PUBLIC VERSION UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NJOY, LLC, NJOY HOLDINGS, INC., *Petitioners*,

v.

JUUL LABS, INC., Patent Owner

Case IPR2024-00223 U.S. Patent No. 10,709,173

DECLARATION OF DR. JOHN COLLINS IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

1. I have been retained on behalf of JUUL Labs, Inc. ("Patent Owner") in connection with the above-captioned *inter partes* review (IPR). I have been retained to provide my opinions in support of Patent Owner's Preliminary Response. I am being compensated for my time at the rate of \$450 per hour. I have no interest in the outcome of this proceeding.

2. In preparing this declaration, I have reviewed and am familiar with the Petition for IPR2024-00223, U.S. Patent No. 10,709,173 ("the '173 patent") and its file history, and all other materials cited and discussed in the Petition (including the declaration of Petitioner's expert William Singhose, Ph.D.), and cited and discussed in this Declaration.

3. The statements made herein are based upon my own knowledge and opinion. This Declaration represents only the opinions I have formed to date. I may consider additional documents as they become available or other documents that are necessary to form my opinions. I reserve the right to revise, supplement, or amend my opinions based on new information and on my continuing analysis.

I. <u>QUALIFICATIONS</u>

4. I have been employed since 2008 at the Consortia for Improving Medicine with Innovation and Technology ("CIMIT") and am currently the Director of Innovation Platforms. CIMIT is a non-profit consortium of Boston's leading teaching hospitals and universities along with a growing network of national and

international affiliates. CIMIT is an operating unit within Massachusetts General Hospital where I have a faculty appointment.

5. Much of my responsibility at CIMIT is to facilitate collaboration among scientists, engineers, clinicians, and entrepreneurs to speed the discovery, development, and implementation of medical innovations into practice. I focus on assisting investigators in moving technologies from the lab into products and services that improve patient care. My focus has been on developing and implementing CIMIT's CoLab and GAITS platforms.

6. By way of example of CIMIT's work, it was recently responsible for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) sponsored RADx Tech program. The program has committed more than \$1.5 Bn to develop and accelerate the commercialization of innovative point of care SARS-CoV-2 (COVID) tests into practice. That program supported more than 100 organization and resulted in 55 FDA authorized tests, including the 1st over-thecounter test for home use, and the production of over 7 billion tests¹.

7. Also since 2008, I have been employed as the Chief Technology and Innovation Officer for Reed Collins, LLC. At Reed Collins I provide consulting to

¹ See NIH Website, accessed 2/28.2024: https://www.nibib.nih.gov/covid-19/radx-tech-program

non-profits as well as start-ups. Non-profit clients include Oxford University in the UK and Howard University in the US.

I received a Ph.D. (1988) and M.S. (1982) in mechanical engineering 8. from the Massachusetts Institute of Technology ("MIT"), as well as a B.S. (1980) in mechanical engineering, with a minor in economics, from Rensselaer Polytechnic Institute ("RPI"). At MIT, I worked in the Fluids Lab under the direction of Professors Asher Shapiro and Roger Kamm. My academic work focused on mechanical engineering with a concentration on fluid dynamics and heat/mass transfer, with my Ph.D. and M.S. theses applying these principles to pulmonary dynamics. My M.S. thesis was on high frequency ventilation: at the time a novel way to ventilate babies without over-pressurization of the lung, avoiding damage to the lung during ventilator assist. My Ph.D. thesis was on analytical and numerical modeling of forced exhalation from the lung. The results were a computational model of the lung that allowed for more sophisticated diagnostics based on the results of the simple Forced Expiration Pulmonary Function ("FEPF") test.

9. I now have over 40 years of product design, development, and consulting experience covering a wide range of industries and products. Over that time, I have had a consistent focus on medical devices and related technologies, which includes my particular expertise in design, fluid mechanics and heat/mass transfer. In addition to doing engineering work, my responsibilities have included

assembling and managing teams to develop new consumer, industrial and professional products.

10. I also have experience as an innovator and inventor. I am a named inventor on more than twenty U.S. patents, with foreign counterparts in addition, on new products and manufacturing processes. My CV is attached as Exhibit 2002 and contains a list of my US Patents and all the publications that I have authored in the last 10 years.

11. Prior to my time at CIMIT and Reed Collins LLC in 2008, I held various leadership positions at technology and product development companies. From 1982-1986, I worked at Booz, Allen & Hamilton, where I developed a number of consumer and industrial products. After taking time to return to MIT and complete my Ph.D., I was then employed by Arthur D. Little ("ADL") until 1988. I then joined ADL as a design engineer and helped form its medical products business. I progressed to being responsible for the Technology and Innovation ("T&I") Directorate, with more than 250 staff as Sr Vice President until 2002.

12. From 2002-2008, I worked in close collaboration with CEO and owner, Dr. Kenan Sahin, to form TIAX LLC from the resources of the ADL T&I Directorate. TIAX is and was a privately held technology transformation organization focused on advancing and developing technologies for commercialization in several core technology areas, including clean energy and

materials, health and wellness, appliances and HVAC systems, and enhanced security. During my tenure at TIAX, part of which I served as president, the World Economic Forum recognized TIAX as a Technology Pioneer in 2002 and as a New Champion in 2007. For a full list of my employment history, see my CV, attached as Exhibit A to this report.

13. My experiences cover a broad technology base across a diverse set of industries, including in the areas of medical devices, energy, consumer products, emission technology for automobiles, and alternative smoking products.

14. By way of example, while at ADL, I worked with an operating unit within Philip Morris USA ("PM USA") called Chrysalis Technologies, Inc. ("Chrysalis") on an alternative smoking product that was battery-powered and puff-activated. Also, while at ADL, and then continuing that work at TIAX, I continued that work with Chrysalis on several related projects. These projects built off of and utilized the prior capillary aerosol generator research and development at PM USA and Chrysalis (the results of which are reflected in patents such as U.S. Pat. No. 5,743,251 to Howell et al.; U.S. Pat. No. 6,501,052 to Cox et al.; and U.S. Pat. No. 6,491,233 to Nichols) and applied it to efforts to atomize very low flow rates of liquid fuel for efficient combustion. One application was for a low-power, fuel based electric power generator (U.S. Pat. App. No. 2006/0093977 to Pellizzari I), and

another was for a clean emission "coldstart" fuel injector for automobiles (U.S. Pat. No. 7,059,307 to Pellizzari II).

15. By way of further examples of products that I have worked on, I worked with Baxter Healthcare to develop a blood/fluid warmer based on the analytical optimization of the thermal performance of "conventional" resistance heating technology; Bausch & Lomb to develop a microsurgical fluid delivery system that allowed the surgeon to control the flow or pressure of irrigation fluid; and Johnson & Johnson to develop Trocars and clip appliers for minimally invasive surgery.

16. I have also performed services in numerous patent disputes as an independent technical expert and consultant and as an expert witness. I have consulted as an expert in matters involving the design of a variety of medical devices. See Exhibit 2002 for a list of matters in which I have offered expert opinions or testified in court in the last 4 years as well as all prior e-cigarette cases in which I testified or offered expert opinions. In total, I have worked on, testified or offered expert opinions in eight other e-cigarette cases.

II. <u>LEGAL UNDERSTANDING</u>

A. The Person of Ordinary Skill in the Art

17. I understand that a person of ordinary skill in the relevant art at the time of the invention (also referred to herein as "ordinary artisan") is presumed to be

aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity—not an automaton.

18. I have been asked to consider the level of ordinary skill in the field that someone would have had at the time the claimed invention was made. In deciding the level of ordinary skill, I considered the following:

- the levels of education and experience of persons working in the field;
- the types of problems encountered in the field; and
- the sophistication of the technology.

19. A person of ordinary skill in the art relevant to the '173 patent at the time of the invention would have a B.S. in mechanical engineering, electrical engineering, or an equivalent degree, and either at least two years of experience designing electro-mechanical consumer products or an advanced degree in mechanical engineering, electrical engineering, or an equivalent field.

20. I have reviewed the declaration of Dr. Singhose, including his opinions regarding the Person of Ordinary Skill in the Art. Dr. Singhose provides a similar definition of a POSITA: "at least a B.S. degree in Mechanical Engineering, Electrical Engineering, Industrial Design, Product Design, or similar field, with at least two years of industry experience in one of those fields, and such POSA would

have been familiar with electrically powered vaporizing articles, their components, or the underlying technologies." Ex. 1003, ¶20.

21. My opinions set forth in this Declaration would be the same under either my or Dr. Singhose's proposal.

22. I am well-qualified to determine the level of ordinary skill in the art and am personally familiar with the technology of the '173 patent. I was a person of at least ordinary skill in the art at the time of the priority date of the '173 patent regardless of which definition used. Regardless if I do not explicitly state that my statements below are based on this timeframe, all of my statements are to be understood as an ordinary artisan would have understood something as of the priority date of the '173 patent.

B. Legal Principles

23. I am not a lawyer and will not provide any legal opinions. Though I am not a lawyer, I have been advised that certain legal standards are to be applied by technical experts in forming opinions regarding the meaning and validity of patent claims.

1. <u>Obviousness</u>

24. I understand that to obtain a patent, a claimed invention must have, as of the priority date, been nonobvious in view of prior art in the field. I understand that an invention is obvious when the differences between the subject matter sought

to be patented 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.

25. I understand that to prove that prior art, or a combination of prior art, renders a patent obvious, it is necessary to: (1) identify the particular references that singly, or in combination, make the patent obvious; (2) specifically identify which elements of the patent claim appear in each of the asserted references; and (3) explain how the prior art references could have been combined to create the inventions claimed in the asserted claim.

26. I understand that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art, and that obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.

27. I also understand that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. Even if a reference is not found to teach away, I understand its statements regarding preferences are relevant to a

finding regarding whether a skilled artisan would be motivated to combine that reference with another reference.

2. <u>My Understanding of Claim Construction Law</u>

28. I have been informed that patent claims are construed from the viewpoint of a person of a ordinary artisan and that patent claims generally should be understood consistent with their ordinary and customary meaning at the time of the invention. A review of the patent claim language, the patent specification, and its prosecution history are also necessary to determine the proper meaning and scope of the term at issue.

29. I have further been informed that in the specification and prosecution history the patentee may define a claim term in a way that differs from the ordinary and customary meaning. I understand that during prosecution of the patent before the U.S. Patent and Trademark Office, the Applicant may make representations or provide definitions of terms that may affect the scope of the patent claims. In particular, the Applicant may, during the course of prosecution, limit the scope of the claims to overcome prior art and/or disavow claim coverage by making clear and unambiguous statements to that effect.

30. I have been informed that a ordinary artisan may, among other things, consider dictionaries, publications, other patents, and treatises (*i.e.*, "extrinsic evidence"). I understand that extrinsic evidence may generally not be relied on if it

contradicts the meaning of claim language provided by the intrinsic evidence, such as express definitions given for terms in the specification.

3. <u>Secondary Considerations of Non-Obviousness</u>

31. I understand that one of the factual inquiries when determining the obviousness of a patent is to consider objective evidence related to the issue of obviousness, sometimes called "secondary considerations of non-obviousness" or "objective indicia of non-obviousness." I understand that such evidence can often be probative of the issues of obviousness.

32. I understand that examples of objective evidence include (1) commercial success, (2) copying, (3) industry praise, (4) skepticism, (5) long-felt but unsolved need, and (6) failure of others.

33. I understand that there must be a nexus between the patented invention and the evidence of secondary considerations. I further understand that there is a presumption of such a nexus if the claims of the patent are coextensive with a product or products that are the subject of the secondary considerations evidence. I further understand that in order for a claim to be coextensive with a product, one must look at the claims at the whole and not just the new claimed feature. In addition, the claimed invention should not be merely a subcomponent of the products sold but should encompass the entire apparatus.

III. <u>CLAIM CONSTRUCTION</u>

34. In my opinion, all claim terms should be given their ordinary meaning in light of the specification.

35. I understand that in the parallel ITC investigation, the parties dispute the meaning of the claim term "mouthpiece." I understand that Patent Owner contends that it means "portion to be used by a mouth," whereas Petitioners offer the construction "a separate component from the storage compartment to be used by a mouth," arguing that the term should be limited to the preferred embodiments of the '173 patent. Pet. 6.

36. However, I agree with Petitioners that for purposes of deciding institution of the Petition in this preliminary stage, it is not necessary for the Board to resolve this construction.

IV. <u>GROUND 1: PETITIONERS DO NOT SHOW THAT VERLEUR</u> <u>ALONE RENDERS OBVIOUS THE CHALLENGED CLAIMS</u>

37. In my opinion, Verleur does not render obvious any of the challenged independent claims. The Petition's only ground of challenge against the independent claims of the '173 patent relies on Verleur alone in view of a POSITA. Pet. 5. Thus, because Verleur does not render obvious the challenged independent claims, none of the Petition's remaining grounds stand either.

38. In my opinion, Petitioners have not shown that Verleur discloses "an air inlet passage having a first side formed by an exterior surface of the cartridge and a second side formed by an internal surface of the receptacle" that "is

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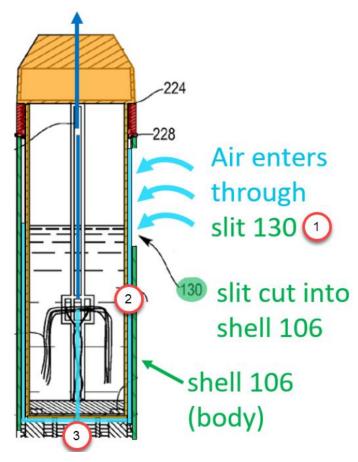
JLI Ex. 2001, Page 12

configured to deliver the air to the heater chamber" (or "heating element" for claim 20). I note that Petitioners do not assert that these limitations are obvious, but even if they had, as I explain below, the evidence shows they are not obvious.

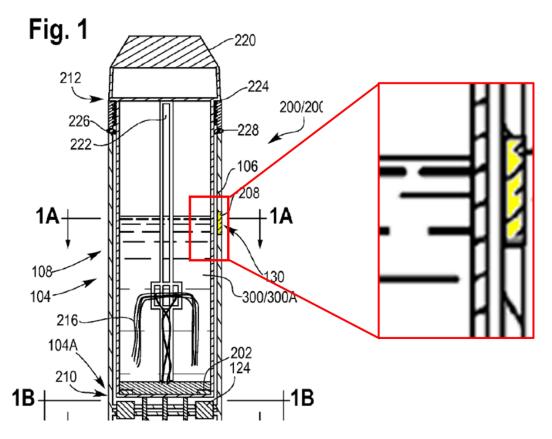
39. In arguing that Verleur discloses these limitations, Petitioners make three assumptions that are not supported by Verleur nor a POSITA's understanding of Verleur. These are: (1) the presence of an air inlet where Verleur discloses a window, (2) the presence of an airflow gap between the cartridge and outer shell, and (3) the presence of a central hole at the bottom of the cartridge.

40. All three assumptions are required to support Petitioners argument that Verleur discloses the "air passage inlet" limitations. Thus, if any one of these assumptions is wrong, then Petitioners' entire argument fails. And each of them is wrong.

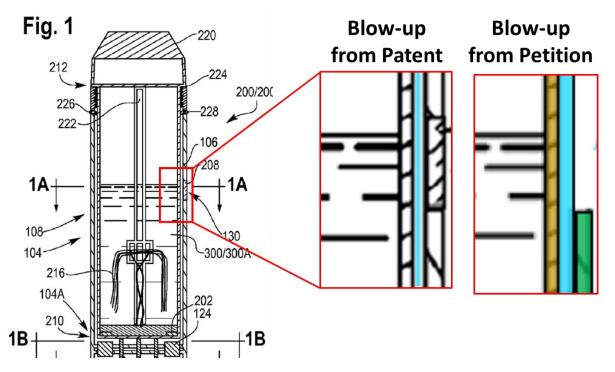
41. The three assumptions are best depicted by Petitioners' highly modified and annotated version of Figure 1, reproduced below. I have added red-circled numbers to indicate the three false assumptions that Petitioners make.



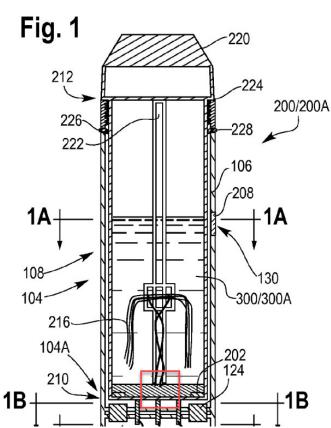
42. The first assumption Petitioners make is that they assume that "air enters at window 130" which they label an "inlet passage." Pet. 33. However, nowhere does the specification state that window 130 is an inlet that allows air to enter. As highlighted in yellow in Figure 1 reproduced below with a portion blown-up to see the window 130, it is actually depicted as covered, not as an inlet, nor is it as long as Petitioners make it.



43. The second assumption that Petitioners make is that they assume the existence of an air gap between the outer shell 106 and the removable cartomizer this gap is what Petitioners assert to be part of the claimed "air inlet passage." Although Figure 1 depicts a gap, Verleur never says it is used for airflow—in fact, Verleur never discusses it at all. As shown below, in Petitioners' modified Figure 1, Petitioners make the gap (in light blue in right blow-up) appear wider than it is actually depicted in Figure 1 (in light blue in left blow-up).



44. The third assumption that Petitioners make is that they assume that there is a hole in the center of the bottom of the removable cartomizer that allows air to flow into the cartomizer. Verleur does not describe or depict any such hole, and in fact discloses an electrical contact where the hole would be. Petitioners modify Figure 1 to depict such a hole. As shown in the highlighted red box I added, there is no such hole depicted in Figure 1.



45. I address each of these assumptions in turn.

A. Verleur does not disclose Assumption 1: that "window 130" is an air inlet

46. Petitioners first assume that "window 130" is an air inlet. Pet. 30.

Verleur does not disclose that window 130 is an air inlet, and, in my opinion, a POSITA would not interpret window 130 to be an air inlet. As I shall explain later, Verleur knew how to describe an air inlet on the outside of the shell, since one is described in a different embodiment that Petitioners do not rely on—there, the air inlet is "aligned" in a way that does not read on the claim limitations.

47. Window 130 is a window. Verleur makes this clear, stating that the purpose of "window 130" is "to view internal components of battery portion 100," JLI Ex. 2001, Page 17

such as "to permit a user ... to view the cartomizer 200 when it is inserted into cartomizer chamber 108." Ex. 1005, ¶37. In other words, the purpose of "window 130" is to, for example, allow a user to easily see how much fluid remains in the removable cartomizer.

48. Verleur states that window 130 may be covered by glass or plastic (which is how it is depicted in Figure 1), but also that it may be a "slit cut into shell 106." Ex. 1005, ¶37. Regardless, Verleur's only description of window 130 is as a window for viewing—Verleur never describes it as an air inlet. Verleur does not describe window 130 as being configured for air to enter, or that it is in fluid connection with the mouthpiece where a user inhales. And a POSITA would not expect window 130 to be such an air inlet given the disclosure.

49. I note as an initial matter that Verleur does not require airflow through the cartomizer (which I mean to refer to air flowing from an inlet to a separate outlet) in this first embodiment—it could be a "fuming" type device. Such devices heat the liquid in an enclosed space and the liquid that is vaporized substantially expands in an otherwise closed volume and exits through the inhalation tube where it can be inhaled. Consistent with the device described in Verleur, a fuming type device can have buttons on the exterior of the shell for users to press/actuate to cause the current to flow to the heater rather than using a pressure sensor to automatically detect a puff/draw. Ex. 1005, ¶27. Fuming devices do not require

the user to suck air through the cartomizer, and instead, the vapor is inhaled directly with the potential for ambient air that never passes through the cartomizer to be mixed with the vapor during inhalation.

50. But even if air were to flow through the cartomizer, a POSITA would understand that the amount of airflow in an e-cigarette must be tightly controlled to allow for an adequate user experience—and such tight control requires strict engineering. It was known that the size, shape, and location of air inlets and air passages affects draw resistance, which impacts, among other things, vapor production, the size of the visible vapor cloud, and nicotine delivery to a user. These are details that must be carefully balanced so that the use of the vaporizer simulates the experience of using a cigarette. Petitioners ignore such details and do not even argue the limitation is obvious.

51. These considerations were made by the inventors of the '173 patent as they designed the JUUL Device (which I explain below embodies the '173 patent). The inventors recognized that draw resistance, and the airflow that contributes to it, must be tightly controlled. *See, e.g.*, Ex. 2003, 26

. Others working in the e-

cigarette space at the time of the '173 Patent's invention similarly recognized that many factors contribute to the user experience, including the design of the aerosol formation chamber. *See* Ex. 2023, ¶50.

52. Petitioners, on the other hand, do not account for these factors in arbitrarily designating window 130 as an air inlet.

53. If air were to flow through the cartomizer, a POSITA would not expect that the air would enter through window 130. Instead, a POSITA would understand that air, to the extent the device allows for air to enter, must enter the device elsewhere. Window 130 is proportionally large relative to the rest of the shell and thus a POSITA would understand that the resulting draw resistance is nothing like a traditional cigarette, and as a result the Verleur device would not be usable for its intended purpose as an electronic substitute for a traditional cigarette. Ex. 1005, ¶3. Such a large air inlet would jeopardize the ability of the Verleur device to detect negative pressure during a draw, impacting its ability to properly function.

54. While Verleur states that "[i]nhalation tube 222 may also be in fluid communication with one or more *holes or ducts provided, for instance, in sides of outer shell 106* in order to permit air flow through cartomizer body 208" (Ex. 1005, ¶39), Verleur does not assign an element number to such holes or ducts, does

not equate such holes or ducts with window 130, and does not describe or depict where they are. Figure 1 does not depict any such hole or duct on the outer shell and window 130 is depicted as having a cover. Thus, it is clear these holes or ducts are a different element from window 130 and it is improper for Petitioners to equate the two. And, again, neither Petitioners nor Dr. Singhose opine that such an inlet would be obvious.

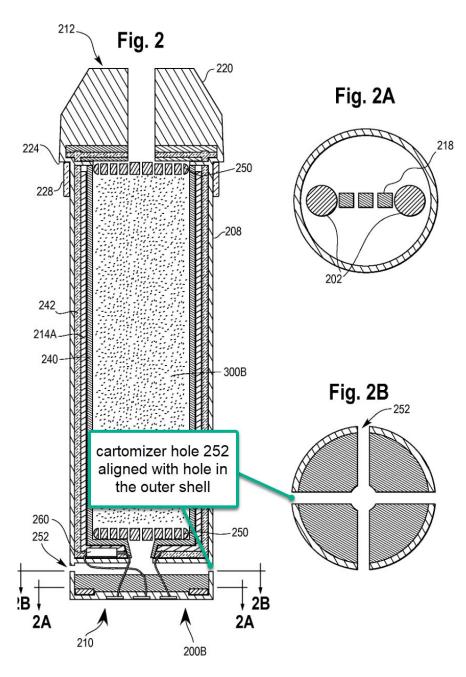
55. Since Figure 1 does not depict holes or ducts nor depict how such holes or ducts would be in fluid communication with inhalation tube 222, to the extent they exist, the placement of such elements is not limited to the placement of other elements in Figure 1. Where they would be present on the shell would need to be in accordance with a POSITA's understanding of Verleur—and not simply placed arbitrarily "anywhere along the length of the outer shell" as Petitioners propose. Pet. 35. Petitioners and Dr. Singhose do not provide any explanation or evidence for why a POSITA would understand the holes to be in any particular place. I think it is clear Petitioners' arbitrary placement of the hole is driven by hindsight to meet the claims rather than an analysis of what a POSITA would consider to be efficacious or desirable.

56. If there is airflow through the cartomizer, then the exact placement of the air inlets is key to the proper functioning of a vaporizer device like the one disclosed in Verleur and is key to whether Verleur reads on the claims. As

discussed above, the size, shape, and location of the air inlet dictates the airflow within the device, which is key to proper operation of an e-cigarette device like the one taught in Verleur. Moreover, the precise placement of the holes or ducts dictates whether the claim limitation is met. For example, if the holes or ducts are (arbitrarily) placed on the shell below the cartomizer in the receptacle and if one (arbitrarily) assumes air enters the cartomizer through its bottom, then there is no "air inlet passage having a first side formed by an exterior surface of the cartridge and a second side formed by an internal surface of the receptacle." Thus, it not correct that placing the hole "anywhere along the length of the outer shell" would necessarily result in air "travel[ing] down a gap (channel) formed by the exterior surface of [the cartomizer] and the interior surface of outer shell 106" as Petitioners argue. Pet. 35.

57. Verleur does describe the placement of holes on the outer shell for an embodiment that Petitioners explicitly do not rely on—the embodiment in Figure 2. Pet. 26-27 ("Petitioners rely on the first embodiment, which is depicted at, *e.g.*, Fig. 1, and *not the second embodiment*, which is depicted at, *e.g.*, Fig. 2."). Figure 2 is a solid matter embodiment that does not use a liquid. However, like the Figure 1 embodiment, the solid matter embodiment still utilizes a removable cartomizer. Ex. 1005, ¶11 ("FIG. 2 illustrates ... a cartomizer ... that may be inserted into the cartomizer chamber of the battery portion of FIG. 1.").

58. In the context of the Figure 2 embodiment, Verleur depicts "one or more holes 252 in the cartomizer body 208," which Verleur calls an "air hole structure," at the bottom region of the cartomizer. Ex. 1005, ¶¶43, 13. A cross-section of the cartomizer is shown in Figure 2B and depicts the holes forming a + shape, with four holes on the outside of the cartomizer body.



JLI Ex. 2001, Page 23

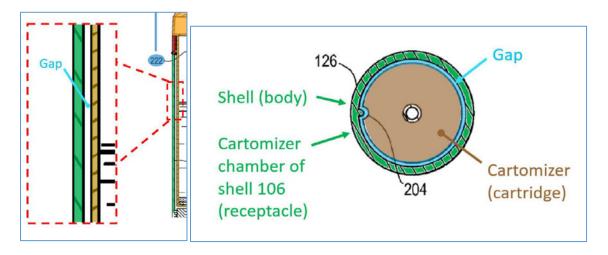
59. For this embodiment, Verleur does expressly provide for the location of a hole on the outer shell. Specifically, the cartomizer holes 252 of the cartomizer body may be capable of *alignment with one or more holes on the outer shell 106* ... so that air from the environment may pass through holes 252 and into container 240." Ex. 1005, ¶43. Given this disclosure in Verleur of where the holes or ducts are located, a POSITA would not understand Verleur's window 130 or any other arbitrary position to have an air inlet in the Figure 1 embodiment. To the contrary, a POSITA would understand that to the extent Figure 1 has a hole on the outer shell for airflow, the holes would be preferably aligned with an "air hole structure" similar to that depicted in Figures 2 and 2B, instead of the arrangement assumed by Petitioners. Ex. 1005, ¶13.

B. Verleur does not disclose Assumption 2: the presence of an air gap between the cartomizer and outer shell

60. Petitioners' second assumption is that Verleur expressly discloses a gap between outer shell 106 and the cartomizer that allows for airflow—without such a specific gap, the device would not meet the "air inlet passage" limitation. However, Verleur does not describe that the gap exists, and a POSITA would not understand such a gap to be provided for the purpose of airflow. To the extent a gap exists, a POSITA would understand that its purpose is to provide clearance to allow the insertion of the cartomizer into the shell's chamber.

61. Petitioners instead rely on the depiction of a gap in Figures 1 and 1A.

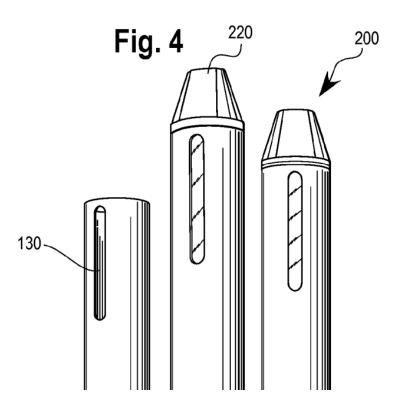
Pet. 28-29. Petitioners' annotated versions of Figures 1 and 1A are provided below.



62. As an initial matter, Petitioners argue that since Figure 2 "does not depict a gap, but instead provides access to external air through holes 202," this must mean Figure 1's gap is for airflow. Pet. 36. However, no such gap is depicted because Figure 2 only depicts the cartomizer. It does not show how it fits when inserted into the battery portion. Ex. 1005, ¶11 ("FIG. 2 illustrates ... a cartomizer in accordance with the disclosure that [it] may be inserted into the cartomizer chamber of the battery portion of FIG. 1.").

63. Also, it is my understanding that a patent's figures are not intended to convey specific dimensions or scale. In fact, Figure 1A does not even depict the inside portion of the cartomizer. In any case, Verleur never discusses or describes the supposed "gap," much less that it allows airflow.

64. Moreover, a POSITA would not understand that the depicted gap is for airflow because there is simply no disclosure about the presence, size, or purpose of this gap. Dr. Singhose does not provide any testimony or evidence as to why a POSITA would understand the gap to be an air passage. Instead, in my opinion, a POSITA would understand that the gap is merely to illustrate that the cartridge is physically separate from the chamber 108, and that the former is insertable into the latter. Without such a depicted gap, it would be difficult to tell from the figures that those components are physically separate and removable. Indeed, Figures 4-7 of Verleur show that the cartridge is flush with the inner shell.



65. Also, as I discussed above, to the extent the device is implemented with airflow through the cartomizer, the amount of airflow through the device must

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JLI Ex. 2001, Page 26

be tightly controlled to allow for a specific amount of draw resistance that allows a satisfactory user experience. *See, e.g.,* Ex. 2003, 26. Neither Petitioners or Dr. Singhose provide any evidence or disclosures in Verleur that a POSITA would consider the alleged gap in Verleur to allow for an adequate user experience.

66. And as I also discussed above, Verleur already discloses a means for allowing airflow into the cartomizer: the use of an "air flow structure" depicted in Figure 2 that is aligned with a hole on the outer shell. Ex. 1005, ¶¶13, 43. Such a mechanism would allow air to flow directly into the cartomizer through aligned holes. But such an air hole structure would not disclose "an air inlet passage having a first side formed by an exterior surface of the cartridge and a second side formed by the internal surface of the receptacle" as claimed.

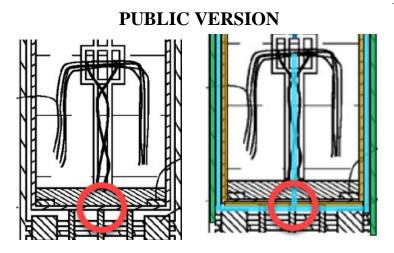
C. Verleur does not disclose Assumption 3: a central airflow hole at the bottom of the cartomizer

67. Petitioners' third assumption is that the bottom of the cartomizer has a center hole to allow airflow into the cartomizer. However, if air enters the cartomizer, it cannot be through what Petitioners depict to be a center hole via their annotated drawings, because Verleur expressly discloses the presence of a solid electrical contact in that location instead.

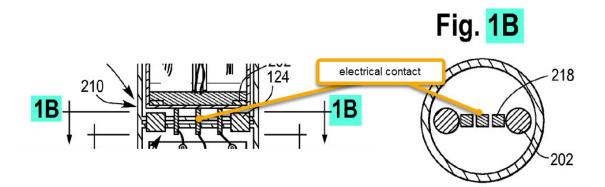
68. Below I provide a comparison of Verleur's Figure 1 (which does not depict a center hole) with Petitioners' annotated Figure 1 (which has been modified to depict a hole). I have marked in a red circle where the difference is.

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JLI Ex. 2001, Page 27



69. As can be see, there is no center hole. Instead, Verleur describes the presence of an electrical contact where Petitioners have arbitrarily placed a hole. This is shown in Figure 1B, which shows that at the center of the cartomizer precisely where Dr. Singhose opines the hole is placed, there is instead a solid "electrical contact 218" or "electrical receiver[] ... thereby establishing an electrical connection between PCB 112 and cartomizer 200." Ex. 1006, ¶¶33, 57; Figs. 1, 1B. I have annotated the figures below to show this.



70. These electrical contacts provide current from the PCB to power theheating element in the cartomizer. Id., ¶39 ("An electrical current may betransmitted to heating element 214 through circuitry in electrical communication08755-00011A/14736772.5JLI Ex. 2001, Page 28

with electrical contacts, which contact pins 122 ... when cartomizer 200A is inserted into chamber 108."). If the electrical contact is in the center of the cartomizer, an air inlet cannot be, nor would it be obvious to modify Verleur to place an air inlet there.

D. Conclusion

71. Thus, Petitioners' three assumptions are incorrect and Verleur does not disclose an "air inlet passage having a first side formed by an exterior surface of the cartridge and a second side formed by an internal surface of the receptacle" that "is configured to deliver the air to the heater chamber" as required by limitations [1.H] and [1.I]. These three assumptions are (1) that what Verleur describes as a window is really an air inlet, (2) that a gap exists and is of a particular size that allows a specific user-satisfying amount of airflow between the cartomizer and outer shell, and (3) that a center hole exists on the bottom of the cartomizer.

72. But Verleur does not disclose any of these things and instead provides disclosures that are clearly inconsistent with the assumptions. And neither Petitioners nor Dr. Singhose provide any evidence that a POSITA would find such assumed elements to be readily apparent or obvious based on Verleur's disclosures.

V. GROUND 2 FAILS FOR THE SAME REASONS AS GROUND 1

73. Ground 2 of the petition challenges claims that are dependent on the independent claims challenged in Ground 1. Thus, they rely on the analysis of Ground 1. In my opinion, Ground 2 fails for the same reasons I discussed above with respect to Ground 1.

VI. <u>SECONDARY CONSIDERATION OF NON-OBVIOUSNESS</u>

74. In my opinion, there is strong, objective evidence that the '173 patent is not obvious. Patent Owner JUUL Labs, Inc. ("JLI") successfully manufactured and sold electronic cigarette devices that embody, and in fact are coextensive with, the '173 patent. These products comprised a JUUL Device and various removable JUULpod cartridges that could be inserted into a JUUL Device. Together, JLI marketed these products as the JUUL System.

75. As I explain below, the JUUL System met the long-felt need for a nicotine alternative to conventional combustion cigarettes. The JUUL System unexpectedly met this need by declining to use cigarette iconography and instead focusing on modularity and a system that would provide the best user experience. As a result, the JUUL System received significant industry praise and commercial success, raising its market share to over 70% within a few years. The success of the JUUL System also led to copying by competitors, including by Petitioners and Petitioners' parent company, Altria Group, Inc ("Altria") (f/k/a Philip Morris), whom I understand is a real party-in-interest.

A. Nexus

76. In my opinion, the JUUL System is coextensive with at least claim 1 of the '173 patent and therefore I understand it is assumed there is a nexus between the '173 patent and the objective evidence relating to the JUUL System. As I show below, the JUUL System embodies claim 1 of the '173 patent, including its main device body and the removable cartridge. Claim 1 is not simply a subcomponent of the JUUL System.

77. The JUUL System practices every limitation of claim 1 of the '173 patent, and in fact, several of the '173 patent's figures are similar to the actual JUUL System product.

1. <u>1[pre]: An apparatus comprising:</u>

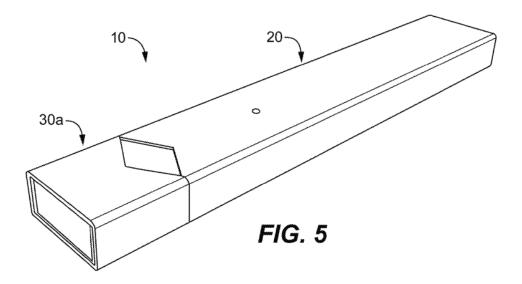
78. In my opinion, the JUUL System is an apparatus that

Ex. 2003, 9, 11. The JUUL System is depicted

below.

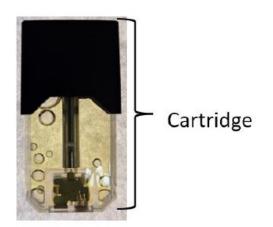


79. This apparatus is consistent with the apparatuses described in the '173 patent and depicted in its figures. *See, e.g.*, Fig. 5.

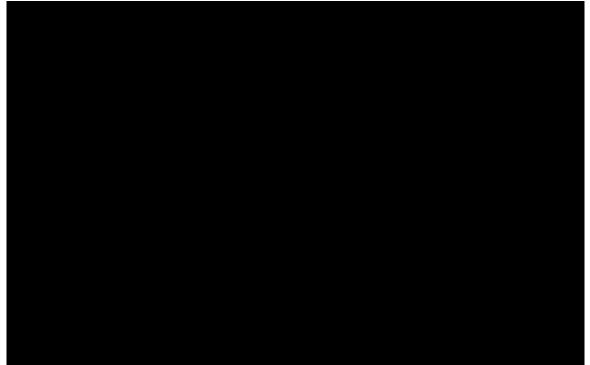


2. <u>1[a]: a cartridge comprising.</u>

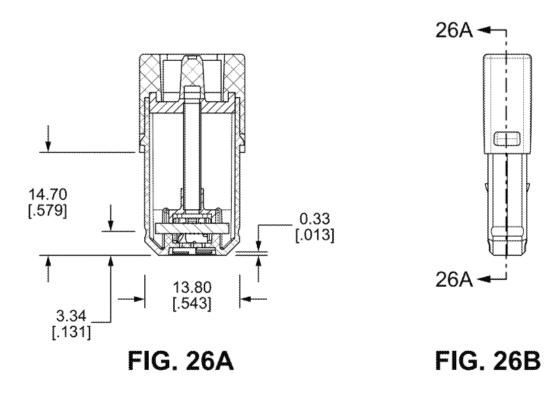
80. In my opinion, the JUUL System comprises a cartridge (specifically a JUULpod) that is insertable into the JUUL Device. Ex. 2004.



81. Below is a schematic of the JUULpod cartridge from one of JUUL's technical documents. Ex. 2003, 26.

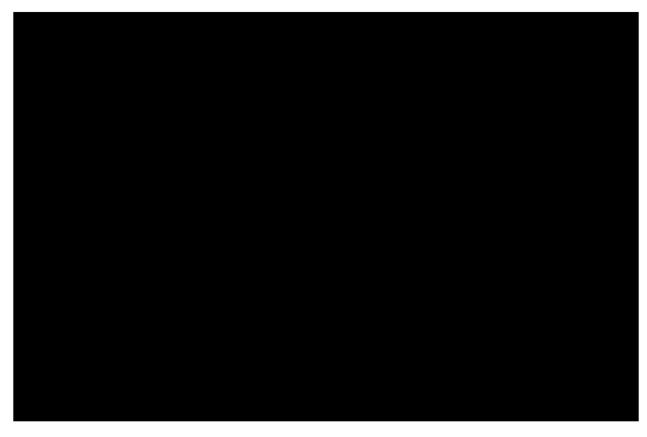


82. The JUULpod cartridge is consistent with the cartridges described in the '173 patent and depicted in its figures. *See, e.g.*, Figs. 26A and 26B.



3. <u>1[b]: a mouthpiece</u>,

83. In my opinion, the JUUL System's JUULpod has a mouthpiece under either parties' proposed construction. For example, as shown below, there are multiple components of the JUULpod, including a separate mouthpiece component. Ex. 2003, 24.



84. The components of the JUULpod cartridge, including its mouthpiece, are consistent with the cartridge components described in the '173 patent and depicted in its figures. *See, e.g.*, Fig. 30.

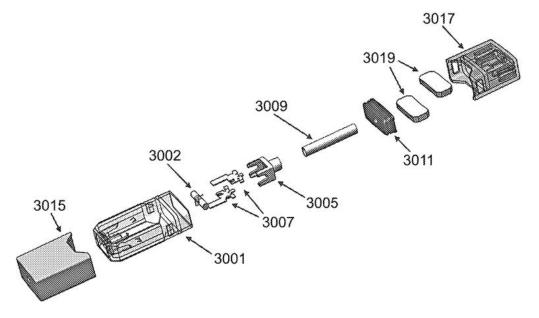


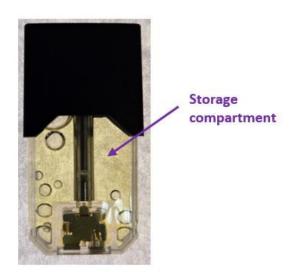
FIG. 30

4. <u>1[c]: a storage compartment configured to hold a vaporizable</u> <u>material, and</u>

85. In my opinion, the JUULpod cartridge contains a storage

compartment for storing the vaporizable liquid, as shown in the below photo. Ex.

2004.



86. According to JLI's techincal documents, a JUULpod

Ex. 2003, 23-24.



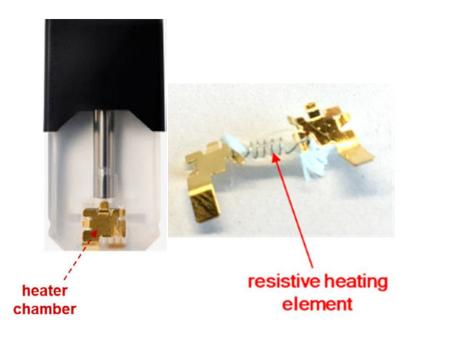
87. The components of the JUULpod cartridge, including its storage compartment, are consistent with the cartridge components described in the '173 patent and depicted in its figures. *See, e.g.*, Fig. 30.

5. <u>1[d]: a heater chamber comprising a resistive heating element</u> <u>configured to heat the vaporizable material, wherein the heating of the</u> <u>vaporizable material generates an aerosol comprising the vaporizable</u> <u>material and air passing along an airflow path;</u>

88. In my opinion, the JUULpod cartridge of the JUUL System contains a

heater chamber comprising a resistive heating element, as shown in the below

photos. Ex. 2005, Ex. 2006.



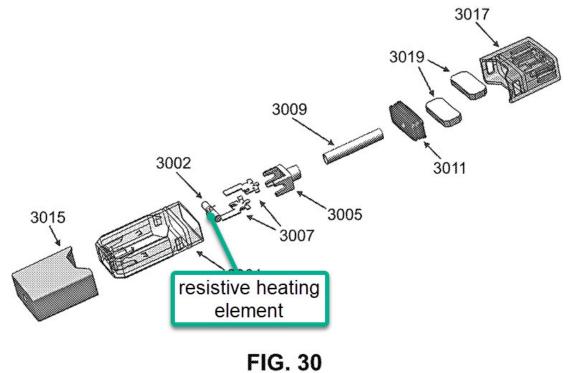
89. In my opinion, the heating element is resistive because it

Ex. 2003, 23. The heating element *heats the vaporizable material* to *generate an aerosol* that is the combination of the vaporizable material and air.

90. The JUUL System's heating element is consistent with the resistive heating elements described and depicted in the '173 patent. *See, e.g.*, Fig. 30.

08755-00011A/14736772.5

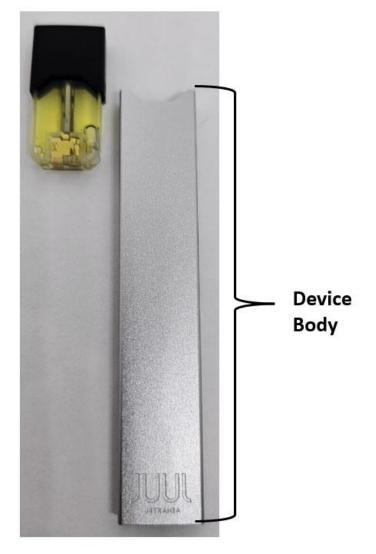
JLI Ex. 2001, Page 37



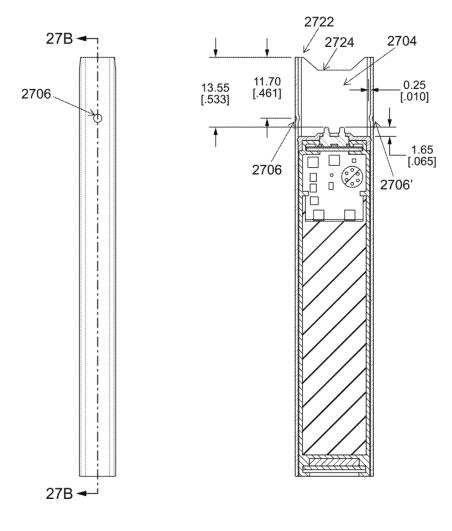
-
- 6. <u>1[e]: a body comprising</u>

91. In my opinion, the JUUL System comprises a JUUL Device body in

which the JUULpod cartridge is inserted. Ex. 2007.



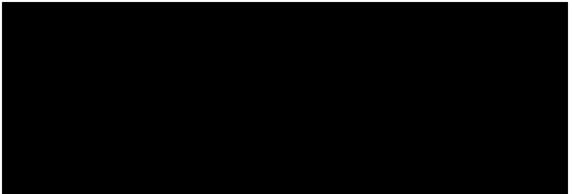
92. The JUUL Device has device body consistent with the device bodies described in the '173 patent and depicted in its figures. *See, e.g.*, Figs. 27A and 27B.



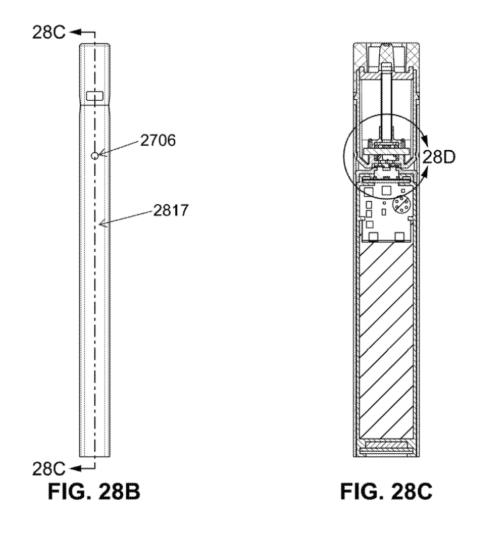


7. <u>1[f]: a receptacle configured to insertably receive and couple</u> to the cartridge,

93. In my opinion, in the JUUL System, the JUULpod can be inserted into and coupled to the JUUL Device's receptacle, as shown below. Ex. 2003, 9.



94. The JUUL System's method of cartridge insertion is consistent with those as described and depicted in the '173 patent. *See, e.g.*, Figs. 28B and 28C.



8. <u>1[g]: wherein the heater chamber is disposed within the</u> receptacle when the receptacle insertably receives and couples to the cartridge,

95. In my opinion, as depicted below, the JUULpod cartridge's heater

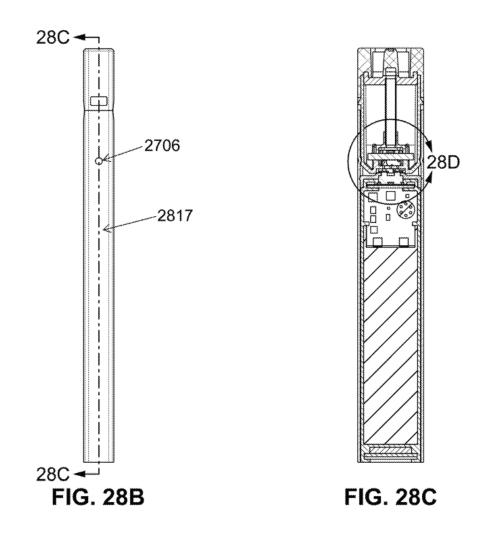
chamber is at the bottom of the cartridge and therefore is disposed within the

JUUL Device's receptacle when the cartridge is inserted. Ex. 2007.



96. The placement of the heater chamber within the receptacle in the

JUUL System is consistent with those as described and depicted in the '173 patent. *See, e.g.*, Figs. 28B and 28C.



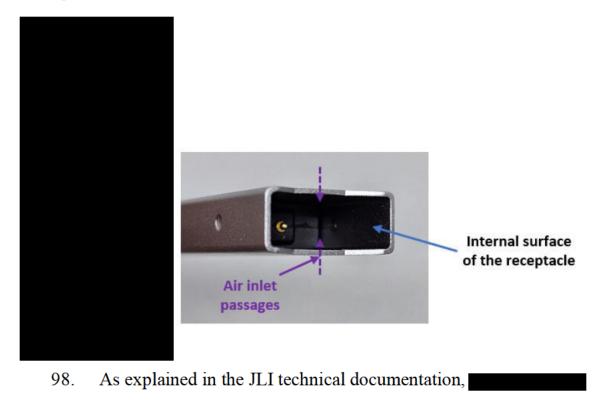
9. <u>1[h]: wherein the airflow path comprises: an air inlet passage</u> <u>having a first side formed by an exterior surface of the cartridge and a</u> <u>second side formed by an internal surface of the receptacle when the</u> <u>receptacle insertably receives and couples to the cartridge,</u>

97. In my opinion, as shown in the below annotated photos, the JUUL

System has an opening which allows air to enter the device where it flows through

a passage created between the outside of the cartridge and the internal surface of

the receptacle. Ex. 2003, 9; Ex. 2008.



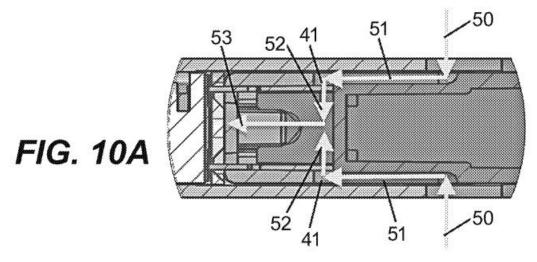
Ex. 2003, 23,

26.

99.	The JUUL System has a		
draw resist	tance that	Ex. 2003, 26-27.	This gap allows for a

100. The JUUL System's airflow passage is consistent with the airflow passages described and depicted in the '173 patent. See, e.g., Fig. 10A.

08755-00011A/14736772.5



10. <u>1[i]: wherein the air inlet passage is configured to deliver the</u> <u>air to the heater chamber; and</u>

101. In my opinion, in the JUUL System, the JUULpod's airflow passage delivers air to the heater chamber. Ex. 2003, 23

This is also depicted in the below diagram

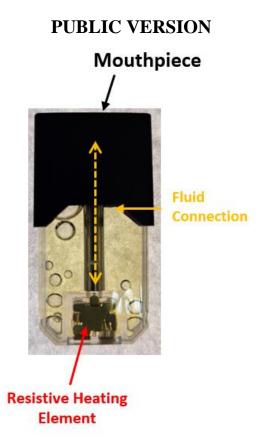
(annotations are in the original). Id., 26.



11. <u>1[j]: a fluid connection in the cartridge, the fluid connection</u> <u>connecting the heater chamber and the mouthpiece.</u>

102. In my opinion, as shown below, in the JUULpod cartridge, there is a

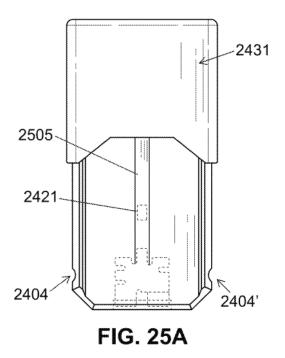
fluid connection connecting the heater chamber and the mouthpiece. Ex. 2004.



103. As described in JLI's technical documentation,

Ex. 2003, 26-27.

104. The JUUL System's fluid connection between heating element and mouthpiece is consistent with those as described and depicted in the '173 patent. *See, e.g.*, Fig. 25A.



B. Long-felt Need

105. In my opinion, the JUUL System met the long-felt need for a satisfying nicotine delivery product that did not have the unhealthy adverse health effects of smoking combustible cigarettes.

106. Before the JUUL System was first introduced in 2015, smoking tobacco cigarettes had long been known to have significant health risks. Both federal and state governments had for decades made it a priority to decrease smoking through regulations, taxes, and informational campaigns about the dangers of smoking.

107. Thus, before 2015, it was known that tobacco smoke kills up to half of its users who don't quit, and more than eight million people die from smoke-

related diseases worldwide each year, including an estimated 1.3 million nonsmokers who are exposed to second-hand smoke. Ex. 2009; Ex. 2010. It was also known that smoke from burning tobacco contains toxic chemical compounds that are directly and primarily responsible for the illness and death caused by cigarettes. Ex. 2011, 3; Ex. 2012, 3. Although nicotine is addictive, an FDA commissioner has recognized that nicotine itself does not directly cause the disease associated with smoking cigarettes. Ex. 2013, 2. Smoking has also caused a significant increase in national healthcare costs. Ex. 2014; Ex. 2015 (CDC estimate of \$240 billion increase in health care costs from smoking).

108. Despite these known adverse health effects, many smokers have struggled to quit smoking because of the addictive nature of nicotine. About 70% of adult smokers report that they desire to give up smoking. Ex. 2016. Yet the average smoker attempts to quit at least 30 times before successfully foregoing smoking for at least a year. Ex. 2017. Moreover, a 2007 study concluded that, at the time, smoking cessation failed over 90% of the time without some form of support. Ex. 2018.

109. In light of the above, companies have long tried to design alternative mechanisms for delivering nicotine to help users quit combustible cigarettes. For example, in the 1980s, Philip Morris and R.J. Reynolds invested billions in

developing "heat-not-burn" cigarettes that deliver nicotine from tobacco without burning it. Ex. 2019, 3-4.

110. Some companies developed early electronic nicotine vaporizer products that resembled combustible cigarettes, often referred to as "cig-a-likes." These early Electronic Nicotine Delivery Systems ("ENDS") products were often white and cylindrical and approximately the same size as a cigarette in order to mimic the shape, look, and feel of a cigarette as well as a LED light at the tip to simulate the glowing tip of a cigarette. Ex. 2020, Ex. 2021, 1. However, despite the long-time availability of these early ENDS products before 2015, widespread consumer adoption did not occur before the JUUL System. Ex. 2022 (finding that although 90% of current and recent smokers were aware of ENDS, only one-third had ever used them, and only one-fifth were actively using them).

111. For example, in 2013, Altria (formerly Philip Morris and currently Petitioners' parent company and RPI to this proceeding) sold through its subsidiary NuMark a cig-a-like product called MarkTen—but Altria did not consider the product to be a success because it "could [not] provide the satisfaction necessary to convert smokers." Ex. 2024, ¶613.

112. On the other hand, JLI took a different approach with its JUUL System, abandoning traditional cigarette iconography altogether, in particular the cylindrical shape, outward-facing, flame-simulating LED, and a screw-in cartridge.

The JUUL System's inventive design provided the user with a fundamentally
different user experience, including with respect to vapor production and nicotine
delivery that satisfied smokers' cravings and that were enabled through practice of
the '173 patent. Ex. 2025, 39:8-41:5 (
); Ex. 2026, 25:6-30:8
); <i>id.</i> , 137:23-143 (
; <i>id.</i> , 33:24-35:6
); <i>id.</i> , 116:15-117:14.
. Ex. 2025, 39:8-41:5, 65:9-
66:19, 81:22-82:18, 84:8-85:4, 87:21-88:2.

113. The industry recognized that the JUUL System products were unique and abandoned the industry norms of emulating the iconography of traditional

cigarettes. Ex. 2019, 3; Ex. 2027. This approach was regarded as technological, elegant, and sophisticated, while also providing satisfactory vapor production and nicotine delivery in a small form factor—all of which were enabled through practice of the '173 patent. Within a few years of the JUUL System launch, JLI became recognized as a leader in the ENDS device market. Ex. 2028, 1, 4; Ex. 2029; Ex. 2030.

114. Thus, in my opinion, the JUUL System met the long-felt need for nicotine delivery systems alternatives to combustible cigarettes.

C. Unexpected Results

115. In my opinion, the JUUL System achieved the unexpected result of a reliable, user-satisfying ENDS system, while departing from industry design norms and attempting to replicate a smokers experience with conventional cigarettes, providing sufficient vapor production and nicotine delivery, and using a relatively small form factor. For example, providing users with a reliable device that also allowed users to view the current liquid level while the pod was inserted in the vaporizer was unexpected in view of the concern about light degradation of the liquid nicotine formulation. Providing adequate airflow for satisfying vapor production and accurate pressure sensing to avoid accidental triggering of the device were also unexpected, as was providing a pod-based device with a liquid

tank as opposed to prior devices that stored liquid in the wick or other sponge-like absorbent material.

116. And for example, designing a reliable, user-satisfying ENDS system that could be manufactured in a cost-efficient manner was also unexpected. *See* Ex.

2025, 39:8-41:5 (
); Ex. 2026, 25:6-30:8 (
); see also id., 137:23-143 (
); ; d = 22; 24, 25; 6	
); <i>id.</i> , 33:24-35:6 (
(1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1	

); *id.*, 116:15-117:14.

117. Altria also made considerable investments in the e-cigarette space before it invested in JUUL. As Altria itself acknowledged, it "really didn't have success with [its] internally developed products," despite all the effort "put ... into engineering reduced-risk products." Ex. 2024, ¶¶144-45. Altria's failed products

included the De-Nic, Accord, SCOR, Marlboro Snus, Marlboro Moist Smokeless Tobacco, MarkTen King Size and MarkTen XL. *Id.*, ¶¶146-202.

D. Industry Praise

118. In my opinion, the JUUL System received widespread recognition from its customers and others in the industry. In the years following its release, the JUUL System became the leading alternative for adult smokers, which analysts called a "runaway success." *See* Ex. 2029; Ex. 2031; Ex. 2032.

119. Altria, Petitioners' parent company, has also praised the JUUL System as revolutionary and fueled by a strong innovation pipeline. Altria has described the JUUL System as "an innovative breakthrough." Ex. 2024, ¶¶213-214. It has acknowledged that while "most of the major players in the e-vapor industry acquired their products, [JUUL] 'is one of the few companies that is responsible for the design and manufacturing of its own products." Id., ¶214. Altria acknowledges that JUUL was "really the first pod product in the marketplace." Id. It has said that "within the context of the classic three-part structure, JUUL offered a number of signature features that resonated with adult consumers, including 'the unique form-factor body, the liquid-level viewing window, the reversible pod with locking gaps, the fresh air flow design, and the simple user operation." Id., ¶219. Altria has acknowledged that "[p]rior to the emergence of Juul, most e-cigarettes were cigalikes" whereas JUUL had a

"simple, intuitive, [and] easy-to-use' product design" which "contributed to JUUL's success." *Id.* ¶¶ 220-22; *see also*, Ex. 2026, 25:6-30:8, 35:7-35:24, 63:3-12, 68:23-69:10, 121:18-122:17.

E. Commercial Success

120. In my opinion, the evidence clearly shows that the JUUL System has enjoyed significant commercial success since its release in 2015. For example, a Wells Fargo analysis of Nielsen data reported that JLI's effective annual dollar sales increased 783% in the 52-week period ending June 16, 2018, reaching \$942.6 million. Ex. 2028, 1. This came from an 882% increase in unit sales over the same period. *Id.* Other analysis made similar findings. *See* Ex. 2032; Ex. 2033, 3 ("JUUL's 4-week sales growth grew over 800% in 2017, with under \$5M in sales during the 4 weeks ending mid-February 2017 and over \$46M in the 4 weeks ended mid-January 2018.").

121. As a result of this huge increase in revenue and unit sales, the JUUL System held dominant market share. For example, by August 2018, one analyst estimated JUUL to have approximately 70% of market share. Ex. 2034, 8; Ex. 2035, 3; Ex. 2032, 4. Another report similarly estimated 72% market share for JUUL by September 2018. Ex. 2036, 2. A report from 2018 also showed that JUUL's competitors saw decreasing market share shortly after the 2015 JUUL System launch. Ex. 2037, 3.

122. The success of JUUL System also contributed to growth in the ENDS market as a whole, which had experienced relatively flat sales before the JUUL System. *See* Ex. 2035, 3, 5; Ex. 2036, 3; Ex. 2038, 4; Ex. 2039, 2; Ex. 2040, 3. The JUUL System accounted for a significant portion of the surveyed weekly volume sales of the ENDS pod retail market in the years following the release of the JUUL System: 43.1% of March 2017 annual growth, 90.7% of March 2018 annual growth, and over 95% of growth from April to September 2018.

123. Altria also recognized the commercial success of the JUUL System in its offers to potentially license JLI's intellectual property.

Ex. 2041, 106:5-107:7.

F. Copying

124. In my opinion, the evidence is clear that others copied the JUUL System. There are several sources that have acknowledged such copying shortly after the JUUL System's release.

125. In prior investigations before the International Trade Commission involving the JUUL System, the Commission itself has observed copying of the

JUUL System. For example, the Commission has observed that "[a] number of competitors, including some respondents, have admitted to using the JUUL system as a reference when manufacturing their own ENDS products." *See* Ex. 2042, 250-51.

126. Industry commentators have also noted copying of the JUUL System. For example, in a letter to the U.S. Food and Drug Administration, industry commentators noted how "[m]any of the newly introduced e-cigarette products appear to be attempting to capitalize on the recent marketing success of Juul" and "new products appear to mimic the sleek design of Juul." Ex. 2043. Copying is further evidenced by competitor marketing material that touts the fact that their products are compatible with the JUUL Device. *See, e.g.*, Ex. 2044 (stating that "[e]ver since the Juul device burst onto the vape market, companies have been churning out ... Juul-compatible pods to keep up with the trend."); Ex. 2047 (advertising JUUL-compatible pods).

127. Altria has also represented that it began "working on an internal podbased product concept designed to appeal to cigarette smokers" in June 2017, two years after JUUL was launched. Ex. 2024, ¶ 190. This effort was called "Project Panama" and was "in the works for less than a year before it was paused to free up resources to fix the many problems plaguing Altria's on-market products." *Id.* Altria has said that "[a]ll told, although Nu Mark ultimately pursued at least a half

dozen internal device projects, many of which were the subject of 'years' of effort, none ever 'yielded fruit.'" *Id.* ¶191.

128. As Altria has admitted, since it was "[u]nable to develop an e-vapor product internally, Altria did what it always did when its innovation efforts failed: It turned to acquiring existing products." *Id.* ¶192. Altria began "searching in the spring of 2017 for opportunities to branch out from MarkTen cig-a-like and to participate in the pod market." *Id.* ¶301. This was because "after August 8, 2016 (the predicate date under the Deeming Rule), Altria 'didn't have the ability . . . to develop anything internally to compete without waiting multiple years to compete, and . . . thought it was important to go scan the environment to see if there were any pod products that were available." *Id.* ¶302. Internally, Altria referred to this project as "Project Mule." *Id.* ¶303.

129. In late-May 2017, Altria's Strategy & Business Development group "surveyed the market" and based on "conversations with a number of different companies" recommended that Altria pursue an acquisition of JLI. *Id.* ¶305. Altria considered JUUL to be the "[t]op performer among adult smokers and vapers" and acknowledged that "Juul offers key benefits of a hybrid-evaporator system,' providing cig-a-like users 'better performance without sacrificing convenience' and open-system users 'convenience in a non cigarette form."" *Id.* ¶307.

130. Altria approached JLI to begin discussing a potential acquisition of, or investment in, JLI in May 2017. *Id.*, ¶¶306, 308. By this point, Altria had admitted that it "found itself with 'virtually nothing in [Nu Mark's] pipeline, inhouse pipeline, for [it] to sell. Cigalike was declining very quickly. The pod business was growing exponentially, driven by JUUL. And … [Altria was] getting [its] butt[] kicked week in and week out." *Id.* ¶324. Starting in 2018 Altria shifted some of its focus to an internally-developed pod-based product, the MarkTen Elite, but ultimately did not see a viable path forward for that product given the lack of demand, product defects including excessive leaking, and constraints imposed by the existing regulatory regime. *See id.* ¶¶570-573, 653-54.

131. Like its parent company Altria, Petitioners' products prior to the release of the JUUL System were cig-a-like products. After the JUUL System was released and Petitioners observed the success of the JUUL System, Petitioners copied the design and features of the JUUL System in releasing its first pod-based product, the NJOY Ace.

VII. <u>CONCLUSION</u>

132. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the

United States. If cross-examination is required of me, I will appear for crossexamination within the United States during the time allotted for cross-examination.

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

Executed: February 29, 2024

/s/ John Collins John Collins, Ph.D.