

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHILIP MORRIS PRODUCTS, S.A.,
Petitioner

v.

RAI STRATEGIC HOLDINGS, INC.,
Patent Owner

Patent No. 9,901,123

Case No. IPR2020-01602

DECLARATION OF CHARLES E. CLEMENS

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I, Charles E. Clemens, do hereby declare:

I. INTRODUCTION

1. I am making this declaration at the request of RAI Strategic Holdings, Inc. (“Patent Owner” or “RAI”) in the matter of the Inter Partes Review (“IPR”) of U.S. Patent No. 9,901,123 (“the ’123 patent”).

2. I am being compensated for my work in this matter at my standard hourly rate of \$585 for such consulting services. My compensation in no way depends on the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials:

- a. The ’123 patent (Ex. 1001) and its file history (Ex. 1002);
- b. Petition for Inter Partes Review of U.S. Patent No. 9,901,123, IPR2020-01602 (Paper 2);
- c. Declaration of Mr. Stewart Fox (Ex. 1003);
- d. Chinese Patent CN2719043Y to Hon, including an English translation (Ex. 1005) (“Hon”);
- e. U.S. Patent No. 4,947,874 to Brooks et al. (Ex. 1006) (“Brooks”);
- f. U.S. Patent No. 2,057,353 to Whittemore, Jr. (Ex. 1007) (“Whittemore”);
- g. European Patent EP 0845220 B1 to Susa et al. (Ex. 1008) (“Susa”);

- h. U.S. Patent No. 4,284,089 to Ray (Ex. 1009) (“Ray”);
- i. PMUSA teardown report on Ruyan device (Exs. 1019, 1020);
- j. RJR teardown report on Ruyan device (Ex. 1023);
- k. U.S. Patent No. 6,095,153 to Kessler et al. (Ex. 1030) (“Kessler”);
- l. Decision – Institution of Inter Partes Review (Paper 9); and
- m. Any other materials referenced herein.

II. PROFESSIONAL QUALIFICATIONS

4. My professional background and technical qualifications are reflected in my curriculum vitae, which is attached as Appendix A.

5. I have over 40 years of experience as an engineer, executive, and consultant in the medical device industry.

6. In 1979, I obtained a Bachelor of Science degree in Mechanical Engineering from San Diego State University.

7. From 1981 to 1995, I worked at IVAC Corporation (now CareFusion, a subsidiary of Becton Dickinson), a company that pioneered intravenous medication delivery systems. During my time at IVAC, I worked in multiple roles, including as a product designer, engineering manager, and technical director for the largest medication delivery system program the company had ever attempted, which resulted in launching the product in both the US and European markets. My work at IVAC involved design, development, marketing, launch, and manufacturing of numerous

drug delivery devices and vital sign monitoring systems. My design and development work at IVAC led to the filing of five patents on which I was a named inventor. The focus of my work was in both durable and disposable products utilizing small mechanisms, plastic injection molded parts produced in quantities of millions, and precision assembly of parts to achieve high production quality and functional reliability.

8. In 1990, I established and managed training for specialized design tools for Design for Manufacturing and Assembly (DFMA), a design process intended for optimizing assemblies and part count for small plastic devices produced in high quantities.

9. From 1995 to the present, I have been operating a medical device design and development consulting company as the Founder and Principal Consultant. My consulting company focuses on developing innovative medical device products and bringing them to market. During this time I have worked extensively on dozens of medical device designs across many clients in the areas of (a) respiratory care devices such as personal inhalers, (b) liquid medication delivery devices, including intravenous (“IV”) systems and injectors, (c) hemodialysis and other blood handling systems, and (d) in-vitro diagnostic systems.

10. As a consultant, I have performed design, analyses, prototyping, and testing activities of numerous inhalation products. Between 1995 and 1998, I

developed a custom closed loop drug vaporizer and reclamation system applied to full and partial liquid ventilation therapy for respiratory distress syndrome in both infants and adults, including designing and building clinical trial systems credited with saving infant lives. This included the design of a unique high volume drug vaporizer utilizing high surface area wicking and heating that was integrated directly in-line with the patient's breathing circuit.

11. Between 1999 and 2000, I developed a low cost, injection molded, high performance drug aerosol generator for use in inhaler products for Aerogen Incorporated. In 2003, I collaborated with HP to develop an optimized print head technology utilizing solid state vaporization to generate respirable aerosol then developed aerosol quality testing systems and directed computational fluid dynamic analysis of a small e-cigarette inhaler product design indicated also for therapeutic inhaled nicotine delivery for InJet Digital Aerosols. Between 2004 and 2012, I assisted several companies in various inhaler product design projects, such as design reviews, risk analyses, and design verification testing. This work was performed for companies such as Dura Pharmaceuticals (2004), KOS Pharmaceuticals BAI (2006), and General Pharm Partners (2012).

12. I am identified as an inventor on 13 issued patents and 3 applications in the field of medical devices, including small mechanisms, plastic injection molding and assembly, patient medication delivery devices, and fluidic control devices.

13. I have worked on and am familiar with hundreds of plastic medical device assemblies and mechanisms throughout my career and have significant experience with medication delivery systems, including MDI-type devices. Further, I have analyzed many injector devices utilizing small plastic dose counting mechanisms.

14. I have reviewed the '123 patent, and I am familiar with the subject matter of that patent, which is within the scope of my education and professional experience.

III. RELEVANT LEGAL STANDARDS

15. I have been asked to provide my opinion as to whether certain claims of the '123 patent would have been obvious to a person of ordinary skill in the art (POSA) at the time of the invention, in view of the alleged prior art.

16. I am an engineer by training and profession. The opinions I am expressing in this Declaration involve the application of my knowledge and experience to the evaluation of certain alleged prior art with respect to the '123 patent. My formal knowledge of patent law is no different than that of any lay person. Therefore, I have requested the attorneys from Jones Day, who represent RAI, to provide me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply current principles related to patent validity to my analysis.

17. It is my understanding that in determining whether a patent claim is obvious in view of the prior art, the Patent Office must construe the claim by giving the claim its plain and ordinary meaning, consistent with the specification and prosecution history. For the purposes of this review, I have construed each claim term in accordance with its plain and ordinary meaning.

18. It is my understanding that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

19. In determining the scope and content of the prior art, it is my understanding that a reference is considered analogous prior art if it falls within the field of the inventor's endeavor. In addition, a reference is analogous prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering his problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

20. To assess the differences between the prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This “as a whole” assessment requires a showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

21. It is my further understanding that the Supreme Court has recognized several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

IV. THE '123 PATENT

A. Technology Background

22. Heated and not burned tobacco smoking articles as alternatives to traditional combusted tobacco cigarettes have been investigated and developed for more than 50 years. The primary objective has been to provide an inhalable substance that is a tobacco derived material in various embodiments as a non-combusted aerosol or vapor form that closely replicates the historical smoking experience of a burned cigarette.

23. Starting in the 1980s, many smoking articles of various kinds utilizing a range of technologies have been proposed and produced through the years ranging from combusting solid or liquid fuel and transferring this heat to tobacco substances in a cigarette form to applying electronic energy to heat and vaporize the tobacco substances. All of these smoking articles include a consumable “cigarette” like element to closely emulate a combustible cigarette. Typical consumable cigarette technology can range from reduced size traditional cigarettes to which heaters are applied, special cartridges with tobacco materials with integral heaters, to carbon tipped cartridges transferring heat to tobacco materials.

24. Electronic energy supplied via battery into conductive elements with resistive properties are common technologies employed in many of these embodiments since the 1990s. These resistive elements are strategically located

around and/or within the tobacco derived materials which also typically includes aerosol forming materials to create the smoking vapors. By the early 2000s, a person skilled in the art would have been well aware of the above technologies which had been deployed in various products and in a variety of approaches.

B. Summary of the '123 Patent

25. I have reviewed the '123 patent and its claims. In this declaration, I address the patentability of the claims challenged by Petitioner, claims 1-7, 9, 11-19, 21, and 23-26.

26. The two independent claims that Petitioner challenges (claims 1 and 15) are reproduced below.

1. An electrically-powered, aerosol-generating smoking article comprising:

an electrical power source within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

at least one electrical resistance heater powered by said electrical power source;

a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw, the controller comprising a sensor adapted for sensing draw on the smoking article by a user; and

a rod-shaped carrier device engaged with the mouth-end of the tubular outer housing and comprising a cartridge providing a liquid storage compartment containing a mixture comprising a tobacco extract and an aerosol-forming material absorbed within an absorbent fibrous material, the cartridge having a generally tubular shape and adapted for airflow therethrough;

wherein the rod-shaped carrier device is operatively positioned such that, during draw, the mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater and volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

* * *

15. An electrically-powered, aerosol-generating smoking article comprising:

an electrical power source in the form of a battery within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

at least one electrical resistance heater powered by said electrical power source;

a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw, the controller comprising a sensor adapted for sensing draw on the smoking article by a user; and

a rod-shaped carrier device removably engaged with the mouth-end of the tubular outer housing and comprising a cartridge providing a liquid storage compartment containing a mixture comprising a tobacco extract comprising nicotine and an aerosol-forming material selected from glycerin, propylene glycol, or a mixture thereof, the mixture absorbed within an absorbent wicking material, the cartridge having a generally tubular shape and adapted for airflow therethrough;

wherein the rod-shaped carrier device is operatively positioned such that, during draw, the mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater and volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

Ex. 1001 at 32:50-33:8, 33:41-34:2.

27. Claims 2-14 depend from claim 1, directly or indirectly. *Id.* at 33:9-40.

Claims 16-26 depend, directly or indirectly, from claim 15. *Id.* at 34:3-30.

28. The '123 patent generally discloses smoking articles that heat tobacco instead of burning it like in traditional cigarettes. *Id.* at 4:42-52. For example, the '123 patent discloses smoking articles that “produce aerosols that are not necessarily ... a result of burning of tobacco, but rather ... a result of the application of heat upon tobacco or materials that are in contact with tobacco.” *Id.* at 4:47-52. Such products are sometimes referred to as “heat-not-burn” articles.

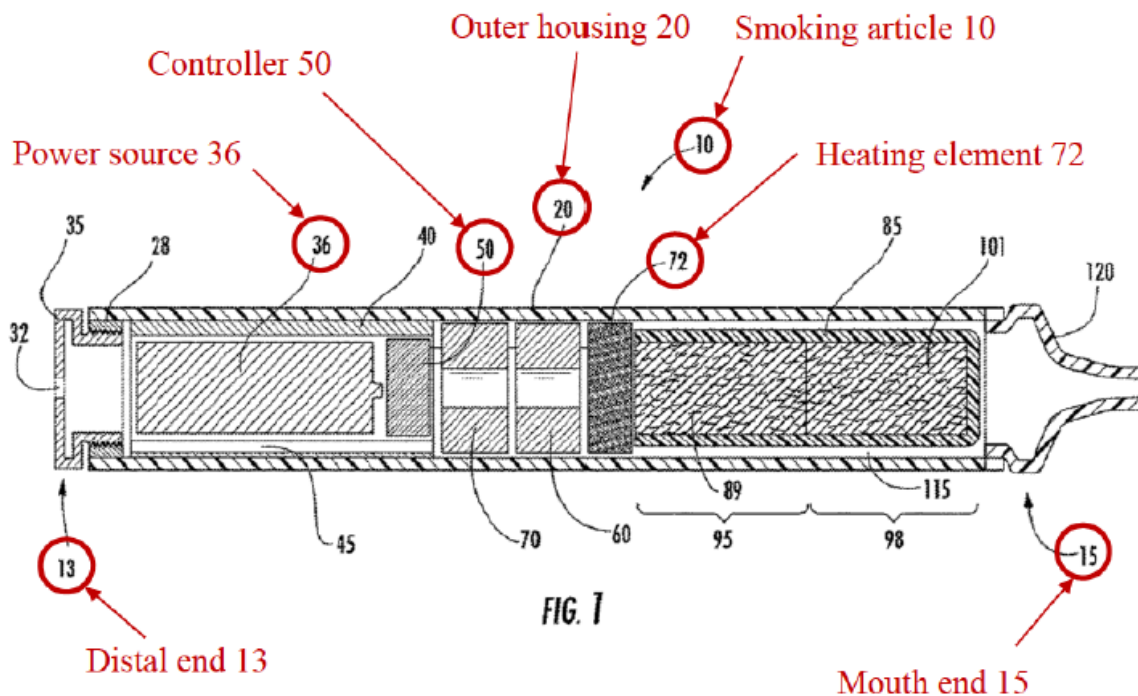
29. In addition to heat-not-burn articles, the '123 patent also describes the use of e-liquid as an aerosol forming material. *Id.* at 13:18-21. For example, the patent discloses aerosol-forming material formulations of mixtures of glycerin and water, or mixtures of propylene glycol and water. *Id.* at 14:13-15.

30. The '123 patent notes that the aerosol-forming material can be maintained within the smoking article in a number of ways. For example, the aerosol-forming material can be contained within a container in liquid form, or soaked within absorbent fibrous materials or sponge-like materials. *Id.* at 14:26-29.

31. The smoking articles disclosed in the '123 patent contain control circuitry that may include a controller for regulating current flow through the device during draw by the user. *Id.* at 30:37-32:34. The controller may be “puff-actuated,”

meaning that the device senses when a user draws (or takes a puff) on the device and then actuates the control circuitry to operate the device. *Id.* at 30:37-32:34, 20:63-67.

32. Figure 1, reproduced below, shows a longitudinal cross-sectional view of one embodiment of the '123 patent invention:



33. The smoking article 10 is “rod-like or tubular in nature, generally akin to a cigarette-type or cigar-type smoking article” and has an outer housing 20 that is likewise “generally tubular in shape.” *Id.* at 19:41-50. The outer housing 20 includes a mouth-end 15 and distal end 13, with “the distal end compris[ing] an opening adapted for intake of air into the smoking article 10.” *Id.* at 19:59-64.

34. An electric power source 36, “such as at least one battery” is located within the outer housing 20. *Id.* at 20:12-13. The smoking article 10 further includes

a controller 50 that is powered by the electric power source 36. (*Id.* at 20:33-43.) The '123 patent describes example circuits that can be included in the controller 50 (*see, e.g., id.* at 20:40-48, 30:37-32:34, describing Figs. 4 & 5) and further states that “[r]epresentative types of electronic control components” for the controller 50 may include those of U.S. Patent No. 4,947,874 to Brooks (*id.* at 20:43-48). Brooks is one of the secondary references Petitioner relies on in the Petition. *See, e.g.,* Petition at 16-17, 25-29.

35. In the embodiment of Figure 1, the smoking article 10 includes a cartridge 85 that contains tobacco 89 of some form and an aerosol-forming material. Ex. 1001 at 22:1-3. “The tobacco 89 and the aerosol-forming material can be in the form of an intimate mixture or provided in separate regions of the cartridge 85.” *Id.* at 22:3-6. The smoking article 10 further includes a resistive heating element 72 that “can be employed in close proximity to an absorbent wicking material such that aerosol-forming material can be wicked or otherwise transferred so as to contact the second resistance element or contact an area in close proximity to the second resistance element (e.g., a region that is exposed to a [sic] the heat produced by the second resistance element).” *Id.* at 21:38-45. “The representative smoking article 10 is assembled such that a certain amount of aerosol-forming material and tobacco components can be wicked or otherwise transferred to heating element 72 or the region in close proximity to the heating element.” *Id.* at 22:20-24.

C. Prosecution History of the '123 Patent

36. I have reviewed the prosecution history of the '123 patent. See Ex. 1002.

37. Claims 1 and 15 of the '123 patent are independent. Independent claim 1 matured from claim 31, which was a new claim added in a Preliminary Amendment filed October 6, 2016 that cancelled all of original claims 1-30 before any examination and added new claims 31-60. *Id.* at 87-94. Independent claim 15 matured from claim 45. *Id.*

38. The Patent Office rejected the claims for nonstatutory double patenting, but the Office indicated that claims 31-60 were allowable over the prior art. *Id.* at 140-147. The Office stated that the closest prior art was U.S. Patent No. 5,692,525 to Counts et al. ("Counts '525"). *Id.* at 142.

39. The Office stated that "Counts does not teach or suggest that the rod-shaped carrier device is operatively positioned such that, during draw, the mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater and volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article." *Id.* at 143-144.

40. Applicant filed a terminal disclaimer (as to several related patents or applications) to overcome the double patenting rejections. *Id.* at 183-184, 187-189. The Office approved the terminal disclaimer. *Id.* at 192.

41. The Office mailed a Notice of Allowance on October 4, 2017. *Id.* at 196. The '123 patent issued on February 27, 2018. *See* Ex. 1001.

V. CLAIM CONSTRUCTION

42. Petitioner did not propose any claim constructions in the Petition and indicated that the challenged claims have their plain meaning. Petition at 10. Based on my review, Petitioner did not explain what the plain meaning of any claim term is in the Petition.

43. It is my opinion that the plain meaning of “wicked into contact,” as used in claims 1 and 15 of the '123 patent (“mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater”), is that the mixture (*i.e.*, the liquid) must be brought into contact with the electrical resistance heater by wicking.

44. This plain meaning is supported by the specification of the '123 patent. For example, the specification states that the resistive heating element 72 “can be employed in close proximity to an absorbent wicking material such that aerosol-forming material can be wicked or otherwise transferred so as to contact the second resistance element or contact an area in close proximity to the second resistance

element (e.g., a region that is exposed to a [sic] the heat produced by the second resistance element).” Ex. 1001 at 21:38-45.

45. A POSA reading the specification of the ’123 patent would understand that, for this embodiment where the heater is located in “proximity” to the wicking material, the liquid (containing the aerosol-forming material) may reach the heater (the second resistance element) in the following ways: (1) the liquid can be “wicked . . . so as to contact” the heater; (2) the liquid can be “otherwise transferred so as to contact” the heater; (3) the liquid can be “wicked . . . so as to contact . . . an area in close proximity to” the heater; or (4) the liquid can be “otherwise transferred so as to contact . . . an area in close proximity to” the heater. Ex. 1001 at 21:38-45.

46. A POSA would understand that the claim language in claims 1 and 15 that explicitly states the liquid mixture “can be wicked into contact” is directed to the first of the four options described above. The claim language “wicked into contact” is not directed to other ways of transferring the liquid mixture, as the ’123 specification explicitly describes ways other than wicking as different options. Ex. 1001 at 21:38-45.

47. There are dependent claims that recite the position of the fibrous or wicking material with respect to the heater. Dependent claim 25 recites that “the absorbent wicking material is positioned in proximity” to the heater, while dependent claims 14 and 24 recite that the fibrous or wicking material is in contact with the

heater. Ex. 1001 at 33:38-40, 34:23-28. These “positional” limitations are separate from the “wicked into contact” language in independent claims 1 and 15. The plain meaning of “wicked into contact” is also consistent with these dependent claims.

VI. LEVEL OF ORDINARY SKILL IN THE ART

48. I understand that Petitioner has proposed that a person of ordinary skill in the art relevant to the ’123 patent would have had a Bachelor’s degree in mechanical engineering, electrical engineering, chemistry, or physics, or a related field, and three to four years of industry experience, or a Master’s degree in mechanical engineering, electrical engineering, chemistry, or physics, or a related field, and one to two years of industry experience.

49. I further understand that for purposes of its Institution Decision (Paper 9), the USPTO’s Patent Trial and Appeal Board (“the Board”) accepted the assessment of the POSA offered by Petitioner. Institution Decision at 7-8.

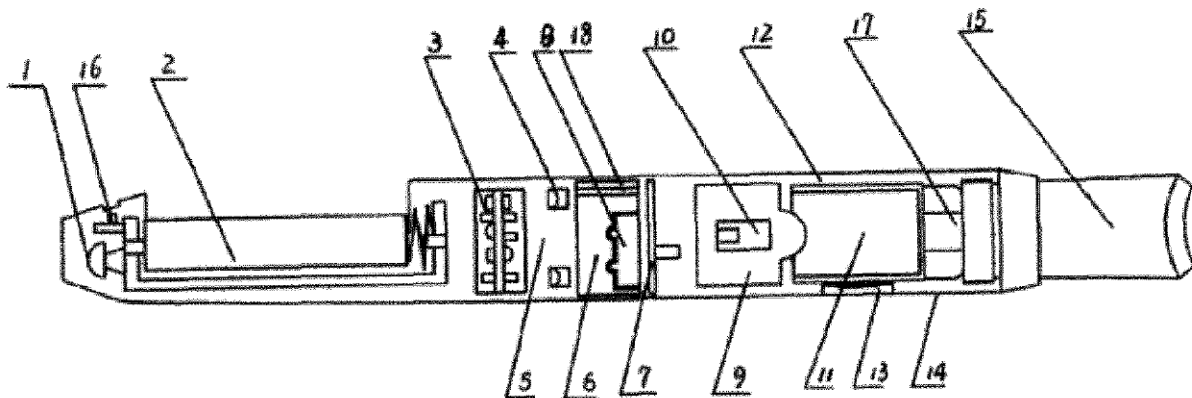
50. I do not dispute Petitioner’s proposed level of ordinary skill in the art.

51. It is my understanding that when interpreting the claims of the ’123 patent, I must do so based on the perspective of the POSA at the time of the alleged invention, which I have been asked to assume is the 2006 time frame based on the patent’s earliest asserted effective filing date of October 18, 2006. I have interpreted the claims of the ’123 patent based on the perspective of the POSA as of that date.

VII. OVERVIEW OF THE CITED REFERENCES

A. Hon (Ex. 1005)

52. Hon describes an electronic atomization cigarette. Ex. 1005 at 4. As shown in Hon's Figure 1 (reproduced below), the electronic cigarette includes air inlet 4, normal pressure cavity 5, sensor 6, vapor-liquid separator 7, atomizer 9 with atomization cavity 10, liquid-supplying bottle 11, and mouthpiece 15 within a shell 16. *Id.* at 6.



53. Hon's Figure 6 (reproduced below) is a structural diagram of the atomizer 9, which includes atomization cavity 10, long stream ejection hole 24, atomization cavity wall 25, heating element 26, porous body 27, bulge 36, and first piezoelectric element 23. *Id.* at 6-7, 11.

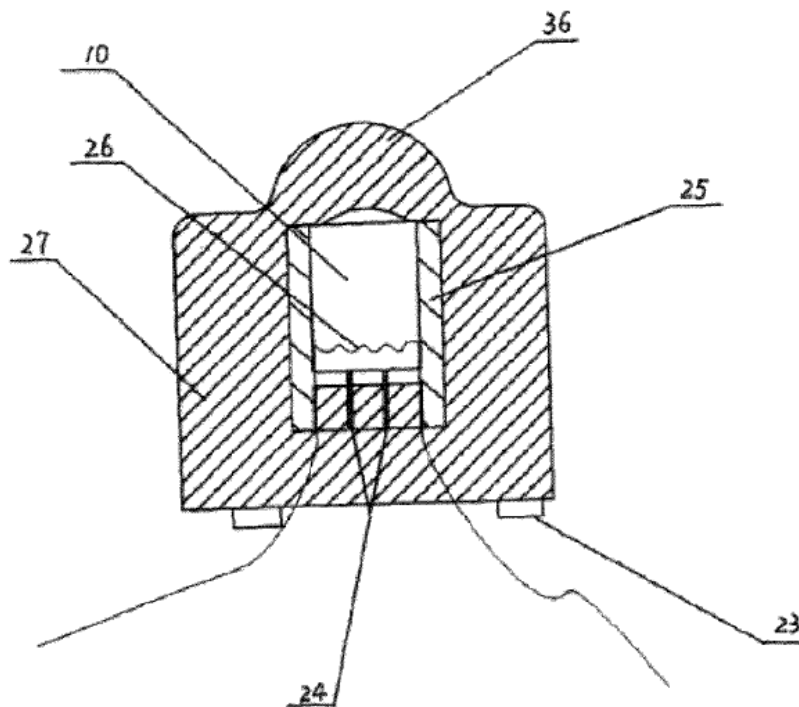


FIG. 6

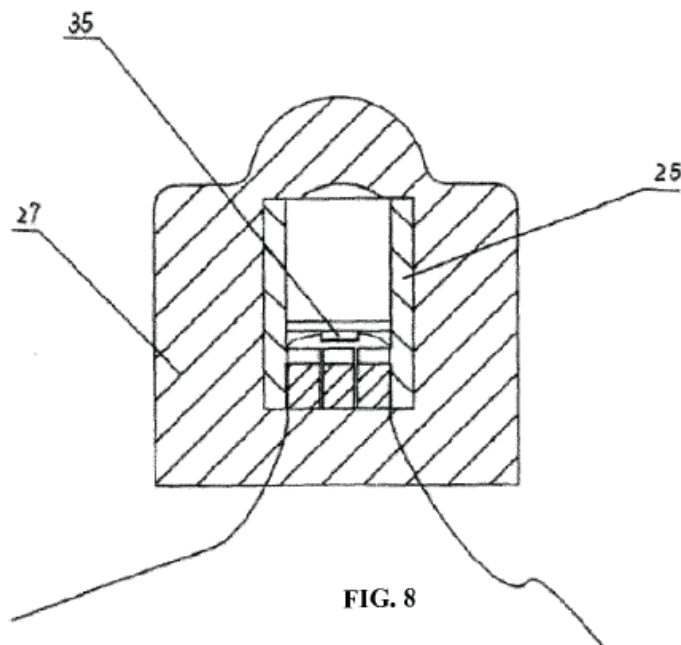
54. The heating element 26 “may be made of platinum wires, nichrome, or iron-chromium-aluminum alloy wires containing rare earth elements.” *Id.* at 6. The atomization cavity wall 25 is surrounded with a porous body 27, which “may be made of foam nickel, stainless steel fiber felt, high molecular polymeric foam, and foam ceramic.” *Id.* “[T]he atomization cavity wall 25 may be made of alumina or ceramic.” *Id.*

55. The bulge 36 of the porous body 27 is in contact with the liquid storing porous body 28 in the liquid-supplying bottle 11 to pull liquid around the outside of the atomizer cavity wall using “capillary infiltration.” *Id.* at 7.

56. When a user draws on (or puffs) the device, a negative pressure is created in the mouthpiece 15 and air flows into the air inlets 4, through air passage 18 of the sensor, through the hole in the vapor liquid separator 7, and then is forced through very small “ejection holes” or slits into the atomization cavity 10 in the atomizer 9. *Id.* “The solution in the porous body 27 is driven by the high-speed airflow of the ejection hole [24] and ejected in the form of droplets into the atomization cavity 10.” *Id.* The nicotine solution is first atomized “ultrasonically by the first piezoelectric element 23” and then “further atomized under the effect of the heating element 26.” *Id.* After atomization, small diameter droplets are suspended in the airstream and form aerosols, which are sucked out via the aerosol passage 12, gas vent 17, and the mouthpiece 15. *Id.*

57. “To simplify the design,” Hon describes another embodiment, where “the first piezoelectric element 23 on the atomizer 9 may be removed, and the atomization of the solution relies only on the heating element 26.” *Id.* The size of the atomizer may then be smaller, and the “connection structure of the entire atomizer electronic cigarette is the same as that of Embodiment 1.” *Id.* Hon also describes another embodiment, shown in Figure 8 (reproduced below), where the first piezoelectric element 23 and the heating element 26 in the atomizer 9 can be omitted, and an additional second piezoelectric element 35 can be arranged in the atomization cavity. In this embodiment, “the airflow via the ejection hole vibrates the focal point

at its center to realize atomization, and the strong ultrasonic atomization effect is achieved.” *Id.*



B. Brooks (Ex. 1006)

58. Brooks “relates to cigarettes and other smoking articles such as cigars, pipes, and the like, which employ an electrical resistance heating element and an electrical power source to produce a tobacco flavored smoke or aerosol.” Ex. 1006 at 1:6-10.

59. The ’123 patent specification expressly discusses Brooks, stating that it discloses “electronic control components” and “sensing mechanism components” for electronic smoking articles. Ex. 1001 at 20:43-63, 21:2-8.

60. Figures 9 and 10 of Brooks illustrate exemplary time-based control circuits and related wiring for preferred controllers. Ex. 1006 at 7:5-7. Each of the

circuits of Figures 9 and 10 includes a power source 34, an electrical resistance heating element 18, a current actuation mechanism 28, and a current regulating circuit for controlling the passage of current through the resistance element during periods of current actuation. *Id.* at 12:39-46, 15:30-35. Figure 9 is reproduced below.

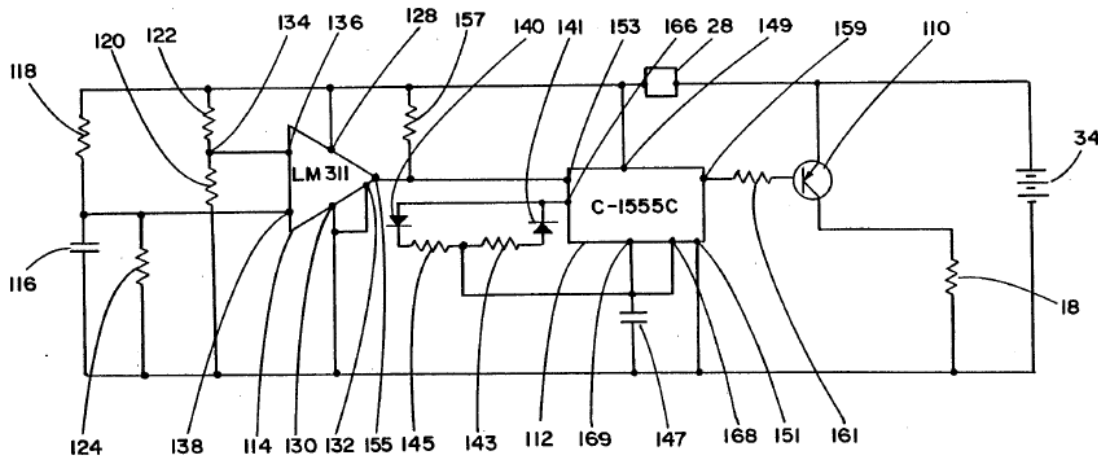
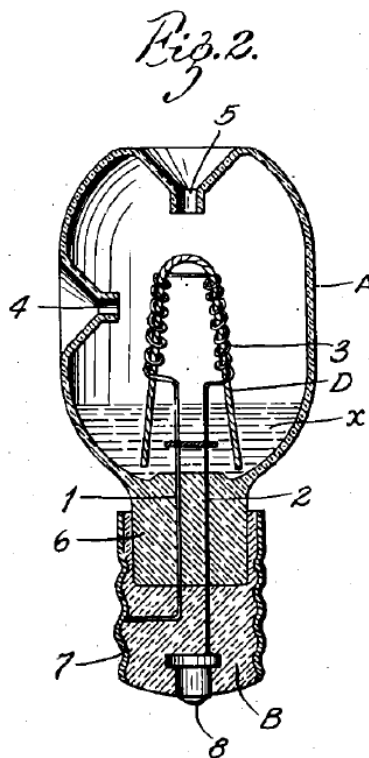


FIG. 9

61. Brooks describes the use of resistance heating elements that are preferably fibrous materials with high surface areas and porous, wettable characteristics to carry an aerosol forming substance. *Id.* at 7:26-33. Brooks more specifically explains that its heating elements are preferably made of carbon. *Id.* at 7:48-60. In its Background and Summary sections, Brooks criticizes the use of nichrome metal resistance heating elements because nichrome metal heating elements are not porous and also lack the desired surface area for use with the Brooks devices. *Id.* at 3:15-40, 4:7-31, 7:30-33.

C. Whittemore (Ex. 1007)

62. Whittemore describes a vaporization unit for a therapeutic apparatus. As shown below in Figure 2, the vaporization vessel A is a hollow glass container that holds liquid medicament x. Ex. 1007 at 1:19-28. The vaporization vessel A includes an electrically-operated heating means with conductors 1 and 2 and a heating element 3. *Id.*



63. The vaporization vessel A includes an air inlet orifice 4 at a point below the upper end of the vessel and a vapor outlet 5 in the top wall of the vessel. *Id.* at 1:28-39. Wick D is a wick material and is “in contact or approximate contact with the heating element” 3, such that the “medicament will be carried by capillary action to a point where it will be vaporized by the heat from the filament 3.” *Id.* at 1:50-2:8. The

wick D forms an inverted v-shaped device that extends “downwardly into the medicament and terminating at or in close proximity to the closed bottom 6 of the vessel A.” *Id.* at 2:10-18. The “unit will operate properly so long as there is sufficient medicament in the vaporization vessel A to engage or contact with a portion of the wick D.” *Id.* at 2:19-25.

D. Susa (Ex. 1008)

64. Susa describes a flavor generation article used for generating flavor as an inhalation target by heating a liquid material with an electric heater. Ex. 1008 at 1:5-10. As the e-liquid material for use with the flavor generation article, Susa describes that the liquid material contains at least a flavor substance. *Id.* at 2:36-37. For example, the liquid material may be “used for enjoying only the flavor, *e.g.*, menthol or caffeine,” and “it can be a material that generates only the flavor.” *Id.* at 6:24-28. “Also, in order to add smoke to the flavor, the liquid material can contain a material which generates aerosol when heated.” *Id.* at 6:28-30. Alcohols, including glycerin, propylene glycol, or their mixture, or other components may be used to generate aerosol. *Id.* at 6:30-34.

E. Ray (Ex. 1009)

65. Ray describes a smoking device for non-burning or non-combustion uses. Ex. 1009 at Abstract. The smoking device includes a container defining a passageway having a vaporizable nicotine, and a means for preventing the evaporation

of the nicotine during periods of non-use. *Id.* “The source of vaporizable nicotine may be an absorbent material which has a nicotine-bearing material absorbed therein. The absorbent may also have absorbed therein a pH adjustment, water, or flavoring ingredients.” *Id.* The device releases nicotine vapors into air drawn through the passageway of the container. *Id.*

VIII. PETITIONER’S ASSERTED GROUNDS DO NOT RENDER CLAIMS 1-7, 9, 11-19, 21, AND 23-26 OBVIOUS

A. Claims 1 and 15: “wicked into contact” limitation

1. Hon does not teach or suggest that “the mixture ... can be wicked into contact with the electrical resistance heater and volatilized.”

66. Mr. Fox states that “Hon alone teaches this claim element when the fibrous/wicking material is ‘positioned in proximity to the at least one electrical resistance heater.’” Ex. 1003 at ¶ 151. I disagree with Mr. Fox.

67. The fact that fibrous/wicking material is positioned in proximity to the heater does not establish that the liquid absorbed by the fibrous/wicking material is wicked into contact with the heater. Regardless of the positioning of the absorbent fibrous material, claims 1 and 15 each still require that the liquid “can be wicked into contact with the electrical resistance heater.” I discussed the “wicked into contact” claim language above in Section V. Hon does not describe that “the mixture ... can be wicked into contact with the electrical resistance heater.” As explained below, high

speed airflow ejects small liquid droplets from the porous body as the air enters the atomization chamber, where the heater is located. Ex. 1005 at 7.

68. Mr. Fox describes only two wicking materials in Hon. Mr. Fox describes the first material as the “liquid storing porous body” inside the liquid supply bottle (Ex. 1003 at ¶ 137) and the second material as the porous body 27 (including bulge 36) of the atomizer. Ex. 1003 at ¶ 151. Neither of these materials wicks the liquid mixture into contact with Hon’s heating element.

69. As relevant to the “wicked into contact” limitation, Mr. Fox describes the operation of Hon as follows:

152. Thus, Hon’s atomizer wicks the liquid from bottle 11 via bulge 36. The liquid mixture wicks (travels via capillary action) from bulge 36 through the porous body 27 that is “wrapped around the atomization cavity wall 25” to ejection holes 24.

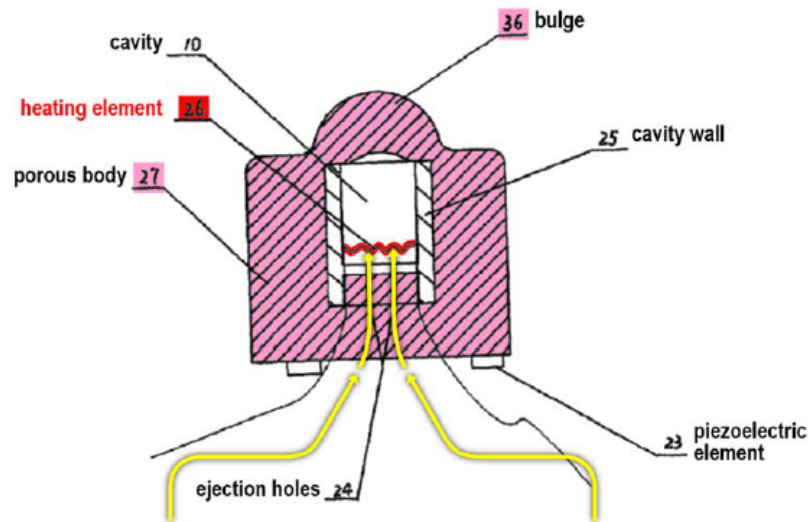


FIG. 6

Hon Fig. 6 (color added), Hon at 6.

153. When the user draws on the device, the liquid “solution in the porous body 27 is driven by the high-speed airflow ... and ejected in the form of droplets into the atomization cavity 10,” where it contacts “heating element 26” and volatilized into an aerosol “which is sucked out via the aerosol passage 12, gas vent 17, and the mouthpiece 15.” Hon at 7.

Ex. 1003 at ¶¶ 152-153.

70. Hon does not affirmatively state that its liquid contacts the heating element 26. Ex. 1005 at 4-7. Both the temperature inside atomization cavity 10 and the negative pressure inside cavity 10 would affect how quickly liquid droplets would vaporize once they enter the cavity, or whether the liquid may contact the heating element 26. Hon does not specifically describe the temperature or the pressure inside atomization cavity 10. *Id.* Mr. Fox does not explain why the liquid would necessarily contact Hon’s heater during operation of Hon’s device or offer any further analysis,

testing, or evidence to support his statement that the liquid “contacts ‘heating element 26.’” Ex. 1003 at ¶¶ 151-153.

71. Even assuming Mr. Fox’s description of the operation of Hon is accurate, it only establishes that the liquid in Hon is **not** wicked into contact with the heater. Rather, the liquid is wicked out of the liquid supply bottle 11 and into the porous body 27, as Hon explains that the transporting of the liquid from supply bottle 11 to bulge 36 is via “capillary infiltration” (i.e., wicking). Ex. 1005 at 7. From there, the liquid is driven into the atomization cavity 10 (which contains heating element 26) via **high-speed airflow**, not wicking. *Id.* In other words, Hon explains that the liquid is ejected from the porous body into the cavity 10 (containing heating element 26) by a different mechanism than wicking.

72. Without the high-speed airflow and additional ultrasonic atomization (via piezoelectric element 23) that Hon describes, the liquid would not move from porous body 27 and into the atomization cavity 10. Mr. Fox does not suggest otherwise in his declaration.

73. As shown below in Mr. Fox’s annotated figure, the heating element 26 is located within a cavity 10, and is not in contact with the porous body 27 at all. As shown, the heating element 26 is located away from the porous body 27, and separated by a cavity wall 25. In this configuration, the liquid is not wicked into contact with

the heater. At best, as Mr. Fox notes, the liquid would contact the heater via the high-speed airflow through the ejection holes 24.

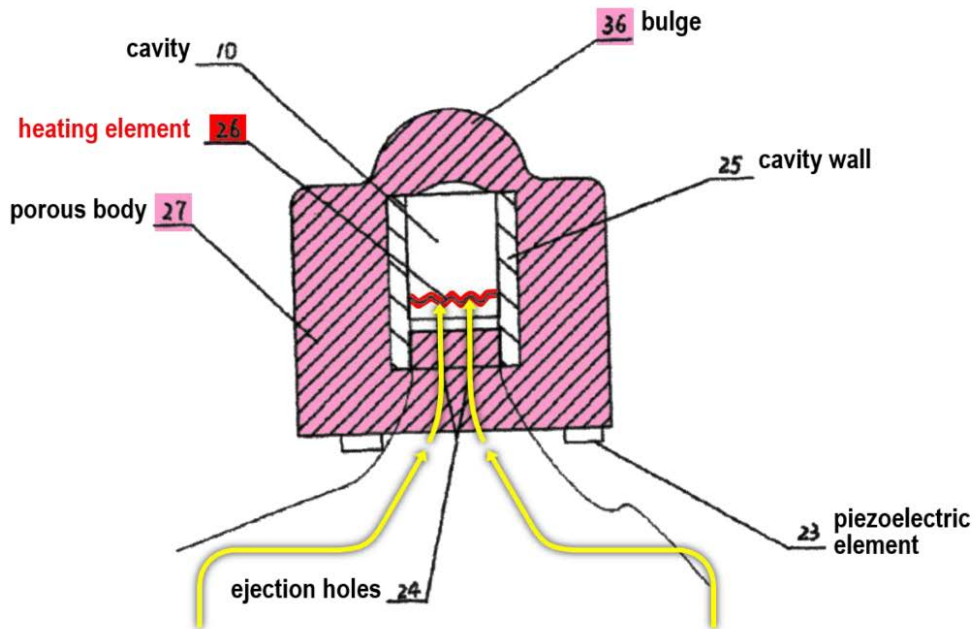


FIG. 6

74. I note further that Mr. Fox appears to concede that Hon does not wick its liquid mixture into contact with the heating element. For example, nowhere in his analysis of this limitation does Mr. Fox affirmatively state that Hon in fact wicks the liquid into contact with the heater. In addition, Mr. Fox's statement that "[a] POSA would have been motivated to modify Hon by replacing its atomizer with a simpler wick/heater design such as in Whittemore (Ex. 1007)," while incorrect, appears to acknowledge that the Hon atomizer does not wick any liquid into contact with the heater. Ex. 1003 at ¶ 156. Mr. Fox further states that "Hon's atomizer relies on the user's draw to carry droplets of the liquid mixture from the ejection holes to the heater

inside of the atomizer cavity.” *Id.* at ¶ 160. In other words, as I explained above, Hon does not describe that its liquid is wicked into contact with the heater; instead, Hon explains that the liquid is ejected into the atomization cavity 10 (where heating element 26 is located) via high-speed airflow through ejection holes. Ex. 1005 at 7.

75. As Mr. Fox states, “a POSA reading the claims would understand that the fibrous/wicking material in claims 1 and 15 may be (i) ‘positioned in proximity to’ the heater, or (ii) it may be ‘in contact with’ the heater.” Ex. 1003 at ¶ 149.

76. As the ’123 patent specification describes, a liquid can be wicked into contact with the heater when the wick and heater are in proximity (Mr. Fox’s option (i) above), but not touching one another. I discussed this above in Section V on claim construction in addressing the “wicked into contact” claim language.

77. A POSA at the time of the invention in October 2006 would have understood that cohesive forces between molecules of a liquid can give rise to strong surface tension of the liquid. A POSA would also have understood that liquids can “bridge” small gaps or distances between the liquid and other surfaces (such as the surface of a heater).

78. An image, taken from www.wonderopolis.org/wonder/what-is-surface-tension (last visited June 28, 2021), demonstrating surface tension is shown below.



As shown here, a pool of water is on a surface of some type, and a person's finger is touching the water. However, the person's finger is not touching the surface on which the water sits. In the example of the '123 patent's wicking material, liquids present in the tobacco/aerosol-forming materials mixture are described as such that a "wicking" mechanism causes contact of the mixture with the heater. In other words, cohesive forces possessed by the aqueous liquids "bridge" the liquid to the heater, where the liquid is vaporized. This vaporization sets up a capillary action (i.e., wicking) which continues to feed more liquid from the '123 patent's wicking material to the heater.

79. When the wicking material and the heater are in proximity to one another as described in the '123 patent, a POSA would understand that cohesive forces and surface tension allow the liquid (on the wicking material) to be wicked into contact with the heater even if the heater and wicking material are separated by a small

distance. The liquid mixture that is present in the wicking material will extend a small distance from the wicking material to the heater, bridging the gap from the wicking material and into contact with the heater. As the liquid is vaporized and drawn away from the heater during draw by the user, the absence of liquid in the wicking material will cause more wicking action within the wicking material, thus wicking more liquid into its place and into contact with the heater.

80. In my opinion, Hon's use of ultrasonic atomization and "high-speed airflow through the ejection hole" to eject Hon's liquid into the atomization cavity where Hon's heating element resides is fundamentally different than wicking the liquid into contact with the heater.

81. For the above reasons, it is my opinion that Hon does not teach or suggest "wherein the rod-shaped carrier device is operatively positioned such that, during draw, the mixture ... can be wicked into contact with the electrical resistance heater and volatilized ...," as recited in claims 1 and 15.

2. A POSA would not have been motivated to modify Hon's device with Whittemore's wick/heater.

82. Mr. Fox alleges, in the alternative, that a POSA would have combined Hon with Whittemore. Ex. 1003 at ¶¶ 156-168. More specifically, Mr. Fox states that "a POSA would have been motivated to modify Hon by replacing its atomizer with a simpler wick/heater design such as in Whittemore (Ex. 1007)." *Id.* at ¶ 156. I disagree with Mr. Fox.

83. Mr. Fox’s primary argument is that a “POSA implementing Hon would have been motivated to replace Hon’s piezoelectric/heater atomizer design with a simpler and cheaper heater/wick design, such as taught by Whittemore, to reduce design costs and effort, reduce manufacturing costs including parts and assembly, and increase the expectation of success.” *Id.* at ¶ 158. In the Institution Decision, the Board found that Mr. Fox’s statement was not supported by evidence. Institution Decision at 27.

84. The Board’s Institution Decision states “neither Petitioner nor Mr. Fox provide objective evidence to support the assertion that Whittemore’s wick and heater is ‘simpler and cheaper’ than Hon’s atomizer, or that using Whittemore’s wick and heater in Hon would have reduced design and manufacturing costs, increased reliability, or increased the expectation of success.” Institution Decision at 27.

85. The Board’s statement is consistent with my review of Mr. Fox’s declaration, and I agree with the Board. Mr. Fox provides no evidence to support that replacing Hon’s atomizer design with Whittemore’s wick/heater design would accomplish any of the things Mr. Fox suggests, or that a POSA would have been motivated to modify Hon to incorporate Whittemore’s wick/heater design from the 1930s.

86. Mr. Fox further argues that moving to Whittemore’s wick/heater design would simplify Hon’s device by allowing for Hon’s piezoelectric element and

associated circuitry to be eliminated (saving cost and complexity). Ex. 1003 at ¶¶ 162-167. Mr. Fox alleges that a POSA would have “eliminate[d] the piezoelectric device and associate [sic] circuitry because it adds significant complexity but is not reliable (or otherwise unhelpful) in production devices.” Ex. 1003 at ¶ 166. Mr. Fox, however, fails to explain why eliminating Hon’s piezoelectric element would cause a POSA to replace Hon’s atomizer with the heater/wick of Whittemore. Mr. Fox also fails to explain why Hon’s piezoelectric element is unreliable.

87. Even if the piezoelectric element was unreliable, Mr. Fox fails to account for the fact that Hon already describes piezoelectric element 23 as being optional. Ex. 1005 at 7. Hon states: “[t]o simplify the design, the first piezoelectric element 23 on the atomizer 9 can be omitted, and the atomization of the solution relies only on the heating element 26.” Ex. 1005 at 7. In this alternative embodiment, Hon states that the atomizer can be made slightly smaller, but otherwise “the connection structure of the entire atomizer electronic cigarette is the same as that of Embodiment 1.” *Id.* Even if a POSA had been motivated to simplify Hon’s device, a POSA would have understood that he/she could have removed the piezoelectric element 23 and continued to use the same or a slightly smaller atomizer.

88. In the Institution Decision, the Board notes that Hon teaches alternative embodiments, including the embodiment where the piezoelectric element is removed for a more simple design. Institution Decision at 26. The Board notes that Petitioner

“does not adequately explain, however, why a POSA would have made further modifications to Hon’s device by replacing Hon’s atomizer with Whittemore’s wick and heater.” *Id.* at 27. I agree with the Board.

89. Whittemore’s wick/heater dates to the 1930s, would have been known by a POSA, and such a design was available to Hon at the time of Hon’s invention. Hon, in designing his device, did not elect to put the wicking material (porous body 27) in contact with the heater (heating element 26). Hon instead chose to separate the porous body and the heater with the walls of the atomization cavity (cavity wall 25). In addition, Hon’s heating mechanism is more efficient than the wick/heater design in Whittemore. Hon’s device and heater are volatilizing copious tiny aerosol droplets at high speed under conditions of negative pressure and high temperature, while Whittemore’s design uses a continuous large volume of room-temperature liquid with a large (relative to Hon) heated and low surface area of cotton string. Hon’s heater will produce more aerosol at a much higher efficiency, while using less power, because of this principle.

90. I note that Mr. Fox’s opinions on his proposed combination of Hon and Whittemore also rely heavily on Mr. Fox’s analysis of a number of devices outside of the Hon and Whittemore references, such devices being referred to as “Ruyan” devices. Ex. 1003 at ¶¶ 159-168. Mr. Fox references a number of Ruyan devices torn down by Reynolds and/or entities related to Petitioner in his declaration. *Id.* I

understand that these Ruyan devices are not part of Grounds 1-3 upon which this IPR was instituted. Institution Decision at 7. It is also my opinion that Mr. Fox has not demonstrated that any of these Ruyan devices are the same as, or even similar to, the Hon device described in Exhibit 1005, or even that the Ruyan devices are prior art to the '123 patent.

91. With respect to the Ruyan device, Mr. Fox, for example, alleges that the Ruyan device “requires a long and slow draw to produce a satisfactory amount of aerosol.” Ex. 103 at ¶ 159. Even if the Ruyan device or the teardowns are considered, Mr. Fox’s allegation is not consistent with the observations in the RJR teardown report itself. For example, the RJR engineers said their “first reaction” of those who tried the Ruyan device was that they were “surprised at how much aerosol is generated during a puff,” and that the “increased aerosol yield from the electronic cigar [was] instantly noticeable.” Ex. 1023 at 15. This contradicts Mr. Fox’s assertion that the Ruyan device required a long and slow draw to produce a satisfactory amount of aerosol.

92. The RJR employees described their testing methodology for analyzing the aerosol yields from the device:

In an attempt to increase aerosol yields from the electronic cigar, we decided to lengthen the duration of the individual puffs from 2 sec to 3 sec duration. This was decided after casual observations that slightly longer puffs by smokers using the electronic cigar and pipe seemed to generate significantly more aerosol.

Ex. 1023 at 11. In this statement, the RJR engineers simply noted the unremarkable observation that a longer draw increases the yield of aerosol, something that would have been well known to a POSA at the time. The RJR engineers never attributed this as a design flaw with the Ruyan device. Nor does Mr. Fox provide any other support that the Ruyan device produced an unsatisfactory amount of aerosol. Mr. Fox also never states that a three second draw would have been deemed unacceptable to users. As stated above, the RJR engineers were “surprised at how much aerosol is generated during a puff,” and found that the aerosol yields “in some cases exceeded yields” from other electronic cigarettes, even under normal draw. Ex. 1023 at 11-12, 15. I disagree with Mr. Fox’s opinion that an alleged unsatisfactory aerosol yield of the Ruyan device would have motivated a POSA to modify the Hon device.

93. With respect to the Ruyan device, Mr. Fox also alleges that a “POSA would have realized that a separate problem with the Ruyan device’s performance may have been with the design of the atomizer itself.” Ex. 1003 at ¶ 160. I disagree. The RJR engineers actually found that “the Ruyan electronic cigar seems to have addressed several shortcomings of some of the earlier attempts at producing a cigarette-like aerosol without combustion.” Ex. 1023 at 14-15. In doing so, the RJR engineers specifically stated that the Ruyan device provided an advancement over previous aerosol generating technology, including Whittemore itself. Ex. 1023 at 14 (“While the idea of generating a cigarette-like aerosol without burning tobacco is not

new (see: Whittenmore [sic], Jr. US 2,057,353; McCormick, US 2,104,266; Brooks, et al., US 4,947,874; Counts, et al., US 5,060,671; Counts, et al., US 5,144,962)) the Ruyan electronic cigar seems to have addressed several shortcomings of some of the earlier attempts at producing a cigarette-like aerosol without combustion.”). Therefore, a POSA would not have been motivated to incorporate the heater/wick design of Whittenmore in the Hon device, where the authors of the teardown report on the Ruyan device expressly found the Ruyan device to be an improvement over Whittenmore.

94. Moreover, even if there were a problem with the design of the Ruyan device, which Mr. Fox has not provided any evidence of, his allegation that “[i]mproving the atomizer shape and/or configuration would require significant effort,” and it would be easier to just swap out the Hon device’s atomizer with the Whittenmore heater/wick (Ex. 1003 at ¶ 160) is entirely unsupported and is pure speculation. In any event, whether it would have been difficult or not to improve the Hon’s atomizer, Mr. Fox has not provided any evidence that it would have been obvious (or any easier) to substitute the Whittenmore design in its place.

95. Mr. Fox also does not describe how a POSA would modify Hon with Whittenmore beyond stating that determining an appropriate wick, heater, and physical arrangement would be “well within a POSA’s skill.” Ex. 1003 at ¶ 161. Because Mr. Fox does not describe how a POSA would modify Hon with the heater/wick of

Whittemore, Mr. Fox cannot say how an unspecified modification would have any predictability of success.

96. For the above reasons, it is my opinion that a POSA would not have been motivated to combine Hon with Whittemore as proposed by Mr. Fox.

B. Claims 1 and 15: “puff-actuated controller ...” limitation

1. Hon does not teach or suggest “a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw”

97. Claims 1 and 15 of the '123 patent each require “a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw, the controller comprising a sensor adapted for sensing draw on the smoking article by the user.”

98. The '123 patent shows that “regulating current flow through the electrical resistance heater during draw” means something more than just turning on the heater. As noted above, claim 1 separately recites a “sensor adapted for sensing draw” in the controller. In reading the claim language and the specification, a POSA would understand that the controller claim limitation requires regulation of current flow during draw.

99. The '123 specification describes details of control circuitry for puff-actuated controllers with reference to Figures 4 and 5. Ex. 1001 at 30:37-32:34, Figs. 4-5. Mr. Fox discusses Figures 4 and 5 and the control circuitry shown in those figures

in his declaration. *See* Ex. 1003 at ¶¶ 54-59. With respect to Figure 4, the '123 patent explains:

That is, during periods of draw, the circuit that provides current through the second resistance heating element is closed, and hence that heating element produces heat. A predetermined quantity of heat can be produced by current controlled by a timer (e.g., a fixed pulse set at about 0.5 second to about 2 seconds in duration). Alternatively, a series of 'on/off' types of pulses can be provided during draw periods. When draw is complete, that circuit is broken. A control mechanism 560, such as a timer, acts to provide for control of the current passing through the circuit, and hence the amount of heat generated by heating element. For example, for longer puff periods, current supplied to the heating element, and hence power for aerosol generation, can be provided by a controlled sequential 'on' and 'off' signal provided by the timer. Typically, the timed period for current flow ranges from about 0.1 second to about 1 second, and about 0.2 second to about 0.6 second generally can be employed; while the 'off' period for between periods of periodic current flow often can range from about 0.1 second to about 0.6 second.

Ex. 1001 at 31:19-39. Here, the '123 patent describes providing a predetermined quantity of heat produced by current controlled by a timer, or providing a series of on/off pulses during draw periods to control the amount of heat. *See also* Ex. 1003 at ¶ 58.

100. With respect to Figure 5, the '123 patent explains:

That is, during periods of draw, the circuit that provides current through the second resistance heating element is closed, and hence that heating element produces heat. When draw is complete, that circuit is broken. In the embodiment shown, the puff control mechanism 590 is provided by a pressure sensor 570 and a threshold detector 580 (e.g., a Schmitt trigger), which can provide for control of the current passing through the second resistance heating element 72, and hence for heat generation by heating element 72 that is proportional to the period and magnitude of the draw. For example, for longer puff periods, current supplied to the

heating element 72, and hence power for aerosol generation, can be provided for longer periods of time. As another example, for deeper or more rigorous puffs, a sensing of stronger draw can be used to provide for greater current flow to the appropriate resistance heating element, and hence provide for a correspondingly greater aerosol generation.

Ex. 1001 at 32: 9-26. Here, the '123 patent describes that the controller can provide for heat generation “that is proportional to the period and magnitude of the draw.” *See also* Ex. 1003 at ¶ 59. A POSA would understand that these examples described in reference to Figures 4 and 5 are control circuitry adapted to regulate current flow during draw.

101. Mr. Fox does not provide any evidence that Hon’s controller regulates current flow during draw. Mr. Fox acknowledges that “Hon’s puff-actuated controller does not attempt to control the heater’s temperature.” Ex. 1003 at ¶ 110. Hon’s disclosure does not include anything like the control circuitry described with reference to Figures 4 and 5 of the '123 patent for controlling current flow to the heater.

102. Mr. Fox’s declaration explains that Hon includes a reed switch that initiates heating upon sensing draw. Ex. 1003 at ¶¶ 102-104; Ex. 1005 at 6-7. Turning the current on is performed by the reed switch and is not current regulation, and turning the current off does not happen “during draw,” because the switch only opens after the draw has been completed. Hon’s circuit arrangement turns on and off both the heater and the oscillator (for ultrasonic atomization by the piezoelectric element)

at the same time based on the reed switch closing and opening. Ex. 1005 at 6-7, Fig.

12. Thus, Hon does not perform any current regulation during the draw period.

103. The final contention Mr. Fox provides with respect to Hon's disclosure and this claim limitation relates to circuit element U2. Ex. 1003 at ¶ 105. Mr. Fox states: "Hon's circuit also regulates current in that it stops current flow if voltage drops below a certain level. Specifically, if battery voltage is too low, circuit element U2 will turn off FET U1 (even if K1 is shut), and thus stop current flow through the heaters." Ex. 1003 at ¶ 105.

104. Hon states that "U2 is the low voltage detection element used for the over-discharge protection of the lithium ion battery." Ex. 1005 at 6. Hon provides no further explanation regarding this low-voltage detecting element. Hon does not state that element U2 will "stop current flow through the heaters" as Mr. Fox contends, and certainly does not say that it will do so during draw. This low-voltage detecting element is a battery protection feature that samples the voltage level, without regard to draw, which a POSA would understand. In fact, the low voltage element would prevent the heater from turning on when the voltage level is too low, even when the user took a draw. I disagree with Mr. Fox that the low-voltage detecting element in Hon's circuit discloses a controller adapted to regulate current flow to the heater during draw.

2. A POSA would not have found it obvious to modify Hon's device with the control circuitry from Brooks

105. Mr. Fox alleges, in the alternative, that it would have been obvious to a POSA to incorporate the “more sophisticated” circuitry disclosed in Brooks into Hon's device. Ex. 1003 at ¶¶ 108-119. I disagree.

106. Mr. Fox first asserts that “a POSA would have been motivated to improve Hon's current regulation to better control the temperature of the heater, such as in a manner taught by Brooks.” Ex. 103 at ¶ 108. I disagree that a POSA would have been motivated to modify Hon to better control the temperature of Hon's heating element. I have reproduced Mr. Fox's annotated version of Hon Figure 6 again below, as well as Hon Figure 1.

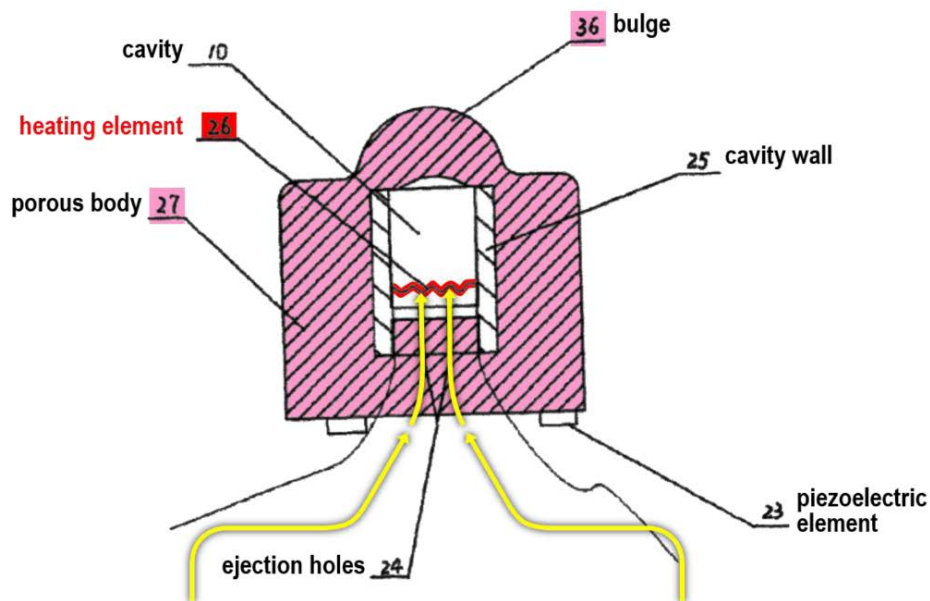
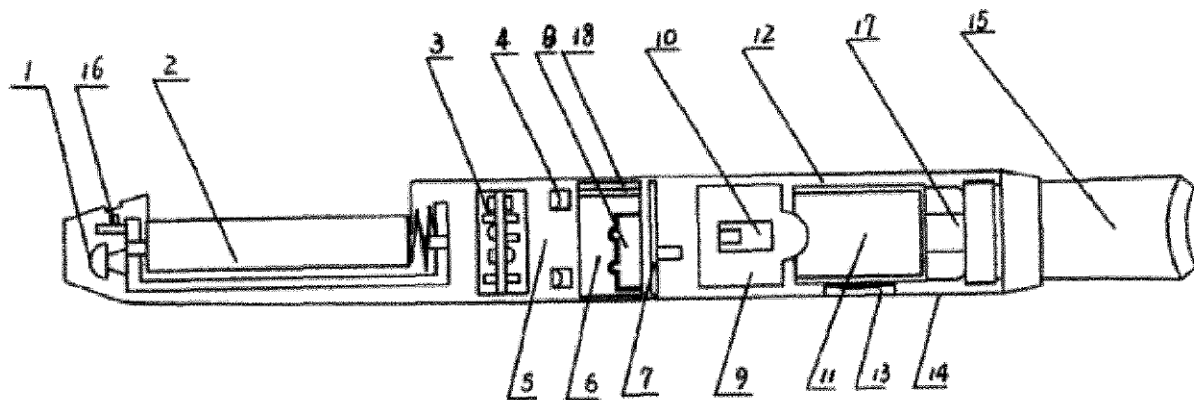


FIG. 6



107. Hon's atomizer is structured with a very small, super-heated atomization cavity 10 inside cavity wall 25, which may be made of a ceramic (an insulator to help concentrate heat). Ex. 1005 at 6. Droplets of liquid solution are ejected into the super-heated cavity, which is under negative pressure, to aerosolize the liquid droplets. Hon explains that heating element 26 is a high temperature metal wire such as platinum or nichrome. Ex. 1005 at 6. These metal wires can withstand extremely high temperatures, well in excess of 1000 °C. *See, e.g.,* Exhibits 2014, 2015.

108. The Brooks circuitry uses duty cycles (which I further explain below) to cycle the Brooks heater on and off. Ex. 1006 at 13:65-14:34, 14:54-67, 17:57-64, 18:44-56. Modifying Hon's device to use the Brooks control circuitry that uses duty cycles would have reduced the power to Hon's heater and required unnecessary additional circuitry and power consumption to implement. Further, Brooks would not have provided any advantage in Hon's device. Hon's heating element can withstand extreme temperatures and is designed to super heat Hon's small atomization cavity, and a POSA would not have been motivated to "improve Hon's current regulation to

better control the temperature of the heater” as Mr. Fox alleges, because Brooks’s temperature control is not needed for Hon’s device given its construction.

109. As discussed above, Hon describes a dual-stage atomizer that uses a piezoelectric element 23 to first provide atomization ultrasonically. Ex. 1005 at 6-7. Hon’s device has a “Colpitts oscillator” that forms a large portion of Hon’s exemplary circuit (shown in Figure 12). Ex. 1005 at 6, Fig. 12. This high-frequency oscillator is “fine-tuned to resonate with the annular first piezoelectric element 23, supplying liquid molecules with energy.” Ex. 1005 at 7. As discussed above, Hon’s device turns on both the heater and the oscillator at the same time – once draw is sensed – and when draw is over, the reed switch opens and current is no longer supplied to the heating element and oscillator. Ex. 1005 at 6-7. The ultrasonic atomization makes the droplets small enough that the heat and negative pressure in the atomization cavity can efficiently atomize further and vaporize the droplets without the need for additional control circuitry. If a POSA just replaced Hon’s controller with the Brooks circuitry, as Mr. Fox appears to suggest a POSA would have done, the Brooks control circuitry would shut off Hon’s oscillator (and the ultrasonic atomization stage) when the current is cycling on and off in accordance with the duty cycles used by Brooks, which would not be desirable. Mr. Fox does not account for the unique nature of Hon’s dual-stage atomizer and why a POSA would have allegedly found it obvious to use Brooks’s control circuitry with the Hon dual-stage atomizer.

110. Mr. Fox also asserts that “a POSA implementing Hon would have been motivated to incorporate more sophisticated current-regulating circuit [sic], such as those in Brooks, that allow the use of a high-powered heater that can rapidly heat up to the optimum temperature (providing the aerosol generation sooner), and then maintain that optimum temperature by reducing the current (or more precisely, average current) for the remainder of the puff.” Ex. 1003 at ¶ 110. I disagree with Mr. Fox.

111. Mr. Fox has not shown that a POSA would have been motivated to use a higher-powered heater in Hon’s device. Mr. Fox again makes reference to the Ruyan device and the alleged lack of sufficient aerosol generation in the Ruyan device as providing the impetus for using a higher-powered heater in Hon. Ex. 1003 at ¶¶ 109,

112. As I discussed above when addressing Mr. Fox’s analysis of Hon and Whittemore, Mr. Fox has not shown that the Ruyan device is prior art, nor has Mr. Fox shown that RJR’s engineers actually found the aerosol generation of the Ruyan device to be insufficient as he alleges.

112. Even assuming more rapid heating would have been desirable, which I do not believe Mr. Fox has shown, the Brooks controller would not heat Hon’s heating element more rapidly. Hon fully activates its high temperature metal wire heating element upon sensing draw by the user, and Hon’s heater stays powered on during the entire draw. Ex. 1005 at 6. Brooks, as noted above, discloses control circuitry that

uses duty cycles that are less than 100% (*e.g.*, 50%). Ex. 1006 at 13:65-14:34, 14:54-67, 17:57-64, 18:44-56. By applying less power, Brooks's controller heats more slowly than Hon's controller that provides 100% current to the metal wire heating element upon sensing draw. If a POSA wanted to heat Hon's heater more rapidly, he/she would use a battery with a higher voltage, not modify Hon's controller to replace it with a different controller (such as the Brooks controller).

113. Mr. Fox also does not describe all of the additional changes that would need to be made, and therefore does not explain how a POSA would have had a reasonable expectation of success by just incorporating the Brooks control circuitry into Hon's device. For example, a POSA would have understood that he/she could not incorporate Brooks's circuitry into Hon without also replacing the heater, and also potentially the battery. Even operating at a 75% duty cycle, the circuit would provide about half as much power to the heater, thus leaving the heater undersized to heat the aerosol.

114. In addition, Brooks describes "using relatively large power sources, capable of generating 10 to 40 watts of power or more" and that an "18 volt battery usually generates sufficient power (*i.e.*, about 18 watts)" for its device that uses carbon heating elements. Ex. 1006 at 4:50-57, 10:18-33. Hon discloses use of a rechargeable lithium ion battery, but does not explicitly describe the voltage of power it generates. Ex 1005 at 6-7. Figures 1-3 of Hon show a battery 2 that appears to be about the size

of a standard AA/AAA batter, which would operate at about 1.5 V. Ex. 1005 at Figs. 1-3. Hon's device also provides a slim, cigarette-sized form factor, as shown in those figures, and the "relatively large" batteries of Brooks would have required significantly increasing the size of Hon's device, which would not have been desirable to a POSA.

115. Mr. Fox, again, relies on the Ruyan device in an attempt to support the proposed combination of Hon and Brooks by arguing that teardown reports show that a "substantially higher-power heater could have been used in the Ruyan" device. Ex. 1003 at ¶ 112. Mr. Fox does not explain, however, why a POSA would necessarily understand that the Ruyan device battery would have been sufficient to support the addition of both Brooks's control circuitry and a "substantially higher-power heater," nor does he explain how or why the Hon battery is the same as, or even similar to, the Ruyan device battery.

116. Mr. Fox's proposed modification to Hon's device results in not just alterations to Hon's control circuitry, but also to the heater and battery as well. In my opinion, this is not a mere simple substitution of circuitry, but rather a redesign of the internal components of Hon. Other than conclusory statements that a POSA would know how to do it, Mr. Fox does not explain with any specificity how this modification would be implemented, or why a POSA would have had a reasonable expectation of success in doing so. As noted above, Mr. Fox focuses on what he

purports is an improvement to control of Hon's heater, but Mr. Fox does not appear to account for several aspects of Hon's design, including the dual-stage nature of the atomizer, the oscillator, and the high temperature metal heating elements.

117. Separately, Mr. Fox notes that the '123 patent identifies Brooks as disclosing a suitable controller for a vaping device. Ex. 1003 at ¶ 115. While this may be true, it does not mean that it would have been obvious to a POSA to incorporate such a controller into Hon, and it does not address the other modifications that would have needed to be made to Hon if such a controller were incorporated. For example, the '123 patent does not describe a dual-stage atomizer with an ultrasonic first stage like Hon's device, or a small, super-heated atomization cavity into which liquid droplets are ejected via high-speed airflow like Hon's device. Mr. Fox does not address these issues, and thus has failed to show how or why a POSA would have had a reasonable expectation of success in making this modification.

118. Brooks describes the use of resistance heating elements that are preferably carbon fibrous materials with high surface areas and porous, wettable characteristics to carry an aerosol forming substance. Ex. 1006 at 7:26-60. Brooks criticizes the use of nichrome metal resistance heating elements because they are not porous and lack Brooks's desired surface area. Ex. 1006 at 3:15-40, 4:7-31. For example, Brooks states that a nichrome metal resistance heater in the prior art is believed to have a surface area of about $0.01 \text{ m}^2\text{g}$, while the surface area of Brooks's

carbon heaters is greater than 1 m²g (and preferably “above about 50 m²g, more preferably above about 250 m²g, and most preferably above about 1000 m²g”). Ex. 1006 at 4:12-22, 7:30-33. Thus, Brooks teaches the use of carbon resistance heating elements that are porous, require more energy to heat, and have surface areas that are at least 100 times greater (and most preferably 100,000 times greater) than a nichrome wire resistance heating element. Mr. Fox offers no reason why a POSA would have been motivated to look to Brooks, which describes a completely different type of heater from Hon and criticizes nichrome metal wire heaters (one of Hon’s preferred options for its heating element), to improve the temperature control or management of Hon’s metal wire heating element.

119. Finally, Mr. Fox appears to rely only on the combination of Hon and Whittemore for disclosure of the “wicked into contact” limitation, as he concedes that the liquid in Hon contacts the heater via airflow, not wicking (as I discussed above). In Mr. Fox’s proposed combination, the Hon device would have to first be modified to include the heater/wick arrangement of Whittemore. Mr. Fox provides no explanation at all regarding how the use of the Brooks circuitry would affect the heater from the Whittemore device, or whether they would even be compatible. For this additional reason, Mr. Fox has failed to show that a POSA would have been motivated to make this combination, or that it could have been made with a reasonable expectation of success.

C. Selected dependent claims would not have been obvious for additional reasons.

1. Claims 11 and 23: “the cartridge is electrically conductive”

120. Claims 11 and 23 of the '123 patent require that the cartridge is “electrically conductive.”

121. Mr. Fox concedes that the Hon cartridge is made of plastic and thus does not disclose this limitation. Mr. Fox’s only contention is that “many different materials would be suitable or at least obvious to try.” Ex. 1003 at ¶ 179. I disagree.

122. Mr. Fox provides no reason for why a POSA would have used any of the materials in Hon in place of the plastic material that it actually used. Mr. Fox does not identify any defects or problems with Hon in this regard. Additionally, in Hon’s device, the heater is in the power unit, not the cartridge, so there would be no reason or motivation for a POSA to make the cartridge electrically conductive – as there might be in a device where the heater element is instead in the cartridge, and not the power unit.

123. And further, even if a POSA did make the cartridge out of a different material such as metal, as Mr. Fox proposes, it still would not be electrically conductive as there would be nothing in the device transferring any electrical current to it. None of the wires in Hon are connected to the cartridge in any way.

124. Mr. Fox also includes citations and contentions relating to Kessler (U.S. Patent No. 6,095,153, Ex. 1030) and its disclosure of fine wire mesh to absorb and

retain liquid. Ex. 1003 at ¶¶ 188-189. But these metal mesh materials have nothing to do with whether the cartridge is electrically conductive, and refer instead to the absorbing of the liquid. These issues would not have motivated a POSA to modify Hon's cartridge (whether using Hon's atomizer or modified with Whittemore's wick/heater) to make it "electrically conductive," and Mr. Fox has not stated any motivations that the POSA would have had apart from his "obvious to try" explanation. Ex. 1003 at ¶ 189.

2. Claims 14 and 24: "wherein the absorbent fibrous material is in contact with the electrical resistance heater"

125. Claims 14 and 24 of the '123 patent require that the absorbent fibrous or wicking material "is in contact with the electrical resistance heater."

126. Mr. Fox concedes that Hon does not disclose that the absorbent fibrous material is in contact with the heater, and instead relies entirely on the combination of Hon and Whittemore for this limitation. Ex. 1003 at ¶ 193. I discussed above in Section VIII.A.2 why it would not have been obvious to combine Whittemore with Hon, and expressly incorporate that discussion here.

DECLARATION

I, Charles E. Clemens, declare that all statements made herein on 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.

Date: 1 July 2021

By: 

Charles E. Clemens

Appendix A

CHARLES E. CLEMENS

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Encinitas, CA 92024

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SUMMARY

Mr. Clemens is a seasoned Engineering professional with over 40 years Product Development experience in the HealthCare and Biomedical industries. He brings extensive design and systems level experience in Drug Delivery, Respiratory Care, Blood Handling, and In Vitro Diagnostic product & technology development, Program/Project Management, Risk Management & Analysis. Mr. Clemens utilizes excellent collaborative skills to achieve the most from people and technology. Importantly, he brings a great appreciation of effective application of Quality System Regulations, ISO13485:2016 / ISO 9001 standards to all his work. Mr. Clemens also has over 20 years Expert Witness experience in the areas of Medical Device Product Liability and Patent Infringement cases.

PROFESSIONAL

Senior Consultant Associate / Program Manager – Fallbrook Engineering Inc. 1995 - 2021

Provides consulting services in the capacity of Senior Program Manager and Senior Mechanical Engineer for a wide variety of medical device product development projects including drug delivery devices, blood handling systems, surgical tools, and in-vitro diagnostic systems. Also provides Expert Services in the areas of product liability and patent related matters.

Senior Consultant / Project Manager – BIT-Group USA, Irvine, CA 2014 - 2017

Provides part-time consulting in the capacity of Project Manager and/or Systems Engineer for various In Vitro Diagnostic product development projects.

Invetech - USA, San Diego, CA (Part of Fortive Company - split off from Danaher) - Sept 2010 to April 2012 full time – Consultant 2012 - 2016

Provides consulting services in the capacity of Program Manager and Senior Mechanical Engineer for various medical device product development projects. Additionally, Mr. Clemens advises Invetech in the development of new Clients and business in the Medical Device markets in North America. Invetech is an international product development company based in Australia specializing in Consumer and Industrial products, Life Science, In-Vitro Diagnostics, and Medical Devices.

CLEMENS CONSULTING COMPANY 1995 – Present

Technical & Management Consultant specializing in Medical Device and In Vitro Diagnostic Product Development as well as Expert Witness services for Medical Device product liability and patent litigation.

Principal Consultant / Project Manager

Provides design and development consulting services both as an independent consultant and in conjunction with various consulting associates:

Products & Areas of Expertise:

IV Drug Delivery Systems
IV Disposable Sets & Components
Insulin Delivery Systems
Drug Injector Pens
Dialysis Systems & Disposables
POC In Vitro Diagnostic Devices
Liquid Drug Inhalers
Pyrolytic Carbon Implants
Thermal Droplet Generation
Blood Pressure Monitoring Systems

Expert Witness – Medical Devices
Pulmonary Breathing Circuits
Digital Thermometry
Prostate Seeding Needles
Liquid Biocompatible Adhesive Delivery
Active “Smart” Implants
Medical Support Appliances
Liquid Drug Humidifiers
Test Fixture Design
Manufacturing Process Development

Some Specific Experiences:

- Program Director for new Blood Separation & Collection System product line
- Co-invented a peristaltic blood pumping and control system for portable dialysis.
- Designed and optimized an insert molded ultrasonic drug aerosol generation device
- Developed several conceptual clinical and disposable Inhaler devices
- Improved design of a wearable hemodialysis system and early development of clinical trial systems
- Developed Award winning and patented fluidics design for cassette based clinical diagnostic system for DNA sample processing – Osmetech plc and now GenMark Dx
- Investigated patented low flow precision technology (Thermal Time of Flight) for application to drug delivery and blood handling systems.
- Conceived and developed a unique drug evaporation system integrated with state-of-the-art Hudson humidifiers and Siemens ventilators
- Directed Engineering design efforts for an Insulin Pump start-up company - Bionica, Inc.
- Optimized a patented venting method for sterilized laryngeal mask products.
- Developed a unique drug compatible Pellathane™ coated heater wire for breathing circuits
- Qualified a unique pressure sensing sub-system by optimizing disposable / sensor interface
- Developed RF welding process for custom pneumatic orthotics
- Numerous product liability and patent litigation assignments – listing provided upon request

CLEMENS CONSULTING COMPANY (con't)

1995 – present

Clients and Associates (not inclusive):

Alaris Medical Systems / Carefusion Corp.
Sparton - Aubrey Group
Invetech USA / AUS
Alliance Pharmaceuticals Corp
BIT-Group USA
Pozzi Wilson Atchison, LLP
Mission Medical Inc. / Terumo
White & Case, LLP

Becton Dickinson / Nanogen Inc JV
Osmetech Clinical Micro Systems
Knobbe Martens Olsen & Bear
Cohesion Inc.
Fallbrook Engineering Inc
Aerogen Inc.
InJet Digital Aerosols
Xcorporeal Inc.

CareFusion Corp., San Diego, CA (Formerly IVAC Corp. / Alaris Medical Systems / Cardinal Health) **1981-1995** – (Now wholly owned subsidiary of Becton Dickinson)

Largest U.S. Medical Drug Delivery Systems and Vital Signs devices manufacturer.

Technical Leader - Development Engineering

(1991-1995)

Worked in a cross-functional team environment with Marketing, Quality, and Manufacturing Team Leaders and facilitated the product concept generation, design feasibility, and business plan generation for the Signature Edition program. This was Alaris's first "Heavy-weight" program team and was run as a company within a company.

- Provided engineering management and supervision to all electrical, mechanical, software, and disposables engineering personnel (30+) for the inception, development, and introduction into production of IVAC's largest product development program in its' history (Signature Edition).

CHARLES E. CLEMENS resume

- Directed the technology investigation, selection and development of the Signature Edition fluid delivery platform system, a \$35M development effort with over \$300M market potential over the following eight years. Participated in upper-management presentations and meetings developing the Signature Edition product positioning, feature selection, and final business plan.
- Traveled to 20+ major cities & 50+ Hospitals in the US and Europe to interface directly to Doctors, Clinicians, Nurses, as well as Regulatory Agencies to gather critical drug delivery knowledge to be used in a Quality Function Deployment effort. This effort resulted in the strategic focus of the entire product development program.
- Initiated & directed a competitive technical benchmarking effort of US & European drug delivery systems which provided the foundation for the marketing strategy as well as the fundamental measuring parameters for the design team.
- Responsible for both the instrumentation and plastic disposable interface, invention, detail design, and development as well as drug / system compatibility and functional conformance. Established Team Leaders in a consensus driven process to achieve business plan goals with respect to budget, timelines, and company goals. Additionally, all the design specifications, performance qualification plans and procedures, and process plans and procedures were achieved through the same process.
- Established the schedule, which all team members utilized for their planning. Helped define a new development and planning process, which was later used as a model for IVAC's SOP's. These SOP's were the basis for successful ISO 9000/9001 design control approval. I was directly involved in the ISO implementation and qualification process.
- Provided technical direction in the review and selection of all out-sourced suppliers and industrial design companies. Helped train the technical team with new skills in the area of Quality Function Deployment (QFD), DFMA, Design of Experiments (DOE), and the Performance Excellence (PE) process. Utilized all new processes in the development of the Signature Edition program.
- Managed all engineering efforts provided by several outside consultants for the program such as IDEO Industrial design / mechanical development and engineering, Battelle Labs for elastomer development, noise and vibration analysis, and Failure Analysis Associates for plastic failure analysis.
- Coordinated a patent review process for the program with Fulwider, Patton, Lee & Utecht, a Los Angeles law firm. Supervised the creation of over 50 disclosures, many of which have been filed with the U.S. Patent Office and granted patent status.

Department Manager – Mechanical Development Engineering (1984-1990)

- Managed all mechanical engineering resources of up to eighteen Engineers with an annual budget of over \$1.5M. Responsibilities included the mechanical development and market introduction of six new Drug Delivery systems and over a dozen new plastic disposable products.
- Provided technical consulting participation on corporate teams in the analysis of technology being considered for purchase by the company such as syringe pumps, fluid flow control devices, rotary peristaltic pumps, and specialized medical grade pressure transducers. In this capacity also provided Expert opinions for Patent and Product Liability issues facing the company.
- Trained in Eli Lilly management program and provided Technical Resources to Lilly instrument and disposable combination products during 1990 – 1995.
- Managed the company machine shop with six Model Makers and Machining Specialists utilizing eight production mills and two CNC mills.

CHARLES E. CLEMENS resume

- Managed the Development Test Lab, which had four Senior Test Technicians and full laboratory equipment used for design verification testing. I managed the main test strategies and procedures for this test lab.
- Directed the effort to select & implement new CAD systems for the mechanical engineering resources, (SDRC-Ideas then Solidworks). I hired resources to train and maintain the system, and integrated outside suppliers who interfaced their CAM systems. Directed efforts to establish an in-house CAD-CAM link between the design group and the PCB layout group and machine shop for rapid prototyping. I implemented extensive use of rapid prototyping on all projects such as computer modeling, solid modeling, stereolithography equipment selection and capital approval, and urethane cast molds.

Department Manager – Instrument Sustaining Engineering (1981-1983)

- Managed mechanical engineering resources of eight Mechanical Engineers with an annual budget of \$500K. Responsibilities included all the mechanical engineering tasks in transitioning several new Instrument products and Disposables products from development to production, while maintaining all existing production needs.
- Position supervised the combined departments of Instrument Mechanical and Disposable Products sustaining engineering. I was responsible for recruiting, training, mentoring, and reviews of all mechanical engineering personnel.
- Responsible for skillful interdepartmental collaboration between Engineering, Quality, Operations, and Marketing to resolve critical design issues impacting production, or field issues demanding immediate attention.

CARBOMEDICS INC., Austin, TX

1979 - 1981

Manufacturer of proprietary Pyrolytic carbon coated bio-implants (e.g. heart valves)

Program Manager - Process Development Engineering

- Re-designed processing methods, then planned and implemented a \$1M project to move an existing Pyrolite® coating facility from San Diego, Ca. to Austin, Texas. I was responsible for the technical process / facility improvements, laboratory construction, and coating process validation in the new building.
- Lead the development of a new mono-leaflet implantable heart valve
- Invented and directed the proprietary design of an accurate rotary dry chemical delivery system to feed zirconium oxide granules to a fluidized bed coating process.

EDUCATION

San Diego State University, San Diego, CA : Bachelor of Science - Mechanical Engineering, 1979

San Diego State University, San Diego, CA : MBA Coursework, 1980 – 1982

Ancillary Coursework and Certifications:

Design of Experiments (DOE)

Performance Excellence (PE)

Quality Function Deployment (QFD)

Design for Manufacturability (DFMA)

Total Quality Management (TQM)

Numerous Quality Management Skills Courses

PATENTS

US / European:

US 10,596,310 Portable Dialysis Machine
US 9,517,296 Portable Dialysis Machine
US 8,597,505 Portable Dialysis Machine
US 8,114,288 System and Method for conducting hemodialysis and hemofiltration
US 7,863,035 Fluidic Devices
US 9,086,371 Fluidic Devices
US 5,563,347 Pressure Sensing Vessel Adapted to be Preloaded Against a Sensor
EP 0 781 402 Pressure Sensing Vessel Adapted to be Preloaded Against a Sensor
US 5,575,632 Engineered Pumping Segment
EP 0 781 379 Engineered Pumping Segment
US 8,771,511 Disposable Apparatus and Kit for Conducting Dialysis
US 9,415,152 Disposable Apparatus and Kit for Conducting Dialysis
US 10,034,973 Disposable Apparatus and Kit for Conduction Dialysis
US 10,092,905 Tissue Sample Container and Methods
US 10,201,331 Biopsy Tissue Sample Transport Device and Method of Using Thereof

Canadian:

CA 2,199,406 Engineered Pumping Segment

Applications – US & International pending:

US20030224371 Integrated Cartridge for Sample Manipulation
US20060040311 Integrated Cartridge for Sample Manipulation
US20040042930 Reaction Chamber with Capillary Lock for Fluid Positioning and Retention