

Patent No. 8,365,742 Petition
For *Inter Partes* Review

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JT INTERNATIONAL S.A.,
Petitioner

v.

Fontem Holdings 1 B.V.,
Patent Owner

Patent No. 8,365,742
Issue Date: February 5, 2013
Title: AEROSOL ELECTRONIC CIGARETTE

Inter Partes Review No. IPR2015-01587

**DECLARATION OF JEFFREY ARTHUR SCHUSTER, Ph.D.,
UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITIONERS PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 8,365,742**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. QUALIFICATIONS	1
III. MATERIALS CONSIDERED	3
IV. STANDARDS and DEFINITIONS	4
V. THE ‘742 PATENT	6
A. Overview of the ‘742 Patent.....	6
1. The Description.....	6
2. The Prosecution History of the ‘742 Patent.....	7
3. The Issued Claims	11
VI. CLAIM CONSTRUCTION	12
A. “Cigarette Bottle Assembly”	12
B. “Cigarette Bottle Assembly is Detachably Located In One End of the Shell”	14
C. “Frame”	16
D. “Run-through Hole”	17
E. “Substantially”	18
F. “Atomizer”	21
G. “Fits With the Atomizer Assembly Inside It”	23
H. “Porous Component”	24
I. “Electronic Cigarette”	25
VII. analysis of prior art	26
A. Takeuchi	26
B. Cox	27
C. Brooks.....	28
D. Whittemore	28
E. Liu.....	29
F. Susa.....	31

TABLE OF CONTENTS
(continued)

	Page
VIII. OPINIONS REGARDING INVALIDITY OF '742 PATENT CLAIMS	32
A. GROUND 1: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF TAKEUCHI.....	33
B. GROUND 2: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF TAKEUCHI IN FURTHER VIEW OF COX.....	39
C. GROUND 3: CLAIMS 1 AND 3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF BROOKS.....	40
D. GROUND 4: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF BROOKS IN FURTHER VIEW OF WHITTEMORE.....	44
E. GROUND 5: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF LIU IN FURTHER VIEW OF SUSA.....	46
F. GROUND 6: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 102 AS BEING ANTICIPATED BY SUSA	50
G. GROUND 7: CLAIM 3 IS UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF SUSA.....	55
H. GROUND 8: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF SUSA IN FURTHER VIEW OF WHITTEMORE.....	56
IX. CONCLUSION.....	59

I, Jeffrey Arthur Schuster, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained on behalf of Petitioner JT International S.A. (“JTI”) for the above-captioned Petition for *Inter Partes* Review (“IPR”) of U.S. Patent No. 8,365,742 (“the ‘742 patent”).

2. I am being compensated for my time in connection with this IPR at my standard consulting rate of \$185.00 per hour. My compensation is not affected by the outcome of this matter.

3. I also submitted a declaration in support of JTI’s Petition for *Inter Partes* Review of U.S. Patent No. 8,375,957 (*Inter Partes* Review No. IPR2015-01513). U.S. Patent No. 8,375,957 is directed to an electronic cigarette.

II. QUALIFICATIONS

4. My curriculum vitae, which is attached to this declaration as Exhibit A, provides an accurate identification of my background and experience.

5. My field of expertise includes research, development and design of pulmonary drug delivery devices.

6. 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 a technical expert in this matter.

7. I graduated from UC Berkeley in 1985 with a B.A. in Physics. I graduated in 1993 from UC Berkeley with a Ph.D. in Physics.

8. My experience has included co-inventing multiple pulmonary drug delivery systems, directing a group of engineers and scientists in developing next generation aerosol drug delivery technology, leading technology transfer of needle free autoinjector technology, managing multiple companies' patent portfolios, leading an inhalation drug delivery technology company, leading drug delivery business development, leading development of multiple aerosol drug delivery platforms, and leading a drug delivery technology selection effort for a major biotechnology company.

9. About fifteen years ago, I helped evaluate an e-cigarette with a heating element and nicotine resin that was being sold in China. In particular, I proposed an e-cigarette design that would be smaller and more compact than the one I evaluated.

10. I have contributed to the development of needle-free jet injectors, an implantable pump, and a flow cytometry system.

11. I started *eficia*, which developed an innovative digital health compliance monitor for drug delivery devices including inhalers and autoinjectors.

12. I am an inventor on 33 US patents, along with numerous foreign equivalents, in the areas of pulmonary drug delivery and needle free injection, and

I have managed multiple patent portfolios in these areas encompassing hundreds of U.S. and foreign patent assets.

13. I am affiliated with The American Association of Pharmaceutical Scientists; The American Association for Aerosol Research; The Controlled Release Society; and The International Society for Aerosols in Medicine.

14. I have authored several peer-reviewed publications and book chapters on aerosol drug delivery.

15. Based on my education and years of experience in the field of pulmonary drug delivery devices, I believe I am qualified to provide opinions about how one of ordinary skill in the art at the time of the patent filing would have interpreted and understood the '805 patent and the prior art discussed below.

III. MATERIALS CONSIDERED

16. In preparing this declaration, I have reviewed, among other things, the following materials: (a) the '742 patent (Ex. 1001) and its prosecution history (Exs. 1009-1015); (b) U.S. Patent No. 6,155,268 to Takeuchi ("Takeuchi", Ex. 1003); (c) U.S. Patent No. 6,234,167 to Cox ("Cox", Ex. 1004); (d) U.S. Patent No. 4,947,874 to Brooks ("Brooks", Ex. 1005); (e) U.S. Patent No. 2,057,353 to Whittemore ("Whittemore" Ex. 1006); (f) EP 0 845 220 to Susa ("Susa", Ex. 1007); (g) PCT Patent Publication No. WO 2007/078273 A1 to Liu ("Liu", Ex. 1008); (h) 14-cv-01645 Joint Claim Construction Chart (Ex. 1016); (i) 14-cv-

01645 Rulings on Claims Construction (Ex. 1017); and (j) JTI's Petition for *Inter Partes* Review of the '742 patent.

IV. STANDARDS AND DEFINITIONS

17. I have been informed and understand that if a prior art reference discloses or contains each and every element of a patent claim arranged in the manner recited in the claims, either expressly or inherently, it anticipates and therefore invalidates the claim under 35 U.S.C. § 102. I understand that claim limitations that are not expressly found in a prior art reference are inherent if the prior art necessarily functions in accordance with, or includes, the claim limitations.

18. I have also been informed and understand that the subject matter of a patent claim is obvious if the differences between the subject matter of the claim and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. I have also been informed that the framework for determining obviousness involves considering the following factors: (i) the scope and content of the prior art; (ii) the differences between the prior art and the claimed subject matter; (iii) the level of ordinary skill in the art; and (iv) any objective evidence of non-obviousness. I understand that the claimed subject matter would have been obvious to one of ordinary skill in the art if, for

example, it results from the combination of known elements according to known methods to yield predictable results, the simple substitution of one known element for another to obtain predictable results, use of a known technique to improve similar devices in the same way or applying a known technique to a known device ready for improvement to yield predictable results. I have also been informed that the analysis of obviousness may include recourse to logic, judgment and common sense available to the person of ordinary skill in the art that does not necessarily require explication in any reference.

19. I have been informed and understand that claims are construed from the perspective of one of ordinary skill in the art at the time of the claimed invention, and that during *inter partes* review, claims are to be given their broadest reasonable construction consistent with the specification.

20. In my opinion, a person of ordinary skill in the art would have a four-year degree in Mechanical Engineering, Electrical Engineering, Physics, or equivalent, as well as at least four years of experience in designing pulmonary drug delivery devices. I apply this as the level of ordinary skill in the art for purposes of my Declaration in support of this IPR.

21. I have been informed that the relevant date for considering the patentability of the claims of the '742 patent is assumed to be May 2007. Based on my education and years of experience in the fields of pulmonary drug delivery

devices, I believe I am qualified to provide opinions about how one of ordinary skill in the art at the time of the patent filing in 2007 would have interpreted and understood the '742 patent and the prior art discussed below.

V. THE '742 PATENT

A. Overview of the '742 Patent

1. The Description

22. The '742 patent is generally directed to an aerosol electronic cigarette such as shown in Figure 1 below.

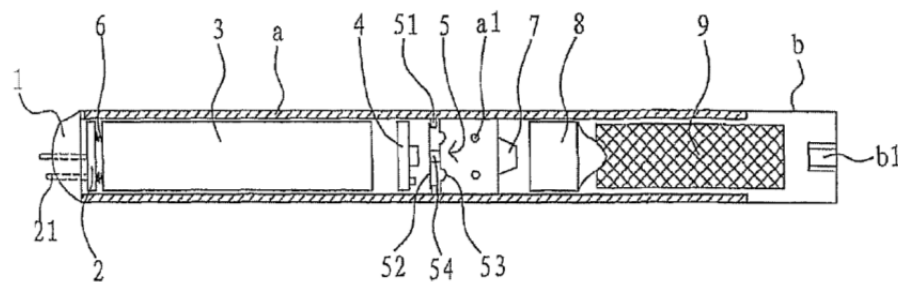


Figure 1

23. Hollow shell (a) contains an atomizer and battery assembly. (*Id.* at 2:30–37.) A cigarette bottle assembly includes a cigarette holder shell (b) containing a perforated component for liquid storage 9. (*Id.* at 3:49–51.) The cigarette bottle assembly fits with the atomizer assembly. (*Id.* at 3:6–21.) The porous component of the atomizer assembly contacts the liquid storage of the cigarette bottle assembly, achieving “capillary impregnation” for the liquid supply. (*Id.* at 4:37–40.)

24. Figures 17 and 18 depicting the atomizer are reproduced below.

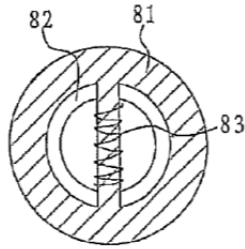


Figure 17

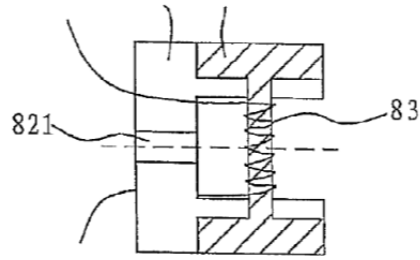


Figure 18

25. In the above embodiments, porous component 81 is set on frame 82. (*Id.* at FIGS. 1, 17–18; 5:42–46.) Heating wire 83 is wound around the portion of the porous component which extends across the central opening of run-through hole 821. (*Id.* at FIGS. 17 and 18; 5:42–49.)

2. The Prosecution History of the ‘742 Patent

a. Preliminary Amendment

26. The application which led to the ‘742 Patent was filed on April 5, 2011 as U.S. Application Serial No. 13/079,937. The application was a divisional application of U.S. Patent Application No. 12/226,818, filed on October 29, 2008 (now U.S. Patent No. 8,156,944), which is the national stage entry of PCT Application No. PCT/CN2007/001575, filed on May 15, 2007, which claimed priority to CN Patent Application No. 2006/20090805, filed on May 16, 2006. (Ex. 1015.) The application was filed with 29 original claims. (*See* Ex. 1009.) In an April 5, 2011 Preliminary Amendment, the Applicant cancelled all 29 original

claims, added one new claim, and amended the specification. (*Id.* at 2–3.)¹ Among other changes, the new claim included the additional limitation of the “cigarette bottle assembly [. . .] fits with the said atomizer assembly inside it” (the original claims simply recited the “cigarette bottle assembly fits with the said atomizer assembly”). (*Id.* at 3.) Neither the original nor the amended specification discuss the atomizer assembly fitting inside the cigarette bottle assembly.

b. First Office Action Rejects Claim 30 as Indefinite

27. On July 19, 2012, the Examiner rejected the sole claim, claim 30. (Ex. 1010.) Specifically, claim 30 was rejected under 35 USC § 112 as being indefinite. (*Id.* at 2.) The Examiner found that it was unclear which “part” and “side” to which the Applicant was referring in the claim recitation of “the said porous component is wound with heating wire in the part that is on the side in the axial direction of the run through hole” (*Id.*) Although the Examiner indicated that Claim 30 would be allowable if the § 112 rejection was overcome, the Examiner explicitly stated that Hon ‘043 was the closest prior art and that only one limitation was lacking.

The Examiner believes that the closest prior art record, namely the CN 2719043 reference, neither teaches nor reasonably

¹ For ease of reference, and to avoid confusion, all citations to office actions or responses are to the numbered page on the original office action or response.

suggests an aerosol electronic cigarette having the claimed combination of structural features, including “*an atomizer, which includes a porous component and a heating body; the said heating body is heating wire . . . the heating wire is wound on the said porous component*”.

(*Id.* at 2–3 (emphasis added).)

c. Applicant Adds “Heating Wire Wound on a Porous Component”

28. In response to the first office action, on August 3, 2012 Applicant made amendments to claim 30 in which “porous component is wound with heating wire in the on the side in the axial direction of the run-through hole” was replaced with “the heating wire is wound on a part of the porous component that is substantially aligned with the run-through hole.” (Ex. 1011 at 2 (claim 30) and 4 (Remarks).) Applicant also added new claims 31-32. (*Id.* at 2–3.) With respect to these new claims, Applicant argued that “[n]ew claim 31 is similar to claim 30 and includes the elements of claim 30, but written with more common English usage.” (*Id.* at 4.) Further, “[n]ew claim 32 is similar to claims 30 and 31 but describes a heating wire wound on a part of the porous component substantially aligned with the run-through hole . . . and with the porous component in contact with a liquid supply in the housing . . .” (*Id.*) Finally, Applicant alleged that “[n]ew claims 31 and 32 are believed to be allowable for the same reason that claim 30 is indicated to be allowable at paragraph 4 of the Office Action.”

29. Four days later, on August 7, 2012 Applicant supplemented its response to the July 19, 2012 Office Action. (Ex. 1012.) In the supplemental response, the Applicant provided a substitute specification with numerous substantive changes from the previous version. (*Id.* at 2.)

d. Examiner Interview

30. Although the prosecution history does not show any additional rejections after the Applicant filed the August 7, 2012 response, Applicant conducted an examiner interview on August 14, 2012. (Ex. 1013.) The Examiner Interview Summary states that during the interview, the Examiner and the Applicant's counsel discussed claims 30, 31 and 32 as well as the following prior art references: "Voges, U.S. Patent No. 6,196,218; Robinson, U.S. Patent No. 1,775,947; Counts, U.S. Patent No. 5,144,962; Brooks, U.S. Patent No. 4,947,875; Japan Tobacco, EP 0 845 220 B1; Hon Lik WO/2004/095855; and Hon Lik WO/2005/099494". According to the Summary, "[n]o agreement was reached." (*Id.*)

e. Notice of Allowance

31. On November 14, 2012, the USPTO issued a notice of allowance. (Ex. 1014.) The '742 Patent issued on February 5, 2013. Claims 30, 31 and 32 issued as claims 1, 2 and 3, respectively. (Ex. 1001.) On July 2, 2013, the USPTO issued a certificate of correction. (Ex. 1015.)

3. The Issued Claims

32. I refer to the elements of the issued claims as follows:

U.S. Patent No. 8,365,742	
1[a]	An aerosol electronic cigarette, comprising:
1[b]	a battery assembly, an atomizer assembly and a cigarette bottle assembly, and a shell that is hollow and integrally formed;
1[c]	the battery assembly electrically connected with the atomizer assembly, and both are located in the shell;
1[d]	the cigarette bottle assembly is detachably located in one end of the shell, and fits with the atomizer assembly inside it;
1[e]	the shell has through-air-inlets;
1[f]	the atomizer assembly is an atomizer, which includes a porous component and a heating body;
1[g]	the heating body is heating wire;
1[h]	the atomizer includes a frame;
1[i]	the porous component is supported by the frame;
1[j]	the heating wire is wound on the porous component;
1[k]	the frame has a run-through hole;
1[l]	a heating wire wound on a part of the porous component that is substantially aligned with the run-through hole; and
1[m]	with the porous component also positioned substantially within the cigarette bottle assembly.
2[a]	An electronic cigarette, comprising:
2[b]	a battery assembly and an atomizer assembly within a housing with the battery assembly electrically connected to the atomizer assembly;
2[c]	a liquid storage component in the housing;
2[d]	with the housing having one or more through-air-inlets;
2[e]	the atomizer assembly including a porous component supported by a frame having a run-through hole;
2[f]	a heating wire wound on a part of the porous component in the path of air flowing through the run-through hole; and
2[g]	the porous component substantially surrounded by the liquid storage component.
3[a]	An electronic cigarette, comprising:
3[b]	a battery assembly and an atomizer assembly within a housing with the

U.S. Patent No. 8,365,742
battery assembly electrically connected to the atomizer assembly;
3[c] with the housing having one or more through-air-inlets and an outlet;
3[d] the atomizer assembly includes a frame having a run-through hole, and a porous component between the frame and the outlet;
3[e] a heating wire wound on a part of the porous component which is substantially aligned with the run-through hole; and
3[f] with the porous component in contact with a liquid supply in the housing.

VI. CLAIM CONSTRUCTION

33. I have been asked to provide my opinion on the following claim terms: “cigarette bottle assembly,” “cigarette bottle assembly is detachably located in one end of the shell,” “frame,” “run-through hole,” “substantially,” “atomizer,” “fits with the atomizer assembly inside it,” “porous component,” and “electronic cigarette” by discussing what one of ordinary skill in the art at the time of the patent filing would regard as the broadest reasonable interpretation consistent with the specification. My opinion agrees with the position set forth in JTI’s Petition for *Inter Partes* Review.

A. “Cigarette Bottle Assembly”

34. I understand that JTI has proposed to construe “cigarette bottle assembly” as “an enclosed unit containing component parts for cigarette material.” I agree with JTI’s proposed construction for the reasons explained below.

35. Claim 1 recites “cigarette bottle assembly” which the ‘742 patent describes as including two parts: a cigarette holder shell (b) and a perforated liquid storage component 9. (Ex. 1001 at 3:49-51; FIGS. 4, 11-12.) A porous component

absorbs cigarette liquid from the liquid storage component 9. (*Id.* at 3:63-67.) The cigarette bottle assembly includes air channel (b1), which serves as the inhalation port. (*Id.* at 5:18-21.) In the Summary of the Invention section, the '742 patent just refers to "bottle assembly." (*Id.* at 1:30.)

36. Figures 3 and 4 illustrate different views of the detached cigarette bottle assembly.

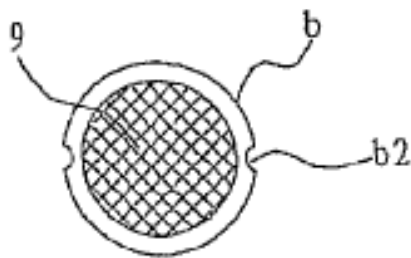


Figure 3

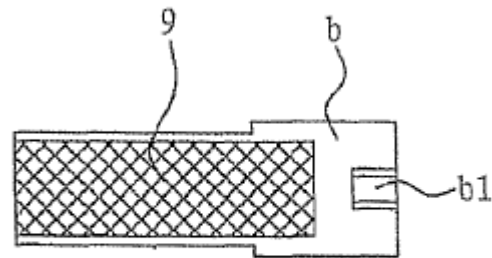


Figure 4

37. Given the above disclosures, JTI's proposed construction of "cigarette bottle assembly" is consistent with the specification.

38. JTI's proposed construction is also consistent with the plain meaning of "assembly."

39. McGraw-Hill Dictionary of Scientific and Technical Terms defines "assembly" as a "unit containing the component parts of a mechanism, machine or similar device." (Ex. 1020 at 139.)

40. Therefore, I agree the broadest reasonable interpretation of “cigarette bottle assembly” consistent with the specification is “an enclosed unit containing component parts for cigarette material.”

B. “Cigarette Bottle Assembly is Detachably Located In One End of the Shell”

41. Claim 1 further states: “the cigarette bottle assembly is detachably located in one end of the shell.”

42. I understand that JTI has proposed to construe “cigarette bottle assembly is detachably located in one end of the shell” as “the cigarette bottle assembly located at a boundary or terminal surface of the shell may be separated and removed from another part of the electronic cigarette.” I agree with JTI’s proposed construction for the reasons explained below.

43. The ‘742 patent describes that the “cigarette bottle assembly is detachably located in one end of the shell.” (*Id.* at Abstract; *see also* 2:35–38.) The relationship of these parts is depicted in Figure 1 below illustrating an assembled electronic cigarette with an exemplary cigarette bottle assembly attached. Figure 2 below illustrates the detachment of the cigarette bottle assembly from shell (a) of the electronic cigarette.

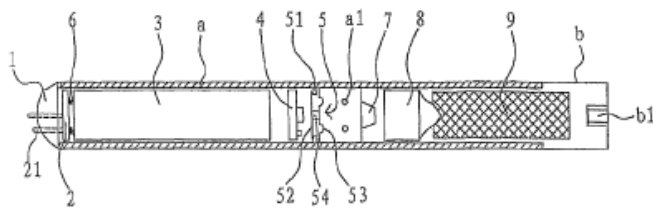


Figure 1

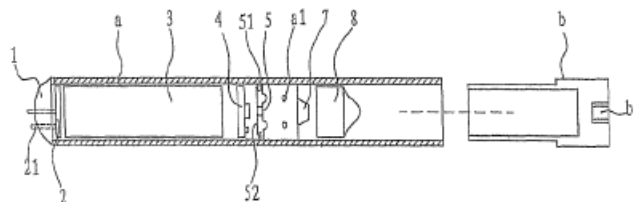


Figure 2

44. Given the above disclosures, JTI's proposed construction of "cigarette bottle assembly is detachably located in one end of the shell" is consistent with the specification.

45. The Webster's New World Collegiate Dictionary defines "detach" as "to unfasten or separate and remove; disconnect; disengage." (Ex. 1018 at 392.) American Heritage Dictionary defines "end" as an "outside or extreme edge or physical limit; a boundary." (Ex. 1022 at 607.) JTI's proposed construction is thus consistent with the plain and ordinary meaning of "cigarette bottle assembly is detachably located in one end of the shell."

46. Therefore, I agree the broadest reasonable interpretation of "cigarette bottle assembly is detachably located in one end of the shell" consistent with the specification is "the cigarette bottle assembly located at a boundary or terminal surface of the shell may be separated and removed from another part of the electronic cigarette."

C. “Frame”

47. All three independent claims of the ‘742 Patent recite a “frame.” (Ex. 1001 at 6:19, 34 and 45.) For example, Claim 1 states: “the atomizer includes a frame” and the “porous component is supported by the frame.” (*Id.* at 6:19–20.)

48. I understand that JTI has proposed to construe “frame” as a rigid structure, or combination of structures, for direct or indirect support. I agree with JTI’s proposed construction for the reasons explained below.

49. The ‘742 patent describes the term “frame” as a structure with a porous component “set on” it. (*Id.* at 5:42–46.) The relationship of these parts is illustrated in Figures 17 and 18 below, which depicts an exemplary frame 82 providing support for the porous component 81, as well as the heating wire 83. (*Id.* at 5:42–49.)

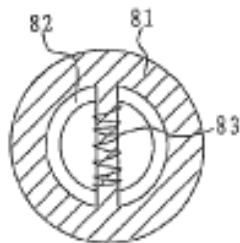


FIG. 17

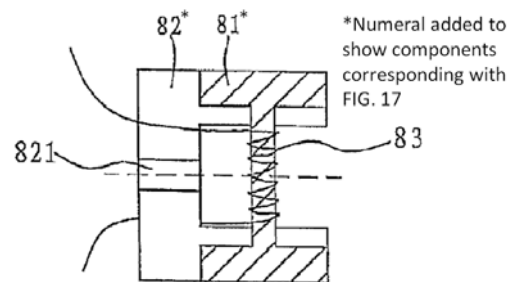


Figure 18

FIG. 18

50. Given the above disclosures, JTI’s proposed construction of “frame” is consistent with the specification.

51. The OXFORD AMERICAN DICTIONARY & THESAURUS defines “frame” as “the basic rigid supporting structure of anything.” (Ex. 1019 at 581.) JTI’s proposed construction is thus consistent with the plain and ordinary meaning of “frame.”

52. I understand the term “frame” was the subject of claim construction proceedings in *Fontem Ventures B.V. and Fontem Holdings I B.V. v. VMR Products, LLC*, Case No.: 2:14-cv-01655 (and related cases consolidated with Case No. 2:14-cv-01645). (Ex. 1017, Court’s Rulings on Claims Construction.) In those proceedings, the Patent Owner took the position that “frame” means “a support.” (*Id.* at 5.) Disagreeing with that construction, the court held that “frame” means a “rigid structure.” (*Id.* at 7.)

53. Therefore, I agree the broadest reasonable interpretation of “frame” consistent with the specification is “a rigid structure, or combination of structures, for direct or indirect support.”

D. “Run-through Hole”

54. All three independent claims of the ‘742 Patent recite a “run-through hole.” (Ex. 1001 at 6:22, 34 and 45–46.) For example, Claim 1 states: “the frame has a run-through hole.”

55. I understand that JTI has proposed to construe “run-through hole” as “a passageway.” I agree with JTI’s proposed construction for the reasons explained below.

56. The ‘742 patent describes the “run-through hole” as a passageway that connects with the atomizing chamber (*Id.* at 3:19–21.) For example, the run-through hole may be a passageway 821 positioned on the air inflow side of the atomizer (*id.* at 5:45–47, FIG. 18), or passageway 813 at the aerosol outflow side of the atomizer. (*Id.* at 4:25–30, FIG. 5.)

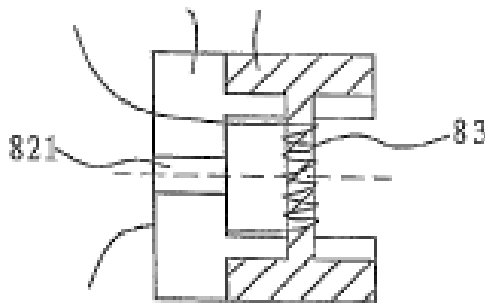


FIG. 18

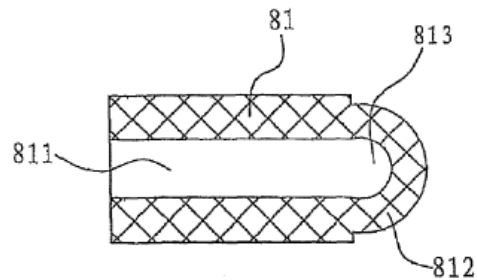


Figure 5

FIG. 5

57. Given the above disclosures, JTI’s proposed construction of “run-through hole” is consistent with the specification.

58. Therefore, I agree the broadest reasonable interpretation of “run-through hole” consistent with the specification is “a passageway.”

E. “Substantially”

59. All three independent claims of the ‘742 patent recite the term “substantially.” (Ex. 1001 at 6:24, 37 and 49.) Specifically, claims 1 and 3 require

a porous component that is “substantially aligned with the run-through hole,” and claim 2 requires a porous component that is “substantially surrounded by the liquid storage component.” (*Id.*)

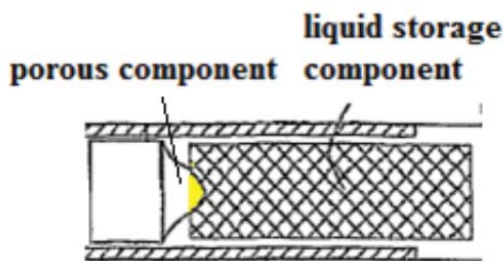
60. I understand that JTI has proposed to construe “substantially” as “largely, whether less or more than a majority.” I agree with JTI’s proposed construction for the reasons explained below.

61. The ‘742 specification does not refer to “substantially.” The ‘742 patent file history shows that the term “substantially” was added to the claims by Applicant during prosecution in an August 3, 2012 Amendment. (Ex. 1011.) In particular, claim 1 was amended to require a porous component that is “substantially aligned with the run-through hole”; claim 2 was added to require a porous component that is “substantially surrounded by the liquid storage component”; and claim 3 was added to require a porous component that is “substantially aligned with the run-through hole.” (*Id.*)

62. According to the district court’s claim construction ruling, “substantially” means “largely but not completely.” (Ex. 1017 at pp. 26.)

63. As to the interpretation of “largely,” the majority of the porous component need not be aligned with the run-through hole (claims 1 and 3) or surrounded by the liquid storage component (claim 2).

64. The specification never discloses an embodiment in which a majority of the porous component is “substantially surrounded” by the cigarette bottle assembly. Rather, the majority of the porous component is not surrounded by the liquid storage component in the embodiments disclosed in the ‘742 patent (yellow). (Ex. 1001 at FIG. 1.)



65. Given the above disclosures, JTI’s proposed construction of “substantially” is consistent with the specification.

66. I understand the term “substantial” to generally mean sufficiently large or considerable in size or magnitude. Similarly, American Heritage Dictionary defines “substantial” as “[c]onsiderable in importance, value, degree, amount, or extent[.]”. (Ex. 1022 at 1791.)

67. JTI’s proposed construction is thus consistent with the plain and ordinary meaning of “substantially.”

68. According to the district court’s claim construction ruling, “substantially” means “largely but not completely.” (Ex. 1017 at p. 26.) I understand the district court was not required to give the term its broadest

reasonable interpretation. Under the court's definition, the majority of the porous component need not be aligned with the run-through hole (claims 1 and 3) or surrounded by the liquid storage component (claim 2). Indeed, in the figures of the '742 Patent, the majority of the porous component is not surrounded by the liquid storage component. (*See, e.g.*, Ex. 1001 at FIG. 1.)

69. Because the term "substantially" must be given its broadest reasonable interpretation, "completely" should not be excluded in this context in my opinion. Exact alignment of the porous component with the run-through hole and completely surrounding the liquid storage component are consistent with the specification of the '742 patent. By way of example, the part of the porous component 81 that the heating wire 83 is wound on appears in the drawings to be in exact alignment (*i.e.* no off-set) with the run-through hole, even though the claims recite "substantial" alignment. (*See, e.g.*, Ex. 1001 at FIGS. 17, 18.).

70. Therefore, I agree the broadest reasonable interpretation of "substantially" consistent with the specification is "largely, whether less or more than a majority."

F. "Atomizer"

71. Claim 1 states: "atomizer," and claims 2 and 3 recite an "atomizer assembly."

72. I understand that JTI has proposed to construe “atomizer” as “a device that converts a substance into an aerosol or vapor.” I agree with JTI’s proposed construction for the reasons explained below.

73. The specification discloses that an “atomizer assembly is an atomizer (8), which includes a porous component (81) and a heating rod (82).” (*Id.* at 3:6–8.)

74. The ‘742 patent does not use a traditional definition of “atomizer,” which is a “device that forces a liquid out of a very small hole so that it becomes a fine spray.” (Ex. 1023 (<http://www.merriam-webster.com/dictionary/atomizer>).) This traditional definition of “atomizer” has not changed from when the ‘742 patent was filed to now.

75. In contrast, the ‘742 patent uses the term “atomizer” to mean an aerosol generator wherein a liquid is heated and thereby vaporized whereupon it condenses to form an aerosol, i.e., a condensation aerosol generator. (Ex. 1001 at 4:23–32.) In the art, condensation aerosol generators are not generally considered to be atomizers.

76. Given the above disclosures, JTI’s proposed construction of “atomizer” is consistent with the specification.

77. The American Heritage Dictionary defines “atomize” as “2. [T]o reduce to tiny particles or a fine spray.” (Ex. 1022 at 117.) As a spray is

comprised of liquid particles, it can be understood that “tiny particles” is referring to solid (*i.e.* non-liquid) particles.

78. Merriam-Webster Dictionary defines “aerosol” as “a suspension of fine solid or liquid particles in gas.” (Ex. 1023 (<http://www.merriam-webster.com/dictionary/aerosol>).) The meaning of “aerosol” has not changed from the time of the ‘742 patent to now.

79. JTI’s proposed construction is consistent with this aspect of an atomizer.

80. Therefore, I agree the broadest reasonable interpretation of “atomizer” consistent with the specification is a device that converts a substance into an aerosol or vapor.

G. “Fits With the Atomizer Assembly Inside It”

81. Claim 1 states: “the cigarette bottle assembly is detachably located in one end of the shell, and fits with the atomizer assembly inside it.” (Ex. 1001 at 6:12–14.)

82. I understand that JTI has proposed to construe “fits with the atomizer assembly inside it” as “contacts the atomizer assembly.” I agree with JTI’s proposed construction for the reasons explained below.

83. The ‘742 patent describes that the atomizer assembly “fits with” the cigarette bottle assembly. (*Id.* at 1:30–33 and 2:36–38.) The atomizer includes a

protuberance 812 that “fit[s] with” (i.e. contacts) a cigarette bottle assembly. (*Id.* at 3:15–23.) The phrase “inside it” or even the word “inside” is not used in the specification.

84. Given the above disclosures, JTI’s proposed construction of “fits with the atomizer assembly inside it” is consistent with the specification.

85. Therefore, I agree the broadest reasonable interpretation of “fits with the atomizer assembly inside it” consistent with the specification is “contacts the atomizer assembly.”

H. “Porous Component”

86. All three independent claims of the ‘742 patent recite a “porous component.” (*Id.* at 6:17, 33 and 46.) For example, Claim 1 states: “the atomizer assembly is an atomizer, which includes a porous component and a heating body.”

87. I understand that JTI has proposed to construe “porous component” as “part which liquid or gas can pass through or be absorbed by.” I agree with JTI’s proposed construction for the reasons explained below.

88. The ‘742 patent describes the porous component as constructed of foamed ceramics, foamed metal, polymer foam, or fiber felt for example, “providing the remarkable capabilities in liquid absorption and diffusion, and the ability to absorb the liquid stored in the cigarette bottle assembly.” (*Id.* at 3:23–27.)

89. Given the above disclosures, JTI's proposed construction of "porous component" is consistent with the specification.

90. The McGraw-Hill Dictionary of Scientific and Technical Terms defines "porous" as "[c]apable of absorbing liquids" (Ex. 1020 at 1549) and "component" as a "constituent part of a system." (Ex. 1020 at 424.) Merriam-Webster online defines "porous" as "having small holes to allow air or liquid to pass through." (Ex. 1023 (<http://www.merriam-webster.com/dictionary/porous>).) JTI's proposed construction is thus consistent with the plain and ordinary meaning of "porous."

91. Therefore, I agree the broadest reasonable interpretation of "porous component" consistent with the specification is a "part which liquid or gas can pass through or be absorbed by."

I. "Electronic Cigarette"

92. The preamble of claims 2-3 recite the term "electronic cigarette," and the preamble of claim 1 recites "aerosol electronic cigarette."

93. I understand that JTI has proposed to construe "electronic cigarette" as an "electronically controlled device for inhalation by a user of vaporized or aerosolized material, which device can be used as a substitute for cigarette smoking."

94. The '742 patent does not use either preamble term in a manner inconsistent with their plain meaning. Consistent with plain meaning, the specification refers to “[a] component for liquid storage of the cigarette bottle assembly (which) stores the nicotine liquid. Smokers can enjoy the feel of smoking” (Ex. 1001 at 1:38–40), and refers to the atomizer as forming and delivering an “aerosol” (*Id.* at 4:25–33.) (Ex. 1001 at 4:25–32.) Similarly, prior art electronic cigarette patents refer to vaporized or aerosolized material. (*See, e.g.*, Ex. 1007, 10:48–49 (“aerosol generation material”);)

95. Therefore, I agree the broadest reasonable interpretation of “electronic cigarette” consistent with the specification is an “electronically controlled device for inhalation by a user of vaporized or aerosolized material, which device can be used as a substitute for cigarette smoking.”

VII. ANALYSIS OF PRIOR ART

A. Takeuchi

96. Takeuchi, entitled “Flavor-Generating Device,” describes a “simulated smoking” device for generating flavored aerosol to be inhaled by a user. (Ex. 1003 at 1:4–9.) The device includes a casing 12 partitioned by a partition wall 13 into an upper chamber 121, with a heater 42, and a lower chamber 122 with a detachable battery 44 and a liquid container 32. (*Id.* at 4:26–38; 6:15–29; 8:59–9:7; FIGS. 1, 8.)

97. The casing 12 includes an air intake port 18 and an air inlet port 26. (*Id.* at 5:4-7; 9:8-9.) The upper chamber 121 includes a squeeze plate 24 having a squeeze hole 24a to direct air from the air intake port 18 toward the outlet of a capillary tube 36. (*Id.* at 4:61-67; 8:5-10.)

98. The battery 44 powers the heater 42 for gasifying the liquid flavor source 34. (*Id.* at 6:4-22.) The heater 42 is mounted on capillary tube 36 (*Id.* at 6:8-9.) or heater 425 can be provided on the end of intercommunicating pore structure 302. (*Id.* at 10:61-63.) The device may be used as a “simulated smoking article” and liquid flavor source 34 may contain “tobacco components such as tobacco extracts and a tobacco smoke condensate. (*Id.* 5:40-52.) The liquid flavor source is delivered to the heater by capillary force, where it is evaporated (*id.* at Abstract.) and can form an aerosol. (*Id.* 5:33-35.)

B. Cox

99. Cox, entitled “Aerosol Generator and Methods of Making and Using an Aerosol Generator,” describes an aerosol generator. Cox was not cited during prosecution of the ‘742 patent. The aerosol generator is formed of a first component, including a material to be turned into an aerosol, removably attached to a second component including a battery. The two components can be attached end to end or side by side. (Ex. 1004 at 3:46-60.) The material is introduced from a material source 37 into a tube 27 disposed in a mouthpiece section 49 when a

valve 35 is opened. (*Id.* at 4:39–45.) Within the tube 27 the material is heated by heater 33 supplied with electrical energy by the battery until the material is volatilized and subsequently condenses to form an aerosol. (*Id.*) The material source 37 includes a flexible container 45. (*Id.* at 4:62–65.)

C. Brooks

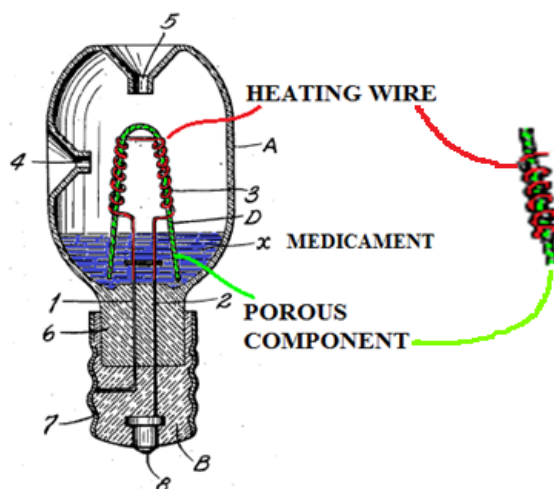
100. Brooks, entitled “Smoking Articles Utilizing Electrical Energy,” is directed to an electronic smoking article in the form of a cigarette, cigar or pipe to provide a tobacco-flavored aerosol without burning tobacco. (Ex. 1005 at 3:63–4:2; 12:3–4.) The smoking article includes a battery 34, a resistance heating element 18, and a disposable smoking cartridge 94. (*Id.* at 7:15-25; 12:3-15.) The battery 34 provides electrical energy to the heating element 18. (*Id.* at 5:68–6:4.)

101. When a user draws on the suction end of the smoking article, the heating element 18 is heated to volatilize the aerosol-forming substance, producing an aerosol passed into the mouth of the user. (*Id.* at 5:42–50.) The heating element 18 is porous for carrying the aerosol-forming substance. (*Id.* at 7:26–30.) A plug 16 includes an air flow passageway 46 to the heating element 18. (*Id.* at 8:33–42.)

D. Whittemore

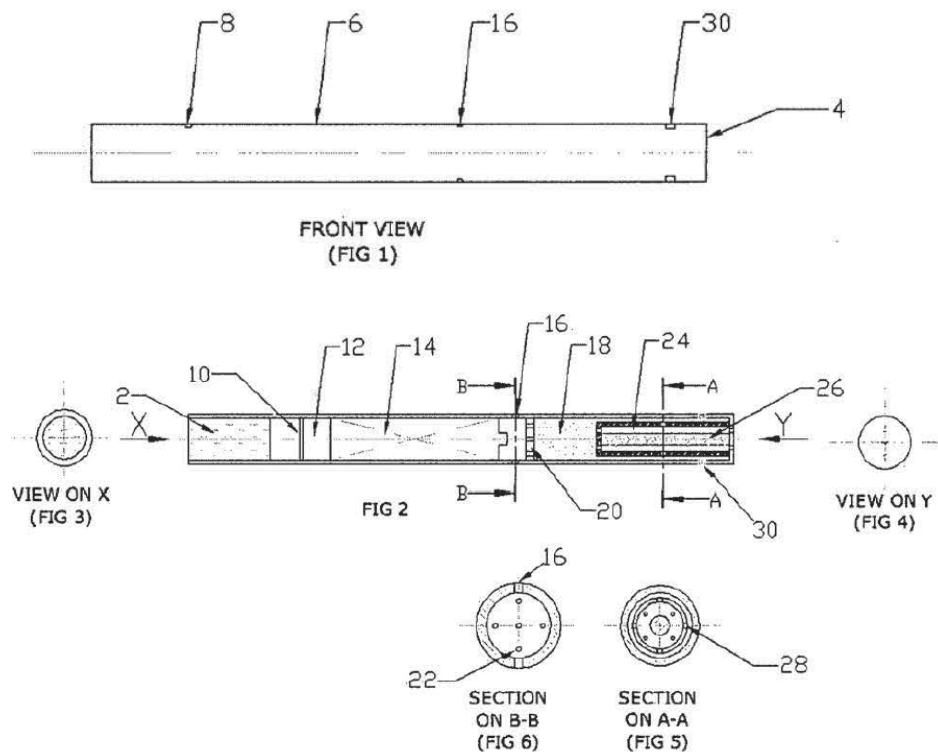
102. Whittemore, entitled “Vaporizing Unit for Therapeutic Apparatus,” discloses a vaporizing vessel holding a wick (D) surrounded by a coiled heating

element (3) and extending into a medicament (x). (Ex. 1006 at 1:50–2:8; 2:38–46 (claim 1); FIG. 2.) The wick resides in the medicament, and the heating element is wound around the wick. (*Id.* at 2:18; FIG. 2.) The “heating element or filament 3” is used such that “a portion of said wick is always in contact or approximate contact with the heating element or filament 3” whereby 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 FIG. 2; 1:50–2:8.)



E. Liu

103. Liu, entitled “No Tar Electronic Smoking Utensils,” is directed to a simulated cigarette having a container formed of porous material for storing a liquid mixture. (Ex. 1008 at Title, Abstract.) Figure 1 below is an enlarged side view of the Liu simulated cigarette, and Figure 2 below is a cross-sectional view of the simulated cigarette. (*Id.* at 4:15–19.)



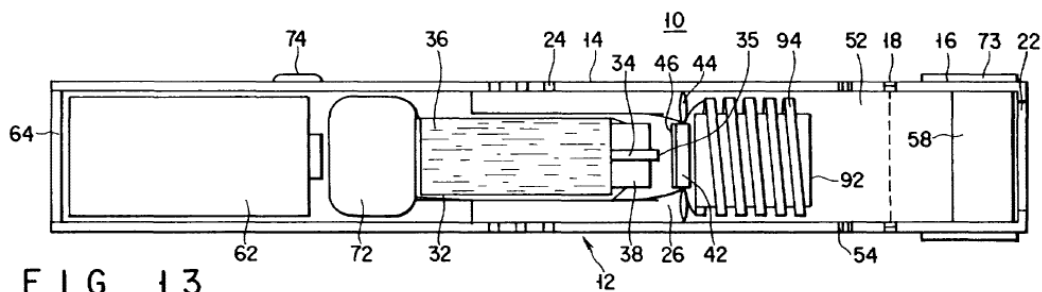
104. Within outer casing 6 is a cylindrical battery chamber 12 that houses battery 14. (*Id.* at 5:30–32.) Outer casing 6 is provided with a plurality of apertures 16 adjacent to battery chamber 12 to permit air entry into the battery chamber. (*Id.* at 5:32–6:2.) Liquid container 18 is separated from battery chamber 12 by dividing wall 20, which is provided with a plurality of apertures 22 to allow air to enter from battery chamber 12 into liquid container 18. (*Id.* at 6:2–7.) Liquid container 18 is formed of porous material, facilitating the distribution and mixing of air and liquid. (*Id.* at 6:11–14.)

105. Vaporizer heater assembly housing 24 (“heater housing”) contains heater wire 26 spirally wound on a central ceramic insulating rod. (*Id.* at 6:18-19)

The heater housing 24 is mounted in the mouthpiece end of liquid container 18. (*Id.* at 6:16-18.) Apertures 28 on the walls of heater housing 24 allow the entry of liquid and air from liquid container 18 into heater housing 24. (*Id.* at 6:20-22.)

F. Susa

106. Susa describes a simulated smoking flavor producing article. (Ex. 1007 at 1:14-17; 2:13-21.) Figure 13 is a schematic view showing the flavor generation article.



107. The electronic cigarette provides a casing 12 (casing main body 14), air intake ports 24, power supply 62, a material container 32, liquid material 36, a support member 44, coil heater 94, and formed body 92. (*Id.* at FIGS. 1, 13; 1:5-10; 5:15-17, 33-36, 48-58; 7:30-32, 50-55; 8:36-40; 14:54-15:46.)

108. The “casing 12” comprises a “first portion 12a” and “a second portion 12b.” (*Id.* at Abstract; 5:17-22; FIG. 1.) The air intake ports 24 in the first portion 12a receive air into the casing 12. (*Id.* at FIG. 1, 5:33-36.) The material container 32 storing the liquid material 36 is “detachably fixed” in the first portion 12a of the casing. (*Id.* at 5:51-58.)

109. The coil heater 94 is disposed around the formed body 92 for heating the formed body 92. (*Id.* at FIG. 13; 15:37–40.) Formed body 92 contains “good air permeability” and a “material that generates a flavor or the like to be inhaled by the user,” including, for example, “menthol, caffeine, or a tobacco component, e.g., a tobacco extracted component or a tobacco smoke condensate[.]” (*Id.* at FIG. 13; 15:5–17.)

VIII. OPINIONS REGARDING INVALIDITY OF ‘742 PATENT CLAIMS

110. For Ground 1, it is my opinion that claims 1-3 of the ‘742 Patent are invalid as obvious under 35 U.S.C. § 103 based on Takeuchi. (Ex. 1003.)

111. For Ground 2, it is my opinion that claims 1-3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103 based on Takeuchi in view of Cox. (Ex. 1004.)

112. For Ground 3, it is my opinion that claims 1 and 3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Brooks. (Ex. 1005.)

113. For Ground 4, it is my opinion that claims 1-3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Brooks in view of Whittemore. (Ex. 1006.)

114. For Ground 5, it is my opinion that claims 1-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Liu (Ex. 1008) in view of Susa. (Ex. 1007.)

115. For Ground 6, it is my opinion that claim 1 of the '742 Patent is invalid as being anticipated under 35 U.S.C. § 102 based on Susa.

116. As Ground 7, it is my opinion that claims 2-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Susa.

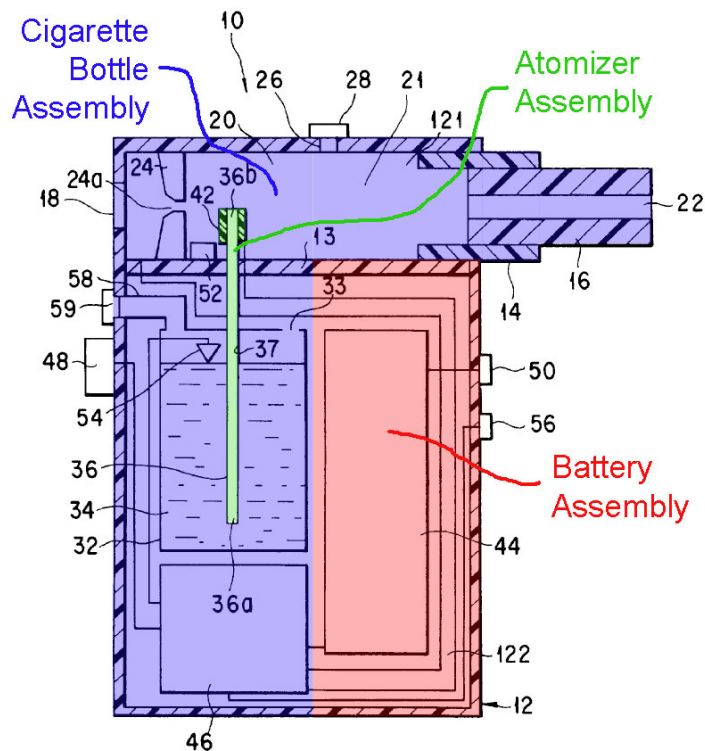
117. As Ground 8, it is my opinion that claims 1-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Susa in view of Whittemore.

**A. GROUND 1: CLAIMS 1-3 ARE UNPATENTABLE
UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW
OF TAKEUCHI**

118. Takeuchi alone renders obvious claims 1-3 of the '742 patent.

119. As for claim 1, and as shown in Figure 1 below Takeuchi discloses an aerosol electronic cigarette comprised of a battery assembly (source 44 in red), a cigarette bottle assembly (components in blue) with an atomizer assembly fitted inside of it (heater 42, liquid passageway 37 in green), surrounded by a hollow shell (casing 12). (Ex. 1003 at 4:30-38; 5:58-6:29.) The battery assembly (source 44) is electrically connected to the atomizer (specifically to heater 42 (*Id.* at 6:12-

29; 6:55–62.).) The cigarette bottle assembly is detachable from the battery assembly. (*Id.* at 6:12–14.)



120. The source 44 and heater 42 are located in a casing 12 and electronically connected. (*Id.* at 6:23-29; 6:55-62.) The casing 12 has through-air-inlets. The shell has air inlets (air intake 18) (*Id.* at 8:5–10.) and outer air introduction hole 26. (*Id.* at 5:4–7.) Because the source 44 is removable (*id.* at 6:12–14), the cigarette bottle assembly is detachably located in one end of the shell and the atomizer assembly fits inside it. FIG. 15 shows an embodiment of the atomizer assembly wherein the atomizer includes a porous component (intercommunicating pore structure 302) and a heating body (heater 425). (*Id.* at 10:59–63.)

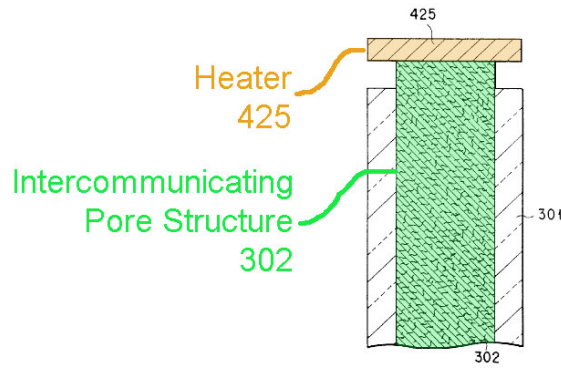
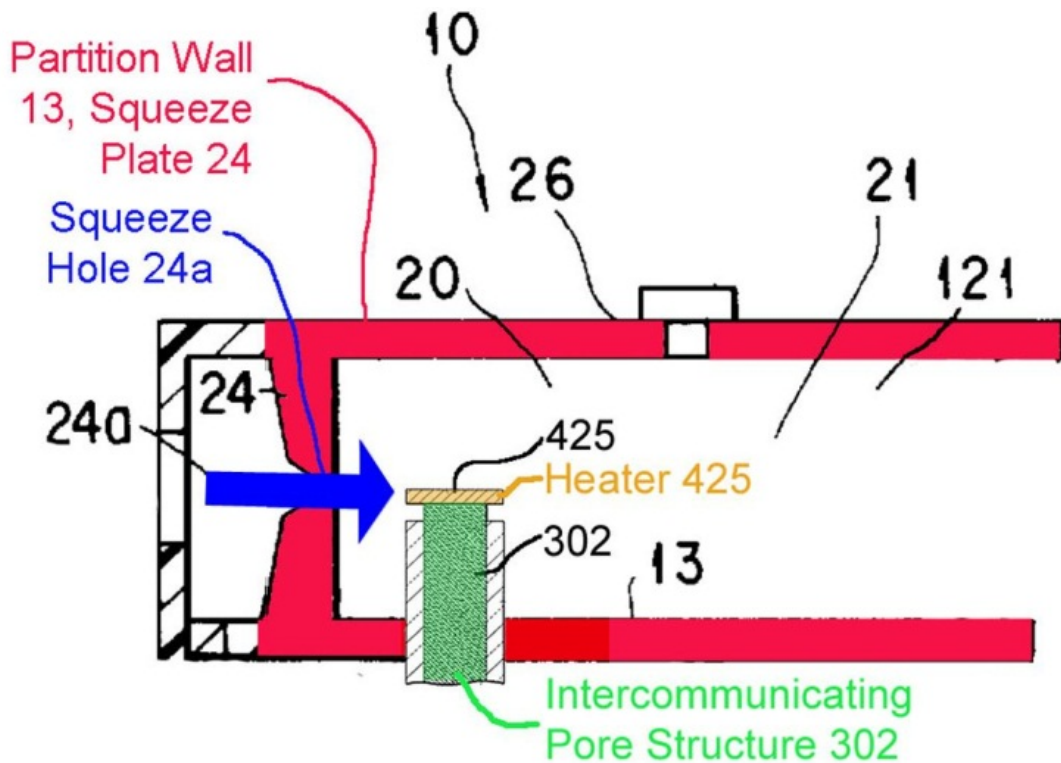


FIG. 15

121. A person of ordinary skill in the art would understand Figure 15 of Takeuchi discloses an alternative liquid passageway 36 in the form of an intercommunicating pore structure 302. Takeuchi teaches that disclosed “features can be combined appropriately depending on the object of the flavor generating device.” (*Id.* at 11:4–6.) The figure below shows a portion of the embodiment of Figure 1 with the atomizer embodiment shown in Figure 15. Based on the disclosure and object of Takeuchi, I find it appropriate to combine Figure 1 and Figure 15 in the manner shown.



122. As shown in the figure above, Takeuchi discloses a frame (in red) comprised of partition wall 13 and squeeze plate 24 and the top portion of the casing 12 as shown. Alternatively, the frame can be taken to be only partition wall 13 and squeeze plate 24. The porous component (intercommunicating pore structure 302) is supported by the frame. The frame has a run through hole (squeeze hole 24a) that is substantially aligned with the heating body (heater 425). (*Id.* at 4:63–67.)

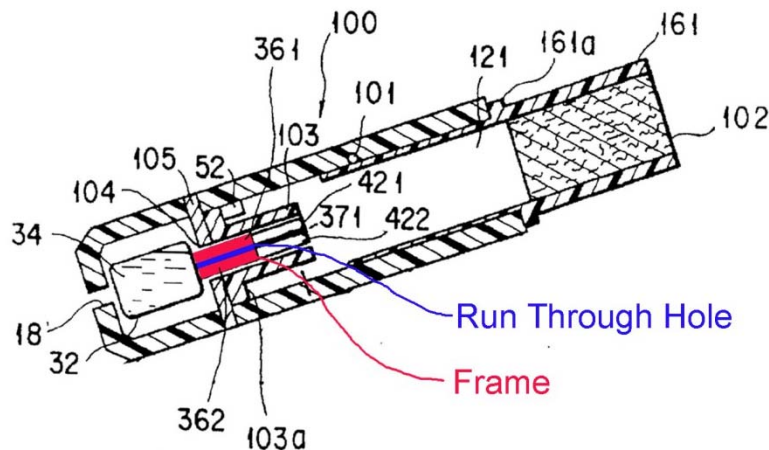
123. The frame supports a porous component (intercommunicating pore structure 302), and the porous component is substantially aligned with the run-through hole (passageway 371) in the frame. (*Id.* at 3:35-50; 9:23-35;10:50-67;

FIGS. 1, 8, 14-15.) The porous component is positioned substantially within the cigarette bottle assembly. (*Id.* at 3:42-47; 10:53-59; FIGS. 1, 15.)

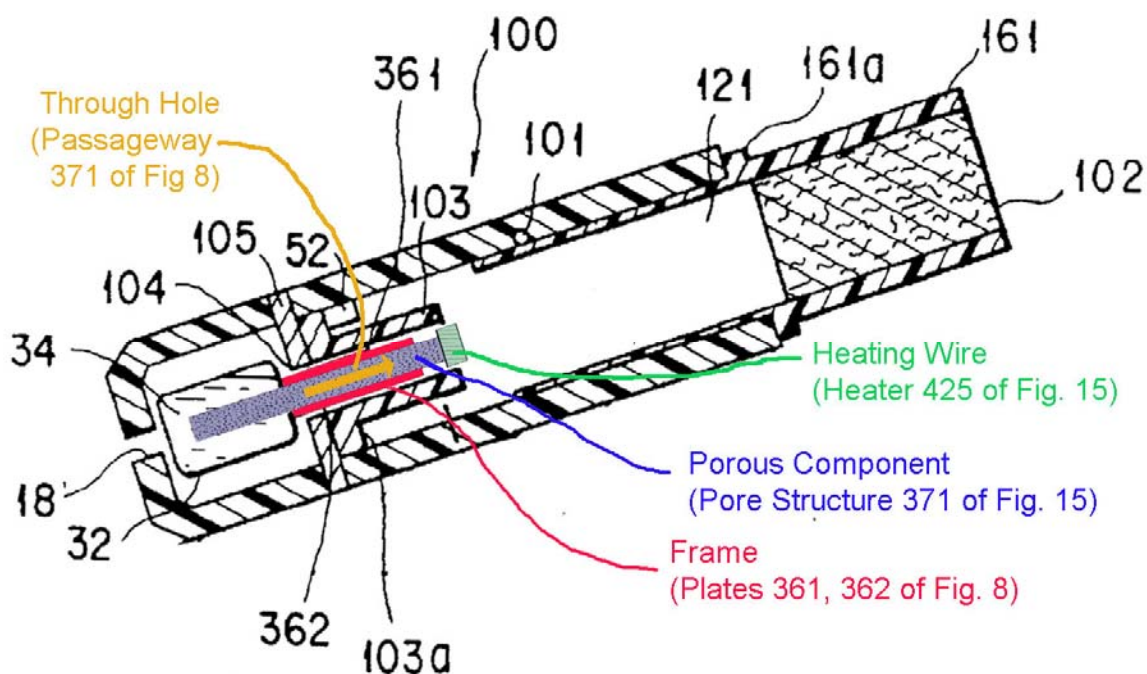
124. As to claim 2, Takeuchi discloses the run-through hole with air flowing through (squeeze hole 24a). (*Id.* at 4:61-67; 8:5-10.) Takeuchi further discloses the porous component (intercommunicating pore structure 302) substantially surrounded by the liquid storage component (liquid container 32). (*Id.* at 3:42-47; 10:53-59.)

125. As to claim 3, Takeuchi discloses the porous component between the frame and outlet (inhalation port 22, mouthpiece 161, *see* figures above). (*Id.* at 6:56-7:2; 9:8-34; 10:50-67; FIGS. 1, 8, 14-15.) Takeuchi further discloses the porous component (*e.g.* 302, 372, 301) in contact with a liquid supply (liquid flavor source 34). (*Id.* at 3:35-46; 10:50-59.)

126. To the extent that the frame as shown above does not disclose the porous component between the frame and the outlet, Figure 8 shows another embodiment of the flavor generating device of Takeuchi. As shown in the figure below (the top portion of Figure 8), the device provides a frame (plates 361 and 362) and a run through hole (liquid passageway 371). (*Id.* at 8:35-44.)



127. Takeuchi teaches that disclosed “features can be combined appropriately depending on the object of the flavor generating device.” (*Id.* at 11:4–6.) The figure below shows the embodiment of Figure 8 with the atomizer embodiment shown in Figure 15. Based on the disclosure and object of Takeuchi, I find it appropriate to combine Figure 8 and Figure 15 in the manner shown.



128. Based on the broadest reasonable interpretation of “frame,” the plates 361 and 362 are a frame for the intercommunicating pore structure 302, which has an enclosure 301. The plates at least support the intercommunicating pore structure 302 by directly supporting the enclosure 301.

**B. GROUND 2: CLAIMS 1-3 ARE UNPATENTABLE
UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW
OF TAKEUCHI IN FURTHER VIEW OF COX**

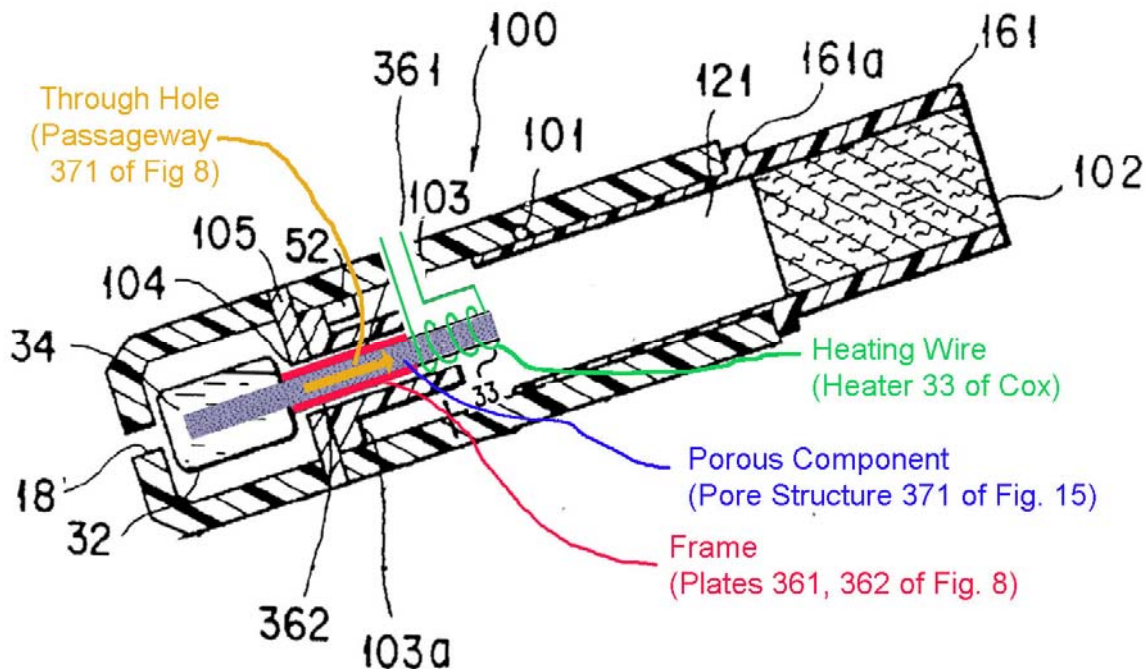
129. To the extent Takeuchi may not disclose a cigarette bottle assembly detachably located in one end of a shell, Cox discloses such a cigarette bottle assembly (first component 23 containing flexible container 45). (Ex. 1004 at 3:48–60; FIG. 1.)

130. It would have been obvious to a person of ordinary skill in the art to implement a cigarette bottle assembly detachably located on one end of the shell in order to more readily replace the cigarette bottle assembly, facilitate filling or eliminate the need for refilling by using a prefilled bottle, and separate from the more expensive components of the smoking device.

131. It also would have been obvious to one of ordinary skill in the art doing such would obviate the need to refill the liquid and therefore eliminate removable cap 59 of Takeuchi.

132. To the extent that heater 425 of Takeuchi is not disclosed to be a heating wire wound on porous element 302, Cox discloses a heating wire (heater body 33) wound on a porous component 227.

133. It would have been obvious to a person of ordinary skill in the art to implement such a heating wire as the heater 425 of Takeuchi because a wound heating wire is straightforward to design and manufacture. This proposed combination is shown below.



C. GROUND 3: CLAIMS 1 AND 3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF BROOKS

134. Brooks alone renders each limitation of Claims 1 and 3 obvious.

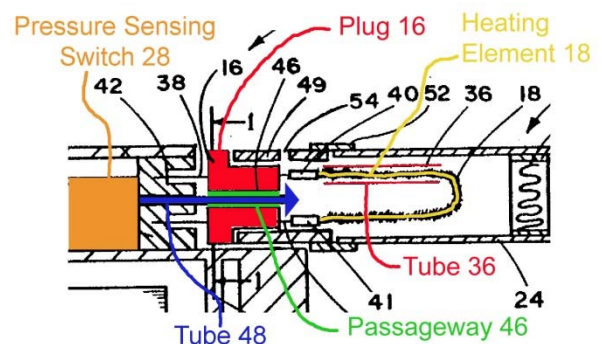
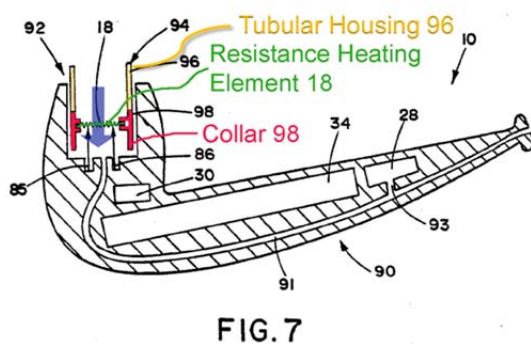
135. As to claim 1, Brooks discloses an aerosol electronic cigarette in the form of a cigarette or pipe, and utilizes an electrical power source to provide a

tobacco-flavored smoke or aerosol and other sensations of smoking. (Ex. 1005 at FIGS. 1 and 7; Abstract.) Brooks provides a shell (case 26 and overwrap 24 or bowl 92 and stem 90) which contains a battery assembly (battery 34), an atomizer assembly (heating element 18), and a cigarette bottle assembly with the atomizer fit inside it (disposable smoking cartridge 94, cigarette 12). (*Id.* at 7:15–25; 12:3–38.) The cigarette bottle assembly is detachably located in one end of the shell. (*Id.* at 11:1–2; 12:4–6.) Battery 34 and heating element 18 are electrically connected. (*Id.* at 7:15–25; 12:39–46; FIG. 9.) The cigarette 12 includes through-air-inlets (air inlet openings 54). (*Id.* at 8:43–57; FIG. 1.) Similarly, the smoking cartridge 94 has an air inlet end. (*Id.* at 12:28–33; FIG. 7.)

136. The heating element 18 may include “porous metal wires or films,” “carbon yarns” or “porous substrates” for example. (*Id.* at 7:65–8:3.) An aerosol forming substance is carried by the heating element 18. (*Id.* at 7:26–30.) Therefore, the heating element 18 is both a heating body which can be a heating wire and a porous component.

137. In the pipe embodiment, the heating element 18 is supported by a collar 98 connected to an outer tubular housing 96 of the smoking cartridge 94. (*Id.* at 12:16–19.) As shown in FIG. 7 below, the heating element 18, collar 98 and tubular housing 96 together constitute the cigarette bottle assembly (smoking cartridge 94) in which the porous heating wire is positioned substantially within.

The heating element 18 is supported by the plug 16 and tube 36 in the cigarette embodiment. (*Id.* at 8:31–57.) The plug 16 (in combination with tube 36) and collar 98 each include a passageway (run-through hole). (*Id.* at 8:31–42; 9:43–46; 12:16–19.) As shown in annotated FIGS. 7 and 1 below, plug 16 in combination with tube 36 or collar 98 constitute a frame with a run through hole aligned with the porous component.



138. It would have been obvious to a person of ordinary skill in the art to replace the porous heating wire of Brooks with a separate heating wire and separate porous component. The porosity of the wire, which impacts the ability to hold liquid, impacts the resistance of the wire, and thus its heating properties. Similarly the diameter of the wire effect both the resistance and the ability to hold liquid. Separating the heating wire from the porous component would allow for independent optimization of the ability to hold liquid and the thermal properties of the heating.

139. It would have been obvious as well to have the separate heating wire wound around the separate porous component. Not only would doing so improve ease of manufacture, but it also would provide more efficient and uniform heating due to greater surface area contact between the porous component and the formulation.

140. In its background section, Brooks cites and describes Whittemore, which discloses a heater wire wrapped around a porous component (wick). (Ex. 1005 at 1:57–61.)

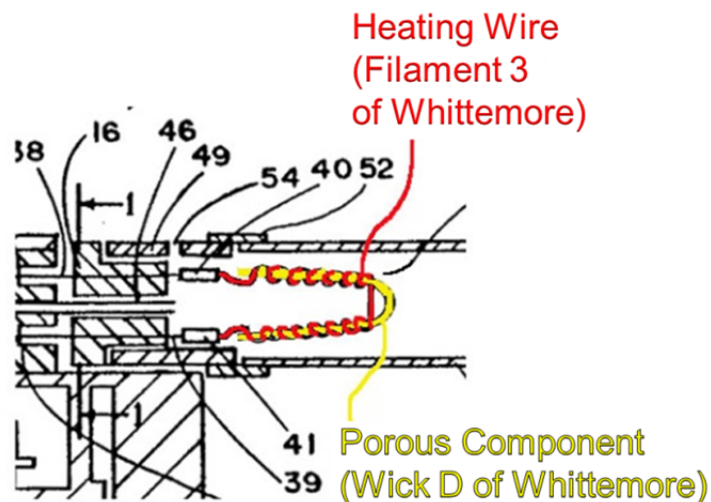
141. The Brooks and Whittemore devices both use an electrical heating element and aerosol formation to generate a vapor.

142. Thus, Whittemore provides an additional reason for a person of ordinary skill in the art to replace the porous heating wire of Brooks with a heating wire wound on a porous component.

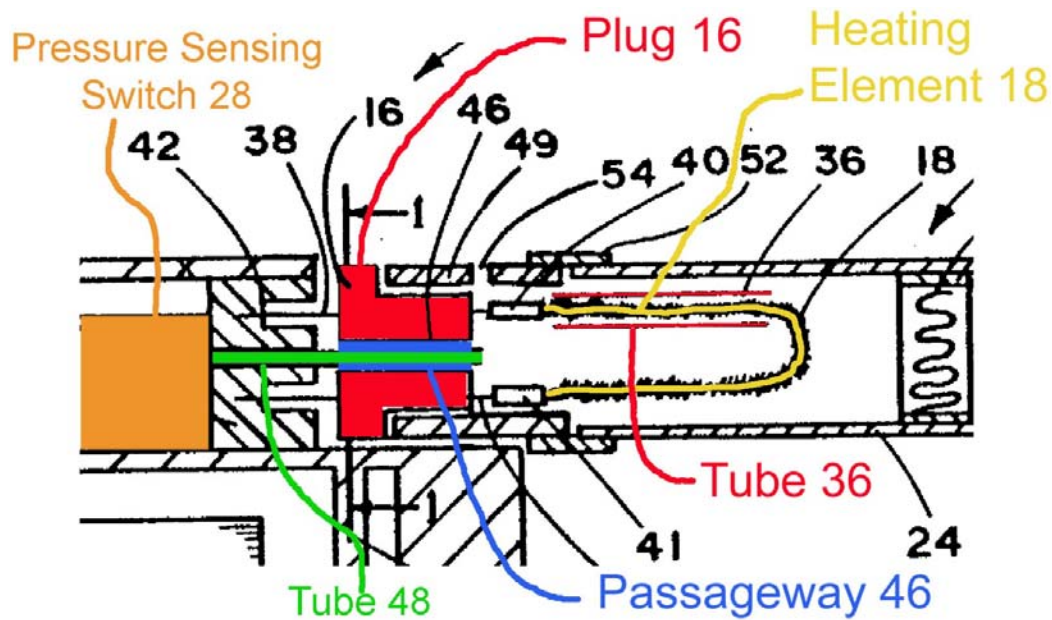
143. Furthermore, as to claim 3, it would have been obvious to a person of ordinary skill in the art to extend the porous component of Brooks into a liquid supply, thereby using the capillary action readily achieved in a porous element to increase the number of puffs available to a user. See this liquid contact as described in Whittemore for example. (Ex. 1006 at 1:50-2:8; FIG. 2.)

D. GROUND 4: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF BROOKS IN FURTHER VIEW OF WHITTEMORE

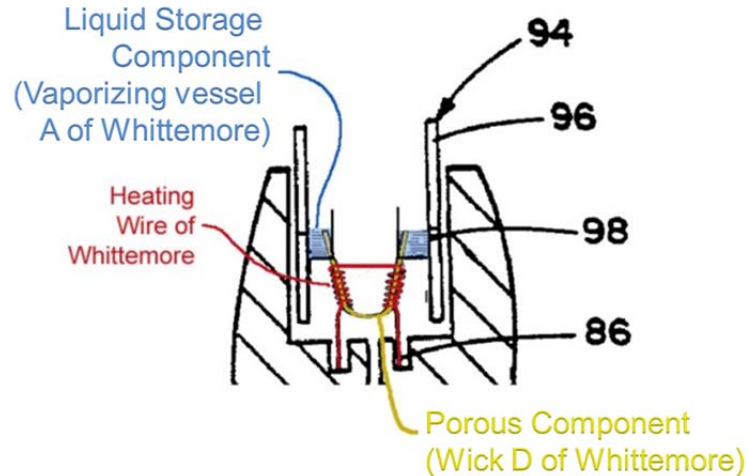
144. To the extent claims 1 and 3 are not obvious based on Brooks alone, the claims are obvious based on Brooks in view of Whittemore. It would have been obvious to a person of ordinary skill in the art to replace the porous heating wire of Brooks with the heater coil wrapped porous component of Whittemore to allow for separating the porous and thermal properties of the heating wire in order to independently optimize the properties of each. This reason is further explained in Ground 3 above. The illustration below shows the combination of the heating wire and the porous component of Whittemore with the device of Brooks.



145. Claim 2 is obvious based on Brooks in view of Whittemore. Brooks discloses a run-through hole (passageway 46) with air flowing through. (Ex. 1005 at 9:41-50; FIG. 1.) Air travels through passageway 46 to create a pressure change for detection by a sensor (“switch 28”). (*Id.*)

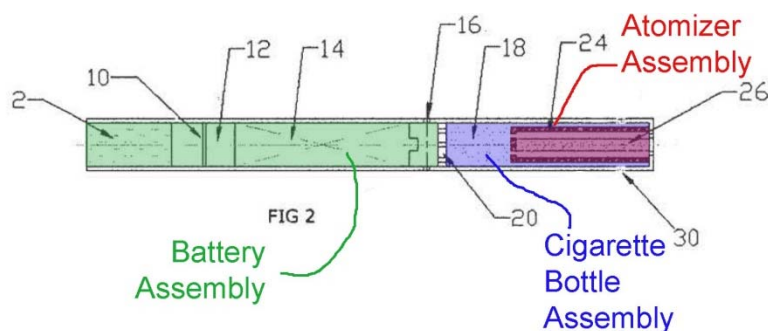


146. Whittemore discloses a porous component (wick D) substantially surrounded by a liquid storage component (vaporizing vessel A). (Ex. 1006 at 2:8–25; FIG. 2.) It would have been obvious to a person of ordinary skill in the art to substantially surround the porous component of Brooks with the liquid supply of Whittemore, thereby using the capillary action readily achieved in a porous element to increase the number of puffs available to a user. It would also be obvious to replace the porous heating wire of Brooks with the heating wire wound on the porous component of Whittemore to allow for separating the porous and thermal properties of the heating wire in order to independently optimize each property. This reason is further explained in Ground 3. The illustration below shows the Brooks smoking device of Figure 7 as modified by the liquid storage, heating wire, and porous component of Whittemore.



E. GROUND 5: CLAIMS 1-3 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF LIU IN FURTHER VIEW OF SUSA

147. The Liu simulated cigarette comprises a battery assembly (battery chamber 12), atomizer assembly (heater housing 24), and cigarette bottle assembly (area to the right of dividing wall 20, including liquid container 18). (Ex. 1008 at 5:8–12; 5:31–6:7.) The shell includes through-air-inlets (apertures 16). (*Id.* at 6:1–2.)



148. The battery chamber 12 and the heater housing 24 are located in a shell (casing 6). (*Id.* at 5:31–32; 6:16–19.) The battery chamber 12 is electrically connected with a heater wire 26 housed in the heater housing 24. (*Id.* at 7:11–15.)

The atomizer (heater housing 24) fits inside of the cigarette bottle assembly (see figure above). The liquid container 18 is formed of porous material for mixing air and liquid. (*Id.* at 6:11-14.) The heater housing 24 is an atomizer given it includes a heater wire 26 for forming an aerosol. (*Id.* at 6:20-22; 7:16-19.) The heater wire 26 corresponds to “the heating body is [a] heating wire.”

149. The heater wire of Liu is wound on a ceramic rod, not a porous component. Susa, however, refers to a “formed body 92” with “good air permeability” (and therefore porous also) that “generates a flavor or the like to be inhaled by the user [. . . .]” (Ex. 1007 at 14:54-5:4, 15:13-17.) The “formed body 92” can contain, by way of example, “menthol, caffeine, or a tobacco component, *e.g.*, a tobacco extracted component or a tobacco smoke condensate component [. . . .]” (*Id.* at 15:5-12.)

150. And while Susa discloses “formed body 92” as a solid, that alone does not mean “formed body 92” cannot be porous. Academic Press Dictionary of Science and Technology defines “solid” as having “the greatest tendency to resist forces that would alter its shape,” *e.g.*, not a liquid or a gas. (Ex. 1021 at 2030.)

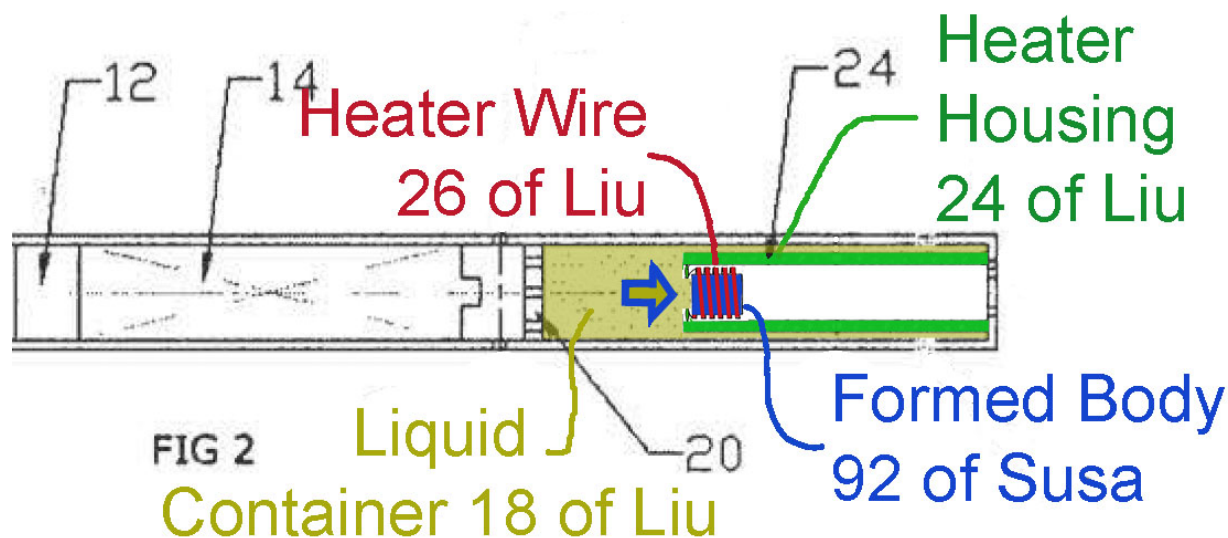
151. Indeed, Susa discloses “formed body 92” as a component having “good air permeability.” (Ex. 1007 at 15:13-17.) Academic Press Dictionary of Science and Technology defines “permeability” as the “capability of a porous substance or membrane to allow a liquid to filter through it.” (Ex. 1021 at 1612.)

Similarly, Merriam-Webster dictionary online defines “permeable” to mean “allowing liquids or gases to pass through.” (Ex. 1023 (<http://www.merriam-webster.com/dictionary/permeable>).) Based on these definitions, a body that is permeable—such as “formed body 92”—is porous.

152. It would have been obvious to a person of ordinary skill in the art to have the heater wire of Liu wound on the air permeable “formed body 92” of Susa, instead of the ceramic rod of Liu, and place the air permeable “formed body 92” of Susa in contact with the air permeable porous element in liquid container 18 of Liu. This combination would result in the porous component bringing the liquid into contact with the heater wire of Liu in a more controlled and reproducible way than the liquid drawn into the heater housing by the user’s inhalation air as disclosed by Liu.

153. It then would have been obvious to a person of ordinary skill in the art to support the porous component added to Liu with a frame. The ceramic rod in Liu is supported by the heater housing 24. (Ex. 1008 at 6:18–19.) Similarly, a person of ordinary skill in the art would have reason to implement a frame to support the porous component, which presumably would be lighter than the ceramic rod in Liu, as opposed to having the entire housing for support. Further, the frame could be used to direct the air centrally in the heater chamber onto the

porous element, rather than outside of the heater wire as shown in Liu. This proposed combination of Liu and Susa is illustrated below.



154. Liu does not explicitly disclose that its cigarette bottle assembly (area to the right of “dividing wall 20,” including liquid container 18) is detachably located at one end of the shell. Susa however discloses that its cigarette bottle assembly is detachably located in one end of the shell. (Ex. 1007 at Abstract; 5:20–22.) It would be obvious to a person of ordinary skill in the art to have the cigarette bottle assembly of Liu detachably located in one end of the shell as in Susa in order to facilitate replacement or replenishment of the cigarette bottle assembly when exhausted by making it separable from more expensive and durable components of the simulated cigarette such as the battery assembly.

155. As to claim 2, the run-through hole limitation is disclosed for the same reasons as explained above as to the run-through hole limitation of claim 1.

When the ceramic rod in the heater housing is replaced with the porous component for the reasons discussed above, the porous component becomes “substantially surrounded” by the liquid storage component, and the air that is drawn through the liquid container 18 of Liu is drawn through the run-through hole. (*See supra* at ¶¶152–153.)

156. As to claim 3, Susa discloses a porous component (“formed body 92”) between frame (“support member 44”) and the outlet (“suction port 22”). (*Id.* at 15:47–51; FIGS. 12-13.) Second, it would have been obvious to a person of ordinary skill in the art to place the porous component, that is, air permeable porous “formed body 92” of Susa, in contact with the air permeable, porous contents of “liquid container 18” of Liu: The contact between “liquid container 18” and “formed body 92” would facilitate absorption and transport of the liquid from “liquid container 18” to “formed body 92” for vaporization using “coil heater 94” for heating.”

**F. GROUND 6: CLAIMS 1-3 ARE UNPATENTABLE
UNDER 35 U.S.C. § 102 AS BEING ANTICIPATED BY
SUSA**

157. Claims 1-3 of the ‘742 patent are unpatentable under 35 U.S.C. § 102 as being anticipated by Susa. As shown below in FIG. 13 (showing only the relevant components), Susa discloses a battery assembly (“power supply 62”), atomizer assembly (“formed body 92”; “heater coil 94”) and cigarette bottle

assembly (the area to the right of “control circuit 72.”). (Ex. 1007 at FIG. 13; 8:36–40; 8:36–45; 14:54-15:46.) The battery assembly is electrically connected to the atomizer assembly (*id.* at 15:37–40) and they are both located in the shell (casing 12/casing main body 14). (*Id.* at FIG. 13.) The shell has through-air-inlets (air intake ports 24). (*Id.* at 5:33–36; 17:1-3.)

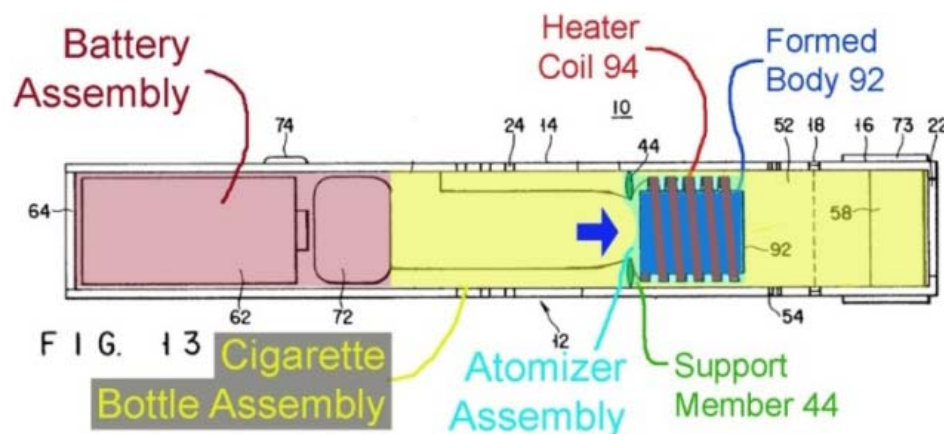
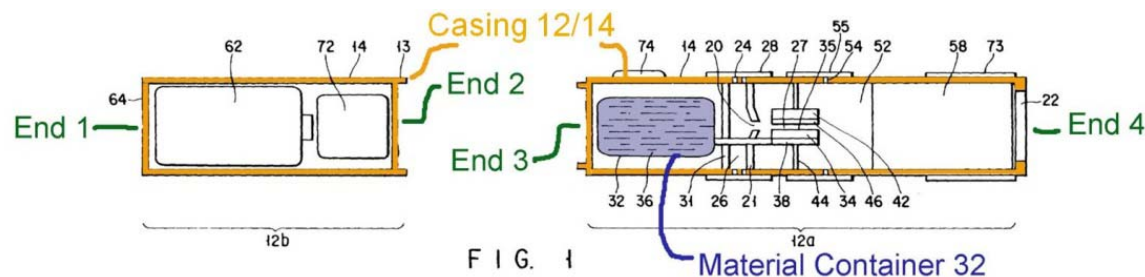


FIG. 13

158. Other embodiments disclosed in Susa also refer to “[a] flavor generation article 10 with a cylindrical casing 12” (made up of “first portion 12a” and “second portion 12b”) having “an outer diameter that the user can hold the casing 12 in his mouth.” (*Id.* at 5:15–17.) The cigarette bottle assembly therefore can consist of the area inside “first portion 12a” also. (*Id.* at FIG. 1.)

159. As shown in Figure 1 below (modified to more clearly show the detachability of the device), the cigarette bottle assembly is detachably located in one end of the shell, as “material container 32 for storing a liquid material 36” is

“detachably fixed” in one end of the “casing 12” (“casing main body 14”). (*Id.* at FIG. 1, 5:51–55.)



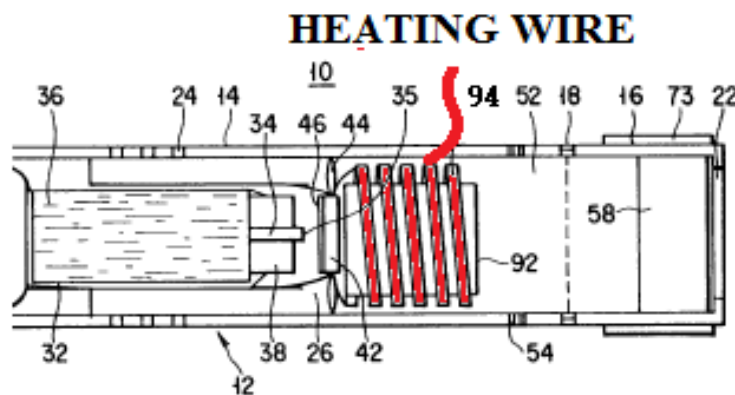
160. Although the embodiment in Figure 13 does not expressly show that “casing 12”/“casing main body 14” is detachable, detachment of the casing is reasonably implied from Figure 1. Susa states “The characteristic features of the respective portions of the present invention have been described divisionally by way of several embodiments in order to facilitate understanding of the present invention. These characteristic features can be appropriately combined 15 in accordance with the object. More specifically, the present invention can be practiced in various embodiments other than those shown in the drawings within the spirit and scope of the invention”. (*Id.* at 17:11–19.) To the extent detachment would not be implied into Figure 13 itself, it would be appropriate to combine the detachability in Figure 1 with the embodiment of Figure 13, given the object of the Susa disclosure as a whole. (*Id.* at FIGS. 1, 12; 5:20-30; 14:54–15:4.) Moreover, at least a part of the atomizer assembly (*i.e.* “formed body 92”), which is disposed

within cigarette bottle assembly (*e.g.* area inside “first portion 12a” or area to the right of “control circuit 72”), can be detached. (*Id.* at FIG. 12; 14:54–15:4.)

161. The atomizer assembly is an atomizer including a porous component (*e.g.* “formed body 92”) and a heating body (“heater coil 94”). (*Id.* at FIG. 13; 15:5–17; 15:31–36.) The atomizer includes a frame (“support member 44”), which “is formed to have a slit only at its central portion” (*i.e.* a run through-hole) in order to regulate and let air through. (*Id.* at FIG. 13; 13:20–23; 17:4–10.)

162. The frame supports the porous component (“formed body 92”). (*Id.* at FIG. 13; 15:47–51.) As explained in Ground 5, “formed body 92” disclosed as a solid is porous especially given it has “good air permeability.” (*Id.* at 15:13–17.)

163. Susa refers to a “formed body 92” with “good air permeability” (and therefore porous also) that “generates a flavor or the like to be inhaled by the user [. . . .]” (*Id.* at 15:13–17.) A “coil heater 94” can be “disposed around the formed body 92” to heat “formed body 92” also. (*Id.* at 15:31–36.)



164. And while Figure 13 discloses a ceramic heater 42, Susa reasonably implies that ceramic heater 42 is optional for the vaporization of the contents in “formed body 92” and is primarily used when heat capacity of “formed body 92” is high. (*Id.* at 15:37–46.) Therefore, the electronic cigarette device of Susa can be used with “coil heater 94” as the only heating component. (*Id.*)

165. The porous component is substantially aligned with the run-through hole in the frame (“support member 44”). (*Id.* at FIG. 13; 13:20–23; 15:47–51; 17:4–10.) The porous component is also positioned substantially within the cigarette bottle assembly (area inside “first portion 12a” or area to the right of “control circuit 72”). (*Id.* at FIGS. 1, 13.)

166. As to claim 2, Susa discloses the run-through hole with air flowing through. (*Id.* at FIG. 13; 13:20–23; 15:47–51; 17:4–10.) Susa further discloses the porous component (“formed body 92”) substantially surrounded by the liquid storage component (area inside “first portion 12a” or area to the right of “control circuit 72”). (*Id.* at FIGS. 1, 13.)

167. As to claim 3, Susa discloses the porous component (“formed body 92”) between the frame (“support member 44”) and outlet (“suction port 22”). (*Id.* at FIG. 13.) Susa further discloses the porous component (“formed body 92”) in contact with a liquid supply in the housing (“casing 12”/“casing main body 14”). (*Id.* at 15:5–12; FIG. 13.) “Formed body 92” contains the tobacco extracted

component or tobacco smoke condensate component. (*Id.* at 15:5–12.) Such extracted or smoke condensate components can contain liquid (tobacco contains resin, for example). If “formed body 92” was not porous but somehow interpreted to be formed of solid tobacco components, the tobacco components would not be capable of diffusing to the surface to replace the tobacco components that had been previously vaporized. “Formed body 92” contains and, therefore, is inherently in contact with tobacco components in a liquid state.

G. GROUND 7: CLAIM 3 IS UNPATENTABLE UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW OF SUSA

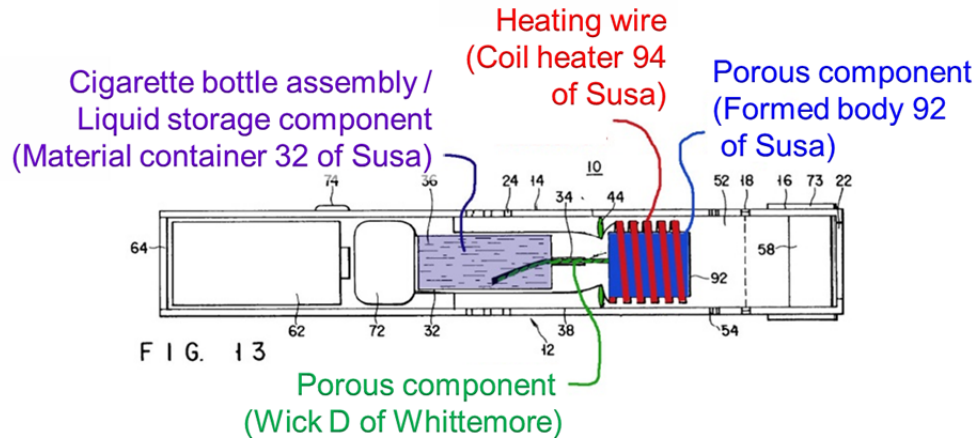
168. To the extent that Susa does not inherently disclose the state of the supply in “formed body 92” to be a liquid (or any other state of matter), it would have been obvious to one of ordinary skill to modify Susa so that the supply is liquid. “Formed body 92” is the flavor generating article to be heated in the embodiments disclosed in Figures 12-13. (Ex. 1007 at 14:54–15:46, FIGS. 12-13.) For other embodiments, Susa is replete with examples where the flavor generating article is a “liquid material 36” that can be a “tobacco extracted component or a tobacco smoke condensate component” and heated into an aerosol for inhalation by the user. (*Id.* at FIGS. 1, 8–10; Abstract (57); 5:51–58; 6:7–25.) Therefore, as explained in Ground 6, the obvious choice would be to have formed body 92 contain and therefore be in contact with tobacco components which are in a liquid state as disclosed in the other embodiments of Susa.

**H. GROUND 8: CLAIMS 1-3 ARE UNPATENTABLE
UNDER 35 U.S.C. § 103 AS BEING OBVIOUS IN VIEW
OF SUSA IN FURTHER VIEW OF WHITTEMORE**

169. To the extent the cigarette bottle assembly (claim 1) and liquid storage component (claim 2) disclosed in SUSA are limited to “material container 32” only and, therefore, “formed body 92” would not be in contact with the cigarette bottle assembly/liquid storage, SUSA combined with Whittemore render obvious claims 1-2.

170. Whittemore discloses i.) a bottle assembly in the form of “vaporizing vessel A” that is detachably located in one end of the shell (*i.e.* the “vaporizing unit”) and fits with the atomizer assembly (“wick D” and “filament 3”) inside it (claim 1); ii.) the porous component of the atomizer assembly (“wick D”) positioned substantially within the bottle assembly (“vaporizing vessel A”) (claim 1); and iii.) the porous component (“wick D”) substantially surrounded by the liquid storage component (“vaporizing vessel A”) (claim 2). (Ex. 1006 at 1:19–28; 1:39–45; 1:50–2:18, FIGS. 1–2.)

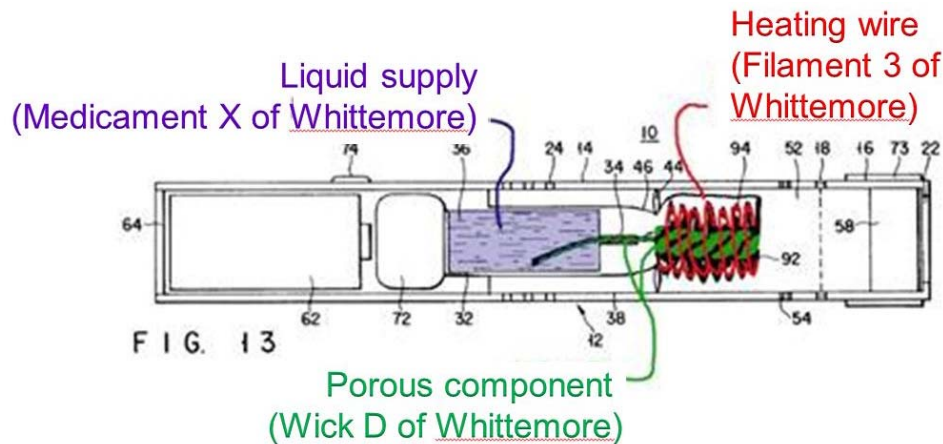
171. It would have been obvious to one of the ordinary skill to modify SUSA so that “formed body 92” is attached to “wick D” from Whittemore so that “wick D” would extend into and be inside “material container 32.” The proposed combination is shown in the modified figure below:



172. This modification is motivated by the fact that the wick would facilitate absorption and transport of “liquid material 36” from “material container 32” to “formed body 92” for vaporization using “coil heater 94” for heating. The user would therefore be able to use the device longer before needing to replace “formed body 92” or replenish the liquid in “formed body 92.” The need in certain embodiments (including the embodiment of FIG. 13) to discharge or “splash” “liquid material 36” onto “ceramic heater 42” for heating would be eliminated. (Ex. 1007 at 7:39–43.) This method as disclosed by Susa would inevitably lead to splashing and loss of “liquid material 36” and inconsistent vaporization of the liquid, which would be eliminated by the proposed combination. Fewer parts would be required, and the heating control functions would be simplified as well.

173. It also would have been obvious to one of the ordinary skill to modify Susa so that “material container 32” of Susa would contain “Medicament X” of

Whittemore, and Whittemore's wick D and filament 3 would be used as the atomizer. The proposed combination is shown in the modified figure below:



174. One motivation for this modification is to allow absorption and transport of “Medicament x” from “material container 32” to “wick D” for vaporization using “filament 3” for heating. The user would therefore be able to use the device without needing to replace “formed body 92” or replenish the liquid in “formed body 92.” The need in certain embodiments (including the embodiment of FIG. 13) to discharge or eject “liquid material 36” onto “ceramic heater 42” for heating would be eliminated. (*Id.* at 7:39–43.) This method as disclosed by Susa would inevitably lead to splashing and loss of “liquid material 36” and inconsistent vaporization of the liquid, which would be eliminated by the proposed combination. Fewer parts would be required, and the heating control functions would be simplified as well.

175. Another motivation for the modification would be that “Medicament X” would no longer splash around as it might in “vaporizing vessel A” of Whittemore if the liquid is in a container such as Susa’s “material container 32.” The modification would allow for transport and storage, for example in a user’s pocket, as well.

176. Whittemore also discloses the porous component of the atomizer assembly (“wick D”) in contact with a liquid supply (“medicament x” in the housing (“vaporizing unit”) (claim 3). (Ex. 1006 at FIGS. 1–2; 1:50–2:8.) Therefore, to the extent Susa alone does not anticipate or render the limitation of “the porous component in contact with a liquid supply in the housing” in claim 3 obvious, Susa in combination with Whittemore render the limitation obvious. The motivations to combine would be the same as mentioned in the preceding paragraphs in this Ground.

IX. CONCLUSION

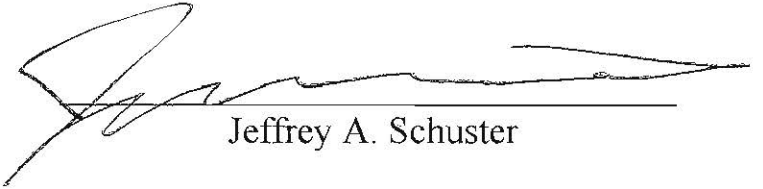
177. For the reasons explained above, I conclude: claims 1-3 of the ‘742 Patent are invalid as obvious under 35 U.S.C. § 103 based on Takeuchi; claims 1-3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103 based on Takeuchi in view of Cox; claims 1 and 3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Brooks; claims 1-3 of the ‘742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Brooks in view of

Whittemore; claims 1-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Liu in view of Susa; claim 1 of the '742 Patent is invalid as being anticipated under 35 U.S.C. § 102 based on Susa; claims 2-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Susa; and claims 1-3 of the '742 Patent are invalid as being obvious under 35 U.S.C. § 103(a) based on Susa in view of Whittemore.

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: July 14, 2015



Jeffrey A. Schuster

Exhibit A

Jeffrey Arthur Schuster, Ph.D.

900 N. Humboldt St., San Mateo, CA 94401

510.258.2182 schuster.jeffrey@gmail.com

Summary

An experienced leader, inventor, and entrepreneur with over 20 years in medical product development. Expertise in all aspects of medical device and combination product development, including technology evaluation, project management, clinical trials, pilot manufacturing, intellectual property, and technology transfer

Expertise

Medical Devices
Drug Delivery/Combination Products
Pulmonary Drug Delivery
Digital Health
Drug Delivery Compliance Monitoring
Intellectual Property
Due Diligence
Hematology
Technical/Project Management
Technology Scouting and Evaluation
Contracts
Device/System Development
Autoinjectors / Needle Free Injection
Pharmaceuticals

Experience

July 2013-Present

eficia

San Mateo, Ca

President and Founder

- *eficia* has developed a novel digital health compliance monitor for drug delivery devices including inhalers and autoinjectors

Feb 2007-Present

Jeffrey Arthur Schuster, Ph.D.

San Mateo, Ca

Consultant

- Contributed to the development of novel inhalation, needle free injection, and other technologies
- Managed the intellectual property portfolio of multiple pharmaceutical companies
 - IP strategy/ patent writing
 - Patentability/freedom to operate
 - Responding to office actions
 - IP training
- Developed detailed project plan for a medical device company moving into combination products
- Led drug delivery technology selection effort for a major biotechnology company
- Business development
- Due diligence
- Technology evaluation

June 2008-Present

Triple Ring Technologies

Newark, CA

Consultant

- Led a team focused on drug delivery related business development
- Project lead for the development of a novel hematology optics sub-system
- Business development and commercial intelligence
- Development of a novel catheter based valvuloplasty system

-
- Development and analytical modeling of a novel implantable pump
 - Preparation of a white paper for a novel low cost infusion system
 - Leadership of a technology opportunity evaluation task force
 - Development and evaluation of a novel X-ray imaging technology
 - Submitted multiple proposals to potential clients

Feb 2007-Feb 2008

Respire Pharmaceuticals

Oakland, Ca

President and Founder

- Co-founder of Respire Pharmaceuticals
- A novel inhalation drug delivery technology, and a proprietary product for the treatment of sexual dysfunction

Sept 2005-Feb 2007

Aradigm Corporation

Hayward, Ca

Senior Director, Drug Delivery Research

- Managed Aradigm patent portfolio of 114 US patents and numerous foreign filings
- Chair of the Intellectual Property Management Group
- Principle investigator for a Phase II SBIR grant to study adapting Aradigm technology to vaccination
- Negotiated a strategic alliance with Ingeniatics Tecnologías for development of a novel aerosol drug delivery technology
- Participated in multiple business development activities
- Led technology scouting activities as chair of the Technology

Evaluation and Strategic Acquisition committee

- Co-inventor of a novel single dose inhaler, the AERx Ease™

Jan 2004-Present

Applied Isotope Technology

Pittsburg, PA

Scientific Advisor

Aug 1999-Sept 2005

Aradigm Corporation

Hayward, CA

Director, Technology

- Directed a group of 18 engineers and scientists
- Project and scientific lead for the “next generation” aerosol drug delivery technology (AERx Essence™)
- Played a lead role in the technology transfer of Intraject® needle free autoinjector from Weston Medical to Aradigm
- Managed Aradigm patent portfolio of 114 US patents and numerous foreign filings
 - Aradigm rated as having the 23rd best pharma patent position in 2005 (ipIQ's “Patent Scorecard™”)
- Chair of the Intellectual Property Management Group
- Chair of Aradigm Meeting Effectiveness Team
- Principle investigator for a Phase I SBIR grant to study adapting Aradigm technology to vaccination
- Participated in multiple business development activities
- Member of the New Product Planning Committee
- Chair of the Technology Evaluation and Strategic Acquisition committee, led tech scouting activities
- Member of the Development Committee

1998-Aug 1999

Aradigm Corporation

Hayward, CA

Manager, Aerosol Technology Development

- Led a research group consisting of 12 engineers, scientists, and research associates
- Successfully facilitated the technology transfer of AERx system from R&D to operations
- Head of system integration team

1996–1997

Aradigm Corporation

Hayward, CA

Senior Scientist

- Led development of the AERx pulmonary delivery system through phase I clinical trials
- Led effort to characterize and improve basic aerosol generation technology
 - Improved system efficiency by 36%.

1994-1995

Miris Medical/Aradigm Corporation

Hayward, CA

Scientist

- Co-invented a novel, highly efficient pulmonary drug delivery system (AERx™)

Education	Ph. D., Physics, UC Berkeley, Berkeley, CA 1993
	B. A., Physics, UC Berkeley, Berkeley, CA 1985
	-With distinction in general scholarship
Patents	33 issued US patents (see list below)
Affiliations	The American Association of Pharmaceutical Scientists
	The American Association for Aerosol Research
	The Controlled Release Society
	The International Society for Aerosols in Medicine

ISSUED U.S. PATENTS

Needle free injectors and design parameters thereof that optimize injection performance, US Patent **8,734,384**, Issued May 27, 2014

Device for readying a needle free injector for delivery, US Patent **8,287,489**, Issued October 16, 2012

Device for readying a needle free injector for delivery, US Patent **7,776,007**, Issued August 17, 2010

Method and system for LASER machining, US Patent **7,767,930**, Issued August 3, 2010

Method and device for non-destructive analysis of perforations in a material, US Patent **7,301,621**, Issued November 27, 2007

Methods and compositions for treating erectile dysfunction, US Patent **7,258,850**, Issued August 21, 2007

Method and device for non-destructive analysis of perforations in a material, US Patent **7,148,960**, Issued December 12, 2006

Temperature controlling device for aerosol drug delivery, US Patent **7,143,766**, Issued December 5, 2006

Temperature controlling device for aerosol drug delivery, US Patent **6,845,216**, Issued January 18, 2005

Temperature controlling device for aerosol drug delivery, US Patent **6,694,975**, Issued February 24, 2004

Temperature controlling device for aerosol drug delivery, US Patent **6,629,526**, Issued October 7, 2003

Method and device for non-destructive analysis of perforation in a material, US Patent **6,624,885**, Issued September 23, 2003

Method of fabricating porous membrane with unique pore structure for aerosolized delivery of drugs, US Patent **6,551,542**, Issued April 22, 2003

Aerosol-forming porous membrane with certain pore structure, US Patent **6,543,442**, Issued April 8, 2003

Temperature Controlling Device for Aerosol Drug Delivery, US Patent **6,263,872**, Issued July 24, 2001

Method and Device for Creating Aerosol with Porous Membrane with Certain Pore Structure, US Patent **6,230,706**, Issued May 15, 2001

Temperature Controlling Device for Aerosol Drug Delivery, US Patent **6,131,570**, Issued October 17, 2000

Disposable Member for use in Aerosolized Delivery of Drugs, US Patent **6,123,068**, Issued September 26, 2000

Device for Aerosolized Narcotics, US Patent **6,098,620**, Issued August 8, 2000

Method of Reproducibly Effecting a Patient's Glucose Level, US Patent **6,098,615**, Issued August 8, 2000

Aerosol Forming Porous Membrane with Certain Pore Structure, US Patent **6,070,575**, Issued June 6, 2000

Disposable Package for use in Aerosolized Delivery of Antibiotics, US Patent **6,014,969**, Issued January 18, 2000

Device for Aerosolized Delivery of Peptide Drugs, US Patent **5,960,792**, Issued October 5, 1999

Dynamic Particle Size Control for Aerosolized Drug Delivery, US Patent **5,957,124**, Issued September 28, 1999

Device and Method of Creating Aerosolized Mist of Respiratory Drug, US Patent **5,934,272**, Issued August 10, 1999

Creating an Aerosolized Formulation of Insulin, US Patent **5,915,378**, Issued June 29, 1999

Device and Method for Directing Aerosolized Mist to a Specific Area of the Respiratory Tract, US Patent **5,906,202**, Issued May 25, 1999

Disposable Package for Use in Aerosolized Delivery of Drugs, US Patent **5,823,178**, Issued October 20, 1998

Collapsible Container for Measuring Particles in a Sample Fluid, US Patent **5,770,152**, Issued June 23, 1998

Disposable Package for use in Aerosolized Delivery of Drugs, US Patent **5,718,222**, Issued February 17, 1998

Systems for the Intrapulmonary Delivery of Aerosolized Aqueous Formulations, US Patent **5,660,166**, Issued August 26, 1997

Systems for the Intrapulmonary Delivery of Aerosolized Aqueous Formulations, US Patent **5,544,646**, Issued August 13, 1996

Dynamic Particle Size Control for Aerosolized Drug Delivery, US Patent **5,522,385**, Issued June 4, 1996

PUBLICATIONS

"Personalized Medicine: Development of Inhalation Systems Tailored to the Individual", David Cipolla, Hak-Kim Chan, Jeff Schuster, and Dino Farina, *Therapeutic Delivery* **1**, No. 5 (2010).

"Development of a Novel Single Dose Inhaler", Schuster, J., Ament, B., Walsh, M., and Holst, P., *Respiratory Drug Delivery X* (R.N. Dalby et. al. Eds.), DHI, River Grove, 417 (2006)

"Pulmoshield: A System for Pulmonary Vaccination", Holst, P., Tin, R., Ament, B., Walsh, M., and Schuster, J., *In Respiratory Drug Delivery X* (R.N. Dalby et. al. Eds.), DHI, River Grove, 424 (2006)

"Gamma Scintigraphic Evaluation of a Miniaturized AERx® Pulmonary Delivery System for Aerosol Delivery to Anesthetized Animals Using a Positive Pressure Ventilation System" Deshpande, D., Blanchard, J., Schuster, J., Fairbanks, D.,

Hobbs, C., Densmore, C., Beihn, R., Farr, S., and Gonda, I. *Journal of Aerosol Medicine* **18**, No 1 (2005)

"AERx[®] Essence[™]: Efficiency and Breath Control Without Electronics" Noymmer, P., Schuster, J., Holst, P., Rosell, J., Ament, B., Wilbanks, T., Srinivasan, S., Morishigue, R., and S. Farr, in *Respiratory Drug Delivery IX* (R.N. Dalby et. al. Eds.), DHI, River Grove, 255 (2004)

"Pulmonary Delivery of Drugs by Inhalation" Igor Gonda and Jeffrey Schuster, in *Modified-Release Drug Delivery Technology*, Michael J. Rathbone, Jonathan Hadgraft, and Michael S. Roberts, Eds., Marcel Dekker, New York (2003)

"The AERx Pulmonary Drug Delivery System" Jeffrey Schuster and S. J. Farr, in *Modified-Release Drug Delivery Technology*, Michael J. Rathbone, Jonathan Hadgraft, and Michael S. Roberts, Eds., Marcel Dekker, New York (2003)

"Expanding Applications for Precision Pulmonary Delivery" Stephen Farr, Jeffrey Schuster, and Christa Nicholas, *Drug Delivery Technology* **2**, no. 3 (2002)

"Recommendations to the Food and Drug Administration: Metered Dose Inhaler Tests and Methods in the Chemistry, Manufacturing, and Controls Draft Guidances for Metered Dose Inhalers" ITFG/IPAC Tests and Methods Technical Team, *Drug Information Journal* **36** (2002)

"Suppression of Electrostatic Charging of AERx[™] Aerosols" Joan Rosell, Jeff Schuster, Kui Liu, Igor Gonda, Sudarsan Srinivasan, Deepa Deshpande, *Journal of Aerosol Medicine* **14**(3):405 (2001)

"Comparison of in vitro and in vivo efficiencies of a novel unit-dose liquid aerosol generator and a pressurized metered dose inhaler" Stephen J Farr, Simon J. Warren, Peter Lloyd, Jerry K Okikawa, Jeffrey A. Schuster, Antony M. Rowe, Reid M. Rubsamen, and Glyn Taylor, *International Journal of Pharmaceutics* **198** (2000)

"AERx: Synthesis of Technologies to Provide Therapeutic Benefits via Pulmonary Drug Delivery", David Cipolla, Stephen Farr, Max Fiore, Igor Gonda, Eric Johansson, Peter Lloyd, Jerry Okikawa, Franklin Okumu, Rajesh Patel, Reid Rubsamen, Steve Ruskewicz, and Jeffrey Schuster, *Polymer Preprints* **40**, no. 1 (1999)

"Pulmonary Administration of Biotech Drugs- the Way They Deserve to be Delivered" J. Schuster, R. Rubsamen, P. Lloyd, S. Farr, D. Cipolla, and I. Gonda, in *Aerosole in der Inhalationstherapie II*, Dustri Verlag, 1998, Munich.

"Design and Testing of Aerosol Delivery Systems for Reproducible Clinical Performance" D. Cipolla, S. Farr, I. Gonda, C. Herst, R. Lee, P. Lloyd, G.

McKinley, R. Rubsamen, J. Schuster, and C. Zellhoefer, *Journal of Aerosol Medicine* **11**, Suppl. 1 (1998)

"Design and Performance Validation of a Highly Efficient and Reproducible Compact Aerosol Delivery system: AERx™" Schuster, J., Farr, S., Cipolla, D., Wilbanks, T., Rosell, J., Lloyd, P., and Gonda, I., In *Respiratory Drug Delivery VI* (R.N. Dalby et. al. Eds.), Interpharm Press, Buffalo Grove, 83 (1998)

"Inhalation Delivery Systems with Compliance and Disease Management Capabilities", I Gonda, J. Schuster, R. Rubsamen, P. Lloyd, and S. Farr, *Journal of Controlled Release* **53** (1998)

"Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System", M. Elizabeth Ward, Annie Woodhouse, Laurence E. Mather, Stephen J. Farr, Jerry K. Okikawa, Peter Lloyd, Jeffrey A. Schuster, and Reid M. Rubsamen, *Clinical Pharmacology and Therapeutics* **62**, no. 6 (1997)

"The AERx™ Aerosol Delivery System", J. Schuster, R. Rubsamen, P. Lloyd, and J. Lloyd, *Pharmaceutical Research* **14** (1997)

"Microprocessor-Assisted Lung Delivery: Control of Compliance for Optimum Local and Systemic Therapy", I. Gonda, M. Cousins, S. Farr, P. Lloyd, J. Lloyd, L. Mather, J. Okikawa, R. Rubsamen, J. Schuster, G. Taylor, E. Ward, and S. Warren, *Proceedings of the International Symposium on the Controlled Release of Bioactive Materials* **23** (1996)

"AERx- Development of a Novel Liquid Aerosol Delivery System: Concept to Clinic", S. Farr, J. Schuster, P. Lloyd, J. Lloyd, Jerry Okikawa, and R. Rubsamen, *Respiratory Drug Delivery V*, Interpharm Press, Buffalo Grove (1996)

"A Simple Test for Non-Gaussianity in CMBR Measurements", Paul Graham, Neil Turok, P. M. Lubin, and J. Schuster, *Astrophysical Journal* **449**, no. 2 (1995)

"Constraining Theories of Galaxy Formation using the Cosmic Background Radiation", J. Schuster, *Center for Particle Astrophysics Newsletter* (Sept-Oct 1993)

"UCSB HEMT-ACME South Pole 1990-1991 Results", J. Schuster, T. Gaier, J. Gundersen, P. Meinhold, T. Koch, M. Seiffert, C. Wuensche, and P. Lubin, *Annals for the 16th Texas Symposium/ 3rd Symposium on Particles, Strings, and Cosmology* (1993)

"Cosmic Background Radiation Anisotropy at Degree Angular Scales: Further Results from the South Pole", J. Schuster, T. Gaier, J. Gundersen, T. Koch, M. Seiffert, P. Meinhold, C. Wuensche, P. Lubin, *Astrophysical Journal* **412** (1993)

"The Advanced Cosmic Microwave Explorer: A Millimeter-Wave Telescope and Stabilized Platform", P. Meinhold, A. Chingcuanco, J. Gundersen, J. Schuster, M. Seiffert, P. Lubin, D. Morris, and T. Villela, *Astrophysical Journal* **406** (1993)

"University of California at Santa Barbara Anisotropy Program- Degree Scale Results from the South Pole 1990-1991", T. Gaier, J. Schuster, J. Gundersen, P. Meinhold and P. Lubin, *Proceedings of the National Academy of Sciences of the United States of America* **90**, no. 11 (1993)

"A Degree Scale Measurement of the Anisotropy of the Cosmic Background Radiation", T. Gaier, J. Schuster, J. Gundersen, T. Koch, M. Seiffert, P. Meinhold, and P. Lubin, *Astrophysical Journal* **398** (1992)

"The Cosmic Background Radiation Anisotropy Program At UCSB", P. Meinhold, T. Gaier, J. Gundersen, T. Koch, J. Schuster, M. Seiffert, P. Lubin, *Trends in Astroparticle Physics*, UCLA (1990)

"Cosmic Background Anisotropy Measurement at Ten Degrees", T. Gaier, J. Schuster, P. Lubin, *Antarctic Journal of the United States* **24**, no. 5 (1990)

PRESENTATIONS

"Development of a Disposable, Pre-filled, Needle-free Injection Product" *APSTJ 31st Conference on Pharmaceutical Technology*, Hamamatsu, Japan, 14 July 2006

"Utilizing Mechanical and Nano-Technology Approaches to Optimize Bolus Liquid Aerosol Delivery from AERx®" *International Society for Aerosols in Medicine 15th International Congress*; Perth, Australia; 15 March 2005.
Chair of "Future Directions in Delivery Systems" Session, 18 March 2005.

"The Automated Inhaler: Why are First Generation Designs Still Dominating the Clinic?" *Portable Inhalers 12th Annual Conference*; London, England; 13 December 2004.

"Aerosol Inhalation Technologies for Mass Vaccinations" *The Aerosol Society, Drug Delivery to the Lungs XV*; London, England; 9 December 2004.

"Moving Towards Smaller and More Cost Effective Aqueous Inhalers" *Aqueous Droplet Inhalers*; London, UK; 21 October 2003

"Emerging Technologies for Aerosol Drug Delivery" *Inhalation Drug Delivery: An International Symposium*; Princeton, NJ; 3 December 2002

"The Next Ten Years" *Portable Inhalers 10th Annual Conference*; London, England; 28 January 2002.

Keynote Address:

"New AERx In-Vivo Results" *International Society for Aerosols in Medicine 13th International Congress*; Interlaken, Switzerland; 21 September 2001

"Dose Titration with the AERx System" *The Aerosol Society, Drug Delivery to the Lungs XI*; London, England; December 2000.

Chair of "Lung Deposition" Session

"Developing system for aerosol drug delivery that are independent of ambient conditions." *The Aerosol Society, Drug Delivery to the Lungs X*; London, England; December 1999

"Pulmonary Delivery of Biopharmaceuticals" *Western Regional Meeting, American Association of Pharmaceutical Scientists*; San Diego, California; April 1999

"A Monte Carlo Simulation of Cascade Impaction Data in the Size Range Relevant to Pharmaceutical Aerosols" *Annual Meeting, American Association of Aerosol Research*; Cincinnati, Ohio; June 1998

"Design and Performance Validation of a Highly Efficient and Reproducible Compact Aerosol Delivery System: AERxTM" *Respiratory Drug Delivery VI*; Hilton Head, South Carolina; May 1998

The AERxTM Aqueous Aerosol Delivery System, *The Aerosol Society, Drug Delivery to the Lungs VIII*; London, England; December 1997

"What Does it take to Deliver Biologicals to the Lung Efficiently and Reproducibly?" *IBC Eighth Annual Conference on Asthma & Allergy*; Boston, Massachusetts; November 1998

"A Factorial Study of the AERxTM System" *Annual Meeting, American Association of Aerosol Research*; Denver, Colorado; October 1997

"The AERxTM Approach for Improving Pulmonary Drug Delivery" *Nasal and Pulmonary Drug Delivery V*; Stockholm, Sweden; September 1997

"In-Vitro, In-Vivo, and Theoretical Delivery from a Unit Dose Aerosol Drug Delivery System", *Annual Meeting, American Association of Aerosol Research*; Orlando, Florida; October, 1996

"AERxTM, a Novel, Breath Actuated, Unit Dose, Small Volume nebulizer", *International Society for Aerosols in Medicine, Focus Symposium, Aerosol Therapy with Small Volume Nebulizers: Laboratory to Bedside*; Tours, France; September 1996

"Metering of Reproducible Doses of Aerosols to the Lung", *1996 Conference on Pharmaceutical Science and Technology*; Chicago, Illinois; August, 1996

"AER_xTM- A Unit Dose, Breath Actuated Aerosol Drug Delivery System", *Western Regional Meeting, American Association of Pharmaceutical Scientists*; South San Francisco, California; March, 1996

Award- Best Podium Presentation

"Concepts Important to the Respiratory Delivery of Aqueous Aerosols", *1995 Conference on Pharmaceutical Science and Technology*; Chicago, Illinois; August, 1995

"Sizing of Medical Aerosols- a Comparison of Data from the Andersen Cascade Impactor, the Aerometrics Phase Doppler Particle Sizer, and the Aradigm Direct Optical Particle Sizing Instrument", *26th Annual Meeting of the Fine Particle Society*; Chicago, Illinois; August, 1995

"Cosmic Background Radiation Anisotropy at 1.5°", *American Astronomical Society 182nd Annual Meeting*; Berkeley, California; June, 1993

"Cosmic Background Anisotropy at 1.5 Degrees: Results from the South Pole", *Los Alamos Astrophysics Colloquium*; Los Alamos, New Mexico; April, 1993

"The Most Sensitive Measurement to Date of CBR Anisotropy", *Brown University Astrophysics Colloquium*; Providence, Rhode Island; February, 1993

"UCSB HEMT-ACME: South Pole Results", *16th Texas Symposium/ 3rd Symposium on Particles, Strings, and Cosmology*; Berkeley, California; December, 1992

"Cosmic Background Radiation Measurements from the South Pole", *Lawrence Berkeley Laboratory Conference on the Cosmic Background Radiation*; Berkeley, California; December, 1992