

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

R.J. REYNOLDS VAPOR COMPANY,
Petitioner,

v.

FONTEM HOLDINGS 1 B.V.,
Patent Owner.

Case No. **IPR2018-00634**
Patent No. **9,456,632**

**DECLARATION OF RICHARD MEYST IN SUPPORT OF
PATENT OWNER PRELIMINARY RESPONSE TO PETITION FOR
INTER PARTES REVIEW**

I, Richard Meyst, declare as follows:

Personal Background

1. I am currently the President and Chief Executive Officer of Fallbrook Engineering, Inc. I am an engineer and consultant in the field of electromechanical devices, including medical devices. A copy of my CV, which includes, among other things, my academic credentials and my employment history, is attached as Exhibit A.

2. I have been retained by Patent Owner Fontem Holdings 1 B.V. as an expert witness in the above-captioned proceeding. I am being compensated for the time I spend on this proceeding at a rate of \$425 per hour. My field of expertise in this matter is electromechanical and medical devices. This Declaration is based upon my knowledge, skill, experience, training, and education in my field of expertise, and upon information reviewed in connection with my retention as an expert witness in this matter.

3. I received an M.S. (1972) and B.S. (1971) in mechanical engineering from the University of Wisconsin, Madison. My undergraduate academic work focused on design, manufacturing methods, fluid mechanics, and heat transfer. My graduate academic focus was on computer-based automatic controls of systems and my Master's thesis was on the concept development, design, fabrication, and

testing of a prototype bench-top implantable mechanical human heart.

Additionally, I have participated in industry seminars and training programs covering design of experiments, statistical analysis, biocompatibility testing, sterilization method selection and validation, design of plastic parts, design for manufacturability, package design and testing, cellular therapy, and many others.

4. As an engineer, designer, consultant, program manager and entrepreneur at Fallbrook Engineering, Inc., I have been involved in the advanced design and development of a wide range of medical technology products for the healthcare industry for more than 30 years. Prior to 1989 when I became a partner in Fallbrook Engineering, I held various engineering and management positions at healthcare, medical device, and consumer product companies, including USCI (a division of CR Bard, Inc.), Fenwal (a division of Baxter Travenol Laboratories), Oak Communication, Imed Corp., a division of Warner Lambert, and Diatek Corp.

5. During my 45+ year professional career, I have focused on electromechanical devices and related technologies requiring expertise in design, fluid mechanics, thermodynamics, heat transfer, electronic power sources, circuit design and fabrication, sensors, manufacturing technologies, and other areas of engineering design and manufacturing methods. Based on my experience, I have developed extensive knowledge in medical product design and development, product prototyping, design verification and validation, production startup,

manufacturing engineering, risk analysis, and strategic planning. In addition to doing engineering work, my responsibilities have included running a medical design and development consulting firm which includes assembling and managing technical teams to develop new medical, consumer, industrial, and professional products.

6. I have also been a Principal Investigator on several NIH SBIR grants from the National Heart, Lung, and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. I have served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and am a long-time member. I am a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation, the San Diego Regulatory Affairs Network, the American Association for Clinical Chemistry, and the American Filtration & Separation Society.

7. I have also been a long-time member of the Medical Device Steering Committee of BIOCOM, the largest regional life science association in the world. I have twice been a juror in the annual Medical Design Excellence Awards competition, the premier awards program for the medical technology community, as well as a judge in the San Diego CONNECT capital competition for startup companies. I am also an experienced inventor and innovator. My inventions have been awarded 16 U.S. Patents, and I have applications pending. I have been an

invited speaker and have presented talks at numerous scientific and medical industry meetings. Exhibit A includes a list of my patents, publications and presentations, and professional associations.

8. I have also served as an independent technical expert witness or consultant relating to numerous intellectual property and patent litigations, product failure analyses, analyses of the use and misuse of various medical devices, development contract disputes, and medical product liability matters. A list of my expert assignments within the past four years appears in Exhibit A.

Items Reviewed

9. I have reviewed the specification, claims, and portions of the file history of U.S. Patent No. 9,456,632 ("632 Patent," Ex. 1001). I have also reviewed the Petition for *Inter Partes* Review filed by Petitioner R.J. Reynolds Vapor Company in this matter ("Petition," Paper 2) and related exhibits, including the declaration of Petitioner's expert, Dr. Robert H. Sturges ("Sturges," Ex. 1002). I have paid particular attention to the exhibits that are discussed in the Sturges declaration.

The '632 Patent and Claims

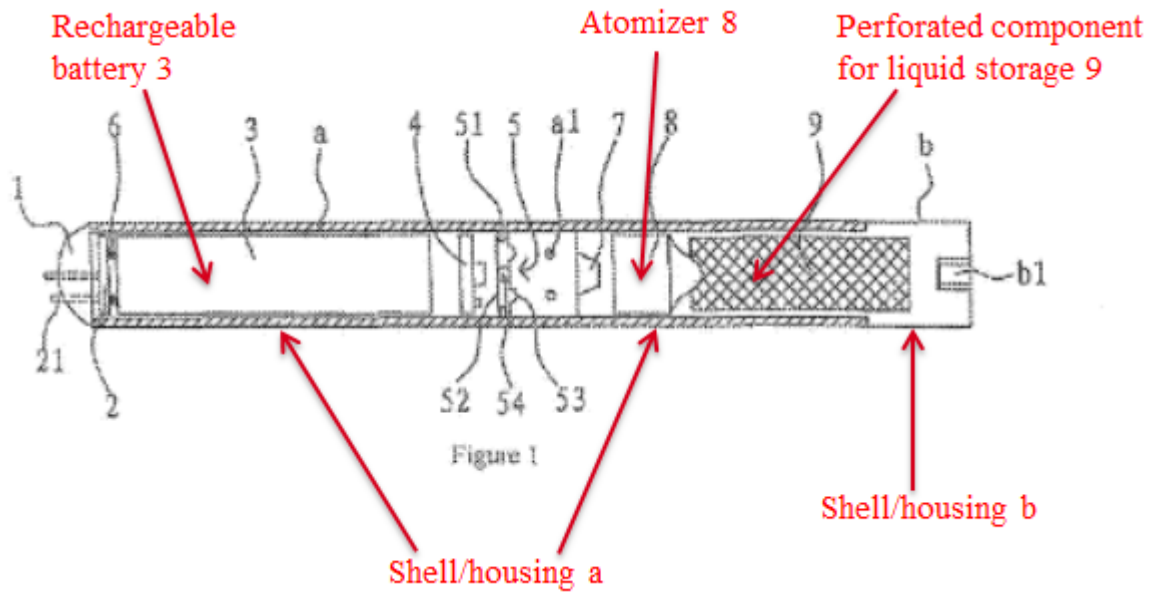
10. The '632 Patent describes a vaporizing device, which may be an electronic cigarette or cigar. For the sake of brevity, I will henceforth refer to an

electronic vaporizing device. However, all of my comments apply to an electronic cigarette or cigar as well.

11. In one embodiment, the '632 Patent describes a vaporizing device comprising an elongated cylindrical housing that contains a liquid storage component, a battery assembly, and an atomizer assembly. The battery assembly contains a battery, and the battery assembly and atomizer assembly are electrically connected.

12. The challenged claims (claims 14–16 and 18) of the '632 Patent recite a vaporizing device. The vaporizing device comprises a liquid storage component, battery assembly, and atomizer assembly, all contained in an "elongated cylindrical housing" that has "one or more air inlets." The atomizer assembly includes an "atomization chamber" with a "front end opening" and a "back end opening" that allow air to flow through the atomization chamber. Within this air flow path is a "heating wire coil" that is wound on a "porous component" that is "perpendicular to a longitudinal axis of the elongated cylindrical housing."

13. In one embodiment, the annotated version of Figure 1 of the '632 Patent below depicts many of the components recited in the claims, including an elongated cylindrical housing made up of shell a and shell b, a battery assembly including a battery 3, an atomizer assembly including atomizer 8, and liquid storage component 9.



14. One example of a heating wire described in the '632 Patent is a metal wire wound on a porous component as shown in the annotated versions of Figures 17–18 below. '632 Patent (Ex. 1001), 6:1–5: "the atomizer assembly . . . includes a frame (82), the porous component (81) set on the frame (82), and the heating wire (83) wound on the porous component (81)." "The heating wire is made of platinum wire, nickel-chromium alloy wire or iron-chromium alloy wire containing rare earth, or is flaked." '632 Patent (Ex. 1001), 3:59–61.

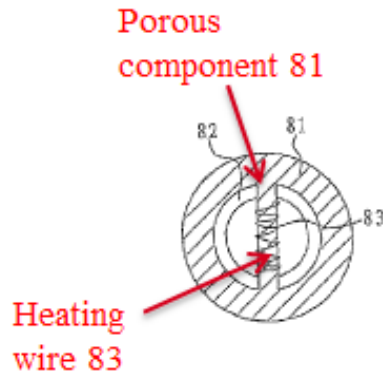


Figure 17

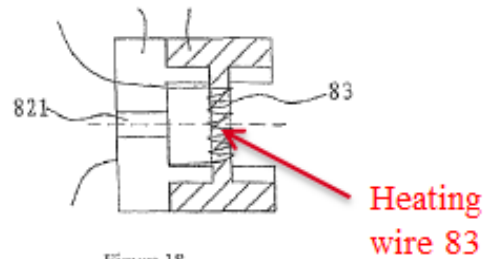


Figure 18

Claim Construction

15. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless a patentee sets out a different definition or clearly disavows claim scope. I further understand that extrinsic evidence such as expert or inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.

16. I understand that there is a similar legal standard for claim construction known as the broadest reasonable interpretation standard that gives claim terms their broadest reasonable construction based on the claims, specification, prosecution history, and extrinsic evidence. My opinions below are

the same under both the broadest reasonable interpretation standard and the claim construction standard described in the previous paragraph.

Person of Ordinary Skill in the Art

17. I also understand that claims are to be interpreted from the perspective of a person of ordinary skill in the relevant art at the time of invention. To assess the level of ordinary skill in the art, I understand that one may consider such factors as: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. I understand that the relevant time for assessing the level of skill in the art is the earliest time of filing of an application supporting the claimed inventions, which in this case for the '632 Patent is May 16, 2006. In my opinion, a person of ordinary skill in the art of the '632 Patent would be a person with a mechanical or electrical engineering degree, industrial design degree, or a similar technical degree, or equivalent work experience, and 5–10 years of working in the area of electromechanical devices, including medical devices. I have reviewed Petitioner's expert's opinion that a person of ordinary skill in the art at the time of the invention would have "at least the equivalent of a Bachelor's degree in electrical engineering, mechanical engineering, or biomedical engineering or related fields, along with at least 5 years

of experience designing electromechanical devices, including those involving circuits, fluid mechanics and heat transfer." Sturges (Ex. 1002), ¶28. My opinions below are the same under either formulation for a person of ordinary skill in the art at the time of the invention.

18. I have reviewed the claims of the '632 Patent, and based on the claim language, specification, prosecution history, and extrinsic evidence, I describe my opinions below as to how a person of ordinary skill in the art at the time of the invention would have interpreted certain claim terms.

Liquid Storage Component

19. The challenged '632 Patent claims require a "liquid storage component" in the "elongated cylindrical housing." Petitioner and Sturges do not construe this term.

20. In my opinion, the ordinary and customary meaning of "liquid storage component" is "a component for storing liquid." This is consistent with the disclosure in the '632 Patent specification. The '632 Patent discloses "[a] component for liquid storage of the cigarette bottle assembly stores the nicotine liquid." '632 Patent (Ex. 1001), 1:58–59. In certain embodiments, "the cigarette bottle assembly includes . . . a perforated component for liquid storage (9)." '632 Patent (Ex. 1001), 4:5–7. The "perforated component for liquid storage (9) is made of such materials as PLA fiber, terylene fiber or nylon fiber, which are

suitable for liquid storage." '632 Patent (Ex. 1001), 4:7–11. In the device, one end surface of the perforated component for liquid storage (9) is positioned against the porous component (81) of the atomizer 8 to absorb liquid from the perforated component for liquid storage (9) via capillary impregnation for liquid supply. '632 Patent (Ex. 1001), 4:21–25; 4:62–65. Thus, the cigarette liquid bottle and/or the fiber provide a store for liquid for vaporization by the atomizer. Moreover, Figures 1, 3–4, 12, and 19 consistently show such a liquid storage component, represented by the shaded area.

21. My opinion is also supported by extrinsic evidence. Merriam Webster's Collegiate Dictionary defines "storage" as "space or a place for storing." Ex. 2084, p. 1230. Random House Webster's Dictionary defines "storage" to mean "capacity or space for storing." Ex. 2085, p. 1877.

22. My understanding based on the '632 Patent's claims, specification, and prosecution history is that a "liquid storage component" is "a component for storing liquid." This is consistent with the ordinary and customary meaning of this term.

Obviousness Analysis

23. I understand that Petitioner has argued that claims 14–16 and 18 of the '632 Patent are unpatentable on the ground that they are obvious based on the

combination of U.S. Patent No. 4,947,874 ("Brooks") (Ex. 1003), and U.S. Patent No. 2,057,353 ("Whittemore") (Ex. 1004). Petition (Paper 2), pp. 7–8, 24–29.

24. I understand an *inter partes* review will be instituted only if the Petitioner has shown a reasonable likelihood that a claim is unpatentable based on the cited prior art.

25. I understand that a patent may not be obtained if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time of the invention to a person of ordinary skill in the art. To my understanding, a claimed invention is not obvious just because each of its elements was independently known in the prior art. Instead, it is my understanding that Petitioner must provide an explicit analysis showing there was a reason to combine the known elements in the manner covered by the claims.

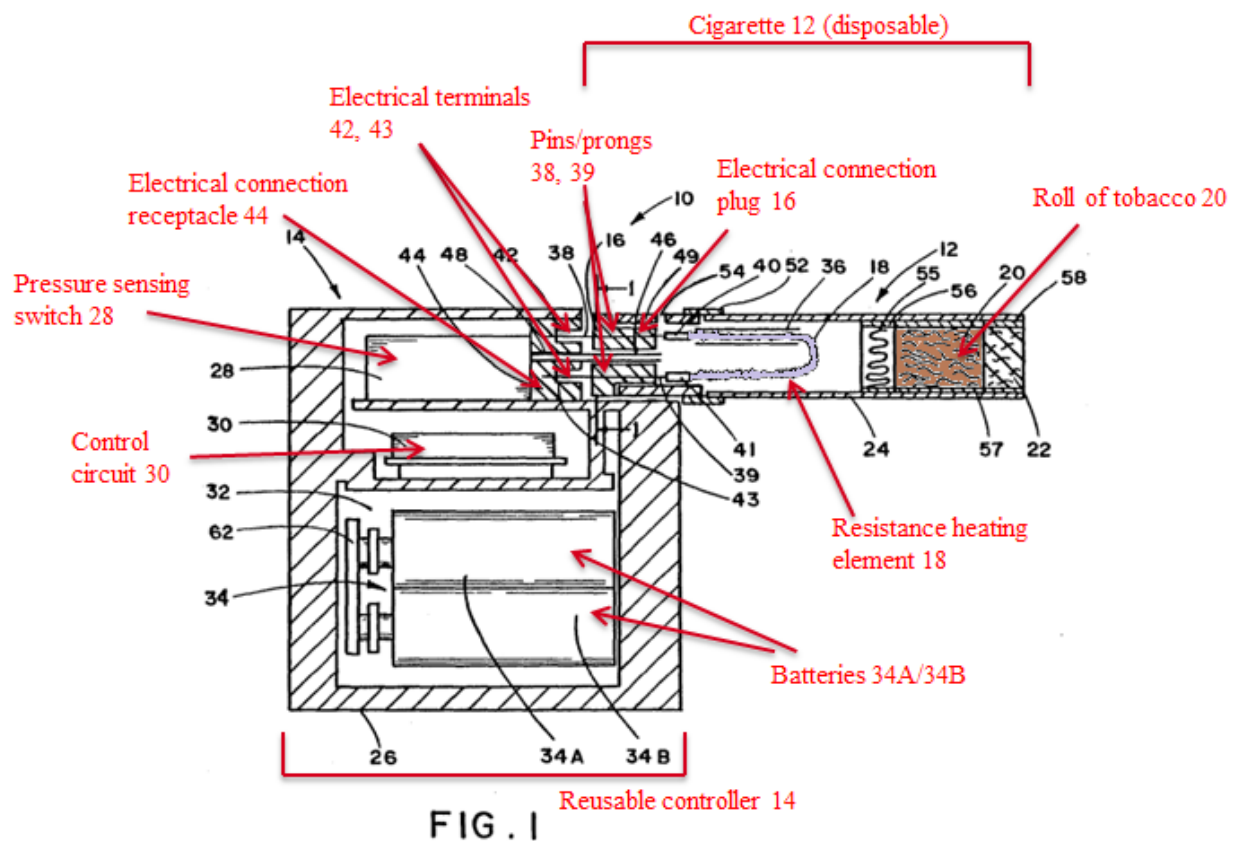
26. My understanding is that obviousness is not proven by mere conclusory statements or conclusory expert testimony. Instead, I understand there must be some articulated reasoning with rational underpinning to satisfy the legal standard for proving obviousness. I also understand that obviousness cannot be based on a hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.

27. After reviewing and analyzing the '632 Patent, the Petition, and the documents cited in the Petition, it is my opinion that Petitioner has not shown a reasonable likelihood that any of claims 14–16 and 18 of the '632 Patent are obvious over the combination of the cited references because (a) Brooks does not teach or suggest using a heating wire coil wound on a porous component, (b) a person of ordinary skill in the art would not have been motivated to modify Brooks' device by winding Brooks' "resistance heating component" around the "porous substrate" in view of Whittemore, (c) a person of ordinary skill in the art would not have been motivated to modify Brooks' device by replacing Brooks' "resistance heating component" and "porous substrate" and replacing them with Whittemore's coiled heating wire/wick, (d) Brooks does not disclose a separate liquid storage component in addition to the porous heating element, and (e) Brooks does not disclose a battery assembly in an elongated cylindrical housing. I reached these conclusions based on my analysis as further described below.

Overview of Brooks

28. Brooks discloses "smoking articles utilizing electrical energy." Brooks (Ex. 1003), Title. These smoking articles include a component disclosed as heating element 18. Heating element 18 is shown in annotated Figure 1 of Brooks, below. As shown in the figure, heating element 18 (purple) and tobacco roll 20 (brown) are located inside disposable cigarette cartridge 12. Brooks (Ex. 1003),

7:17–20. Reusable controller 14 is a separate portion of the device that connects to disposable cigarette cartridge 12. The reusable controller contains several components, including, for example, batteries 34A and 34B, pressure sensing switch 28, and control circuit 30. Brooks (Ex. 1003), 4:35–38; 7:20–25. The disposable cigarette component 12 can be disposed of and replaced with a new one. Brooks (Ex. 1003), 5:58–62.



29. Brooks consistently discloses that heating element 18 is fibrous or porous, electrically resistant (and thus heats up when current is applied), and holds an "aerosol forming substance." Brooks (Ex. 1003), 7:26–30, 7:48–8:3. The

preferred heating element 18 is a carbon filament yarn or carbon felt manufactured by American Kynol, Inc., and Brooks lists part numbers for those preferred heaters. Brooks (Ex. 1003), 7:48–65. The carbon filament yarns and carbon felts disclosed in Brooks are advantageous as heating elements because those materials on their own are both electrically resistant (i.e., heat up when current is applied) and are capable of holding liquid within their fibrous materials, like a sponge. They also have high surface areas of over 1,500 m²/g, allowing them to transfer heat efficiently. Brooks (Ex. 1003), 4:7–22, 7:34–36, 7:48–62. The "[p]referred heating elements normally have low mass, low density, and moderate resistivity, and are thermally stable at the temperatures experienced during use." Brooks (Ex. 1003), 7:34–36. The preferred carbon yarn and felt heaters meet those criteria. Each of Brooks' working examples uses one of the preferred carbon filaments or felts. Brooks (Ex. 1003), 17:1–4, 18:36–39, 19:16–19, 20:14–18, 22:7–10.

30. Brooks does not disclose a liquid storage component separate from this heating element. Because a single structure, the heating element, is both resistant and holds the aerosol forming substance in a fiber or porous material, the "aerosol forming substance is in a heat exchange relationship with the electrical heating element." Brooks (Ex. 1003), 7:26–30, 7:48–8:8. The heating element must be permeable to air and have a large surface area (preferably greater than 1 m²/g). Brooks (Ex. 1003), 4:7–29, 7:26–33. According to Brooks, a heating

element having this design is "particularly advantageous" because it is "capable of holding and efficiently releasing relatively large quantities of liquid aerosol forming substances;" specifically, an amount of liquid sufficient to provide enough aerosol for 6–10 puffs from the device, the equivalent of the number of puffs for a typical traditional cigarette. Brooks (Ex. 1003), 3:30–34, 4:25–31, 6:32–36.

31. Brooks' preferred heating element must also have "low mass, low density, and moderate resistivity," be "thermally stable at the temperatures experience during use," "heat and cool rapidly," use energy efficiently, facilitate "almost immediate volatilization of the aerosol forming substance," avoid wasting aerosol forming substance, and allow for "precise control of the temperature range experienced by the aerosol forming substance." Brooks (Ex. 1003), 7:34–47.

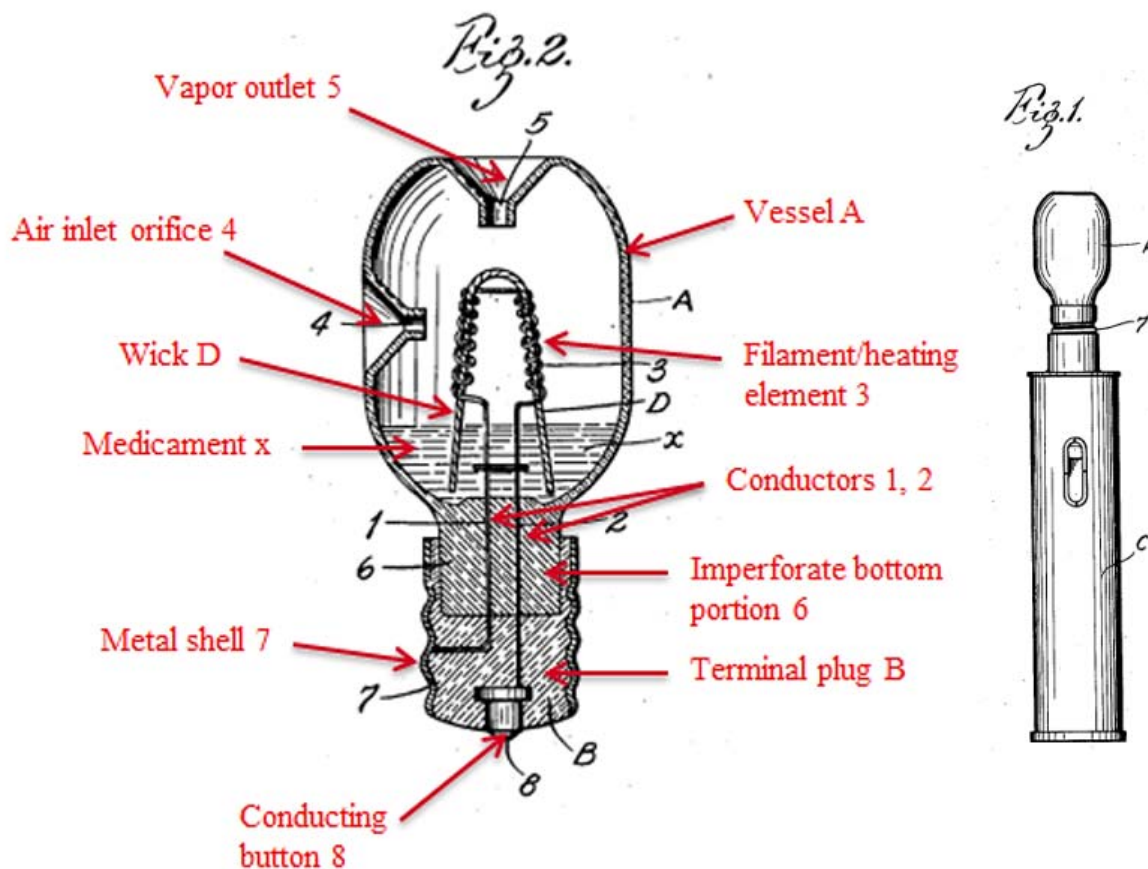
32. Brooks discloses that tobacco roll or tobacco charge 20 can be "tobacco filler such as strands or shreds of tobacco laminae, reconstituted tobacco, volume expanded tobacco, processed tobacco stems, or blends thereof," or "[e]xtruded tobacco materials and other forms of tobacco, such as tobacco extracts, tobacco dust, or the like." Brooks (Ex. 1003), 9:1–6.

Overview of Whittemore

33. Whittemore discloses a "vaporizing unit" that contains a filament/heating element 3 connected to conductors 1 and 2. This "vaporizing unit" is illustrated in annotated Figure 2 of Whittemore, below. Filament/heating

element 3 is coiled around wick D, which transports liquid medicament x from a liquid source to the coil using capillary action by contacting the liquid source.

Figure 1 of Whittemore, below, illustrates the vaporizing unit screwed into flashlight C. Electricity flows from the conductors to filament/heating element 3, causing the filament/heating element to heat up and vaporize "liquid medicament" that is transferred to the filament/heating element via wick D. Electricity is provided by screwing metal shell 7 of terminal plug B into "a terminal socket forming part of an electric circuit, such, for example, as the receptacle or socket of an ordinary flashlight C." Whittemore (Ex. 1004), p. 1, left col., ll. 39–45.



The "porous substrate" and "resistance heating component" of Brooks form a heating element and are not separate components

34. As discussed above, Brooks discloses that heating element 18 can be made from a variety of materials, including fiber and porous materials. All of Brooks' working examples utilize these materials: Example 1 uses carbon filament yarn having Catalogue No. CFY-0204-1, Examples 2–5 use carbon filament yarn having Catalogue No. CFY-0204-2, and Example 6 uses carbon filament felt having Catalogue No. ACN-211-10. Brooks (Ex. 1003), 17:1–4, 18:36–39, 19:16–19, 20:14–18, 22:7–10.

35. Among the "[o]ther suitable heating elements" identified by Brooks are "porous substrates in intimate contact with resistance heating components." Brooks (Ex. 1003), 7:65–8:2. Sturges interprets this sentence as disclosing an alternative "'intimate contact' embodiment" that "necessarily" includes a separate porous substrate and a separate resistance heating component. Sturges (Ex. 1002), ¶45. I disagree. In view of the specification as a whole, a person of ordinary skill in the art would recognize that the "resistance heating component" and "porous substrate" in this sentence are not separate components.

36. Simultaneously heating and volatilizing the aerosol forming substance would involve both the "porous substrates" and the "resistance heating components" from this embodiment. The atomizer's "porous substrates" are an

integral subpart of the heater that holds the aerosol forming substance, which is necessary for atomization, providing the liquid in intimate proximity to the heater's "resistance heating components" to allow for efficient heat transfer. The "resistance heating components" increase in temperature in response to the flow of current and cause the aerosol forming substance to atomize. Both subparts of this embodiment are necessary to achieve atomization and both work in concert to carry out that function. If either subpart were missing from heating element 18, the atomizer would not generate vapor. As such, both subparts of this embodiment are part of Brooks' atomizer.

37. Brooks does not disclose precisely how the "porous substrates" and "resistance heating components" referenced at 8:1–2 are combined to form a single heating element, other than to say that they are in "intimate contact." However, based on the disclosure of Brooks, a person of ordinary skill in the art would understand that they are not separate components in direct contact with one another, but rather that they are intimately connected within a single component. This is consistent with the disclosure of Brooks as a whole, which as discussed below repeatedly discloses the use of porous heating elements in which liquid is impregnated directly into the pores of the heating element.

38. Sturges states that Brooks cites Whittemore's disclosure as "an example of a resistance heating component (i.e., filament coil) in intimate contact

with a separate porous substrate (i.e., the wick)." Sturges (Ex. 1002), ¶60. I disagree. Brooks discusses Whittemore, along with other references, only in the Background section and in the context of disparaging prior art devices including devices using heater coils. Brooks states that none of these prior art devices had any significant commercial success or provided the user with the smoking sensation, hence, the Brooks device aims at overcoming these problems. Brooks (Ex. 1003), 3:49–60. One of ordinary skill in the art would not have any reason to modify Brooks' device to incorporate elements from prior art devices that Brooks considers inadequate.

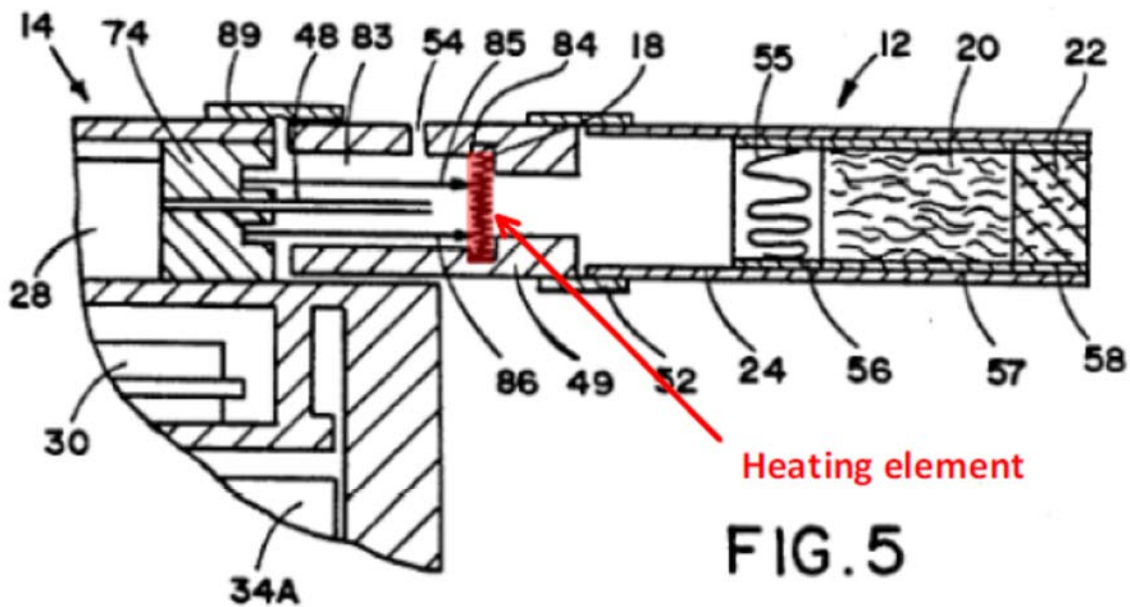
39. I disagree with Sturges that Brooks teaches an alternative location of the aerosol forming substance. According to Sturges, "the aerosol forming substance can be located either 'on the resistance heating element *or elsewhere in the article*.'" Sturges (Ex. 1002), ¶46, emphasis added. This is an incomplete citation of Brooks. Brook discloses: "As used herein...'aerosol' is...generated by action of heat from the resistance heating element upon aerosol forming substance ***and/or tobacco flavor substances*** located on the resistance element or elsewhere in the article." Brooks (Ex. 1003), 6:45–52 (emphasis added). When the teachings of Brooks are taken as a whole, one would understand that it is not the aerosol forming substance but rather the tobacco flavor substances located "elsewhere in the article."

40. In my opinion, when Brooks is read correctly, the "intimate contact" language at 8:1–2 would not have been interpreted to mean that the porous substrate and the resistance heating component are separate components. Hence, one would not have been able to separate them and replace only the resistance heating component with the heater coil of Whittemore.

A person of ordinary skill in the art would have no credible motivation for modifying Brooks' device by winding the 'resistance heating component' on the 'porous substrate'

41. The challenged claims of the '632 Patent require that the atomizer include a heating wire coil wound on a porous component.

42. Petitioner and Sturges argue that Brooks by itself teaches or suggests a heating wire coil wound on a porous component. Petition (Paper 2), pp. 24–25; Sturges (Ex. 1002), ¶55. Sturges cites and annotates Figure 5 of Brooks, below, and states that the heating component "takes the form of a heater coil," shown in green highlight. Sturges (Ex. 1002), ¶55.



Ex. 1003, Brooks at Fig. 5 (Annotated)

Sturges also cites U.S. Patent Application Publication No. 2004/0234916 (Ex. 1014) and U.S. Patent No. 4,922,901 (Ex. 1015) in an attempt to show that Brooks' heating component is in a coil form. Sturges (Ex. 1002), ¶56.

43. It is my opinion that a person of ordinary skill in the art would not have understood the heating elements of Brooks to include a wire heater coil. Brooks states that the heating element 18 depicted in Figure 5 "is a circular disc or pad of carbon felt disposed across an air passageway 83," not a wire heater coil. Brooks (Ex. 1003), 11:54–58. The only mention of coil-shaped heating elements in Brooks is with regard to prior art devices. See, e.g., Brooks (Ex. 1003), 1:57–61, 1:62–2:6, 2:35–43, 2:67–3:14.

44. The other references cited by Sturges do not change my conclusion. Ex. 1014 does not share a common inventor or a common assignee with Brooks and was published in 2004, 16 years after the filing date of Brooks. Therefore, one would not have any reason to look to Ex. 1014 to determine whether Brooks' heating component is in a coil form. Even if one would have any reason to do so, Ex. 1014 states: "Cigarette holders and pipe bowls having an electrical resistance coil to generate heat in order to volatilize tobacco flavors have been described." Ex. 1014, ¶0004, citing U.S. Patent No. 4,922,901 (Ex. 1015) at the end of the quoted sentence. The only connection that Sturges makes between these additional references and Brooks is that Ex. 1015 is "substantially identical to Brooks." Sturges (Ex. 1002), ¶105. Like Brooks, Ex. 1015 mentions coils only in the Background section, not in its actual description of the disclosed device. Therefore, I disagree with Sturges' conclusions that the device of Ex. 1015 uses a heater coil in view of the disclosure of Ex. 1014, and that Brooks uses a heater coil.

45. Petitioner and Sturges argue that alternatively, it would have been obvious to modify Brooks in view of Whittemore by coiling the resistance heating component around the porous substrate of Brooks. Sturges (Ex.1002), ¶¶57–58.

46. As discussed above, the "resistance heating component" and "porous substrate" of Brooks' heating element are not separate components. Accordingly, the suggestion to coil the "resistance heating component" of Brooks around the

"porous substrate" would not work. The "resistance heating component" and "porous substrate" form a single component, and one could not wind one around the other.

47. Even if a person of ordinary skill in the art were to accept Sturges' inaccurate description of the relationship between the "porous substrate" and "resistance heating component" of Brooks, he or she would have no credible motivation to incorporate a heater wire coil as disclosed in Whittemore.

48. Sturges states that Brooks discloses "a heating wire coil wound on a porous component" because Brooks discloses that "the heating element can constitute a 'metal wire.'" Sturges (Ex. 1002), ¶55. However, the sentence of Brooks that Sturges cites for this statement actually states that suitable heating elements include *porous* metal wires. Brooks (Ex. 1003), 7:66. This is consistent with the overall disclosure of Brooks, which repeatedly teaches that the heating element is made of porous materials that can be impregnated with liquid. A person of ordinary skill in the art would not view these "porous metal wires" as the equivalent of the heater wire coil of Whittemore, which is not porous and not designed to be impregnated with liquid.

49. Sturges states that heating elements were known to come in a variety of shapes, and that selecting any particular shape from among these "would have been an obvious design choice." Sturges (Ex. 1002), ¶44. Petitioner argues that a

person of ordinary skill in the art would have been motivated to adapt Brooks to include a heater coil wound on a porous component because "coiled wires promote efficient heat transfer." Petition (Paper 2), pp. 43–44. Similarly, Sturges goes on to state that heater coils were "particularly well-understood" and "known to provide high power density and efficient and uniform heating," and that it was well known to wrap heater coils around a porous material to generate aerosol. Sturges (Ex. 1002), ¶46. Further, Sturges states that Whittemore's wick extends beyond the heating coil to carry more liquid. Sturges (Ex. 1002), ¶113.

50. A person of ordinary skill in the art would consider the porous heating elements disclosed in Brooks to be quite efficient, particularly for the disclosed purpose of the Brooks device (i.e., the delivery of 6–10 puffs via a disposable cigarette component by directly impregnating the heater with liquid). In fact, Brooks itself discloses a number of references, such as McCormick, Kovacs, Nilsson, related to the conventional heater coils in the Background section as prior art. Brooks (Ex. 1003), 1:57–2:6, 2:36–43, 2:67–3:14. Consequently, a person of ordinary skill in the art would not have been motivated to incorporate wire coil, regardless of how "conventional" it may be, to increase heating efficiency. A person of ordinary skill in the art would have recognized that wire heater coils are not necessarily more efficient heaters, and that a heater coil like that of Whittemore would actually be less efficient than the porous heating element of Brooks for the

disclosed purpose, that is, delivery of 6–10 puffs from a single use, disposable unit. A wire heater coil provides a way to get more energy throughput in a small space, but this does not guarantee efficiency. A wire heater coil wrapped around or in contact with a porous body has only line contact, resulting in a contact area that is very limited, the difference in heat transfer contact area would be many orders of magnitude. This results in less efficient heat transfer than what can be achieved with contact over a larger surface area, such as the high surface area (i.e., greater than 1 m²/g, and preferably greater than about 1,000 m²/g) porous heater elements disclosed by Brooks. Brooks (Ex. 1003), 4:12–20. A person of ordinary skill in the art would recognize that a wire heater coil could not achieve the surface area specified by Brooks, i.e., greater than 1 m²/g. This is illustrated by Brooks' reference to Gerth, which uses a Nichrome wire heater. As noted by Brooks, the surface area of the Gerth wire heater is only 0.01 m²/g. Brooks (Ex. 1003), 4:20–22.

51. Sturges cites U.S. Patent Nos. 3,234,357 (Ex. 1012) and 5,743,251 (Ex. 1010) in support of his statement that "[h]eater coils...were known to provide high power density and efficient and uniform heating." Sturges (Ex. 1002), ¶46. Specifically, Sturges cites the following statements: "[t]he wire was wrapped in a fashion that produced close, tight coils to insure good heat transfer to the tube" (Ex. 1010, 11:20–22); and "[i]n order to obtain a stronger heating effect, the wire

in the upper region is wound in a tighter coiled manner than the lower portion" (Ex. 1012, 4:75–5:2). A person of ordinary skill in the art would understand that these statements do not suggest that heater coils promote more effective heat transfer than other heater shapes. Instead, they merely state that tightly coiled heater coils produce better heat transfer than loosely coiled ones.

52. A person of ordinary skill in the art also would not have incorporated a wire heater coil into the Brooks device because Brooks already disclosed specific suitable materials, such as porous heaters and felts. Brooks' resistive fibers and felts have very large wetted surface areas which would expose more aerosol forming substance to the heated surface than wire heaters contacting a porous substrate. Brooks (Ex. 1003), 7:48–65. The large surface area supports efficient heat transfer and release of "relatively large quantities of liquid aerosol forming substances." Brooks (Ex. 1003), 4:25–29.

53. The materials that are disclosed in Brooks are aligned with Brooks' stated desire for high surface area heater elements, and they had lower mass, lower density (due to their porous nature), desired resistivity, and thermal stability. The heaters disclosed in Brooks also had high surface area to mass ratios, which would allow for higher efficiency heating than could be achieved with wire heater coils. Due to their low mass and density combined with a high surface area to weight ratio, they also heated and cooled rapidly. With the knowledge of heater coils as

discussed in the Background section, Brooks chose to use porous materials in its design of the heating element. This fact indicates that the heater coils known in the art did not meet the criteria for Brooks' single use application.

A person of ordinary skill in the art would have no credible motivation for substituting Brooks' "resistance heating component" and "porous substrate" with Whittemore's heating wire/wick combination

54. Petitioner and Sturges go on to state that even if the resistance heating component and the porous substrate of Brooks are not separate components, "it would have been obvious to substitute Whittemore's coiled heating wire/wick configuration for Brooks heating element." Sturges (Ex. 1002), ¶¶63–66; Petition (Paper 2), p. 28. However, just as there would be no credible motivation for incorporating a heater wire coil into the Brooks device given the superiority of the Brooks' heating elements to coil heaters, there also would be no credible motivation for incorporating the wire coil and wick of Whittemore into the Brooks device.

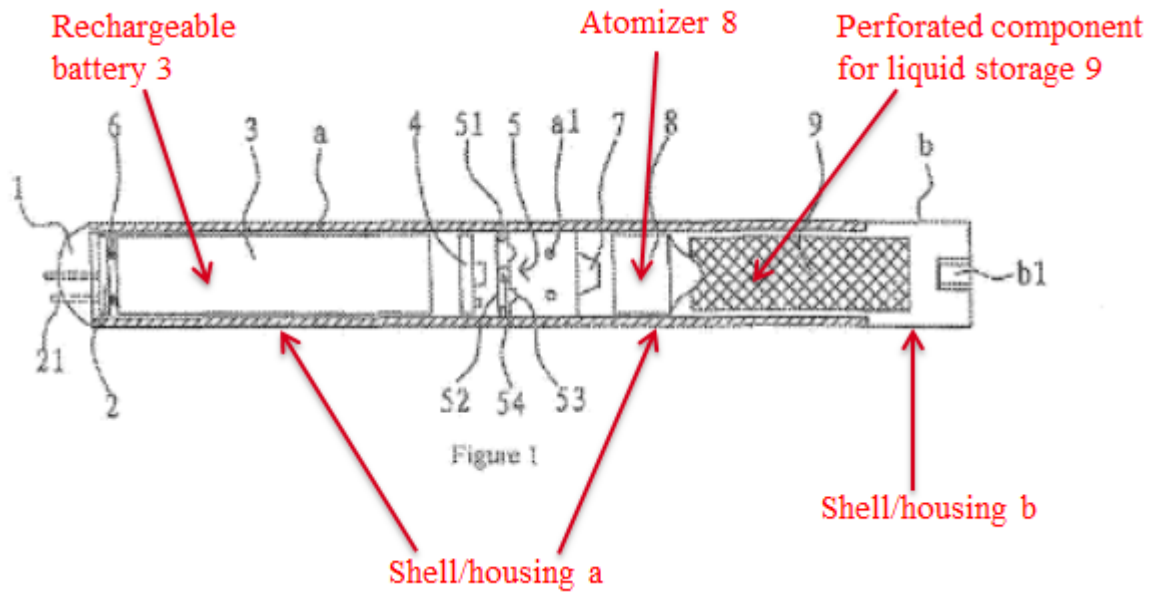
55. The wick of Whittemore contacts a separate liquid source and moves liquid to the heater coil via capillary action. As discussed at length in this declaration, the Brooks device does not utilize a separate liquid source – all of the liquid is directly impregnated in the heater. Thus, there would be no reason to incorporate a wick into the Brooks device, since liquid is not being transferred from outside the atomizer. If the heater coil and wick of Whittemore were inserted

into the Brooks device in place of the porous substrate heating element, there would be no liquid storage component for the wick to draw liquid from. Further, since Whittemore's wick contacts the liquid storage component to move liquid via capillary action, it is not designed to hold liquid over time and would dry out.

Brooks does not disclose a liquid storage component separate from the atomizer assembly

56. Claims 14–16 and 18 of the '632 Patent recite an "atomizer assembly" and a "liquid storage component" within the "elongated cylindrical housing." In these claims, the atomizer assembly and liquid storage component are separate components.

57. This is consistent with the disclosure of the '632 Patent, which presents the atomizer assembly and liquid storage component as separate structures. For example, annotated Figure 1 of the '632 Patent, below, shows the atomizer assembly as a separate component in contact with the liquid storage component, which may contain a perforated component. '632 Patent (Ex. 1001), 4:5–7. The liquid stored in the liquid storage component is transferred to the atomizer assembly, where it is heated and aerosolized. The liquid storage component, not the atomizer itself, functions as the store of liquid in the device. All liquid that eventually gets atomized in the electronic cigarette originates from this liquid storage component.



58. A person of ordinary skill in the art would recognize that heating element 18 of Brooks is part of the atomizer and the liquid is impregnated directly into the heating element. Brooks teaches that current is passed through the heating element, which "experiences an increase in temperature which in turn heats and volatilizes the aerosol forming substance" once the desired temperature range is reached. *See, e.g.*, Brooks (Ex. 1003), 5:1–12, 10:45–48. There is no embodiment of Brooks in which heating element 18 would not be considered part of the atomizer and no other solution storage outside of the atomizer is disclosed by Brooks. Sturges agrees to this: "Heating element 18 generates aerosol or vapor when electric current runs through it and, accordingly, constitutes an 'atomizer.'" Sturges (Ex. 1002), ¶¶124–125. Petitioner asserts that Brooks' "intimate contact embodiment includes an atomizer because it heats up when electricity is applied to

it and the heat converts the aerosol forming substance to an aerosol." Petition (Paper 2), pp. 62–63; Sturges (Ex. 1002), ¶¶60–61, 125.

59. Brooks reiterates numerous times that heating element 18 holds all of the liquid in the disclosed device: "[s]uch heating elements are particularly advantageous in that they are capable of holding and efficiently releasing relatively large quantities of liquid aerosol forming substances" Brooks (Ex. 1003), 4:25–29; "resistance heating element 18 carrying an aerosol forming substance" Brooks (Ex. 1003), 7:17–20; "[t]he resistance heating element 18 ... preferably is a fibrous material having a high surface area and an adsorbant [sic], porous, wettable character, in order to carry a suitable amount of aerosol forming substance for effective aerosol formation" Brooks (Ex. 1003), 7:26–30; and "[p]referably, the heating element 18 is impregnated with or otherwise carries the aerosol forming substance" Brooks (Ex. 1003), 8:4–8. Working examples 1, 3, and 4 further demonstrate impregnating the heating element with a liquid aerosol forming substance. Brooks (Ex. 1003), 17:6–9; 19:21–22; 20:19–21.

60. While there are multiple references in Brooks to heating element 18 being impregnated directly with aerosol forming substance, there is no disclosure of a liquid storage component elsewhere in the device. Brooks (Ex. 1003), 17:1–9, 19:16–22, and 20:14–24.

61. According to Sturges, Brooks discloses that the aerosol forming substances are "located on the resistance [heating] element or elsewhere in the article," citing Brooks (Ex. 1003), 6:45–52. Sturges (Ex. 1002), ¶¶61, 125.

62. Sturges points to the following sentence in Brooks as supporting his conclusion that Brooks discloses a second liquid storage component "elsewhere" outside of the heating element. Sturges' citation of Brooks is incomplete, and the complete citation reads as follows: "...generated by action of heat from the resistance heating element upon aerosol forming substances *and/or tobacco flavor substances* located on the resistance heating element or elsewhere in the article." Brooks (Ex. 1003), 6:49–52; emphasis added. I disagree with Sturges' conclusion regarding this sentence. Brooks does not say that aerosol forming substances may be located elsewhere in the article, but rather that aerosol forming substances *and/or tobacco flavor substances* may be located elsewhere in the article. In view of the Brooks disclosure as a whole, which consistently teaches that liquid is impregnated directly onto the heating element, a person of ordinary skill in the art would interpret "elsewhere in the article" to refer to the tobacco flavor substances, not the aerosol forming substance.

63. Brooks refers multiple times to impregnating liquid directly onto the heating element 18, but never refers to the use of a liquid storage component elsewhere in the device. Brooks (Ex. 1003), 17:1–9, 19:16–22, and 20:14–22.

Storing liquid outside of the heating element, i.e., outside of the atomizer would be inconsistent with the design of Brooks, which incorporates a disposable cigarette component meant to provide 6–10 puffs.

64. Sturges points to the following sentence in Brooks as supporting his conclusion that Brooks discloses a second solution storage area "elsewhere" outside of the heating element. Sturges' citation of Brooks is incomplete, and the complete citation reads as follows: "...generated by action of heat from the resistance heating element upon aerosol forming substances *and/or tobacco flavor substances* located on the resistance heating element or elsewhere in the article." Brooks (Ex. 1003), 6:49–52; emphasis added. I disagree with Sturges' conclusion regarding this sentence. Brooks does not say that aerosol forming substances may be located elsewhere in the article, but rather that aerosol forming substances *and/or tobacco flavor substances* may be located elsewhere in the article. In view of the Brooks disclosure as a whole, which consistently teaches that liquid is impregnated directly onto the heating element, a person of ordinary skill in the art would interpret "elsewhere in the article" to refer to the tobacco flavor substances, not the aerosol forming substance. Brooks discloses that a tobacco roll may be present outside the heating element, which is consistent with my interpretation. Brooks (Ex. 1003), 10:49–53. Figures 1, 5, and 6 of Brooks, which show tobacco roll 20 adjacent to mouth end filter 22, also support this conclusion.

65. Sturges further states that tobacco charge 20 includes a "liquid" such as tobacco extracts, tobacco flavor modifiers such as levulinic acid, and other flavoring agents such as menthol, vanillin, chocolate, licorice, and the like. Sturges (Ex. 1002), ¶118. I disagree. In the paragraph immediately above the citation, Brooks discloses: "Extruded tobacco materials and other forms of tobacco, such as tobacco extracts, tobacco dust, or the like, also can be employed [in the tobacco charge 20]." Brooks (Ex. 1003), 9:4–6. Further, Brooks discloses that "the tobacco charge 20 is overwrapped with a paper overwrap 57." Brooks (Ex. 1003), 9:6–8. The fact that the tobacco materials are "extruded" means that these tobacco materials are unlikely to be liquid but may be in some other solid forms such as gel or paste; and the fact that the tobacco charge is wrapped with paper indicates that the tobacco charge unlikely contains liquid. In fact, nowhere in Brooks discloses that tobacco charge 20 includes a liquid. Even if any of the tobacco extracts or flavoring agents were in a liquid form, they would be blended into the tobacco roll and exist in a solid form.

66. Petitioner and Sturges argue that Brooks' disclosure of "reconstituted tobacco" and "tobacco extract" included in tobacco charge 20 are liquid in view of the teachings of U.S. Patent No. 4,941,486 ("Dube") (Ex. 1033) and U.S. Patent No. 7,337,782 ("Thompson") (Ex. 1034). Petition (Paper 2), pp. 68–69; Sturges (Ex. 1002), ¶107. I disagree. U.S. Patent No. 5,327,917 (Ex. 2081), which is

assigned to Petitioner itself, discloses reconstituted tobacco material in various solid forms such as a "sheet-like form," "rod" form, etc. Ex. 2081, 2:1–10. With respect to tobacco extracts, Brooks discloses a "spray dried tobacco extract," and a "freeze dried tobacco extract." Brooks (Ex. 1003), 8:11–12. Neither reconstituted tobacco nor tobacco extract has to be in a liquid form. In my opinion, Brooks' tobacco roll or tobacco charge 20 is not a solution storage area because it does not contain any liquid.

Brooks' does not teach or suggest a battery/atomizer assembly in an elongated cylindrical housing

67. Claims 14–16 and 18 recite an "elongated cylindrical housing" that contains a "battery assembly" and an "atomizer assembly." See, e.g., Fig. 1 of the '632 Patent showing a device having the shape of a traditional cigarette with battery and atomizer assemblies inside. A POSITA would recognize that the shape of a traditional cigarette is "elongated cylindrical."

68. Petitioner and Sturges argue that "Brooks discloses different shapes for the battery assembly housing (i.e., the controller 14)" which will be "an elongated cylindrical housing" when the "controller housing take on the form of a cigarette holder." Petition (Paper 2), p. 17; Sturges (Ex. 1002), ¶70. I disagree.

69. Brooks does not disclose or suggest a battery assembly within "an elongated cylindrical housing." Nor does Brook teach or suggest a device having a

shape similar to a traditional cigarette when the device includes a battery assembly. Brooks only mentions prior art devices resembling the shape of a cigarette or cigar in the Background section. Brooks (Ex. 1003), 2:29–30, 3:15–16.

70. Brooks discloses that reusable controller can be in the form of a "cigarette holder." Brooks (Ex. 1003), 4:47–49. Petitioner and Sturges argue that a PHOSITA would have understood that a "cigarette holder" shaped controller as described in Brooks is an "elongated cylindrical structure" with an extended open portion to receive a cigarette. Petition (Paper 2), pp. 16–17, 31–32; Sturges (Ex. 1002), ¶70. Petitioner and Sturge argue that a "cigarette holder" need to match the general appearance and shape of a cigarette which is "an elongated cylindrical" and thus is an "elongated cylindrical housing." Petition (Paper 2), pp. 17, 33; Sturges (Ex. 1002), ¶70. I disagree.

71. Brooks discloses multiple embodiments of its disclosed device, but none has an elongated cylindrical reusable controller. See, e.g., Fig. 3 of Brooks, below, showing an assembled device that does not have the shape of a traditional cigarette and a reusable controller that does not have an elongated cylindrical shape although the reusable controller is configured to hold an elongated cylindrical disposable component:

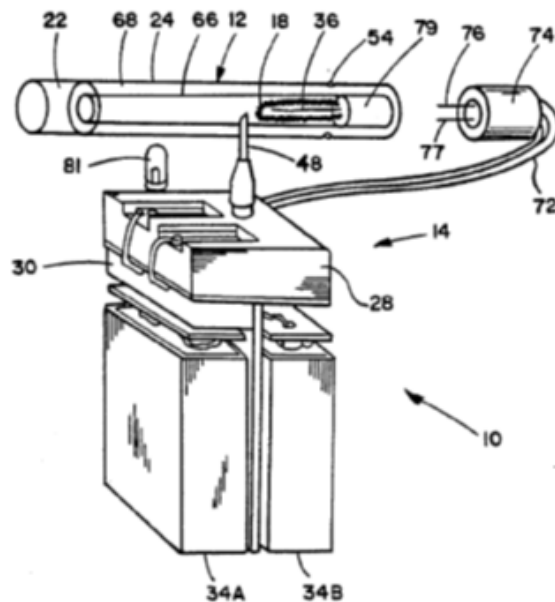


FIG. 3

72. Brooks discloses the embodiment of Fig. 3, above, where the purpose of the reusable controller functioning is to “*hold the cigarette* in a normal fashion.” Brooks (Ex. 1003), 11:31–35 (emphasis added). However, the reusable controller of the embodiment of Fig. 3 does not resemble the elongated cylindrical shape of a traditional cigarette, nor does the assembled device have an elongated cylindrical shape.

Conclusion

73. I conclude that claims 14–16 and 18 of the '632 Patent are patentable over Brooks and Whittemore, either alone or in combination, and that Petitioner has not shown a reasonable likelihood that any one of those claims is unpatentable.

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

Dated: July 18, 2018
in ESCONDIDO, CA

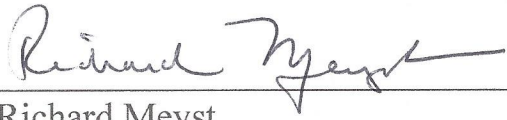

Richard Meyst

Exhibit A

CV for Richard P. Meyst

Selected Expertise

- Medical Product Design / Development
 - FDA-GMP Practices
 - Market / Patent Research
 - Rapid Prototyping
 - Tooling / Process Development
 - Manufacturing / Industrial Engineering
 - Project Planning / Management
 - Risk Analysis / Risk Management
 - Failure Analysis
 - Verification, Validation & Qualification
 - Regenerative Medicine Devices
 - Blood Filters, IV Filters
 - Laparoscopic Surgical Instruments
 - Umbilical Cord Blood Collection
 - Cell Therapy, Stem cells & bioreactors
 - Catheter Based Diagnostics
 - Therapeutic Catheters, angioplasty
 - Drug Delivery/ Infusion Devices
 - High Volume Sterile Disposables
 - Medical Device Regulatory Submissions
 - Grant Writing
 - Expert Witness
-

Biography

Mr. Meyst is an accomplished engineer/program manager/entrepreneur and has been facilitating the advanced design and development of a wide range of successful medical technology products for the health care industry over the last 40+ years. He has extensive knowledge in product design and development, product prototyping, production startup, manufacturing engineering, risk analysis, strategic planning, grant preparation and market research. He has also provided expert witness assistance in IP cases, product failure analysis, and other medical products cases. He has held various engineering, development, operations and management positions at CR Bard, Fenwal Division of Baxter, IMED and other healthcare and consumer product companies. For the last 25+ years he has been an owner of Fallbrook Engineering. Since 2003 he has been the President and CEO. Selected product experience includes implantable vascular prosthesis, DNA amplifiers, vital signs monitoring, drug infusion pumps and systems, medical lasers, surgical instruments, catheters of all kinds, microprocessor based diagnostic and therapeutic instruments, blood cell collection and processing, filtration devices for blood and IV solutions, as well as stem-cell harvesting and cell expansion systems.

Mr. Meyst was a Principal Investigator on an NIH SBIR grant from the National Heart, Lung and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. He served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and is a long time member. He is a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation and the American Filtration Society. He is also a member of the Medical Device Steering Committee of BIOCOM. Mr. Meyst has recently been a juror in the UBM/Cannon Medical Design Excellence Awards competition. His Bachelors and Masters degrees in Mechanical Engineering are from the University of Wisconsin, Madison. He has been awarded sixteen US Patents, has over four applications pending and has been an invited speaker, presenting talks at numerous scientific and medical industry meetings.

Employment History

From: 1989 **Fallbrook Engineering, Inc.**
To: Present Escondido, CA

Position: ***2003-Present: President/CEO***

Fallbrook provides consulting engineering services to client companies in the medical, pharmaceutical, biotech, electronic and consumer product industries. Services include project management, product conception, design and development, product prototyping, design and process validation, manufacturing engineering, production startup, cost reduction, as well as regulatory affairs compliance and submissions. He was also a Principal Investigator on a Phase II NIH SBIR Grant for the development of an improved method for the collection of umbilical cord blood, a source rich in stem cells.

1989-2003: Vice President

Provided consulting engineering services to client companies in the medical, pharmaceutical, cosmetic, electronic and consumer product industries.

From: 1988 **Diatek Corp.**
To: 1989 San Diego, CA

Position: ***Manager, Manufacturing Engineering***

Designed/developed disposable for "next generation" tympanic electronic hospital thermometer. Designed and implemented high speed automated production equipment to produce 1 MM+ units per day. Supported existing vital signs and operating room product lines. Managed facility and plant maintenance departments.

From: 1983 **Imed Corp.**
To: 1988 San Diego, CA

Position: ***Manager, Pilot Engineering***

Ran pilot production facility for new product builds of complex medical electromechanical/electronics and sterile disposables. Managed "Specials" program to offer custom I.V. sets and I.V. pumps per hospital order. Managed team of technicians/engineers to move new products from R&D into Manufacturing.

Technical Product Manager

Managed I.V. disposables product line projects that resulted in \$4 MM annual savings. Developed organized plan, gained corporate support and supervised implementation. Achieved project objectives through design standardization, process simplification, quality/performance enhancements, plus multi-national manufacturing operations.

Manager, Disposable Design

Managed/directed design & implementation of 6 new I.V. disposable product codes, an enteral product line and numerous new components. Supported research of 3rd generation volumetric pump disposable. Supervised department's growth in handling design/drafting, engineering and technician support.

From: 1979 **Oak Industries**
To: 1983 San Diego, CA

Position: ***Manager of Telecommunications***

Consulted to headquarters and domestic operating companies. Managed \$500K annual acquisition and installation of telecom equipment/services. Utilized cost control programs, network optimization and the use of value-added services to save \$350K annually.

Manager, Training & System Development

Planned and directed implementation of facilities projects for nationwide Pay TV network offices/warehouses in Phoenix, Chicago and Dallas. Designed and supervised training programs for installers, service technicians, phone sales and billing agents. Improved overall efficiency by 40% and saved 20% labor cost. Planned/directed the buying and installation of telecom equipment/services serving 600+ users handling 20,000 calls per day.

From: 1974 **Baxter Travenol Labs, Fenwal Division**
To: 1979 Round Lake, IL

Position: ***Program Manager***

Supervised and directed experts in design/development of collection, fractionation, storage and administration of human blood component products. Product scope: sterile medical disposables and electronic, electro-mechanical biomedical hardware. Specific products: Membrane Plasmapheresis, Autologous Blood Collection and General Blood Collection & Administration Sets.

Section Manager

Directed 6 engineers, physiologists and technicians in R&D for entire blood filtration product line. Simplified several blood set codes with 30% increase in manufacturing yield. Pioneered blood set materials evaluation for conversion from ETO to Gamma Sterilization. Designed nonwoven composite filter cartridge for Cadiotomy Bypass Filter. First of code production achievements: Polyester Mesh Blood Administration Sets, Pediatric Microfilter and a Filtration Leukapheresis Disposable Circuit.

Senior Biomedical Engineer

Designed/tested and produced a Microaggregate Transfusion Filter product line for worldwide distribution. (Product performance remained tops through 20+ years of product life. Product is now discontinued.) Served on AAMI Microfilter Standards Committee. Redesigned Platelet Administration Set to improve yield 20%. Managed design of an Autologous Blood Collection Set. Developed filter for collecting cryoprecipitate to produce Factor VIII.

Senior Development Engineer

Reduced Blood Sets' field complaints by 50% through product redesign and manufacturing process modifications. Redesigned existing microfilter to double volume capacity with no cost increase. Introduced ultrasonic assembly techniques for several products to reduce costs and improve reliability.

From: 1972 **USCI, Division of C.R. Bard, Inc.**
To: 1974 Glens Falls, NY

Position: ***Product Engineer, Prosthetic Development***

Supported Vascular Graft and Cardiovascular Catheter product lines. Instituted program to quantify and control variables affecting product quality. Designed/implemented/evaluated specialty test equipment and testing procedures. Developed/wrote product specifications.

Expert Witness, Litigation Experience

Date	2018	Client: Akin Gump
	Case:	Aptar v. 3M & Meck
	Project:	Patent Infringement
Date	2017	Client: The Crites Law Firm
	Case:	Pre-case Evaluation
	Project:	Personal Injury
Date	2017	Client: Better Life Technologies
	Case:	BLT v. Kaiser Permanente
	Project:	Nondisclosure & Trade Secrets
Date	2017	Client: Klinck Law
	Case:	Blendermann v. LifeWave Inc.
	Project:	Patent Infringement
Date	2017	Client: Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
	Case:	Zimmer Surgical v. Stryker Corp.
	Project:	Patent Infringement
Date:	2016	Client: Perkins Coie, LLP
	Case:	Fontem Ventures B.V. et al. v. R.J. Reynolds Vapor Co.
	Project:	Litigation and related IPRs
Date	2016	Client: Greenberg Traurig, LLP
	Case	B. Braun v. BD
	Project:	Patent infringement & IPRs
Date:	2016	Client: Perkins Coie, LLP
	Case:	Fontem Ventures B.V. et al. v. Nu Mark LLC
	Project:	Litigation and related IPRs

Date:	2016	Client: Gallagher Krich, APC
Case:		Cyth Systems v. CareFusion
Project:		Contract dispute
Date:	2016	Client: Davis, Grass, Goldstein & Finlay
Case:		Beatriz Picon v. San Antonio Regional Hospital
Project:		Failure analysis
Date:	2016	Client: Cooley LLP
Case:		Medline Industries, Inc. v. C.R. Bard, Inc.
Project:		Patent dispute
Date:	2016	Client: Hodgson Russ LLP
Case:		Curlin Medical, Inc. v. ACTA Medical, Inc.
Project:		Patent infringement
Date:	2016	Client: PJ West and Associates, Inc.
Case:		Undisclosed
Project:		Medical product failure
Date:	2016	Client: Girardi and Keese
Case:		Deirdree Lagewaard v. Medtronic Minimed, Inc.
Project:		Medical product failure analysis
Date:	2015	Client: Perkins Coie LLP
Case:		Fontem Ventures B.V. et al. v. NJOY Inc. et al.
Project:		Electronic Cigarette IP case: Infringement, Validity and IPRs
Date:	2014	Client: Novak Druce Connolly Bove & Quigg LLP
Case:		Larry G. Junker, Plaintiff v. Medical Components, Inc. and Martech Medical Products, Inc., Defendants
Project:		Catheter design patent
Date:	2014	Client: Lipeles Law Group
Case:		Robinson v Rheingold
Project:		Analysis of failed knee brace

Date: 2014 **Client: Law Offices of George B. Piggott**
 Case: Armand Maaskamp v. Theodore Wortrich
 Project: Technology Ownership and Contracts Dispute

Date: 2014 **Client: Knobbe Martens Olson & Bear LLP**
 Case: Masimo Corporation & Masimo International Sarl v. Shenzhen Mindray
 Bio-Medical Electronics., Ltd.
 Project: I.P. – Patent Infringement and Validity

Date: 2014 **Client: Johnson Moore**
 Case: Rosenwein v. UCLA Hospital, Bard Access Systems, Inc.
 Project: Patient Injury, Root Cause Investigation of Medical Device

Date: 2014 **Client: Orrick, Herrington & Sutcliffe LLP**
 Case: Flextronics v. ICU Medical
 Project: Development Project Arbitration Matter

Date: 2014 **Client: Leavitt, Yamane & Soldner**
 Case: Pre-case Evaluation
 Project: Patient Injury, Root Cause Investigation of Medical Device

Patents

Patent Number	Date Issued	Title
8,522,839	2013	Adapters for use with an anesthetic vaporizer
8,033,306	2011	Adapters for use with an anesthetic vaporizer
7,784,504	2010	Adapters for use with an anesthetic vaporizer
6,669,092	2003	Display apparatus
6,440,110	2002	Apparatus and method for collecting blood from an umbilical cord
6,190,368	2001	Apparatus and method for collecting blood from an umbilical cord
5,993,429	2001	Apparatus and method for collecting blood from an umbilical cord
5,919,176	2001	Apparatus and method for collecting blood from an umbilical cord
RE34,599	1994	Disposable probe cover assembly for medical thermometer
D336,862	1993	Probe cover holder for medical thermometer
5,056,682	1991	Container for fan-folded sheets
4,911,559	1990	Disposable probe cover assembly for medical thermometer.
4,736,736	1988	Cervical traction assembly having head cradle w/ occipital shelf
4,283,289	1981	Blood filter for leukocytes
4,170,056	1979	Blood filter
4,157,967	1979	Blood filter

Education

<u>Year</u>	<u>College/University</u>	<u>Degree</u>
1972	University of Wisconsin, Madison, WI	MS, Mechanical Engineering
1971	University of Wisconsin, Madison, WI	BS, Mechanical Engineering

Publications / Presentations

1. "Effective Strategic Alliances", Tech Coast Life Science Innovation Conference, September 28, 1999
2. "Effective Strategic Alliance Tactics", Tech Coast Life Science Innovation Conference, September 28, 2000, Irvine, CA.
3. "Strategies for Optimal Outsourcing Alliances", MD&M West 2001, January 9, 2001, Anaheim, CA.
4. "Winning Strategies for Commercialization", Tech Coast Life Science Innovation Conference, November 13, 2001, Irvine, CA.
5. "Seeing Green: Finding Money for Product Development" A Presentation for the 2002 Medical Design & Manufacturing Conference, Jan., 2002, Anaheim, CA.
6. "Running the Hurdles with NIH SBIR's" A Presentation for the 4th Annual NIH SBIR/STTR Conference, June 21, 2002, Bethesda, MD
7. "Running the Hurdles with NIH SBIR's", A Presentation for the 5th Annual Winter Conference, Association of University Research Parks, January 17, 2003, Newport Beach, CA
8. "NIH Grant \$ for Your Med Device/Biotechnology Project", Medcon, Conference for the Design and Manufacturing of Medical and Biotech Devices, April 28, 2004, Del Mar, CA
9. "NIH Grant \$ for your Nano-Biotechnology Project", A Presentation for the nanoSIG™ Forum, Commercial Applications in Nano-Bio Technology, February 26, 2004, San Diego, CA
10. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A Presentation to the 2005 AOAC Two-Day cGMP Conference on Pharmaceuticals and Medical Devices, March 10 & 11, 2005, FDA Offices, Irvine, CA
11. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A presentation for Medcon Expo April 28, 2005, Del Mar Fairgrounds, San Diego, CA
12. "Development of a new medical device for the efficient, safe and easy collection of umbilical cord blood." A presentation at the BIOCOM Medical Device Quarterly Event, August 11, 2005, San Diego, CA
13. "Risk Assessment: It's a Risky World out There" A presentation to the San Diego Regulatory Affairs Network, March 16, 2006, San Diego, CA

14. "Device & Diagnostic Development: Concept to Bedside" Panel member at the BIOCOM Medical Device Quarterly Event, October 22, 2008, San Diego, CA
15. "Risk Assessment: It's a Risky World out There" A presentation to a Masters Class at San Diego State University, April 2011, San Diego, CA
16. "Risk Assessment: It's a Risky World out There" A presentation to a Masters Class at the University of California, San Diego, August 2011, San Diego, CA
17. "Bioresorbable Polymers with Medical Devices – A (Still) Emerging Field" A presentation to the Medical Device and Design West Conference, February 13, 2012, Anaheim, CA
18. "Collect 250™, The Safest, Fastest and Most Effective Umbilical Cord Blood Collection System" A presentation to National Heart, Lung, and Blood Institute Innovation Conference, June 11, 2013, San Diego, CA
19. "Secrets to a Successful Startup" a panel member at 30th anniversary MD&M West Conferences, February 11, 2015 in Anaheim, CA

Professional Associations and Additional Activities

- Sr. Member, Society of Plastics Engineers (SPE), Medical Plastic Division
 - Member, AAMI, Association for the Advancement of Medical Instrumentation
 - Member, AABB, American Association of Blood Banks
 - Member, AACC, American Association for Clinical Chemistry
 - Member, American Filtration and Separations Society
 - Member, BIOCOM, San Diego
 - Member, The Designers Accord
 - Member, SDRAN, San Diego Regulatory Affairs Network

 - Served as a juror in the UBM/Cannon Medical Design Excellence Awards competition
 - Served as a judge in a San Diego CONNECT Capital Competition for start-ups
 - Advisor to Valley Center High School Computer Aided Design (CAD) program
-