherein an exterior edge of the posterior wall shape corresponds to the exterior edge of the anterior wall”. SOLMETEX_0000571. In explaining this limitation, Solmetex wrote:

3. *'a posterior wall having a shape corresponding to the defined shape of the anterior wall, wherein an exterior edge of the posterior wall shape corresponds to the exterior edge of the anterior wall'*

The posterior wall is illustrated in FIG. 1C as follows:

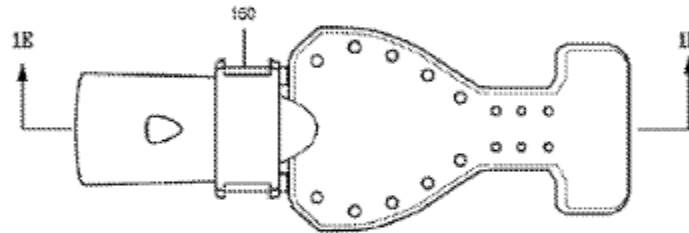


FIG. 1C

As illustrated, the posterior wall (the wall facing the viewer in FIG. 1C) has a defined shape that corresponds to the shape of the anterior wall. Similarly, the shape of the posterior wall is defined by a corresponding exterior edge.

Id. Notably, the anterior wall is substantially identical in shape and size to the posterior wall in FIGS. 1B and 1C.

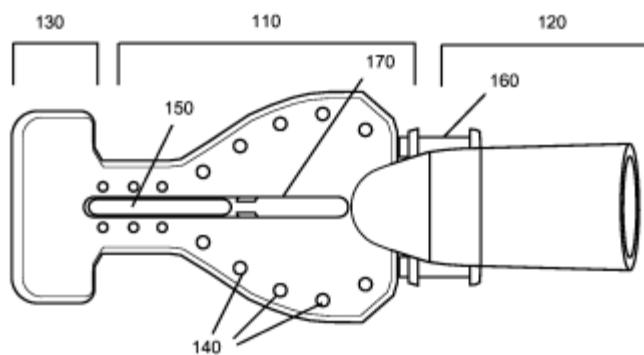


FIG. 1B

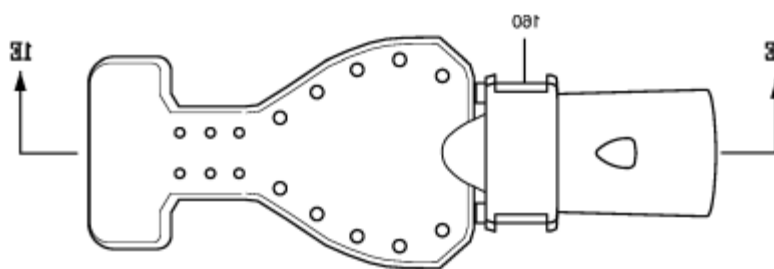


FIG. 1C

Solmetex points to FIG. 1A in a different prosecution history to show support for this limitation, and FIG. 1A, like FIGS. 1B and 1C, show substantially identical anterior and posterior walls.

The claimed main body appears in FIG. 1A (provided below).

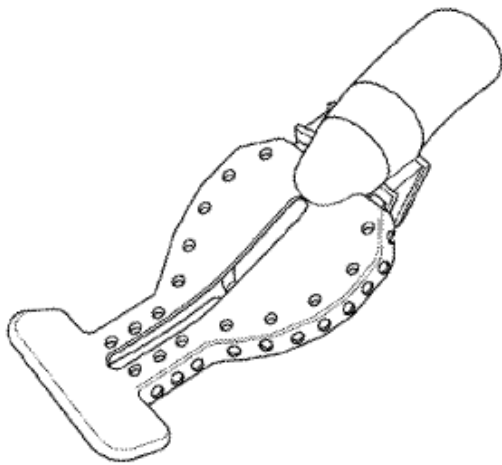


FIG. 1A

As illustrated, the 'pocket' of the 'main body portion' 'at least partially enclos[es]' an 'interior space.' The 'pocket' includes 'a first wall extending from the first end to the second end' and that 'is narrower at the second end than at the first end,' a corresponding 'second wall located a distance from the first wall' and likewise 'extending from the first end to the second end' and 'narrower at the second end than at the first end,' and a 'connecting wall that connects one or more edges of the first wall to one or more corresponding edges of the second wall across the distance.'

SOLMETEX_0002958-59. In yet another prosecution history, Solmetex pointed to specification section describing the inferior sidewall and the superior sidewall as “express support”, even including bolded language suggesting to a PHOSITA that the connecting wall that connects corresponding edges means that the edges must line up substantially identically such that a substantially perpendicular wall could connect those corresponding edges.

Claims 1-2, 4-8, 14-16, and 21-30 are rejected under 35 U.S.C. § 112(b) as purportedly indefinite. *Office Action*, 2. Independent claims 1 and 21 are amended to recite that the ‘connecting wall that connects one or more edges of the first wall to one or more corresponding edges of the second wall across the distance between the first wall and the second wall.’ Express support is found in the *Specification* as follows:

An exemplary main body portion 110, when placed in a mouth, 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. The two walls may **connect at a superior wall and an inferior wall forming a body that is at least partially enclosed.**

...

In some embodiments, a set of holes may also form a mesh along the walls of the **superior and inferior edges.**

Specification, [0035]; [0037]. In addition, the “antecedent basis” issues identified by the *Office*

Id.

133. Thus, for all these reasons, it is my opinion that a PHOSITA would understand these claim terms to mean “a second wall having a substantially identical shape to the shape of the first wall, such that the edges of the second wall are aligned with the edges of the first wall”.

g. “bridge structure”

134. It is my opinion that a PHOSITA would understand the term “bridge structure” to mean “an internal structure attached to the second wall that prevents the collapse of the first and second wall during suction.” I note that the independent claims of the ’329 and ’418 Patent abandoned the “bridge structure language and instead used “a plurality of protrusions” or “a plurality of crests of a wave-shaped structure”. These words claim the exact same function and structure of a bridge structure, and a PHOSITA would understand that the “plurality of protrusions” or “plurality of crests” are the internal bridge structure described by the specification. See Section VI.h.

135. Beginning with the claim language, in for example, the '969 Patent, 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”. As I explained above, the interior space should be construed as “an open space defined by the pocket,” and the pocket should be construed as an enclosure without subdivisions that spans between the anterior wall, the posterior wall, an inferior sidewall and/or a superior sidewall.” Claim 19 of the '969 Patent explains that the bridge structure is “*within* the interior space.” In other words, the bridge structure is an internal structure that exists inside the pocket or enclosure formed by the walls of the main body portion.

136. Other claims are similar. In fact, every asserted independent claim recites that the bridge structure (or wave-like structure, discussed below) either protrudes from or is formed on an “*interior* surface” of the second wall. A PHOSITA would understand that protruding from or being formed on an interior surface means that the bridge structure is an internal structure within the enclosure formed by the walls of the main body portion.

137. The specification confirms this understanding. In three separate occasions, the specification refers to the “bridge structure” as an “internal”. '970 Patent, 2:62-63, 3:27-29, 4:30-34. The specification explains that this “internal, wavelike bridge structure 180” is “on an interior surface of the posterior wall.” *Id.*, 4:30-34. The specification further explains that the bridge structure is only visible in FIG. 5 “without the surrounding walls of the main body portion.” *Id.*, 4:53-54. FIG. 1E shows the bridge structure, but only because FIG. 1E is a “cross-sectional view of the mouthpiece”. *Id.*, 4:51-52. A PHOSITA would understand this identification of “surrounding walls” as an enclosure (i.e., the pocket), and the bridge structure is surrounded by those walls, or enclosed by the walls, which is just another way of saying the bridge structure is

“internal” to the main body portion. Also, like the claim language, the specification explains that this internal bridge structure protrudes from an interior surface of the posterior wall. *Id.*, 2:15-18, 4:48-51. All these sections consistently teach that the bridge structure is an internal structure that exists within the enclosed main body portion.

138. A PHOSITA would understand that the bridge structure must be internal, and “centrally located” (*Id.*, 4:60-61, FIGs. 1E, 5) for that matter, to be effective. The specification explains that the bridge structure’s function is “to ensure that the anterior and posterior surfaces remain separated during suction.” *Id.* at 4:48-51. Thus, the bridge structure is undeniably an anti-collapse structure to prevent the internal portion of the anterior wall from collapsing upon the internal portion of posterior wall due to suction applied through the suction connector. A PHOSITA would understand that the anterior wall collapsing on the posterior wall would block suction like a kink in a hose.

139. As I explained above, prior art solutions prevented collapse of two parallel walls (the anterior and posterior walls) by using transverse walls or a central spine. Black, Hirsch. The First Family of Patents instead prevented collapse using a combination of sidewalls and a bridge structure. From a physics standpoint, the sidewalls would provide anti-collapse function because they are formed perpendicular to the anterior and posterior walls, providing a force against the collapsing force from suction that would bring the two walls together. The anti-collapse function of the sidewalls prevents collapse at the edges, which was a problem the inventor of Hirsch acknowledged with his central-spine design. Hirsch2, 4:67-5:8. However, the anti-collapse force of the sidewalls would not be particularly effective in the center part of the main body portion, where the main body portion 110 is widest and where the suction connector enters the main body portion.

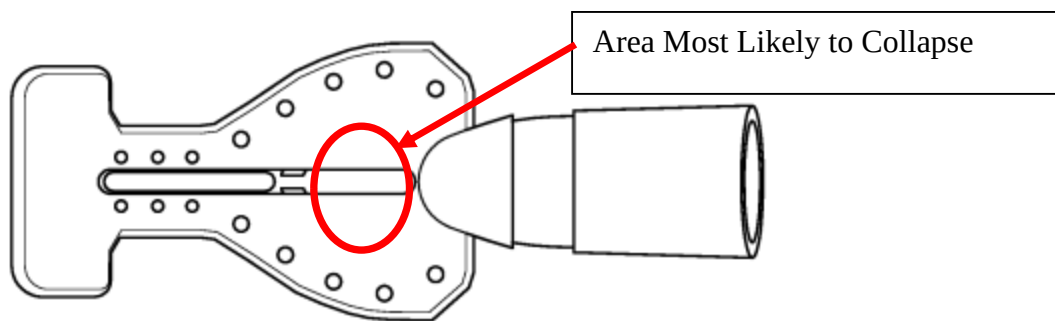


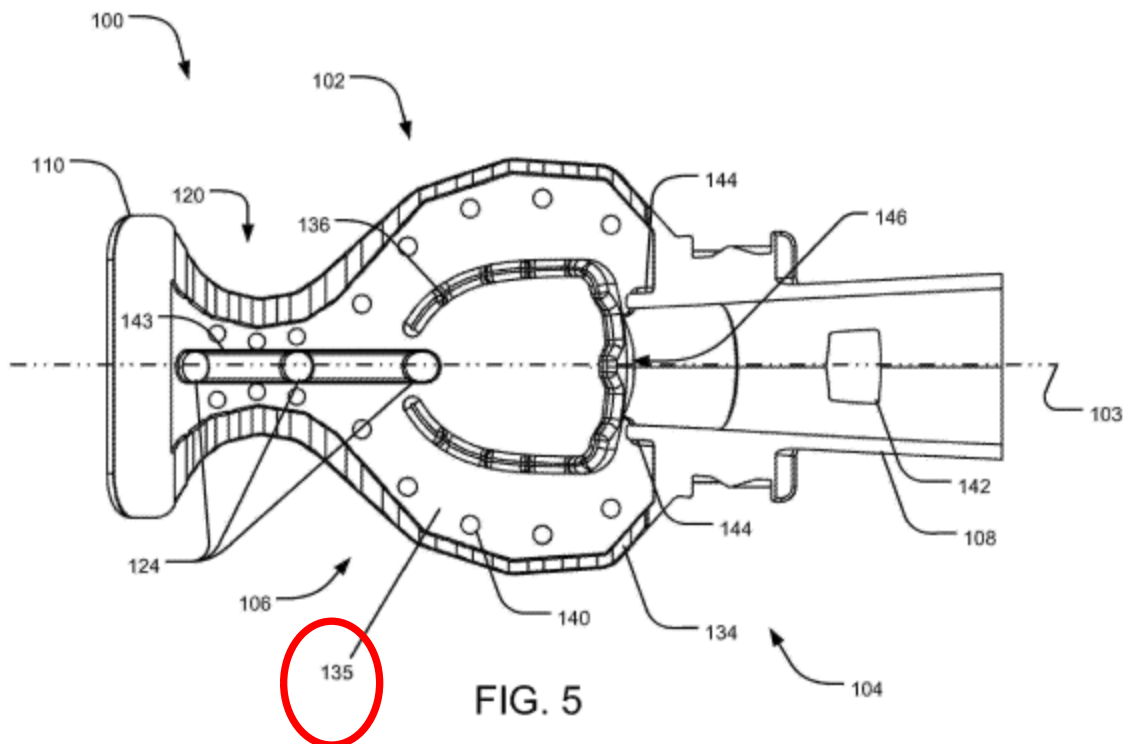
FIG. 2B

As such, the First Family disclosed that additional anti-collapse structure was needed in the center of the main body portion, near the suction connector entry port. '970 Patent, 4:48-61. Hence, the bridge structure and its internal, central location is within the main body portion. *Id.* The enclosed, four-sided, pocket-configured mouthpiece would not work without anti-collapse structure formed in the central region of the mouthpiece. Thus, from a physics standpoint, a PHOSITA would know that the bridge structure must be internal to provide effective anti-collapse function where it is needed, which the specification clearly explains is the sole purpose of the bridge structure. Indeed, if it were not providing anti-collapse function, the bridge structure would simply hinder suction paths, which no PHOSITA would ever attempt to do.

140. The specification never describes the bridge structure as external or formed on an edge of the anterior or posterior wall. Instead, the specification describes and illustrates the bridge structure as “centrally located”. *Id.*, 4:60-61, FIGs. 1E, 5. Again, this stands in stark contrast to how Solmetex described the “intervening walls” of the Second Family. (“At least one anterior intervening wall 127 may extend from at least one edge 128 of the anterior wall 112 partially towards the posterior wall 114 and may have a thickness that extends from the at least one edge 128 to a mid-point between the anterior wall 112 and the posterior wall 114.”). The difference in location language (“extend from at least one edge” vs. “protruding from an interior surface”) is

particularly stark considering that Solmetex used similar language to describe the “wavelike structure” of the bridge structure and the “ridged” nature of the intervening wall. (“Such a bridge structure may protrude from the interior surface in a wave shape with crests and troughs.” vs. “In one example, the anterior intervening wall 127 includes an alternating crest 130 and trough 132.”). It is further notable that the Second Family did not describe the intervening walls formed at “edges” as walls formed on an “interior surface”. Instead, like the First Family, the Second Family only describes the bridge structure and the stability bar as protruding from an interior surface.

141. The Second Family has a nearly identical bridge structure described in nearly the same way. '970 Patent, 4:48-67; '217 Patent, 5:6-45, 7:8-20. The Second Family gives the “interior surface” a reference number (135) and identifies it in FIG. 5.



As shown, the interior surface is a surface *within* the intervening walls 134. FIG. 7 also shows a PHOSITA that the interior surface 135 is visible once the interior is revealed by pulling back the

intervening walls.

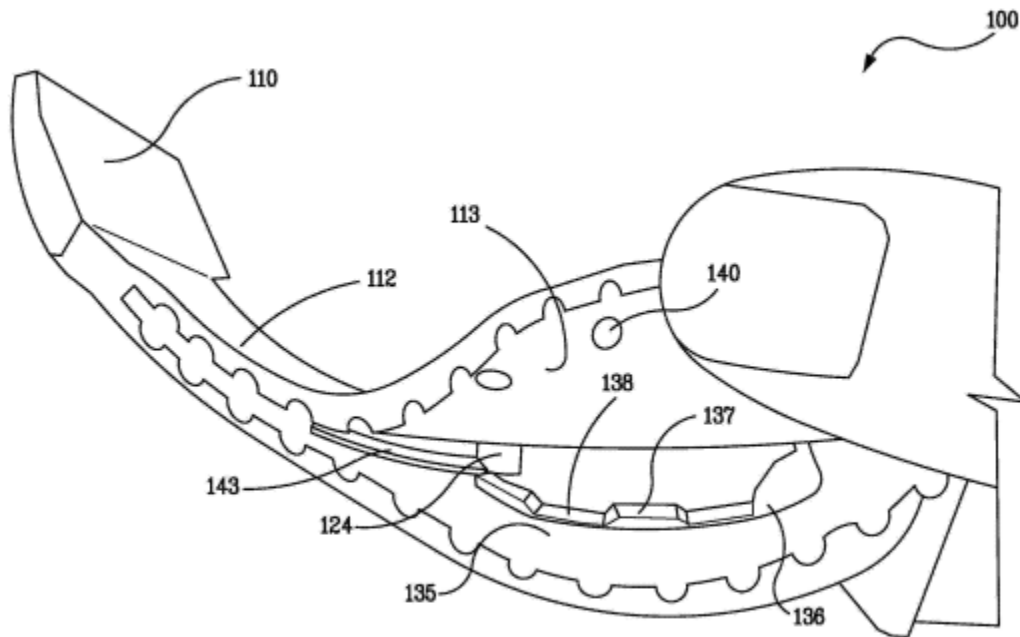
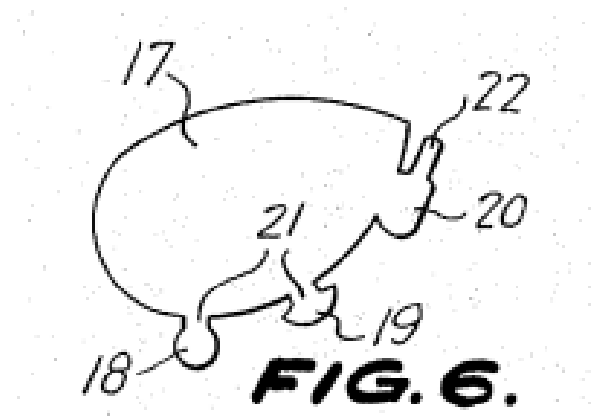


FIG. 7

The mouthpieces of the First Family and the Second Family are very similar, and the bridge structure is described in the same way. '970 Patent, 4:48-67; '217 Patent, 5:6-45, 7:8-20. Thus, the description of the bridge structure from the Second Family is highly relevant and demonstrates that my understanding was Solmetex's understanding (at least before Solmetex tried to stretch its patents to cover Ascentcare's products).

142. The prosecution history further supports that the bridge structure cannot be formed at an edge of the anterior or posterior wall, replace the sidewalls, or be formed anywhere but inside the enclosure created by the walls of the main body portion. In the prosecution history of U.S. Patent No. 9,788,924, an unasserted patent in the First Family, Solmetex differentiated the disclosed bridge structure from a bridge structure "projecting from an edge of the main body". Ascentcare 00005499 and 00005534. More specifically, the Examiner rejected the claim language

“the bridge structure comprising a plurality of protrusions protruding from an interior surface of the posterior wall and substantially extending a distance between the anterior wall and the posterior wall” using U.S. Patent No. 3,802,081 to Rogers (“Rogers”). Ascentcare 00005467-68. The Examiner pointed to element 17 in the Figure below as the main body, and the lugs 18-20 as the “bridge structure comprising a plurality of protrusions protruding from an interior surface of the posterior wall...” *Id.*

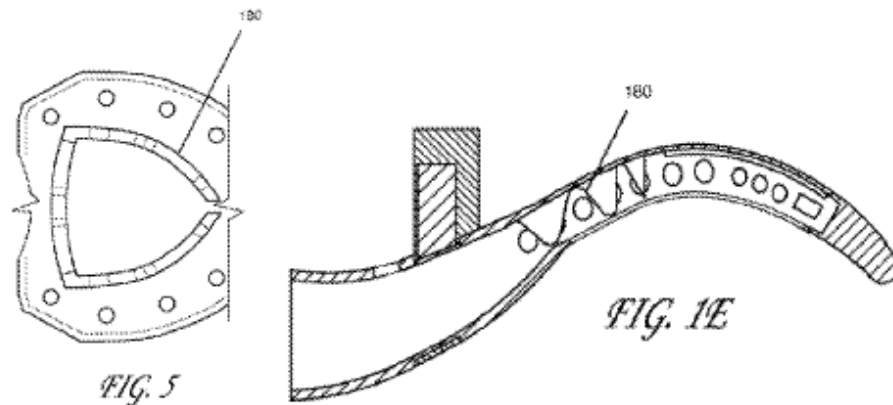


Rogers describes the lugs saying, “Member 17 is provided with a plurality of lugs... projecting from the bottom edge of the main body of the member 17 and being designated respectively at 18, 19 and 20 in the typical embodiment thereof shown in FIG. 6.” Ascentcare 00005467-68; Rogers, 2:7-12. Solmetex disagreed and argued that these lugs, “projecting from the bottom *edge* of the main body” (*Id.*), are “*not formed on the interior surface* of the flexible posterior wall as claimed.” Ascentcare 00005534-35. Thus, according to Solmetex, a projection “projecting from the *edge* of the main body” cannot be a bridge structure that projects from an interior surface. Notably, Solmetex now asserts that a structure formed at the edge of an anterior wall of the First VacuLUX mouthpiece (Solmetex’s Initial Infringement Contentions, Appendix 1, p. 1-11 and 1-12) is a bridge structure formed on an interior surface, despite what appears to be a clear differentiation in a co-pending application that has the exact same specification and claim language. In Europe

during the application of EP3184076, the Examiner said, “If the bridge structure is sandwiched between the anterior and posterior wall, as understood by the description, contact between the bridge and anterior and posterior walls will necessarily occur at the crests and troughs, respectively... or vice versa, depending on which is considered the crest and which is considered the trough.” Ascentcare 00006660. In response, Solmetex argued, “In order to further improve the clarity of the structure of the bridge structure, claim 1 in the claim set filed herewith now additionally specifies that the "plurality of troughs of the wave shape are in contact with the interior surface of the posterior wall" so that it is clear that the bridge structure is sandwiched between the anterior and the posterior wall.” Ascentcare 00006640. Thus, both the Examiner and the Solmetex agreed that the bridge structure was “sandwiched” between the interior surfaces of the anterior and posterior walls. A PHOSITA would understand that a “sandwiched” bridge structure is an internal bridge structure.

143. During prosecution of the '969 Patent, Solmetex said the following:

wall toward the first wall in a wave shape comprising one or more crests and one or more troughs.’ FIG. 5 provides “a close-up view of an internal bridge structure,” while FIG. 1E illustrates a “cross-sectional view of the exemplary mouthpiece in which the bridge structure 180 is illustrated.” [0042]; *see also* FIGs. 1E, 5 (provided below).



As illustrated, 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.’ By contrast, the cited structure of *Hirsch* are purported to be “bridge forming 80 SOLMETEX_0001458. By saying “as illustrated”, Solmetex limited themselves to the bridge structure illustrated by FIGS. 1E and 5. This statement was not made as mere “exemplary support”. Moreover, this statement was made to distinguish the prior art lending further evidence that Solmetex intended to limit themselves to the bridge structure disclosed by the specification and figures.

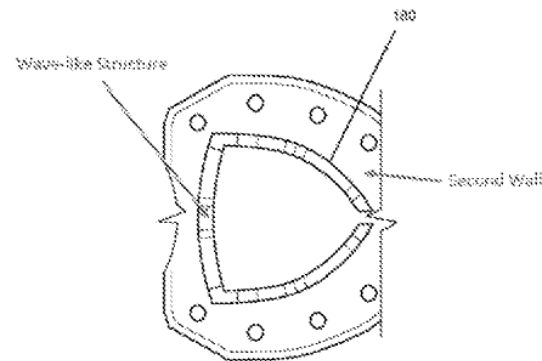
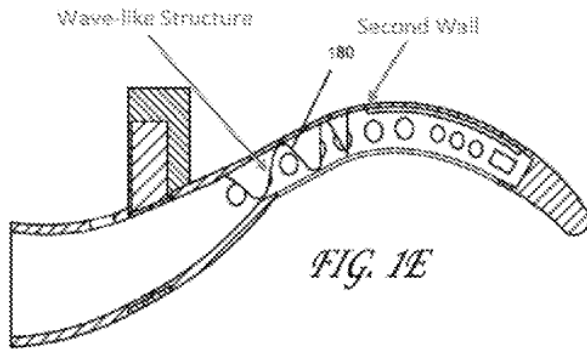
144. Finally, the term “bridge structure” is not a term of art or a term I recognize in the field. It appears to be a term coined by the Solmetex to describe this internal structure. That said, it is undeniable that its function is anti-collapse. Knowing this, and knowing that the First Family of Patents did not disclose, and in fact argued, that the bridge structure cannot be formed at an “edge” of the main body portion, then a PHOSITA would know that the bridge structure must be internal within the enclosed main body portion, and the bridge structure cannot be an formed at an

edge or a side of the main body portion. That is, the bridge structure could not protrude from or be formed on “an interior surface” of the second wall and be a boundary of the enclosed main body portion.

h. “wave-like structure”; “plurality of protrusions”; “plurality of crests”

145. I note that some claims of the '329 Patent and '418 Patent abandoned the “bridge structure” terminology. Claims 9 and 30 of the '329 Patent recite “a plurality of protrusions extending from an interior surface of the second wall toward the first wall in a shape having one or more crests and one or more troughs.” Meanwhile, claims 1, 11, and 20 of the '418 recite a “a plurality of crests of a wave-like structure [] formed on an interior surface of the second wall to provide contact points with the first wall...” While these claims use different words and terminology, a PHOSITA would understand these claims to find support from the “bridge structure” in the specification. This is exactly how Solmetex understood this limitation, considering that Solmetex had to demonstrate support for this limitation in response to a written description rejection during prosecution of the '418 Patent.

- ‘second wall including a wave-like structure’
- ‘plurality of perforations having at least five perforations’



See U.S. Pat. No. 8,911,232 ('232 Patent), FIG. 1E (provided above); see also *id.* at 4:22 (referring to “internal wavelike bridge structure 180”).

SOLMETEX_0009871.

146. To the extent there is any difference in structure, which I cannot see, the fact remains that the “wave-like structure” and the “plurality of protrusions” are both formed on an interior surface of the second wall. This confirms that, even if these structures are slightly different from a “bridge structure” (which again, a PHOSITA would not appreciate any differences in structure, as the bridge structure is the only wave-like structure described with crests and troughs in the specification), these structures are still *internal* structures within the interior space and do not form a boundary or exterior wall of the interior space.

147. Thus, it is my opinion that these claims should be construed the same or very similarly to the “bridge structure”. There is not any specification support for any other conclusion.

i. “an interior surface of the second wall”

148. It is my opinion that the term “an interior surface of the second wall” should mean “a surface of the second wall facing the first wall between, but not including, the edges of the

second wall.”

149. As I explained above in detail, the bridge structure is “an internal structure attached to the second wall that prevents the collapse of the first and second wall during suction.” As I also explained above in paragraphs 135-137 and 140-144, the interior surface is a surface inside an interior space. I incorporate my analysis above here, and a PHOSITA would understand that the interior surface is a surface of the second wall between, but not including, the edges of the anterior or posterior wall, where a sidewall is formed.

150. The First Family does not specifically identify an interior surface in any figure but says, “The main body may further include a 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” (’970 Patent, 2:15-18), and “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.” (*Id.*, 4:48-54).

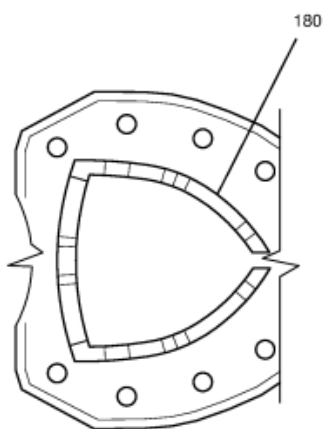


FIG. 5

Here, the specification explains that the bridge structure is formed on an interior surface of the posterior wall, and then explains that FIG. 5 illustrates that bridge structure *without the surrounding walls of the main body portion*. As such, a PHOSITA would understand FIG. 5 to illustrate the interior surface as the surface of the posterior wall that faces the anterior wall and between the inferior sidewall and the superior sidewall. I annotated FIG. 5 to illustrate the portions of FIG. 5 that would be understood by a PHOSITA as the interior surface (in yellow). As seen, the interior surface does not include any area occupied by a sidewall structure, which are formed on the edges of the posterior wall and anterior wall. See Section VI.e.

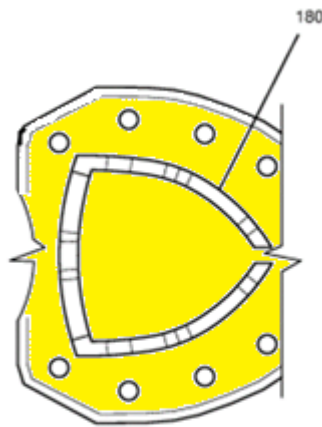
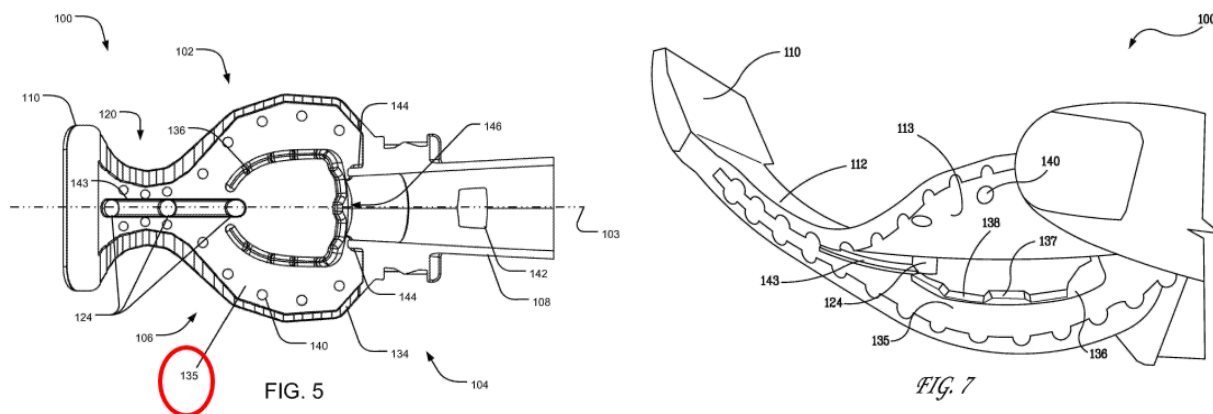


FIG. 5

151. Thus, a PHOSITA would understand that the main body portion includes “surrounding walls” that create the interior space, and the “interior” surface is the surface within that interior space created by those surrounding walls. In other words, the interior surface is surface of the second wall facing the first wall between, but not including, the edges of the second wall.

152. The Second Family specification confirms this understanding by giving the interior surface a reference number (135) and explaining that it is only visible when sidewalls/intervening walls are pulled back.

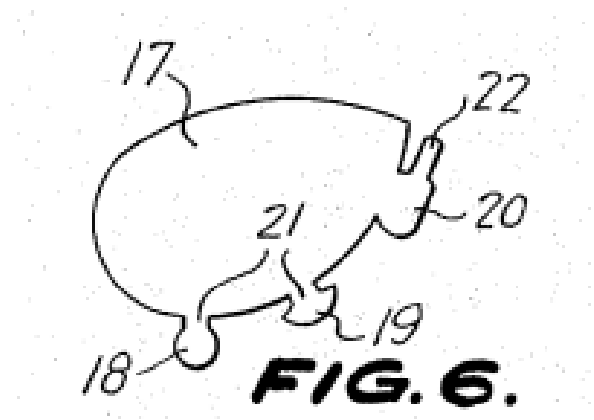


The identification of the interior surface in the Second Family exactly matches my illustration of the interior surface in the First Family. Thus, Solmetex described the interior surface as a PHOSITA would understand, and as I have explained herein, when writing both the First Family and the Second Family.

153. These conclusions track with both my experience and a PHOSITA’s understanding of an “interior surface”. For a surface to be an “interior surface”, the surface is necessarily inside something. There must be some defined boundary enclosing the interior to render the surface an “interior surface”. Consider a kitchen floor. The kitchen floor is reasonably considered an interior surface *of the house*. However, without a constructed house, a floor is not an interior surface, it is simply a floor. Only upon creation of the enclosure of a house would we consider the kitchen floor an “interior surface”. No PHOSITA would consider a foundation or a driveway an “interior surface.” This is simply logical.

154. The prosecution history of the First Family further supports that the interior surface is inside the enclosure created by the walls of the main body portion. In the prosecution history of U.S. Patent No. 9,788,924, an unasserted patent in the First Family, Solmetex differentiated the disclosed bridge structure from a bridge structure “projecting from an edge of the main body”. Ascentcare 00005599 and 00005534. More specifically, the Examiner rejected the claim language

“the bridge structure comprising a plurality of protrusions protruding from an interior surface of the posterior wall and substantially extending a distance between the anterior wall and the posterior wall” using U.S. Patent No. 3,802,081 to Rogers (“Rogers”). Ascentcare 00005467-68. The Examiner pointed to element 17 in the Figure below as the main body, and the lugs 18-20 as the “bridge structure comprising a plurality of protrusions protruding from an interior surface of the posterior wall...” *Id.*



155. Rogers describes the lugs saying, “Member 17 is provided with a plurality of lugs... projecting from the bottom edge of the main body of the member 17 and being designated respectively at 18, 19 and 20 in the typical embodiment thereof shown in FIG. 6.” Ascentcare 00005467-68; Rogers, 2:7-12. Solmetex disagreed and argued that these lugs, “projecting from the bottom *edge* of the main body” (*Id.*), are “*not formed on the interior surface* of the flexible posterior wall as claimed.” Ascentcare 00005534-35. Thus, according to Solmetex, the *edge* of a main body cannot be an interior surface.

j. “third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall”

156. It is my opinion that a PHOSITA would not understand the ’418 Patent to inform what is the scope of this term with reasonable certainty.

157. Particularly, a PHOSITA would not fully understand the third wall’s relationship

to the first and second wall. Indeed, the claim language only states that the third wall has some involvement in spacing apart the first and second walls (“such that the first wall is *spaced* from the second wall”). However, the claim language fails to explain *how* the third wall spaces the first and second wall. More importantly, it fails to inform with reasonable certainty *where* the third wall is placed, its relationship to the first and second wall, and where the third wall forms a connection with the first and second wall. These elements are essential to understanding the invention, and without those essential elements claimed, a PHOSITA would misconstrue the claim language in ways not supported by the original specification.

158. The specification describes a main body portion having an anterior wall, a posterior wall, an inferior wall connecting an inferior edge of the anterior wall to an inferior edge of the posterior wall, and a superior wall connecting a superior edge of the anterior wall to a superior edge of the posterior wall. Together, these elements form “a body that is at least partially enclosed.” ’970 Patent, 3:45-50. The specification discloses no other embodiments of the main body portion. The specification discloses no other “walls”, and the only “third wall” described by the specification is the inferior or superior sidewall. *Id.*; *see also Id.* at 1:61-65.

159. The claimed “third wall” omits the statements about a wall connecting an edge of the anterior wall to an edge of the superior wall, suggesting that the third wall could be connected seemingly anywhere on the first wall and anywhere on the second wall. However, the specification only supports a third wall that connects *edges* of the anterior and posterior wall. The specification never describes a wall, different from the anterior and posterior wall, formed anywhere but the inferior and superior sides.

160. In fact, as I explained above, the inferior and superior sidewalls are critical to the function of the pocket-shaped isolation mouthpiece. More specifically, the sidewalls provide anti-

collapse benefits at the edges of the anterior and posterior wall. With only a bridge structure connected to only one of the anterior or posterior walls, the disclosed mouthpiece lacking connecting sidewalls would not function effectively, and the mouthpiece would seal at the edges of the mouthpiece, blocking suction. This suction blocking would be particularly acute as the mouthpiece would seal near the perforations 140 formed on the anterior and posterior walls, rendering the slit as the only location where suction could occur efficiently.

161. The Examiner agreed with me. During prosecution of the '969, '970, and '686 Patent, the Examiner rejected claims lacking a wall that connects corresponding edges of the anterior and posterior wall. SOLMETEX_0001217-19; SOLMETEX_0002625-26; SOLMETEX_0004105-06, SOLMETEX_0004033-34. Specifically, the Examiner rejected the claims as indefinite for “omitting essential elements”. *Id.* The Examiner deemed that a sidewall connecting the inferior and/or superior edges of the anterior wall to the inferior and/or superior edges of the posterior wall was essential to understanding the claimed isolation mouthpiece and clearly describing the claimed isolation mouthpiece. The Examiner went further, saying claim language lacking a connecting wall that connects an edge of the first wall to an edge of the second wall would allow “for misconstruction(s) of the invention, e.g., the mouthpiece may be an open misshaped article with the first and second walls randomly positioned, connected by a connecting wall which may merely be a thin truss between the first and second walls.”

162. The claim language that was rejected by the Examiner for indefiniteness is nearly identical to the claim language in the '418 Patent. (*Compare* “a connecting wall that connects the first wall to the second wall across the span between the first and second wall” SOLMETEX_0001454 *with* “third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall”, 418 Patent, claim 1.) The Examiner found such language

indefinite and “incomplete for omitting essential structural relationships of elements, such omission amounting to a gap between the necessary structural connections.” SOLMETEX_0001217-19. The Examiner noted that the omitted essential elements included “the pocket forming an interior open space; the connecting wall connecting the first wall to the second wall along exterior edges thereof, defining said interior open space of the pocket”. *Id.* Without those essential elements recited, the Examiner found that “claim 23 allows for misconstruction(s) of the invention, e.g. the mouthpiece may be an open misshaped article with the first and second walls randomly positioned, connected by a connecting wall which may be mere a thin truss between the first and second wall.” *Id.*

163. In response, Solmetex did not argue that the Examiner was incorrect in this finding. Instead, Solmetex simply amended the claims to add the essential elements. Solmetex did not note any disagreement or traverse, not even a suggestion that the amendments to the claims adding the essential elements was done simply to “advance prosecution”, as often occurs. *Compare* SOLMETEX_0001457 *with* SOLMETEX_0004515-16. As a result, a PHOSITA would understand that Solmetex conceded that the Examiner was correct and that these features were essential elements to understanding the claimed invention.

164. It should be further noted that the Examiner in the '686 Patent found that the specification of the First Family “only describes that each of the first and second wall includes superior and inferior edges.” SOLMETEX_0004459. The specification expressly defines “superior” as the side of the mouthpiece touching the roof of the patient’s mouth when placed and “inferior” as the side of the mouthpiece touching the floor of the patient’s mouth when placed. '970 Patent, 3:51-54. By saying the specification only supports and discloses two edges (inferior and superior edges), then the Examiner understood the connecting wall to connect the *entire*

inferior edge or the *entire* superior edge (i.e., a sidewall). I have been informed by counsel that a patent examiner is presumed to be a PHOSITA. Moreover, I agree with the Examiner's understanding of the specification, and a PHOSITA would also agree with the Examiner's understanding of the specification.

165. In an unasserted, sister prosecution related to U.S. 11,576,764, the Examiner said the following:

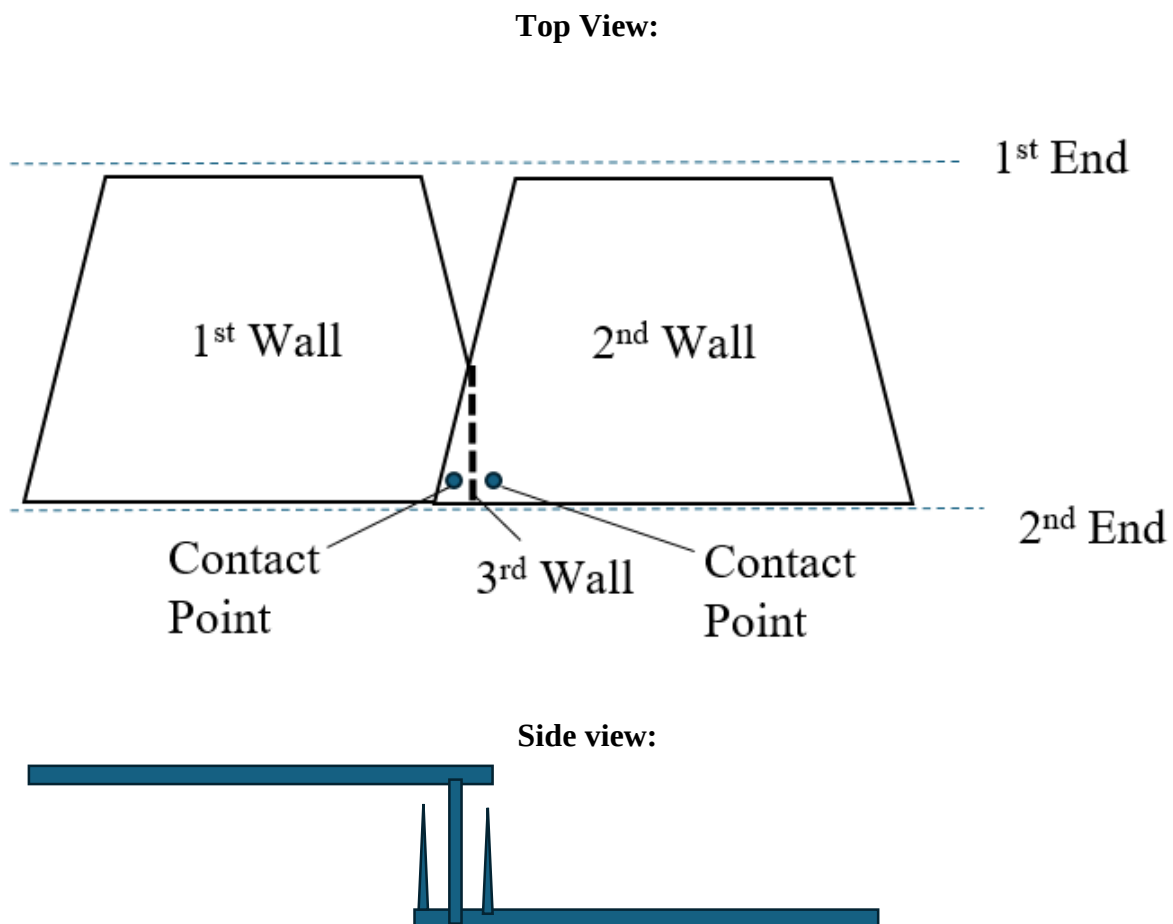
At preliminary review, such omission of the side wall appears to raise new ground(s) of rejection under 112(b) for omitting essential elements (i.e. side wall) and/or essential structural cooperative relationships of elements (e.g. how the main body/pocket/interior space is defined, how the first and second walls relate to each other without the side wall, etc.). See MPEP § 2172.01.

Ascentcare 00004788. It's important to note that the Examiner noted that one of the essential structural cooperative relationship of elements was "how the first and second wall relate to each other without sidewalls." *Id.* This element is missing from claims 1 and 11 of the '418 Patent and is exactly why the claim is indefinite, just as the Examiner of prior-filed applications predicted.

166. Thus, this term is indefinite for the exact same reasons the first Examiner found extremely similar claim language indefinite during prosecution of the '969, '970, and '686 Patents.

167. Indeed, a PHOSITA would find the "third wall..." language indefinite for exactly the reasons that the first Examiner explained. Consider, this claim language provides no relationship at all in terms of placement between the first and second wall. Claim 1 of the '418 Patent, for example, says that the first wall and the second wall have a shape and extend from a first end to a second end of the main body portion. Then, the claim explains that the third wall merely connects the second wall to the first wall such that they are spaced from each other. The claim language includes some description about edges and that the first/second wall "corresponding in shape", but that is essentially it. Finally, although somewhat uninformative, the claim also recites that the wave-like structure forms "contact points" with the first wall. Despite

all this language, misconstructions are still possible, and the claim could still be construed as an open “misshaped article. The illustration below meets all these limitations, and yet, **is** an open misshaped article.



168. What I have drawn above is, exactly as the Examiner predicted, an “open misshaped article” with walls “randomly positioned”.⁷ Even so, what I have drawn above meets every

⁷ I note that I could move the trapezoids above around in all kinds of different directions and still meet the claim language.

limitation of the claim language. Nothing in the specification suggests such an open-sided, misshapen mouthpiece where the anterior and posterior walls do not even need to correspond in location. Indeed, according to the claims of the '418 Patent, all the third wall must do is keep the first and second walls "spaced" apart, which my ridiculous drawing above represents. Moreover, what I have drawn above would not perform dental isolation, would not result in a functioning suction device, and would not work at all in a dental operation. This unreasonably broad claim language is not how a PHOSITA would understand the specification.

169. The unclear claim language allows for misconstructions, as I demonstrated above. More importantly, critical elements of the mouthpiece are missing from the claim language, leading to confusion. As a result, the claim language is indefinite and omits essential elements. Solmetex has conceded on more than three times that these elements are essential yet tried omitting the essential elements again using Track One to get a new Examiner. I have been informed by counsel that omission of cooperative relationships between claim elements, such as an omission amounting to a gap between the necessary structural components, renders the claim incomplete and indefinite. The Examiner was correct that the interior space/pocket of the main body portion must be defined by the walls of the main body portion. SOLMETEX_0004105-06. The claims of the '418 and '329 Patents lack this critical and "essential element", rendering the terms indefinite.

170. Interestingly, the Examiner stated that failure to recite that the connecting wall connects edges of the anterior and posterior wall results in confusion. *Id.*. Indeed, "the mouthpiece may be an open misshaped article with the first and second walls randomly positioned, connected by a connecting wall which may merely be a thin truss between the first and second walls." This is exactly right. The claim language of the '418 Patent does not explain *how* the first and second walls are "spaced", what direction or orientation the space exists. The '418 Patent fails to even

state whether the third wall has any relationship with an interior or inner cavity. Just as the Examiner previously noted, this results in confusion and indefiniteness.

171. It should be noted that Solmetex is using this broad, indefinite language to read on the central spine of the VacuLUX mouthpieces. Solmetex Infringement Contentions, Appendix 10, p. 10-10. However, Solmetex differentiated its sidewalled/pocket configuration from open-sided mouthpieces that have a central spine, like Hirsch. *See* paragraph 63. The VacuLUX mouthpieces are also open-sided mouthpieces with a central spine. The mouthpiece disclosed by the First Family of Patents cannot be both different from a prior art, open-sided mouthpiece having a central spine because it is not an open-sided mouthpiece having a central spine and also read on open-sided mouthpieces having a central spine. This is particularly true given that Solmetex argued that the claimed mouthpiece is different from Hirsch *because* Hirsch's embodiment has a central spine. This is a prime example of Solmetex telling the Examiner one thing to get a patent and telling the public something different when asserting the obtained patent.

172. While the claims of the '418 Patent are clearly invalid for indefiniteness for omitting essential elements, for the exact same reasons the Examiner articulated, the claims also cannot be construed so broadly as Solmetex would like (e.g., that the third wall can include a central spine) because the specification fails to support an embodiment with a central spine, and Solmetex argued around this feature to obtain a patent. Thus, if the Court were to construe the claims as broadly as Solmetex suggests, the result would be invalid claims for lacking written description. I am informed by counsel that if a construction results in invalid claims, then that construction cannot be correct. This claim language also fails to explain how to make the invention, rendering the claim invalid for lacking enablement too.

173. The specification only shows and describes two walls that could be considered a

wall that keeps an anterior wall spaced apart from the posterior wall, and that wall is the inferior or superior sidewall. The specification never suggests a central spine. Instead, the specification describes a centrally located bridge section. A PHOSITA would not read the specification of the First Family of Patents to include a central spine and a bridge structure, especially in view of the way Solmetex differentiated from a mouthpiece having a central spine during prosecution.

174. Because the specification does not support a third wall placed anywhere but the edges, if the Court disagrees that this term is indefinite, then the term must be construed in the same vein as the “connecting wall...” limitations to preserve the validity of the patent. The broad construction demonstrated by Solmetex’s infringement contentions is not supported by the original specification and would result in a violation of the written description requirement.⁸ Because the only wall that connects “the first wall and the second wall such that the first wall is spaced from the second wall” that is supported by the written description is a sidewall that connects an *edge* of the first wall to an *edge* of the second wall, then the third wall must be construed to be a sidewall that connects an edge of the first wall to an edge of the second wall, exactly as described above regarding the claim term “connecting wall...” While the ’418 Patent claims uses different words, the specification only supports one interpretation, and that element is essential to understanding the claimed mouthpiece, meaning that these claims are limited to a wall that connects an inferior/superior edge of the anterior and to an inferior/superior edge of the posterior wall. The specification and file history cannot support any other interpretation.

k. “third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity”

175. It is my opinion that a PHOSITA would not understand either the ’329 Patent to

⁸ I have been informed that omission of essential elements can also violate the written description or enablement requirement.

inform what is the scope of this term with any sort of reasonable certainty for the same reasons discussed above in Section VI.j. Namely, the omitted element that the third wall connects an inferior/superior edge of the anterior to an inferior/superior edge of the posterior wall renders the claim indefinite for omitting essential elements. Or, if the Court does not find the claim term indefinite, then the term must be read in a way that finds support from the specification, which would be to interpret the claim in the same way as the “connecting wall” discussed above. I incorporate my analysis from Section VI.j here.

176. The addition of the limitation “to define an inner cavity” provides additional evidence that the claim should be interpreted to mean that the third wall connects edges of the first and second wall. Indeed, a PHOSITA would understand that an “inner cavity” could not be created without “outer”, external boundaries. I explained above why the terms “inner cavity” and “interior space” mean an enclosed main body defined by an anterior wall, a posterior wall, and sidewalls. See Sections VI.c and VI.d. The inclusion of the “inner cavity” language provides additional evidence that the “third wall” should be interpreted as an enclosing sidewall that defines the *inner* cavity. Indeed, Solmetex differentiated from a mouthpiece with a central spine, meaning that the third wall is limited to a wall connecting inferior or exterior edges of the anterior and posterior wall. All of the prosecution history supports this conclusion.

177. That said, the essential elements are still glaringly omitted for the same reasons discussed above in Section VI.j, and the public should not have to consult the plethora of family member patent applications and the thousands of pages of prosecution history in the First Family to understand that this term means a sidewall connecting a superior/inferior edge of the first wall to a superior/inferior edge of the second wall.

I. “crest”

178. It is my opinion that a PHOSITA would understand the term “crest” to mean “the

full extending distance of a projection of the internal bridge structure.”

179. The claims of the First Family use the term “crest” consistently to describe a component of the “wave shape” of the bridge structure or other similarly named claim elements. For example, claim 18 of the ’969 Patent recites “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.” Other asserted claims are similar where the use of the word “crests” defines the shape of the plurality of protrusions.

180. The specification only describes “crests” in two places, both when describing the bridge structure. The specification says: “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.” ’970 Patent, 2:16-21. Also, the specification teaches, “Such a bridge structure **180** may be formed as an [sic] 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.” *Id.* at 4:54-59.

181. This usage is consistent with the plain meaning of “crest” when describing a periodic waveform, such as a square or sine wave. A PHOSITA would understand a crest to be the locations at which a periodic waveform has its highest amplitude. In view of the specification and claim language, a PHOSITA would understand that the First Family uses the term crest consistent with this plain meaning.

182. As discussed above in Section VI.g, the specification only describes an internal bridge structure. Moreover, every asserted claim recites that the protrusions of the bridge structure protrude from or are formed on an interior surface of the second wall. Thus, the crests are internal

projections because they are components of the internal bridge structure. And true to the plain meaning, the crest are locations where the projections extend the full distance within the interior space of the main body portion.

m. “trough”

183. It is my opinion that a PHOSITA would understand the term “trough” to mean “a location of the internal bridge structure substantially flush to the surface of the second wall within the interior space.”

184. The claims of the First Family use the term “trough” consistently to describe a component of the “wave shape” of the bridge structure or other similarly named claim element. For example, claim 18 of the ’969 Patent recites “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.” Other asserted claims are similar where the use of the word “troughs” defines the shape of the plurality of protrusions.

185. The specification only describes “troughs” in two places, both when describing the bridge structure. The specification says: “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.” ’970 Patent, 2:16-23. Also, the specification teaches, “Such a bridge structure **180** may be formed as an [sic] 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.” *Id.* at 4:54-59.

186. This usage is consistent with the plain meaning of “trough” when describing a periodic waveform, such as a square or sine wave. A PHOSITA would understand a trough to be

different extending distance than a trough, that is self-explanatory from the use of the words crests and troughs. I do not understand the meaning of such additional claim language used to modify the terms “crests” and “troughs”. A PHOSITA would understand a crest of a waveform to have a different amplitude than a trough. If the modifier “that extend different distances of the interior space” modified both crests and troughs, such a modifier is describing the inherent nature of crests and troughs, so it would not make sense to a PHOSITA to add this unnecessary language. A waveform with crests and troughs having the same amplitude is a straight line. So, if the claim requires “alternating crests and troughs”, that language alone would suggest that crests have a different extending distance than a trough. The modifier must mean something other than just describing the basic, well-understood condition that crests have a different amplitude than troughs.

231. The language of claim 23 of the '948 Patent is similar, but omits any mention of troughs. Instead, claim 23 says “a plurality of ridges extending different distances partially across the distance between the first wall and the second wall”. While the ambiguity involving the troughs is removed from this language, it is still unclear whether every ridge must be a different distance than every other ridge to meet this claim language for the reasons discussed above.

232. Thus, the specification and the claim language are unclear. I cannot tell with reasonable certainty whether the claim language “that extend different distances of the interior space” means that each crest extends a unique distance, each trough extends a unique distance, whether all crests extend a different distance than all troughs, all of the above, or something else.

VIII. SOLMETEX'S TERMS

233. I note that Solmetex has proposed several terms as requiring construction. I discussed most of the terms above, particularly those involving the description of the recited “bridge structure” such as “protruding from the interior surface of the second wall...”, “wave shape”, “crests”, and “troughs”. Thus, while the full quotation of the claim language might differ

slightly between Solmetex's proposed terms and Defendant's set of proposed terms, I have discussed above what appears to be the primary disputes. The same is true regarding the two terms identified by Solmetex in the '948 Patent.

234. The only remaining terms that Solmetex proposed are "a mouth prop injection-molded in one piece" and "cutout has a shield shape". Neither of these terms require construction, and these terms have a plain meaning in view of the specification.

235. Regarding the mouth prop being injection molded in one piece, I discussed this above in paragraph 35. The specification explains that the "mouthpiece" (suction connector portion, main body portion, cheek retractor portion) is injection molded as a singular unit, and the mouth prop is separately injection molded as a singular unit. '970 Patent, 3:10-14, 5:40-43. These two, distinct units are detachable and can connect using the strap of the mouth prop. A PHOSITA would understand and know the process of injection molding, so that portion of the term is clearly not at issue. Thus, it is my opinion that the term "a mouth prop injection-molded in one piece" has its plain meaning that the mouth prop is injection molded in one piece. This claim language does not suggest that the mouth prop is integral with the main body portion or any other portion (suction connector portion, main body portion, cheek retractor portion) of the mouthpiece. In fact, by specifying that *only* the mouth prop is injection molded in one piece, a PHOSITA would understand that this further confirms that the mouth prop is a separate, detachable unit from the other portions of the mouthpiece and molded separately.

236. Finally, regarding a "cutout has a shield shape", this term does not need construction. While shields come in many shapes (circular, like Captain America's Shield, rectangular, like Roman phalanx shields), the specification only illustrates and describes a more triangular shield shape, which is sometimes called a heater shield. '970 Patent, FIG. 5, 2C. Indeed,

both elements (bridge structure, cutout) described as having a “shield shape” are depicted as having this same, generally triangular shape. Thus, this term does not need construction in view of the specification.

IX. CONCLUSION

237. In light of the foregoing, it is my opinion the constructions of the above terms identified by the parties are properly construed to have the meanings Ascentcare proposes. It is my opinion such proposals are consistent with the teachings of the patent claims and specifications, as well as the prosecution history, as a PHOSITA would understand these disclosures. It is further my opinion that the additional evidence I identify in the paragraphs above further corroborates Ascentcare’s proposed constructions.

238. All of my opinions stated above are based upon my review of the documents listed in my section Materials Considered. I reserve the right to supplement and/or amend my opinions based on additional information that I receive.