

# EXHIBIT A

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

SHENZHEN HAPPY VAPING TECHNOLOGY  
LTD.,

Plaintiff,

v.

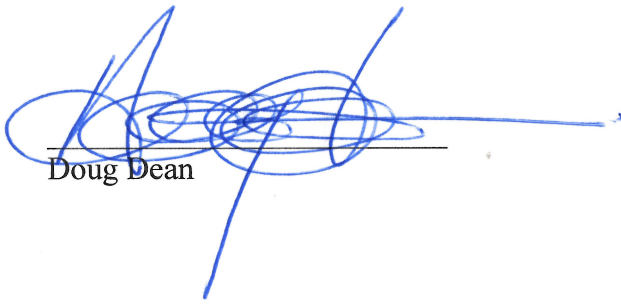
LOGIC TECHNOLOGY DEVELOPMENT LLC,  
and JAPAN TOBACCO INTERNATIONAL  
U.S.A., INC.,

Defendants.

Case No. 22-CV-61407-SMITH

**DECLARATION OF DR. DOUG DEAN IN SUPPORT OF  
DEFENDANTS' CLAIM CONSTRUCTION**

Date: 2023.08.28

  
Doug Dean

I, Doug Dean, declare as follows:

1. I have been retained by counsel for Defendants to provide opinions in this matter regarding the disputed claim terms of U.S. Patent Nos. 9,924,744 (“the ’744 Patent”).

2. I submit this Declaration in support of Defendants’ Claim Construction positions to provide relevant technical background and to explain how a person of ordinary skill in the art (“POSITA”) would understand certain of the disputed claim terms.

3. This declaration is based on information currently available to me, and I am able to testify on the topics addressed in this Declaration. I understand this case is ongoing and I may supplement or amend my opinions based on further information or analysis as I continue my review of documents and information that may later be provided to me.

4. I am being compensated at a rate of \$550 per hour for my work on this matter. My compensation is unrelated to the content of my opinions or testimony and is not based on the outcome of any part of this investigation. I have no interest, financial or otherwise, in the outcome of any litigations between the Parties.

## **I. QUALIFICATIONS**

5. I received my Bachelor of Applied Science in Engineering Physics (specialty, fluid dynamics) from The University of British Columbia, Canada in 1978. I then received my PhD in Electrical Engineering (specialty, biomedical) from The University of British Columbia, Canada in 1985.

6. Since 2021 I have been a co-founder and Director of Engineering at Predictably Human (“PH”). PH was formed to develop advanced precision aerosol drug delivery systems for narrow therapeutic index active ingredients. The therapeutic indications on which the company focuses are related to psychiatric conditions, and substance abuse. In particular, PH is developing Precision Medicine-based systems for treatment of nicotine addiction from e-cigarette vaping

systems and lit-end cigarettes. As Director of Engineering, I am leading the development of advanced aerosolization technologies and devices for the delivery of nicotine-containing aerosols.

7. For the past 30 years of my career, I have been involved in research, development and product engineering for both healthcare and tobacco products that are regulated in the USA by the Food and Drug Administration, and in other countries around the world by similar regulatory agencies. My focus has been on the systems engineering of electronics, integrated circuits, power systems, drug delivery systems, precision monitoring sensors, and real-world data acquisition systems for healthcare applications. I have multiple patents related to medical device technologies, and to the management of risk and quality in complex production environments.

8. From 2014-2021, I acted as an independent consultant providing expertise to tobacco companies and vaping product developers on the topic of nicotine-containing aerosol creation, battery technologies, the design of hand-held devices, and the creation of nicotine liquid blends. I have consulted for Philip Morris International, British American Tobacco, RJ Reynolds, and Japan Tobacco International. I was interviewed extensively by a New York Times journalist on the topic of the evolution of the e-cigarette and vaping market in the US that began in the late 1990s.

9. From 2006-2014, I was the Senior Vice President of Global Research and Development for Philip Morris International. I led the creation of an R&D organization that had the capability to develop next-generation reduced risk tobacco products using processes and quality systems that were appropriate for creation of reduced-risk products, and the accompanying mandatory minimum scientific data, assessments and human clinical trial dossiers that were required by the regulatory agency, the US FDA.

10. From 1986-2006, I held a variety of senior roles in companies that provided

services related to new product development and new product introduction, to medical device, biopharmaceutical, and pharmaceutical manufacturers. I was variously a Vice President at IBM, a Senior Partner at PriceWaterhouseCoopers Consulting, and a Director at Rockwell International and Digital Equipment Corporation. In these roles I led service teams supporting clients with the design and development of new and innovative healthcare products, and with the creation of FDA submission dossiers associated with the approval and registration of these products. During this time I was invited by FDA to participate as a member of several advisory boards that were supporting the Agency as it implemented a new regulatory approach to ensuring the quality and safety of healthcare products.

11. From 1981 through 1986, I was a researcher at a Medical Engineering Resource Unit focused on development of new technologies for non-invasive optical sensing methods for biomechanics and prostheses. These technologies enabled new diagnostic and therapeutic regimes for treatment of spinal-cord pathologies such as lordosis, scoliosis, and kyphosis.

12. I currently am, or have been a Member of the Aerosol Society, a Member of FDA's PAT Advisory Committee to the Office of Pharmaceutical Science, a Member of the Parenteral Drug Association, a Member of the International Society of Pharmaceutical Engineers, a Member of the Institute of Electrical and Electronics Engineers ("IEEE"), a Member of the New York Academy of Sciences, a member of the Canadian Society of Theoretical Biologists, and a Member of the American Mathematical Society.

13. I have been a member of the IEEE, and its Biomedical Engineering Society since 1980, and have multiple peer-reviewed publications in the IEEE Biomedical Engineering Society Transactions. The IEEE is the world's largest association of technical professionals whose objectives include the educational and technical advancement of biomedical, and electrical and

electronic engineering and related disciplines.

14. I have written 118 publications for peer-reviewed journals around the world, including the US, Canada, the UK, Germany, and Japan. On multiple occasions I have been invited to submit academic papers and publications to a variety of prestigious journals. I am the author of two book chapters on orthopedics and neurology/implantable electronic medical devices.

15. Attached as Appendix A is my curriculum vitae, which includes a more detailed statement of my professional qualifications, including education, publications, honors and awards, professional activities, consulting engagements, and other relevant experience. My biography is also attached as Appendix B

## **II. MATERIALS CONSIDERED AND RELIED UPON**

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

- a. The '744 Patent;
- b. The prosecution history of the '744 Patent;
- c. The Parties' Proposed Claim Constructions;
- d. The Parties' Disclosure of Extrinsic Evidence;
- e. The Parties' Proposed *Markman* Exhibits.

17. I have also relied on my technical experience and knowledge, as described above and in my curriculum vitae attached as Appendix A and biography attached as Appendix B.

## **III. SUMMARY OF OPINIONS**

18. It is my opinion that Claims 1 and 2, and all claims depending from Claims 1 and 2, are invalid because multiple terms cannot be understood with reasonable certainty in light of at least the claims, specification, or prosecution history from the perspective of a POSITA and are therefore indefinite.

19. Specifically, Claims 1, 2, and 5 of the '744 Patent include indefinite terms or

depend from indefinite terms and thus are invalid as indefinite because a POSITA cannot understand with reasonable certainty the meaning and scope of the following terms:

| Phrase Requiring Construction                                                                                                                                                                                                                                                                                                         | My Opinion                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| <b>Claim 1</b>                                                                                                                                                                                                                                                                                                                        |                                |
| “the first connection seat has a step-like shape”                                                                                                                                                                                                                                                                                     | Indefinite as discussed below. |
| “one side of the protruding step is provided with a first cylindrical wall having an outer diameter smaller than that of the protruding step”<br><br>“the other side of the protruding step is provided with a second cylindrical wall having an outer diameter smaller than that of the protruding step and having the outer thread” | Indefinite as discussed below. |
| “the central through hole is configured for installing the first positive electrode and the first insulation sleeve”                                                                                                                                                                                                                  | Indefinite as discussed below. |
| <b>Claim 2</b>                                                                                                                                                                                                                                                                                                                        |                                |
| “an inner wall at a lower portion of the second connection seat is provided with a base wall”                                                                                                                                                                                                                                         | Indefinite as discussed below. |
| “the tubular body is provided with a central through hole for installing the second insulation sleeve and the second positive electrode.”                                                                                                                                                                                             | Indefinite as discussed below. |

#### IV. LEGAL UNDERSTANDING

20. I am not a legal expert and offer no opinions on the law or legal standards. Defendants’ counsel has provided me with the following understanding of legal concepts which I understand are relevant to my analysis and opinion in this declaration.

**A. Priority Date**

21. I understand the priority date is the earliest filing date for any related patent applications so long as there has been no break in the priority. I further understand this date is considered the date of the invention claimed.

22. I understand an analysis of the priority date is ongoing and will therefore presume June 25, 2014 is the priority date for the '744 Patent only for purposes of this declaration.

**B. Claim Construction**

23. I understand terms of a patent claim should generally be given their ordinary and customary meaning as understood by a POSITA at the patent's priority date.

24. I understand the claims of a patent, *i.e.*, the numbered paragraphs at the end of a patent, set out specifically what the inventors claim to have invented. I understand that the claims can either be independent or dependent. I understand an independent claim contains all the limitations or elements to practice that claim, without making reference to another claim in the patent. I also understand a dependent claim refers to another claim, adding additional limitation(s) or element(s) to the referenced claim.

25. I understand the written description of the invention found before the numbered claims is referred to as the "specification." I understand the specification, along with the remainder of the patent (*i.e.*, the abstract and figures), provides context and information about the claimed invention. I understand this information may include express definitions of certain terms used in the claims to explain the claimed invention. I understand an inventor may act as their own "lexicographer" when they define a claim term, which in turn informs the POSITA's understanding of the claimed invention.

26. I understand the patent application and related correspondences with the USPTO are commonly referred to as the prosecution history of the patent. I understand the statements made

and the positions memorialized in the prosecution history may explain the claim terms and the scope of the claimed invention. I further understand the prosecution history informs the POSITA's understanding of the claimed invention by memorializing the applicant's and examiner's views of the claim terms at or closer to the time of the invention. I understand in certain circumstances, comments made or actions taken during prosecution of an application may narrow the scope of the claims.

27. I understand claims must be construed in light of and consistent with the intrinsic evidence, which includes the issued patent (*i.e.*, the claims themselves, the figures, and the written disclosure in the specification) and the patent's prosecution history, including prior art considered by the USPTO in the course of prosecution of the patent application.

28. I understand that extrinsic evidence may also be considered when construing claims and may include, for example, technical dictionaries, technical publications and books, treatises, and expert testimony. I understand such extrinsic evidence should relate to information known at or before the time of the application to ensure it provides relevant information.

### **C. Indefiniteness**

29. I understand that under the patent laws, 35 U.S.C. § 112(b), there is a "definiteness" requirement that states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."

30. I understand that a claim is indefinite, *i.e.*, fails to satisfy the definiteness requirement, if it fails to inform a POSITA about the scope of the invention with reasonable certainty. I further understand the claim should be read in light of the patent's specification and prosecution history to determine whether a claim's scope is understandable.

**D. Level of Skill in the Art**

31. I understand the POSITA is a hypothetical person with ordinary capability and skill of the underlying technical principles applicable to the pertinent art at the time of the priority date of the patent. A POSITA is presumed to be one who thinks along the lines of conventional wisdom in the art and is not one who undertakes to innovate. I understand that the POSITA is presumed to have knowledge of all references that are sufficiently related to one another and to the pertinent art, and to have knowledge of all arts reasonably pertinent to the particular problem that the claimed invention addresses. I understand that the POSITA also is presumed to have an understanding of the terms of the art at the time of the invention (*i.e.*, the priority date).

32. I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the type of problems encountered in the art, prior art solutions to those problems, the speed with which innovations are made in the field, the sophistication of the technology, and the educational level of active workers in the field. I understand these factors should be analyzed at the time of the invention. I also understand that not every factor may be present and that one or more factors may predominate.

33. Based on the criteria explained to me, it is my opinion that a POSITA at the time of the alleged invention of the '744 Patent (*i.e.*, on or about the priority date of June 25, 2014) would have had a bachelor's or graduate degree in electrical engineering, physics or mechanical engineering with course work in biomedical devices, and at least two years of industry experience working with electronic cigarettes or electronic aerosol-based drug delivery systems.

34. As of 2014, my experience and expertise exceeded this level of ordinary skill in the art, as explained above and in Appendix A.

**V. THE '744 PATENT**

35. The '744 Patent, filed on June 25, 2014 as CN201420341430 and issued on March

27, 2018, is titled “Electronic Cigarette Having Three Connection Portions.”

36. I understand Plaintiff has asserted independent Claim 1 and dependent Claims 2 and 5 of the ’744 Patent (jointly, “the Asserted Claims”).

37. Claim 1 reads:

1. An electronic cigarette comprising a battery stick, a vaporizer assembly and a mouth piece that are connected together, characterized in that

the battery stick comprises a battery, a casing tube of the battery stick for sheathing the battery, and a first connection portion arranged at an end of the casing tube of the battery stick adjacent to the vaporizer assembly;

the vaporizer assembly comprises a vaporizer, and a casing tube of the vaporizer for sheathing the vaporizer in an inner cavity of the casing tube;

the vaporizer comprises a vaporizer tube body, and a second connection portion arranged at an end of the vaporizer tube body adjacent to the battery stick;

a third connection portion is arranged at an end of the casing tube of the vaporizer adjacent to the battery stick;

the second connection portion and the first connection portion abut against each other to be connected, the third connection portion is detachably connected to the first connection portion by means of a screw thread;

the first connection portion comprises a first connection seat having an outer thread and serving as a negative electrode electrically connected to a negative electrode of the battery, a first positive electrode arranged at a center of the first connection seat and electrically connected to a positive electrode of the battery, and a first insulation sleeve placed between the first positive electrode and the first connection seat;

the second connection portion comprises a second connection seat serving as a negative electrode electrically connected to a heating coil of the vaporizer, a second positive electrode arranged at a center of the second connection seat and electrically connected to the heating coil of the vaporizer, and a second insulation sleeve placed

between the second positive electrode and the second connection seat;

the second positive electrode has a central through hole along an axial direction of the second positive electrode for intercommunicating with a vaporizing cavity of the vaporizer, an end surface of the second positive electrode has a transversal groove along a radial direction of the end surface for intercommunicating with the central through hole;

the third connection portion has an inner thread engaging with the outer thread of the first connection seat;

the first positive electrode and the second positive electrode abut against each other to be electrically connected, the first connection seat and the second connection seat are electrically connected;

the first connection seat has a step-like shape, a protruding step is formed at a middle portion of the first connection seat that has a maximum outer diameter;

one side of the protruding step is provided with a first cylindrical wall having an outer diameter smaller than that of the protruding step, the first cylindrical wall is sheathed with an inner wall of said end of the casing tube of the battery stick, the outer diameter of the protruding step equals an outer diameter of the casing tube of the battery stick;

the other side of the protruding step is provided with a second cylindrical wall having an outer diameter smaller than that of the protruding step and having the outer thread, one end of the second cylindrical wall is provided with a base wall having a central through hole, the central through hole is configured for installing the first positive electrode and the first insulation sleeve.

38. Claim 2 depends from Claim 1 and reads:

The electronic cigarette according to claim 1, characterized in that the second connection seat is a cylindrical body having a protruding platform at one end thereof;

an outer wall of the cylindrical body is sheathed with an inner wall of said end of the vaporizer tube body;

an inner wall at a lower portion of the second connection seat is provided with a base wall, a tubular body is protruded from a center

of the base wall, the tubular body is provided with a central through hole for installing the second insulation sleeve and the second positive electrode.

39. Claim 5 further depends from Claim 2 and reads:

5. The electronic cigarette according to claim 2, characterized in that the outer wall of the cylindrical body is provided with a circular groove configured for mounting a sealing ring.

40. I have also reviewed the specification of the '744 Patent. It is my understanding that this specification contains little to no explanation of the invention beyond the exact language of the claims, as further described below.

41. I have also been provided with the prosecution history of the '744 Patent and reviewed the relevant parts.

42. Of particular relevance, the Examiner issued a non-final rejection on September 26, 2017 rejecting claims as anticipated by prior art and stating what is now Claim 1 was allowable only by including the portion underlined above. ((SHV000065-66.)

**A. Indefinite Claim Terms**

**1. “step-like shape” in the phrase “the first connection seat has a step-like shape”**

43. Claim 1 of the '744 Patent and all claims depending from Claim 1 are indefinite at least because the term “step-like shape” cannot be understood with any reasonable certainty.

44. The term “step-like shape” is not explained anywhere in the specification and is not explained in any respect in the prosecution history.

45. There is no reasonable way for a POSITA to understand the scope of a “step-like shape” from the intrinsic evidence.

46. None of the claims that use the term “step-like shape” provide any clarity to a POSITA as to the scope of “step-like shape,” only that this is a shape associated with the first

connection seat.

47. The term “step-like shape” appears seven times in the ’744 Patent, always as follows:

the first connection seat has a step-like shape, a protruding step is formed at a middle portion of the first connection seat that has a maximum outer diameter

(’744 Patent, 2:11-14, 2:51-54, 5:27-30, Claims 1, 3, 7, and 9.)

48. In only one recitation of “step-like shape” is any further information provided, though this information simply relates to certain reference numerals:

Referring to FIGS. 2 and 4, the first connection seat 11 has a step-like shape, a protruding step 111 is formed at a middle portion of the first connection seat 11 that has a maximum outer diameter.

(’744 Patent, 5:27-30.)

49. The referenced figures 2 and 4 are reproduced herein:

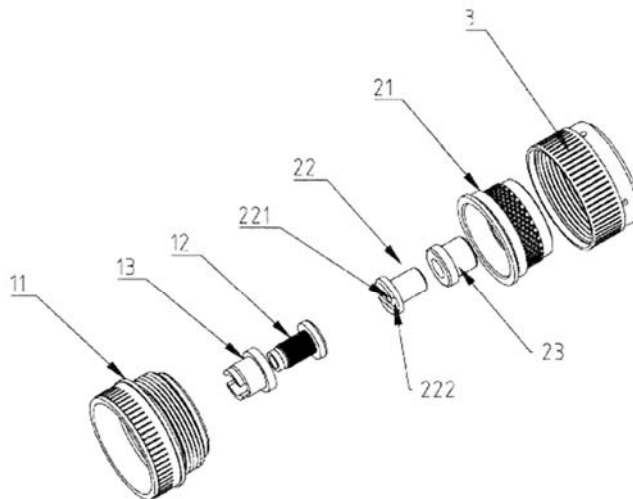


Figure 2

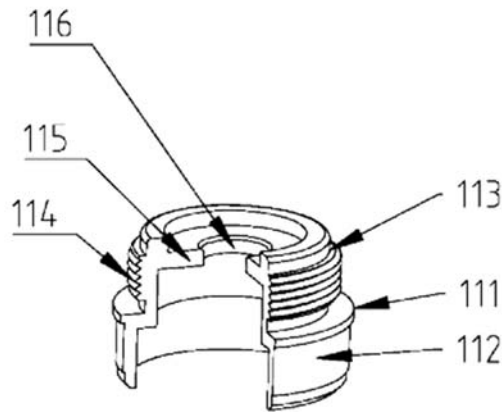


Figure 4

50. Neither figure provides any explanation for the meaning of the term “step-like shape” in the ’744 Patent.

51. None of these uses of “step-like shape” provide any explanation or understanding of what a “step-like shape” would be aside from it being associated with a first connection seat. This is insufficient because the term is broad and cannot be reasonably understood, such as by providing any indication of how much “like” a step a shape must be in order to meet the limitation.

52. As a POSITA, I cannot understand with reasonable certainty what is meant by “step-like shape.” For example, I am unable to determine whether a ramped or curved configuration would be considered sufficiently step-like to fall within the claim.

53. As a POSITA, I also cannot determine the difference between a “step-like shape” and the separately recited “protruding step” that follows it in the claim language. There is also no recited association between these terms in the claims other than their relationship to the first connection seat.

54. I have also been provided the prosecution history and noted that the Examiner, during the prosecution of the ’744 Patent, required the inclusion of the “step-like shape” in independent Claim 1, among other terms noted above, before allowing the patent to issue.

(SHV000065.)

55. In view of the specification and the prosecution history, it is my opinion that a POSITA would not be able to understand the scope of “step-like shape” from the claims, specification, or prosecution history of the ’744 Patent.

**2. “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” in the phrases “one side of the protruding step is provided with a first cylindrical wall having an outer diameter smaller than that of the protruding step” and “the other side of the protruding step is provided with a second cylindrical wall having an outer diameter smaller than that of the protruding step and having the outer thread”**

56. Claim 1 of the ’744 Patent and all claims depending from Claim 1 are indefinite at least because the term “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” in the limitations “one side of the protruding step is provided with a first cylindrical wall having an outer diameter smaller than that of the protruding step” and “the other side of the protruding step is provided with a second cylindrical wall having an outer diameter smaller than that of the protruding step and having the outer thread” cannot be understood with any reasonable certainty.

57. The term “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” is not explained anywhere in the specification and is not explained in any respect in the prosecution history.

58. There is no reasonable way for a POSITA to understand the scope of “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” from the intrinsic evidence.

59. None of these claims that use the term “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” provide any clarity to a POSITA as to the scope of “protruding step is provided with a ... cylindrical wall

having an outer diameter smaller than that of the protruding step,” only that there is a protruding step and two cylindrical walls provided with the protruding step.

60. The language of Claim 1 previously recites that “a protruding step is formed at a middle portion of the first connection seat that has a maximum outer diameter,” and then refers to the “maximum outer diameter” of the protruding step using the language “that of the protruding step” or “the outer diameter of the protruding step.” The language of Claim 1 also recites that “the outer diameter of the protruding step equals an outer diameter of the casing tube of the battery stick.” A POSITA would understand this to mean that the protruding step has one value for its outer diameter, which is referred to previously as a maximum outer diameter. However, none of these claims that use the term “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” provide any clarity to a POSITA as to how any wall with a diameter smaller than the single value outer diameter of the protruding step could be provided with that protruding step. This is a direct contradiction to the definition of the outer diameter of the protruding step explicitly laid out in the claim language.

61. The term “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” appears ten times in the '744 Patent, always as follows:

one side of the protruding step is provided with a first cylindrical wall having an outer diameter smaller than that of the protruding step, the first cylindrical wall is sheathed with an inner wall of said end of the casing tube of the battery stick, the outer diameter of the protruding step equals an outer diameter of the casing tube of the battery stick;

('744 Patent, 2:14-20, 2:54-60, 5:30-36, Claims 1, 3, 7, and 9); or

the other side of the protruding step is provided with a second cylindrical wall having an outer diameter smaller than that of the protruding step and having the outer thread, one end of the second cylindrical wall is provided with a base wall having a central through

hole, the central through hole is configured for installing the first positive electrode and the first insulation sleeve.

('744 Patent, 2:20-25, 5:36-43, Claim 1).

62. In only the following recitation of these phrases is any further information provided, though this information simply relates to certain reference numerals:

Referring to FIGS. 2 and 4, the first connection seat 11 has a step-like shape, a protruding step 111 is formed at a middle portion of the first connection seat 11 that has a maximum outer diameter. One side of the protruding step 111 is provided with a first cylindrical wall 112 having an outer diameter smaller than that of the protruding step 111, the first cylindrical wall 112 is sheathed with an inner wall of said end of the casing tube 101 of the battery stick 10, the outer diameter of the protruding step 111 equals an outer diameter of the casing tube 101 of the battery stick 10. The other side of the protruding step 111 is provided with a second cylindrical wall 113 having an outer diameter smaller than that of the protruding step 111 and having the outer thread 114, one end of the second cylindrical wall 113 is provided with a base wall 115 having a central through hole 116, the central through hole 116 is configured for installing the first positive electrode 12 and the first insulation sleeve 13.

('744 Patent, 5:27-43.)

63. The referenced figures 2 and 4 are reproduced herein:

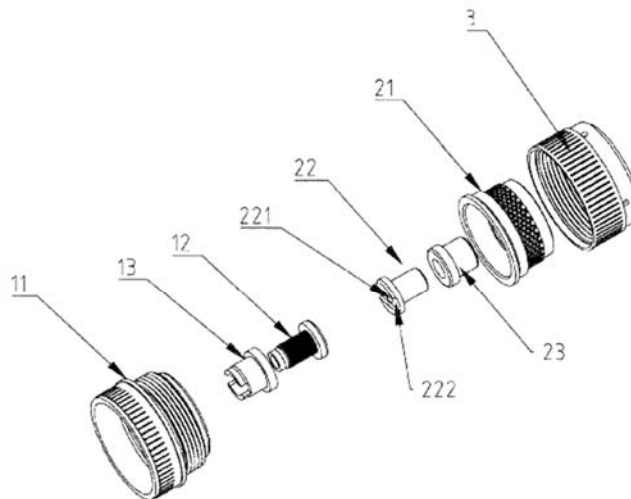


Figure 2

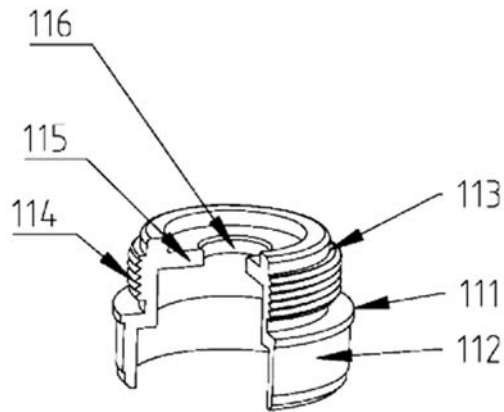


Figure 4

64. These figures do not provide any explanation for the meaning of the term in the '744 Patent. They do, however, confirm my understanding as a POSITA that the protruding step has a single value for its outer diameter, insofar as protruding step 111 appears in the figures to have such a single value.

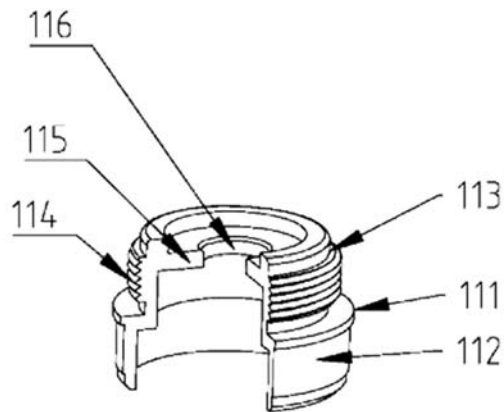


Figure 4

65. None of these uses of “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” provide any explanation or understanding of what a “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” would be aside that there is a protruding step

and two walls provided with a protruding step, but not how a wall with a smaller outer diameter than the single value outer diameter of the protruding step could be provided with that protruding step, due to the protruding step's already assigned outer diameter. This is insufficient because the term is inoperable and cannot be reasonably understood.

66. As a POSITA, I cannot understand with reasonable certainty what is meant by “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step.”

67. I have also been provided the prosecution history and noted that the Examiner, during the prosecution of the '744 Patent, required the inclusion of the two instances of “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” in independent Claim 1, among other terms noted above, before allowing the patent to issue. (SHV000065.)

68. In view of the specification and the prosecution history, it is my opinion that a POSITA would not be able to understand the scope of “protruding step is provided with a ... cylindrical wall having an outer diameter smaller than that of the protruding step” from the claims, specification, or prosecution history of the '744 Patent.

**3. “configured for installing” and “for installing” in the phrases “the central through hole is configured for installing the first positive electrode and the first insulation sleeve” and “a central through hole for installing the second insulation sleeve and the second positive electrode”**

69. Claims 1 and 2 of the '744 Patent and all claims depending from Claims 1 and 2 are indefinite at least because the terms “configured for installing” and “for installing” cannot be understood with any reasonable certainty.

70. The terms “configured for installing” and “for installing” are not explained anywhere in the specification and is not explained in any respect in the prosecution history.

71. There is no reasonable way for a POSITA to understand the scope of “configured for installing” and “for installing” from the intrinsic evidence.

72. None of these claims that use the terms “configured for installing” and “for installing” provide any clarity to a POSITA as to the scope of “configured for installing” and “for installing,” only that a central through hole is provided, but without any indication of how it could be configured for installing.

73. The term “installing” appears eleven times in the ’744 Patent, always as follows:

the central through hole is configured for installing the first positive electrode and the first insulation sleeve.

(’744 Patent, 2:24-26, 3:5-7, 5:41-43, 6:24-26, Claims 1, 3, 7, and 9); or

the tubular body is provided with a central through hole for installing the second insulation sleeve and the second positive electrode.

(’744 Patent, 2:33-35, 5:51-53, Claim 2.)

74. In only three recitations of “installing” is any further information provided, though this information simply relates to certain reference numerals:

Referring to FIGS. 2 and 4...a central through hole 116 is configured for installing the first positive electrode 12 and the first insulation sleeve 13.

(’744 Patent, 5:41-43);

Referring to FIGS. 2 and 5...a tubular body 214 is provided with a central through hole 215 for-installing the second insulation sleeve 23 and the second positive electrode 22.

(’744 Patent, 5:51-53);

Referring to FIGS. 7, 8, and 9...the central through hole 116 is configured for installing the first positive electrode 12 and the first insulation sleeve 13.

(’744 Patent, 6:24-26.)

75. The referenced figures are reproduced herein:

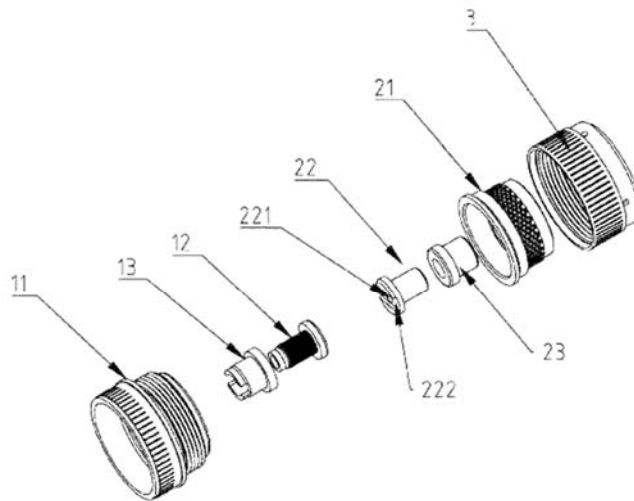


Figure 2

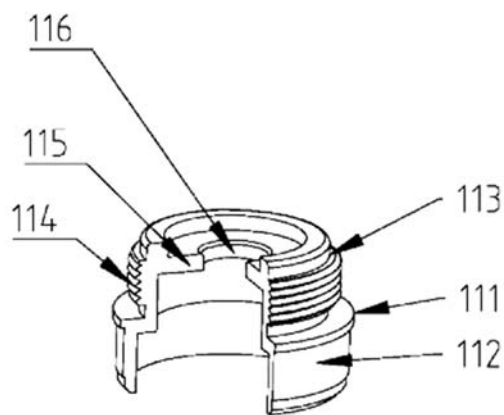


Figure 4

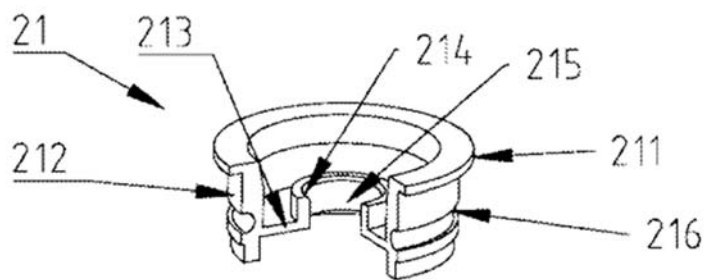


Figure 5

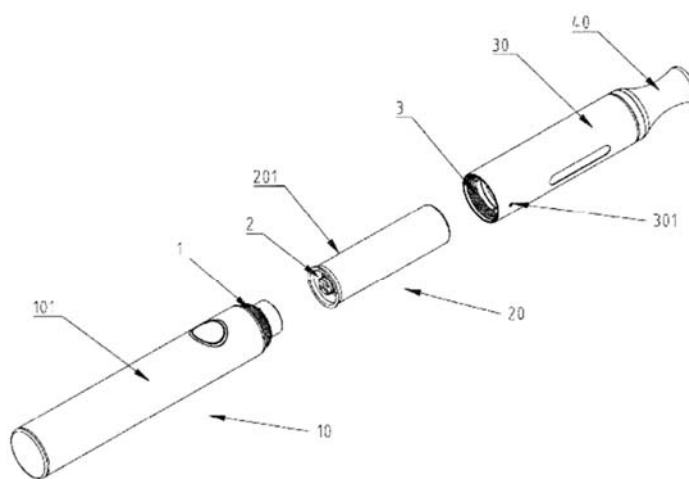


Figure 7

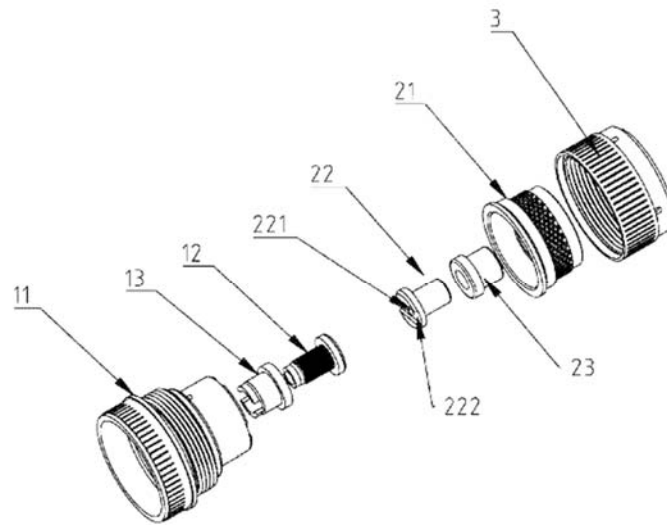


Figure 8

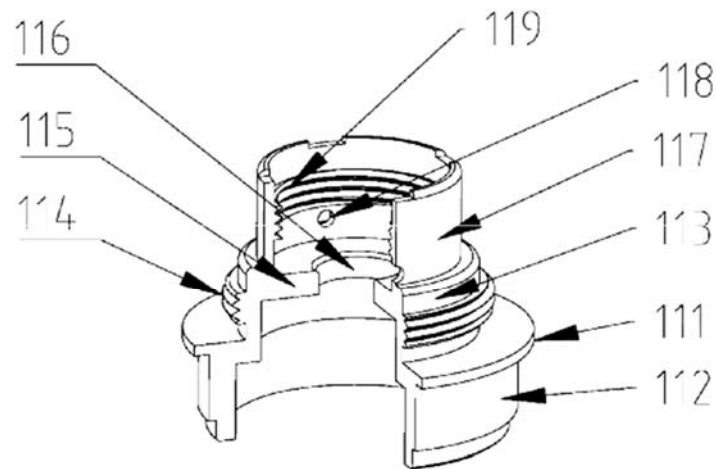


Figure 9

76. None of these figures provides any explanation for the meaning of the terms “configured for installing” or “for installing” in the’744 Patent.

77. None of these uses of “configured for installing” or “for installing” provide any explanation or understanding of what scope of configuration of the central through hole would be

needed “for installing” the indicated elements. This is insufficient because the terms are very broad and cannot be reasonably determined.

78. As a POSITA, I cannot understand with reasonable certainty what is meant by “configured for installing” or “for installing.” I am unable to determine how a central through hole could be so configured, who is doing the installing, when the installing occurs, or in what fashion. Nothing in the specification provides any further explanation or clarity. Indeed, the only instances in the figures in which a central through hole is shown are not in connection with any other elements that would provide an explanation or clarity.

79. Another basis for concluding that these phrases are indefinite and should be found invalid is that they appear to be method steps within an apparatus claim. The “for installing” language renders the phrase unclear such that the claim scope is similarly unclear. The claim language and the specification do not provide any discussion of the “installing” process. In particular, it is unclear how the process of “installing” the recited “first positive electrode” and the “first installation sleeve” within the recited “central through hole” is performed, how it is performed, or when it is performed. It is also unclear whether this limitation relates to the structure of the claimed electronic cigarette or whether it relates to a method of manufacturing it. Thus, Claim 1 is indefinite to a POSITA.

80. I have also been provided the prosecution history and noted that the Examiner, during the prosecution of the '744 Patent, required the inclusion of the “configured for installing” in independent Claim 1, among other terms noted above, before allowing the patent to issue. (SHV000065.)

81. In view of the specification and the prosecution history, it is my opinion that a POSITA would not be able to understand the scope of “configured for installing” or “for installing”

from the claims, specification, or prosecution history of the '744 Patent.

**4. “lower portion” in the phrase “an inner wall at a lower portion of the second connection seat is provided with a base wall”**

82. Claim 2 of the '744 Patent and all claims depending from Claim 2 are indefinite at least because the term “lower portion” cannot be understood with any reasonable certainty.

83. The term “lower portion” is not explained anywhere in the specification and is not explained in any respect in the prosecution history.

84. There is no reasonable way for a POSITA to understand the scope or orientation of a “lower portion” from the intrinsic evidence.

85. None of these claims that use the term “lower portion” provide any clarity to a POSITA as to the scope of “lower portion,” only that this is a portion associated with the second connection seat without any reference as to the orientation of said lower portion. In other words, there is no other relative term such as “higher” or “upper” that could even provide context for gauging the scope of the term “lower portion.”

86. The term “lower portion” appears only three times in the '744 Patent, always as follows:

an inner wall at a lower portion of the second connection seat is provided with a base wall...

('744 Patent, 2:30-32, 5:48-51, Claim 2.)

87. In only one recitation of “lower portion” is any further information provided, though this information simply relates to certain reference numerals:

Referring to FIGS. 2 and 5... An inner wall at a lower portion of the second connection seat 21 is provided with a base wall 213....

('744 Patent, 5:44-51.)

88. The referenced figures 2 and 5 are reproduced herein:

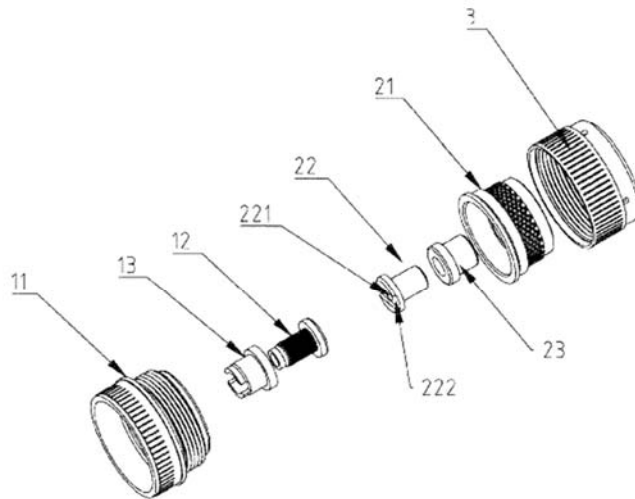


Figure 2

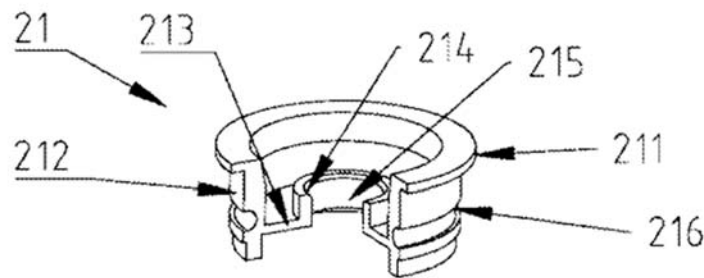


Figure 5

89. Neither figure provides any explanation for the meaning of the term “lower portion” in the ’744 Patent. While I recognize that in Figure 5 a base wall 213 appears to be in a lower half of a second connection seat 21, this is purely a matter of the orientation of the depicted embodiment on the page of the patent. Other orientations of the depicted embodiment are equally as likely such that the location of the base wall 213 would not be defined as a “lower portion.” For example, the embodiment depicted in Figure 5 could be viewed as upside down from the perspective of a user of the end device.

90. None of these uses of “lower portion” provide any explanation or understanding of

what a “lower portion” would be aside from it being associated with a first connection seat. This is insufficient because the term is broad and cannot be reasonably understood.

91. Further, nowhere in the specification are other relevant orienting terms such as up, upper, low, down, proximal, or distal used to allow a POSITA to comprehend the relative location of a “lower portion.”

92. As a POSITA, I cannot understand with reasonable certainty what is meant by “lower portion.” For example, I am unable to determine where a lower portion should be located in relation to other elements.

93. I have also been provided the prosecution history and noted that it does not provide any further explanation or understanding of “lower portion.”

94. In view of the specification and the prosecution history, it is my opinion that a POSITA would not be able to understand the scope of “lower portion” from the claims, specification, or prosecution history of the ’744 Patent.

# APPENDIX A

**Curriculum Vitae - Doug Dean**  
*Vogelsangweg 5a, 6390 Engelberg, Switzerland*  
*+41-79-321-5679 [doug.dean@mac.com](mailto:doug.dean@mac.com)*

A seasoned senior executive/biomedical engineer with over 30 years' experience in Fortune 100 companies in the health care and fast-moving consumer goods sectors. Substantial advisory experience with large multinationals in Asia Pacific, North America and Europe. A strong motivational leader with proven business and people-development capabilities.



**SKILLS**

- Strategic planning and growth.
- Leadership and communication.
- Implementation of radical transformations.
- Management of complex innovation environments.

**EXPERIENCE**

***Predictably Human***

*01.2021-present Co-Founder. Product Development & Regulatory Affairs*

Engineering and product development for a US medtech startup using aerosol drug delivery systems and advanced precision micro dosage technology in support of highly individualized therapies for narrow therapeutic index actives in treatment areas such as substance abuse, renal failure, and oncologic monoclonal antibodies.

***octane126 Ferrari Racing (Switzerland)***

*04.2009-present Client Driver*

***Okanagan Hockey Academy (Europe)***

*01.2015-12.2017 Assisting with the establishment of further European academies*

Working for the love of the game to support the oldest hockey school in Canada.

***Philip Morris International***

*07.2006-12.2014 Senior Vice President, Research & Development and Next Generation Products*

*Executive Officer of the Corporation (until 2012).*

*Strategic Advisor to SVP R&D (until 2014).*

With an annual budget of over \$400 million, led a group of 500 engineers and scientists to create reduced-harm next generation products. Architected, implemented and led a radical R&D transformation. Architected a regulatory strategy for reduced-harm tobacco products. Led acquisition of biotech companies to create a plant molecular farming capability to produce low-cost vaccines. Led development of reduced harm technologies for next generation tobacco products.

***IBM Business Consulting Services***

***(Until 09.2002 PricewaterhouseCoopers Consulting)***

*10.2002-06.2006 Life Sciences/Pharmaceuticals*

*Managing Partner / Vice President – led an international practice group of 1200.*

*Approximately one-hundred engagements with health care products manufacturers.*

***PricewaterhouseCoopers Consulting***

***(Until 06.1998 Coopers & Lybrand)***

*1994-09.2002 Global Pharmaceutical Practice*

*Partner - led an international practice group of 600.*

*Approximately four-hundred engagements with health care products manufacturers.*

*Member, FDA PAT Advisory Committee to the Office of Pharmaceutical Sciences.*

*In-camera advisor to the FDA Commissioner concerning quality by design (QBD).*

***Digital Equipment Corporation Europe***

*1991 - 1994 Process Manufacturing Solutions Business Development, Europe*

*Director*

*Delivered marketing programs for business development in the manufacturing sector.*

## ***Curriculum Vitae - Doug Dean***

*Vogelsangweg 5a, 6390 Engelberg, Switzerland  
+41-79-321-5679 doug.dean@mac.com*

### ***Rockwell International, Allen Bradley Group & Integrated Automation Systems***

*1986 - 1991 Process Manufacturing Centre of Excellence, Canada & United Kingdom  
Director of Research & Development / European Marketing  
Directed development of a suite of software and electronic automation products.*

### ***Shaughnessey Hospital Medical Engineering Research Unit, Canada***

*1981 - 1986 Research & Development  
Project Manager  
Led ground-breaking projects in orthopaedic surgery and prosthetic development.*

### ***HAL Devices Ltd, Canada***

*1975 - 1979 Co-Director  
Formed this company with a fellow engineering student to pay university tuition.  
Assembled kit-computers loaded with custom software for sale to retail pharmacies.*

## **BOARD & ADVISORY APPOINTMENTS**

*2009-2015 The International School of Basel, Switzerland  
International Baccalaureate private school with \$45.0 Mio turnover.*  
*2006-2012 FTR Holding SA, Neuchâtel, Switzerland  
Philip Morris holding company. \$8.5 Bio. revenue.*  
*2008-2012 Philip Morris International Research Laboratories Pte. Ltd., Singapore  
In-vitro research laboratory facility.*  
*2000-2005 PricewaterhouseCoopers & IBM Life Sciences Consulting  
International practice development and governance for an \$800 Mio practice.*

## **FORMAL EDUCATION**

- PhD 1985, The University of British Columbia, Canada, Electrical Engineering (Bioelectronics).
- BAsC 1978, The University of British Columbia, Canada, Engineering Physics (Fluid Dynamics).

## **PROFESSIONAL AFFILIATIONS**

- Former Member, FDA PAT Advisory Committee to the Office of Pharmaceutical Science.
- Associate Member, Parenteral Drug Association.
- Member, International Society of Pharmaceutical Engineers.
- Member, Institute of Electrical and Electronics Engineers.
- Member, New York Academy of Sciences.
- Member, Canadian Society of Theoretical Biologists.
- Member, American Mathematical Society.
- Member, The Aerosol Society.

## **PATENTS, PUBLICATIONS and INVITED PRESENTATIONS (details available)**

- US Patent: Method for Production Refactoring of a Producing Entity, Docket CH920040041US1.
- US Patent: Addiction Cessation Systems, Devices & Methods, Pub. No. US 2022/0256929 A1
- US Patent: Systems & Methods for Smoking Cessation II, Application 63/261,638.
- US Patent: Systems & Methods for Smoking Cessation III, Application 63/263,863.
- More than 100 publications, two book chapters on orthopaedics and neurology/implantable devices.

## **PERSONAL**

- Canadian citizen.
- Married to Fran.
- Myers-Briggs type "E-N-T-P".
- Active in mountaineering and extreme alpine climbing.
- Life-long fan of the Montréal Canadiens.
- Vices: single malt Islay whisky and cigars.
- Ferrarista.

## **LANGUAGES**

- English (native), German (fluent), French (basic)

# APPENDIX B

## Biography - Dr. Doug Dean



Doug is presently a co-founder of a US-based medtech startup developing precision medicine-based medical devices for delivery of narrow therapeutic index active ingredients.

During his 40 year professional career, Doug has lived and worked in Canada, England, Germany and since 1993 in Switzerland. He has been the Senior Vice President of Global Research & Development at Philip Morris International; Vice President Global Pharma-Sector Business Services at IBM; Senior Partner International Pharmaceutical Practice at PricewaterhouseCoopers; European Pharmaceutical Marketing Manager at the Digital Equipment Corporation; Director of R&D at Rockwell International (Dynapro Systems); and a Medical Researcher at the Shaughnessey Hospital Medical Engineering Resource Unit.

Whilst with PwC, Doug was invited to address the US Food & Drug Administration (FDA) Pharmaceutical Science Board on matters pertaining to industry productivity and the economics of regulatory compliance in pharmaceutical manufacturing. Subsequently, he was appointed to a special FDA Advisory Committee Task Force focused on regulatory aspects of Quality by Design. As part of this involvement, he was requested to provide a series of in-camera briefings to an incoming FDA Commissioner on Process Analytical Technologies, clinical trials supplies, and scale-up to commercial volumes.

At Philip Morris International, Doug was recruited to transform the R&D function and create the basis for development of reduced-risk “next-generation” tobacco products. He led the creation of a new R&D unit that was capable of developing and supporting the claims of next-generation products with solid science accepted by the wider independent scientific community. The achievement of independent scientific acceptance of research results from a tobacco company is, in itself, rather remarkable. This capability formed the basis for applications to FDA for US marketing approval as well as performance claims for a PMI modified risk tobacco product. FDA approved these applications, and subsequently issued a “Reduced Exposure Order” authorising PMI to market the iQOS system with scientifically supported statements of product performance.

Doug has a PhD in Electrical Engineering (Biomedical & Bioelectronics) and a Bachelor of Applied Science in Engineering Physics (Fluid Dynamics), both from the University of British Columbia, Canada. He is widely published with over 100 articles in the professional literature.

He is an active alpinist and mountaineer with ascents all over the world from the Arctic to the Himalaya. Doug and his wife, Fran, are passionate Ferraristas and they compete with octane126 in the Ferrari Club Challenge series on race-tracks in France, Germany, Czech Republic, Spain, Hungary, Belgium, the UK, and Italy. Doug supports the Montréal Canadiens and the New Zealand All Blacks; he enjoys cigars and whisky and occasionally ponders alternative approaches to proving the Riemann Hypothesis.