

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 IPR2024-00231
U.S. Patent No. 10,130,123

SUPPLEMENTAL DECLARATION OF JOHN M. COLLINS Ph.D.
IN SUPPORT OF PATENT OWNER'S RESPONSE

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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 Response. I am being compensated for my time at my standard 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 IPR2024-00231, U.S. Patent No. 10,130,123 (“the ’123 patent”) and its file history, and all other materials cited and discussed in the Petition (including the declaration of Petitioner’s expert Joseph McAlexander), and cited and discussed in this Declaration. I have also reviewed the Patent Owner’s Preliminary Reply, Petitioner’s Preliminary Surreply, and the Board’s Institution Decision.

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. QUALIFICATIONS

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

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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 and using them in support of teams advancing healthcare innovations.

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) point-of-care tests into practice. That program supported more than 100 organization and resulted in 55 FDA authorized tests, including the 1st over-the-counter test for home use, and the production of over 7 billion tests¹.

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

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

8. I received a Ph.D. (1988) and M.S. (1982) in mechanical engineering 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,

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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 medical 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 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

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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

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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. LEGAL UNDERSTANDING**A. The Person of Ordinary Skill in the Art (“POSITA”)**

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

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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 '123 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 Mr. McAlexander, including his opinions regarding the Person of Ordinary Skill in the Art. Mr. McAlexander 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 these fields; and such

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POSA would have been familiar with electrically powered vaporizing articles, their components, or the underlying technologies.” Ex. 1003, ¶27.

21. My opinions set forth in this Declaration would be the same under either my or Mr. McAlexander’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 ’123 patent. I was a person of at least ordinary skill in the art at the time of the priority date of the ’123 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 ’123 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. Anticipation

24. I understand that to obtain a patent, a claimed invention must have, as of the priority date, been novel. I understand that to prove that a prior art reference anticipates a patent, the four corners of the prior art reference must describe element

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of the claimed invention, either expressly or inherently. I also understand that the prior art reference must describe the elements arranged as in the claim and that it is improper to combine disparate embodiments to establish anticipation unless a POSITA when reading the reference could at once envisage such a combination.

2. Obviousness

25. I understand that to obtain a patent, a claimed invention must also 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.

26. 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.

27. 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

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combination of components selectively culled from the prior art to fit the parameters of the patented invention.

28. 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.

3. *My Understanding of Claim Construction Law*

29. I have been informed that patent claims are construed from the viewpoint of a person of an 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.

30. 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

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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.

31. I have been informed that an 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.

4. *Secondary Considerations of Non-Obviousness*

32. 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.

33. 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.

34. 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

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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. CLAIM CONSTRUCTION

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

36. Petitioners mention that the construction of the term “pressure value” was disputed in the parallel ITC investigation. I understand that the construction of that term is no longer in dispute.

37. In my opinion, for purposes of deciding institution of the Petition in this preliminary stage, it is not necessary for the Board to resolve this construction.

IV. GROUND 1: PETITIONERS DO NOT SHOW THAT WORM ANTICIPATES THE CHALLENGED CLAIMS

38. In my opinion, Worm does not anticipate any of the challenged claims of the ’123 patent.

39. In my opinion, Worm does not expressly or inherently disclose a “sealed air flow path passing from an air inlet, through the channel and to a heater and an outlet of a mouthpiece” where the channel is “formed between an interior

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surface of the cartridge receptacle and an exterior surface of the cartridge.” As I explain below, Worm instead teaches that air enters the device through a different air inlet and takes a different path to the mouthpiece that does not pass through any channel between the cartridge and the receptacle as the claims require.

A. Worm does not anticipate an “air flow path passing from an air inlet, through the channel and to a heater and an outlet of a mouthpiece”

40. The independent claims 14 and 27 of the ’123 patent require a specific “air flow path” that originates from an air inlet, travels through a channel “formed between an interior surface of the cartridge receptacle and an exterior surface of the cartridge” to a heater, and then goes out of a mouthpiece.

41. Although Petitioners try to show Worm discloses such an “air flow path,” Worm does not. In doing so, Petitioners rely on a purported air inlet and purported channel that is not disclosed by Worm. Worm instead discloses an air inlet and channel that does not meet the claims, which I presume is why Petitioners do not rely on Worm’s express teachings.

42. Specifically, Worm discloses that when air is drawn from the mouthpiece, it “causes air to enter the air inlet channel 788 ... through one or more air inlet apertures 789 and flow into the air flow entry 741a ... from which the drawn air passes through the interior of the base 740 [which is in cartridge 704] and into the cartridge 704,” after which the airflow “proceed[s] ... toward the

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mouthend of the cartridge.” Ex. 1004, ¶75. This airflow path described in Worm is illustrated below in this version of Figure 7 which I have annotated.

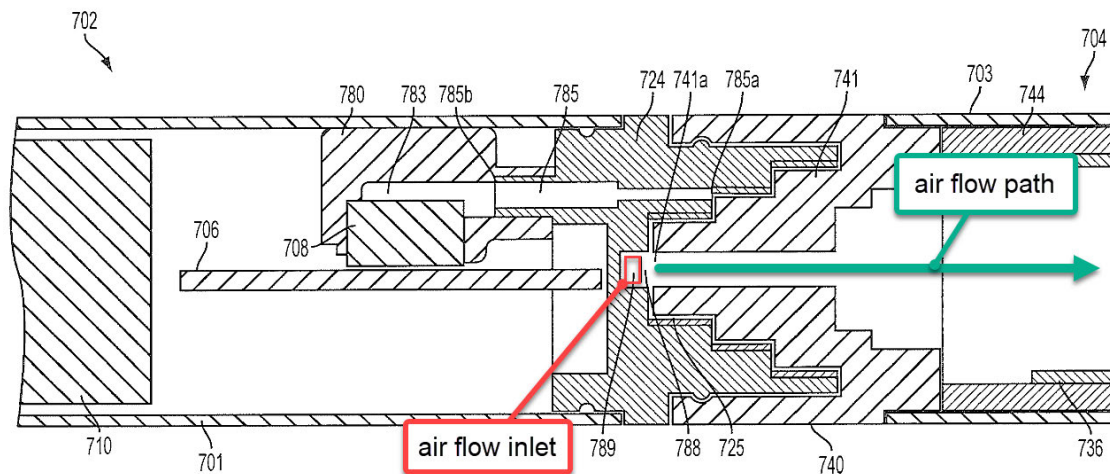


FIG. 7

43. As one can see, Worm expressly discloses that when a user puffs on the device, air flows into the device via air inlet apertures 389 on the side of the coupler, then flows radially inward to the center via the air inlet channel 388 before turning 90° and flowing down the center of the coupler in channel 741a. Airflow traverses through the interior of the control body 702 and proceeds straight into the central air flow entry 741 hole at the bottom of the cartridge 704. For example, as shown in the separate embodiment of Figures 3-6 (namely, the cross-section of Figure 6B), air enters through apertures 389a and 389b, then travels toward the middle of the air inlet channel 388 where a wider portion of the channel is formed. This is shown in the green arrows which I have added.

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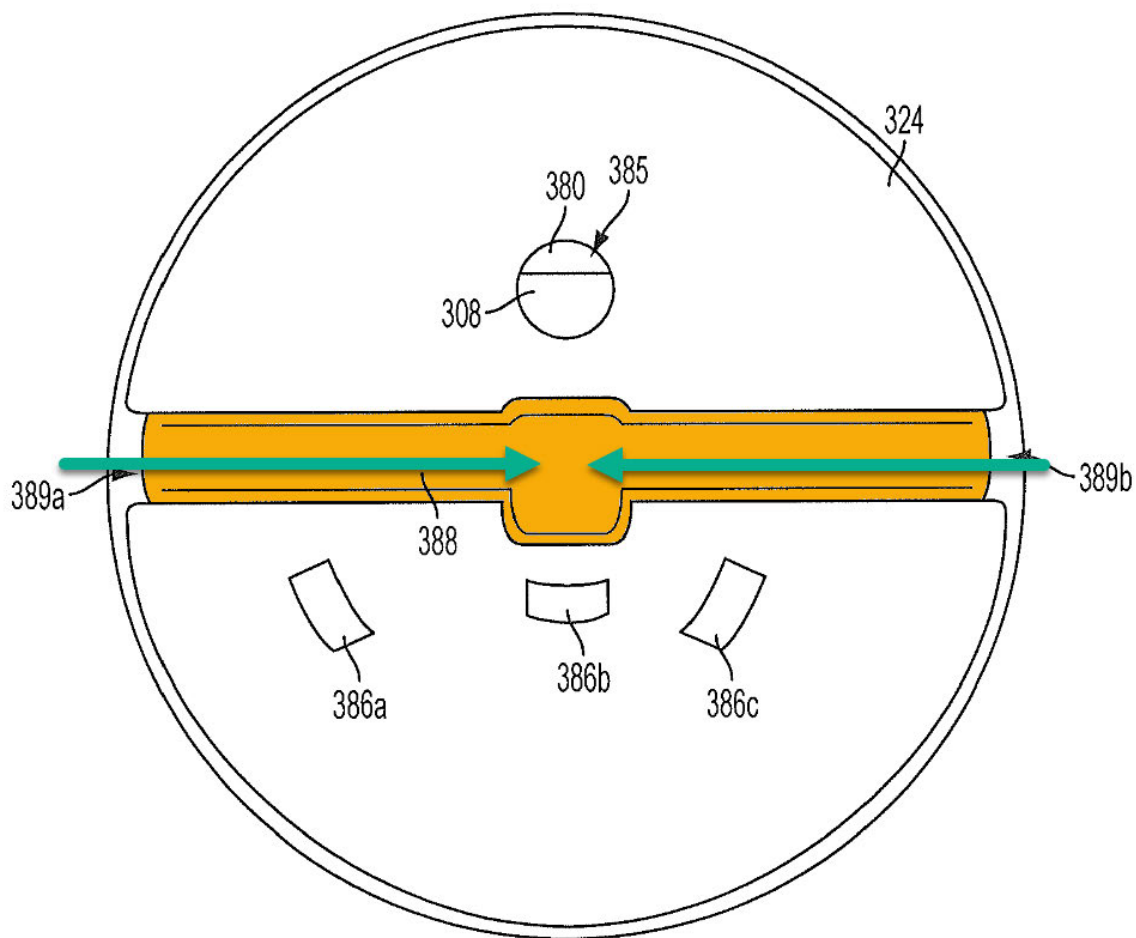
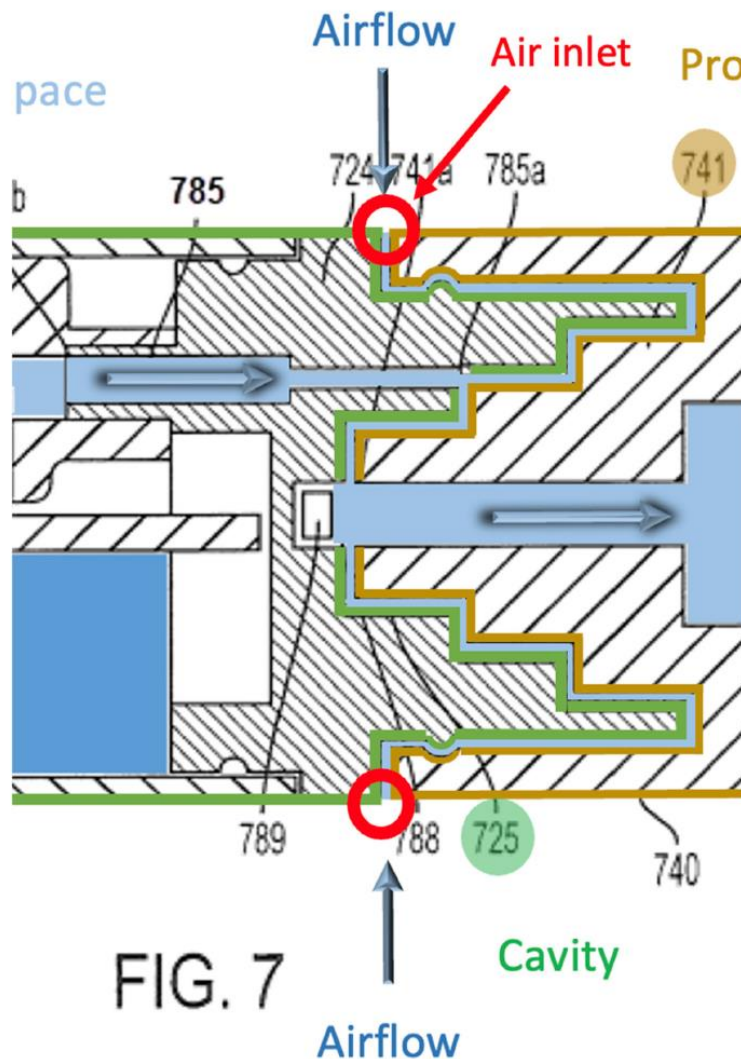


FIG. 6B

44. Petitioners and Mr. McAlexander do not rely on this express disclosure. Instead, they assume the presence of a different air inlet and channel that is not at all described in Worm and which a POSITA would in fact not consider to be present in the device due to its many disadvantages. This is shown in their heavily annotated version of Figure 7 below.

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45. There are several unsupported assumptions that Petitioners make. *First*, Petitioners assert that “Worm depicts the non-airtight interface (channel) as a uniform gap between cartridge 704 and control body 702.” Pet. 17. This is in direct conflict with Worm what teaches and a POSITA would understand. Rather than being a uniform gap, this space is where the electrical contacts in the cartomizer and body must touch each other. Ex. 1004, ¶58. I understand Board acknowledged this deficiency in Worm. Institution Decision, 24.

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46. *Second*, Petitioners assume that there are additional air inlets beyond the “one or more air inlet apertures 789” already taught in Worm. Ex. 1004, ¶75. Worm does not teach any such air inlets, nor is there any reason for such air inlets given the presence of the air inlet apertures 789. As the Board recognized, the fluid mechanics of such a passageway, winding up and down along the protrusions forming the “cavity” in Worm, would cause a reduction in airflow at every turn, such that the primary air inlet passageway, already taught in Worm, would control. Institution Decision, 25.

47. *Third*, Petitioners assume that air flows from these additional air inlets through a winding passage into the center of the device. Worm does not disclose anywhere that such additional air inlets or passage exist. And as I explain below, the fluid mechanics of such a passageway, to the extent it even exists, winding up and down along the protrusions forming the “cavity” in Worm, would likely cause a reduction in airflow at every turn, such that the primary air inlet passageway, already taught in Worm, would control.

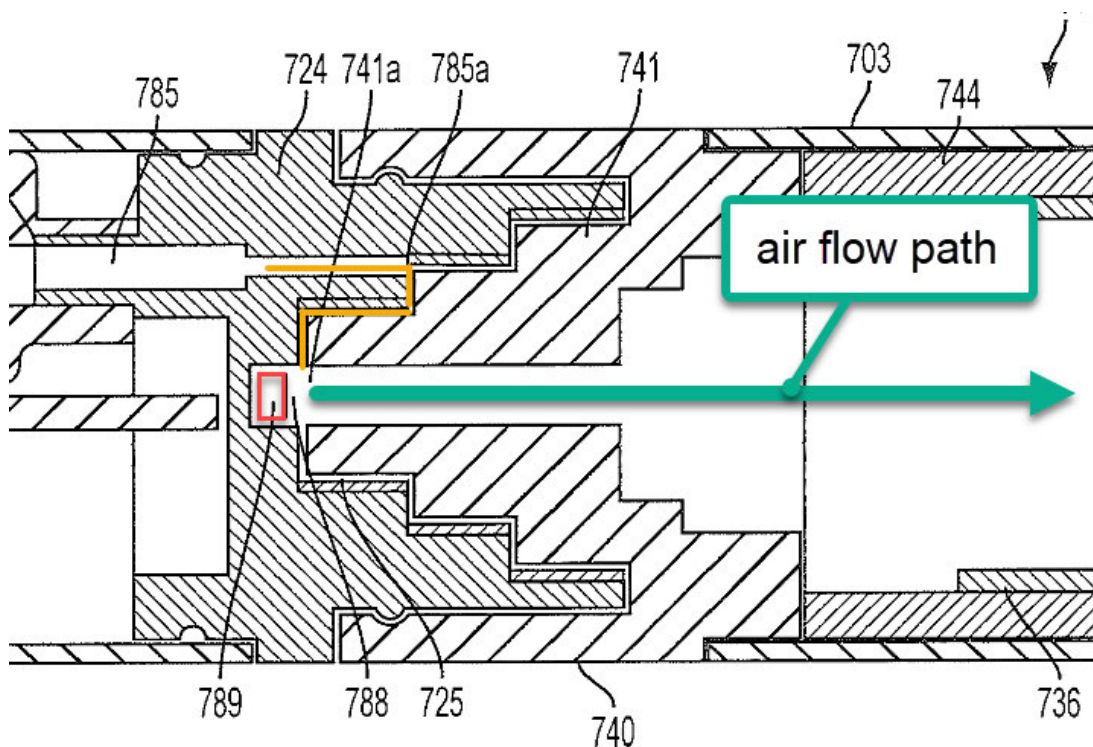
48. Petitioners argue the presence of this additional air inlet and passage because of a gap depicted in Figure 7. But I understand that figures generally should not be relied upon to show specific dimensions or sizes when a specification is silent. Further, a long, variable size channel only needs one

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blockage along its path to prevent or severely restrict airflow throughout the channel.

49. Moreover, the specification explicitly describes that the two faces of the supposed uniform gap must touch each other to make an electrical contact and is completely silent on the existence and function of the alleged air inlets or gaps.

50. Worm does disclose “channel 725” connected to “pressure channel 785,” which is marked orange in the below annotated figure. Pet. 36 (citing Ex. 1004, ¶76). As Worm explains it, this path allows the pressure drop from the inhalation to be “communicated to the pressure channel,” and “does not substantially form an air tight connection.” Ex. 1004, ¶76.



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51. But in my opinion, there is simply no disclosure or need for the airflow path to extend past the pressure chamber—indeed, Worm states that the pressure chamber is an “isolated segment of the device.” *Id.*, ¶15. Moreover, unlike the airflow path from the air inlet 789 to the user’s mouth which impacts the user draw experience, the uniformity of the path to the pressure chamber is not important as the amount of air movement required is negligible.

52. In my opinion, a POSITA would also not understand that Petitioners’ additional inlet and gap, to the extent it exists, is for airflow because Worm does not provide **any** disclosure about the presence, size, or purpose of Petitioners’ inlet or gap. A POSITA would instead understand that airflow travels through the inlets and passages as already described in Worm (namely, the air inlet aperture 789).

53. In addition, a POSITA would consider the winding path alleged by Petitioners to be ineffective for providing a controlled airflow—in fact, a POSITA would understand that “labyrinth seals,” which use pathways such as shown in Worm, could be used to seal connections from fluids. Labyrinth seals are just one type of seal that prevents airflow through a connection between components using nothing more than the geometry of the passageway. It is well-known that a series of right angles in a small passageway, like the one allegedly shown in Worm, diminishes airflow and causes a corresponding drop in any transmitted pressure. The gap Petitioners allege to be a channel has several of these angles. It is also

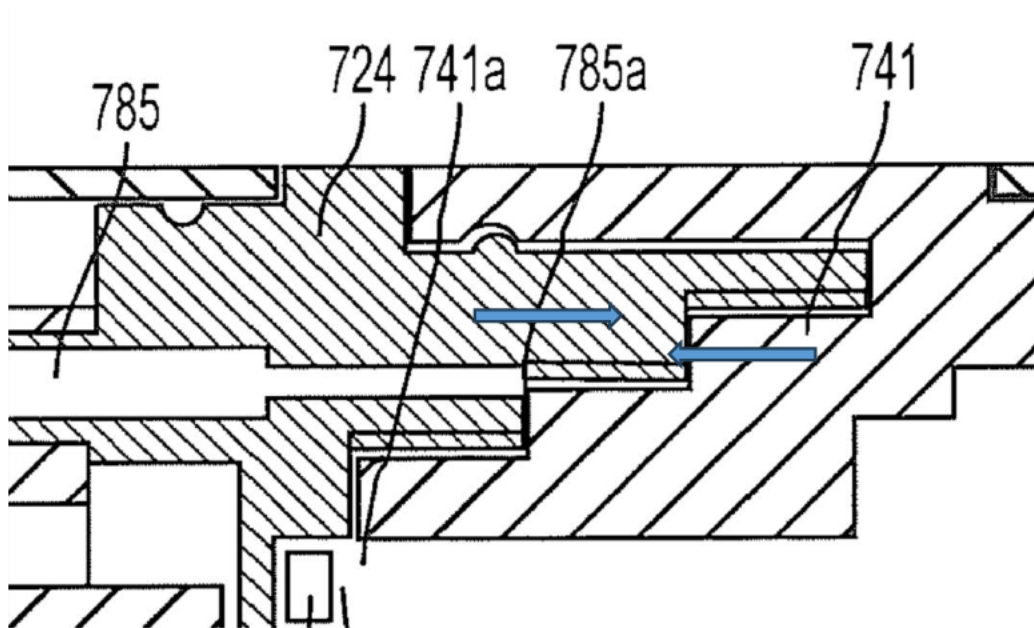
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well-known among ordinary artisans that airflow is a very sensitive function of the size of the passageway and geometry of the switchbacks. Even if Worm did teach a “gap,” it could not be uniform and would need to be small to function as an electrical connector. This results in a minimal airflow, particularly when there is another source of airflow (the disclosed air inlet aperture) that would control the airflow in the device. I also note that Mr. McAlexander acknowledged at his ITC deposition that each angle in Figure 7 “represents an angle that would reduce air flow.” Ex. 2052, 55:6-10, 64:9-12 (“Q And the way [labyrinth seals] work is that every time the fluid encounters another bend, the flow of fluid is reduced, right? A That is correct, yes.”). The Board also acknowledged that “the winding path of the gap would limit air flow.” Institution Decision, 25.

54. Also, if this gap exists, it would likely be sealed from airflow during a user puff. As I have illustrated in the below modified Figure 7, when a user inhales on the mouthpiece of the cartridge 704, the control body 702 and cartridge 704 will be pulled together to form a seal. The resulting negative pressure event is still detected by the pressure sensor 708, because it is in fluid communication with the cavity 725 through the pressure channel 785. However, airflow through Petitioners’ alleged gap would be substantially limited by this sealing action. As such, a POSITA would clearly understand that airflow is not intended to pass

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through the alleged gap and into the cartridge 702. Such a pathway would not be suitable for its intended purpose.



55. For similar reasons, if the gap exists as Petitioners allege, there would be variability in the size of the gap and air inlet depending on usage. As I explain below, such variability is undesirable because it would have an uncontrollable effect on user experience.

56. The specification is also clear that the areas that the Petitioner claims are “a uniform gap between cartridge 704 and control body 702” is incorrect. Pet. 17. Specifically, the specification describes that the electrically conductive heater terminals 138 are configured to direct current flow through the heating element and from the battery 110 when the cartridge 104 is connected to the control body. Ex. 1004, ¶38. The plug 140 engages the coupler 120 to form an electrical connection so that an electrical current can flows from the battery 110, through the coupler and

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plug, and to the heating element 134. *Id.* As such, portions of the electrical contacts in the battery portion (361, 362, and 363) must touch the corresponding contacts in the cartridge. I understand the Board acknowledged that the electrical contacts touching would prevent airflow in the gap. Institution Decision, 24 (“[A]irflow in the gap ... would [be] prevented by electrical contacts ...”).

V. GROUND 2: PETITIONERS DO NOT SHOW THAT WORM RENDERS OBVIOUS THE CHALLENGED CLAIMS

57. In my opinion, Worm does not render obvious the challenged claims. Petitioners present this ground as an alternative to Ground 1, stating that “it would have been obvious to a POSA that the channel formed between the cartridge receptable [sic] and cartridge of Worm permits air to enter the cavity.” Pet. 50. As I explained above, Worm does not disclose any such channel. I also believe Worm does not render obvious any such channel. As I explain below, such a channel would actually be undesirable for several reasons. I understand that the Board agreed with these arguments in its Institution Decision.

58. As an initial matter, I note that Petitioners do not actually provide any rationale for why a POSITA would modify Worm to provide such an air inlet and airflow channel. Nor did they explain why such a modification would have a reasonable expectation of being a successful electrical connector.

59. Petitioners argue that the gap in Figure 7 is “depicted as a uniform gap” and therefore would be obvious to allow airflow. Pet. 50 (quoting Ex. 1004,

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¶76). As I explained above, it is my understanding that patent figures do not convey specific dimensions or sizes without support for the specification, and the specification does not state anywhere that the gap is uniform, let alone that it exists. As I also explained above, Worm's disclosures make it clear that the gap cannot be uniform due to the presence of electrical contacts. Moreover, the distance between the housing and cartridge varies with use, including the formation of a seal when the cartridge is pulled toward the cavity when a user inhales.

60. Petitioners' alleged airflow channel is also undesirable to a POSITA. As I mentioned above, Worm already discloses an airflow inlet and channel. It would be undesirable to add an additional inlet and channel as proposed by Petitioners because such an inlet and channel would be difficult to control and thereby harm user experience.

61. 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 and aerosol production, the size distribution 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 provides the desired user

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experience. I understand that Mr. McAlexander also agrees that when designing an e-cigarette to simulate the feel of a traditional cigarette, it is desirable to have a similar draw resistance and throat hit, both of which are a function of air flow. Ex. 2052, 26:1-27:13. Petitioners ignore such details and do not even argue the limitation is obvious.

62. I note that these considerations were made by the inventors of the '123 patent as they designed the JUUL Device (which I explain below is embodied in the '123 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 '123 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.

63. Petitioners, on the other hand, do not account for these factors in arguing that it would be obvious the alleged gap is an airflow gap.

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64. In order to control the amount of airflow that results in an optimal user experience, it would be preferable and simpler to engineer the size of the air inlet 789 and air passage 788 expressly described in Worm for the optimal dimensions. By contrast, the additional air inlet and passage as proposed by Petitioners are based on several factors that can vary in use, such as the shape of the electrical contacts as well as the distance the cartridge is inserted into the control body which is affected by multiple tolerance stack-ups² and by extraneous factors such as wear and tear of the protrusion/recess mechanism or the amount of inhalation force applied by the user to the cartridge moving towards the control body. Petitioners' alleged air inlet and passage therefore cannot be tightly engineered or controlled to ensure an optimal user experience, if air can even flow through the alleged gap in the first place.

65. Petitioners appear to be at least aware of the issue posed by Worm's express disclosure of air inlet aperture 789 and channel 788. Petitioners argue that "for embodiments where air inlet aperture 389/789 is not used, the only access to ambient air in Worm is the interface between the cartridge and cartridge receptacle" and "[w]ithout access to ambient air from the periphery, a vacuum

² Tolerance stack-ups occur when manufacturing tolerances from multiple components which are assembled together accumulate.

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would be created in the device and the device would become nonfunctional.” Pet. 51.

66. But Worm does not actually state that air inlet aperture 789 is optional. In fact, all of the embodiments that Petitioners rely on (Figures 2, 5, and 7) use the air inlet aperture.

67. Also, Petitioners premise is incorrect. The device could still be functional without access to ambient air. Such a device would 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 mixed with air and inhaled. 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 cartridge to be mixed with the vapor during inhalation.

VI. GROUND 3: PETITIONERS DO NOT SHOW THAT WORM IN VIEW OF LEVITZ RENDERS OBVIOUS THE CHALLENGED CLAIMS

68. In my opinion, Petitioners argument that Worm in view of Levitz does not address any of the problems with the previous grounds. As I have explained above, Worm neither discloses nor renders obvious the presence of the claimed channel—it is not disclosed in the specification, and it would be undesirable. Petitioners Ground 3 does not address these issues. Specifically, Petitioners do not

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argue it would be obvious to modify Worm such that it uses Levitz's airflow channel—probably because Levitz's airflow channel does not disclose the claimed channel “formed between an interior surface of the cartridge receptacle and an exterior surface of the cartridge.” Instead, Petitioners propose that “a POSA would have modified Worm so that outside air enters at the interface between the battery and cartridge connection.” Pet. 56. In other words, Petitioners argue that in view of Levitz, a POSITA would have modified Worm to add an air inlet. Petitioners do not propose any modification to Worm's alleged gap, and so all of the deficiencies with that argument I discussed above, and which the Board acknowledged, apply to this ground.

69. But even if an ordinary artisan were to consider Levitz's air flow path from Figure 16 (which Petitioners annotate below), a POSITA would not be motivated by Figure 16 to modify the connection between Worm's cartridge 704 and control body 702 to create an air flow gap between them.

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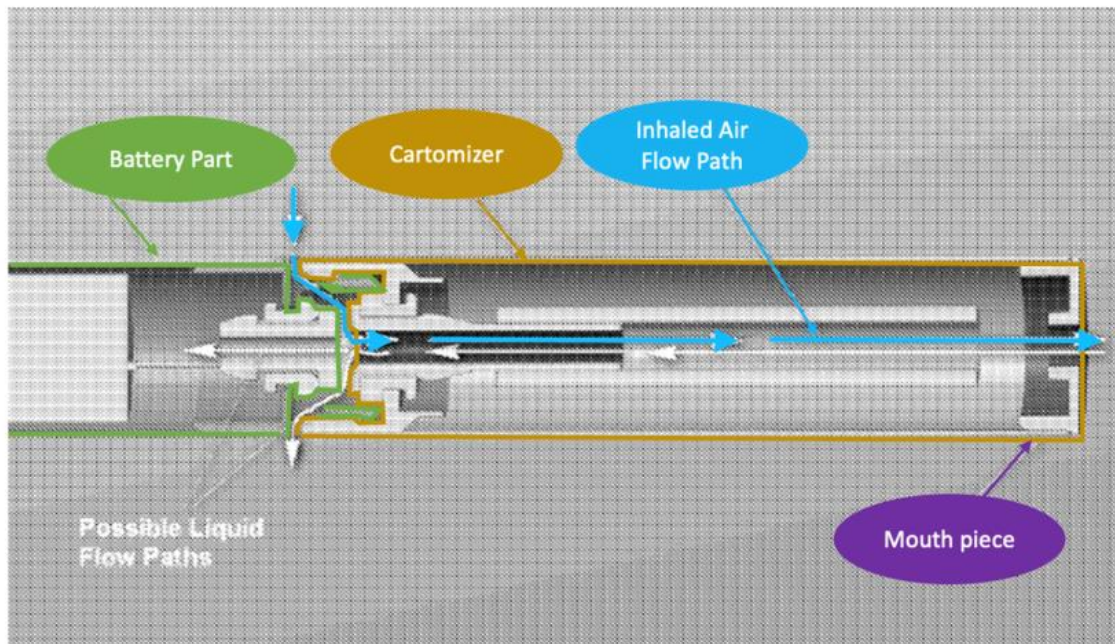


Figure 16

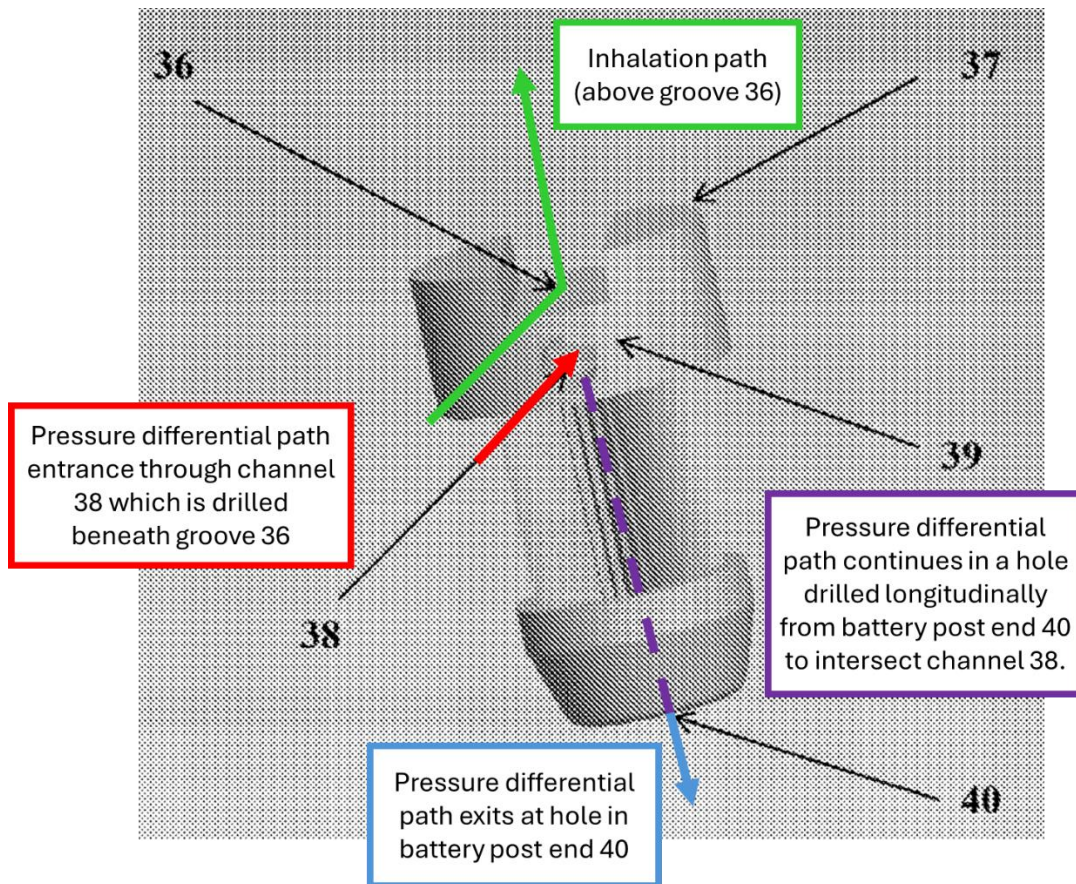
70. This is because Levitz expressly teaches that this Figure 16 embodiment has backflow issues, which is in direct opposition to Petitioners' motivation to "include[] additional pathways for any vapor that backflows." Pet. 59. Specifically, Levitz teaches that the air flow in Figure 16 has a "draw-back ... that upon exhalation, any excess fluid (vapor, saliva, etc.) could be blown ... into the pressure differential channel and into the battery." Ex. 1010, ¶44. Mr. McAlexander acknowledged that in Figure 16, backflow enters the battery part, which "can cause clogging and cause the pressure sensor to fail." Ex. 2054, 17:11-18:23. In other words, assuming a POSITA was motivated to address backflow issues, they would not look to Levitz's Figure 16 which does not solve backflow problems. Instead, Levitz provides a different embodiment in Figures 17 and 18

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that is “designed to minimize this problem.” Ex. 1010, ¶¶45-46. In this design, the pressure differential channel specifically does not run through the connection between the battery and cartomizer as required by the claims, which recite that “the pressure sensor is exposed to a sealed air flow path, ... the sealed air flow path comprising a channel formed between an interior surface of the cartridge receptacle and an exterior surface of the cartridge.” *Id.*

71. Instead, in Figures 17 and 18, the pressure differential channel runs through channel 38 which is not in fluid connection with the cartomizer—Levitz expressly teaches that “there is no direct path for excess liquid to migrate into the Battery compartment.” Ex. 1010, ¶46. Specifically, looking at Figure 17, the inhaled air path (**green**) travels through groove 36 and then upward into the cartomizer. However, the pressure differential path enters (**red**) through the channel 38 drilled below the groove 36 and intersects with a hole (**dashed purple**) drilled from bottom of the battery post to where it exits (**blue**).

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**Annotated Figure 17**

72. Thus, in Figure 18, the pressure differential path is different from the inhaled air path. However, the pressure differential path in Figures 17 and 18 is entirely within the battery part and is therefore not defined by the exterior of the cartomizer and so does not meet the recited limitations for a “sealed air flow path.” Mr. McAlexander acknowledged that the inhalation/backflow path and the pressure differential path are separate. Ex. 2054, 22:20-24:15.

73. Also, Petitioners’ reasons for modifying Worm in view of Levitz are redundant in view of Worm’s actual disclosures. I understand that an obviousness combination cannot be sustained by proposing the combination of two devices that

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provide redundant functionality. Below, I address each of Petitioners' arguments for combining Worm with Levitz. First, Petitioners argue that "the placement of air inlets is a design choice." Pet. 57. In my opinion, the placement of air inlets is not an arbitrary design choice. Their placement, size, and shape will have an effect on draw resistance, which affects user experience, such as vapor and aerosol production, the size of the visible vapor cloud, and nicotine delivery. These considerations must be taken into account and carefully controlled, and thus the placement of the air inlets cannot be arbitrarily chosen. I note that neither Petitioners nor Mr. McAlexander have provided any evidence that, in view of the above considerations, a POSITA would have chosen the specific placement of the air inlets as proposed by Petitioners.

74. And it is my opinion that a POSITA would not have chosen an air inlet as proposed by Petitioners. This is because Worm already describes an air inlet and channel within the control body that can be carefully controlled, whereas the proposed air inlet's size will vary depending on use, tolerance stack-ups and wear-and-tear. Thus, a POSITA would **not** have found it desirable to make Petitioners' modifications, and would have no reason to make such modification given Worm's express disclosure of an air inlet path.

75. Another argument Petitioners make is that a POSITA would be motivated because the additional air inlet provides "additional pathways for any

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vapor that backflows to exit the periphery of the connection rather than into the negative pressure space.” Pet. 59. In my opinion, Worm already addresses any backflow issues. Ex. 1004, ¶76 (“The matched configuration of the cavity 725 and the projection 741 preferably does not substantially form an air tight connection therebetween. Thus, the pressure drop in the cavity 725 is likewise communicated to the pressure channel 785 from the first end 785a to the second end 785b and thus the pressure reduction space 783. Because of the spatial arrangement of the air inlet channel 788 and the first end 785a of the pressure channel 785, however, ***the airflow entry 741 of the seated projection 740 is sufficiently spaced apart from the first end of the pressure channel to prevent or reduce incidence of passage of liquid from the cartridge 704 through the base 740 and into the control body 702.***”). In other words, the inlet and channel expressly disclosed by Worm suitably addresses any potential backflow.

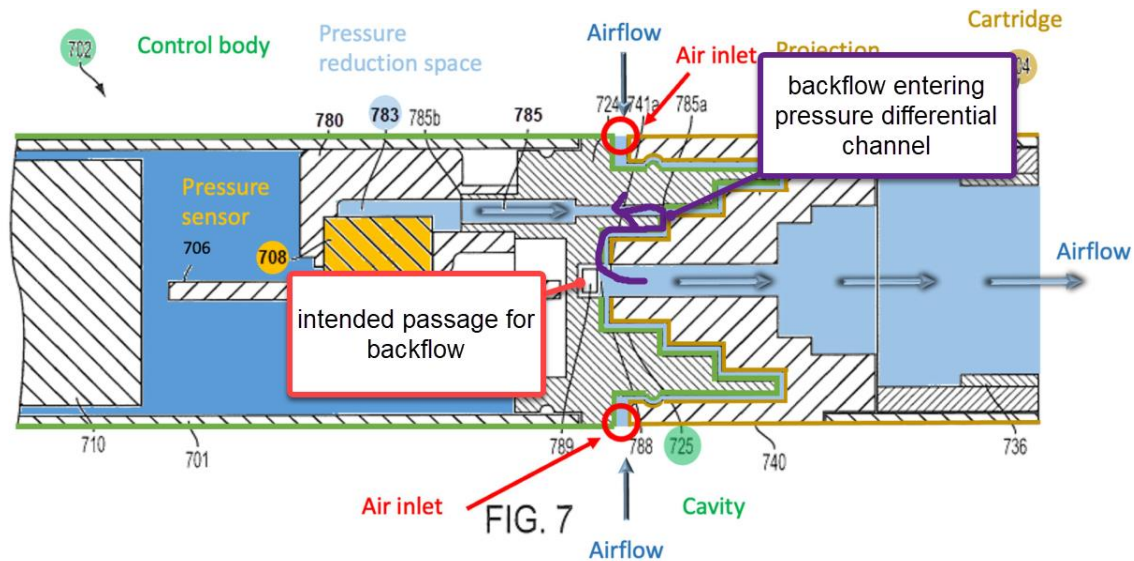
76. Finally, Petitioners argue that because of backflow residue along the channel, “a POSA would have been motivated to use an inlet at the interface between the battery and cartridge section because it would enable the smoker to clean the channel simply by removing the cartridge and cleaning the exposed channel.” Pet. 59-60. However, the user would still need to clean air inlet apertures 789 and channel 788 that are depicted to be much larger. Moreover, because of the winding, perpendicular path of Petitioners’ alleged gap, it is

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unlikely that there would be much backflow residue relative to the air inlet and passage that Worm expressly discloses.

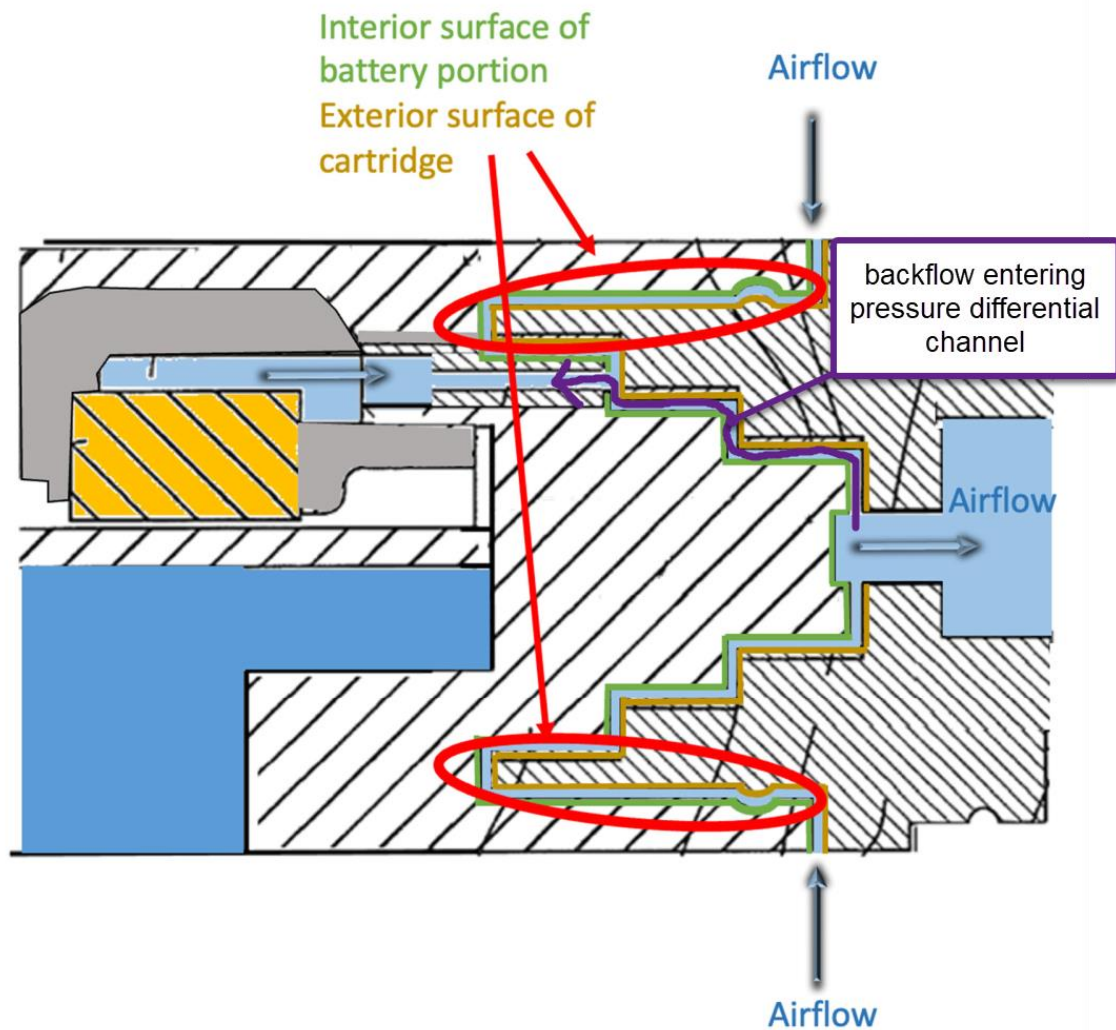
77. Finally, a POSITA would not be motivated by backflow issues to make either of Petitioners' proposed modifications, because Levitz expressly teaches that it is undesirable for the inhalation path to be in fluid communication with the pressure differential channel as that would result in backflow entering "the pressure differential channel and into the Battery." Ex. 1010, ¶¶44, 46. In particular, Levitz teaches that having the pressure differential channel and inhalation channel be the same channel is undesirable, and therefore proposes separating the two. *Id.*; see also Ex. 2054, 23:12-24:15 (acknowledging Levitz's separation of pressure differential channel and inhalation channel is intended to solve backflow problem). Yet Petitioners' proposed modifications to Worm has the same issue, specifically that the inhalation/backflow channel and pressure differential channel are the same path. This is especially the case if Petitioner propose creating a gap between Worm's cartridge 704 and control body 702—as that would result in more backflow entering the pressure differential passage instead of Worm's intended path via inlet aperture 789, which Mr. McAlexander acknowledges is a "separate port." Ex. 2054, 24:16-17. Below in **purple**, I have indicated how backflow could enter the pressure differential chamber if the gaps were large enough.

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78. And in the modification proposed by Petitioners, which removes Worm's pre-existing inlet aperture 789, all of the backflow will enter the pressure differential passage, which will increase backflow problems for the pressure sensor. I have indicated how backflow will enter the pressure differential channel in purple below if the gaps were large enough.

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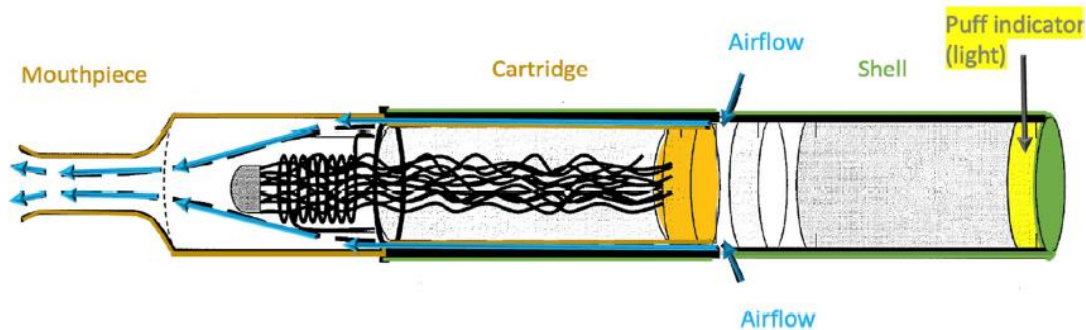


VII. GROUND 4: PETITIONERS DO NOT SHOW THAT THORENS IN VIEW OF WEIGENBERG RENDERS OBVIOUS THE CHALLENGED CLAIMS

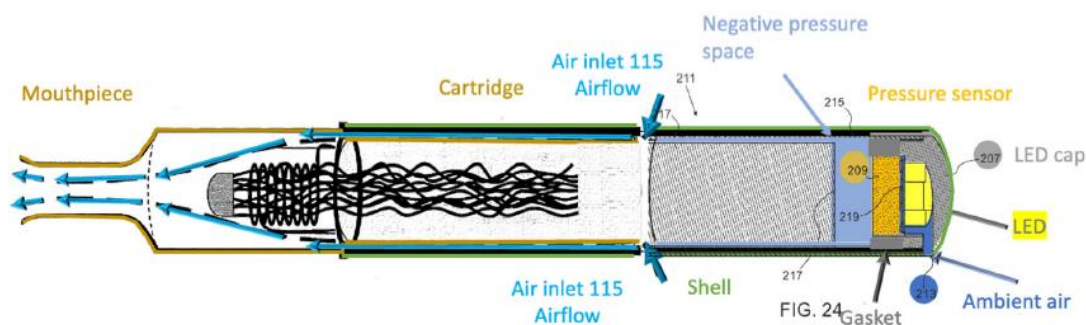
79. In my opinion, Thorens in view of Weigensberg do not render obvious the challenged claims. Petitioners' proposed combination for this ground involves extensive modifications to the body of Thorens' "cig-a-like" system in order to incorporate Weigensberg's pressure sensor chip assembly, which is not even

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necessary in view of Thorens disclosure of an air flow sensor. Petitioners propose modifying Thorens, as annotated by Petitioners below:



80. They propose modifying the above Figure in view of Weigensberg, replacing all of the components at the tip with the components of Weigensberg, as shown below in the Figure heavily modified by Petitioners. Pet. 65-66.



Modified Thorens

81. But there are two major issues with this proposed combination. *First*, a POSITA would not be motivated to combine the references because there are significant changes to Thorens's device which are disadvantageous and they come at the cost of the lack of benefit from replacing Thorens's air flow sensor with a pressure sensor. I understand that the Board agreed this argument has "some

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merit” and the Board questioned whether a POSITA “would have had reason to replace the puff detection system of Thorens with the differential pressure sensor of Weigensberg as proposed” as Petitioner did not “explain[] why an ordinary artisan *would have been motivated* to do so.” ID, 42 (emphasis in original).

Second, even if the references could be combined, the combination does not render obvious a gasket because Thorens and Weigensberg do not disclose a gasket—Thorens discloses a plastic LED cap.

A. A POSITA would not be motivated to combine Thorens and Weigensberg

82. As I showed above, Petitioners’ combination of Thorens and Weigensberg involves significant deleterious changes to Thorens’s device that provide no benefit. Petitioners propose significant changes to the electrical contacts between the battery and the device, and in so doing, remove a circuit for controlling the device. The combination also has dangerous, exposed wiring. This complete re-engineering of Thorens’s device is not at all justified by Petitioners’ motivation to add a pressure sensor for detecting inhalation—as such a sensor is unnecessary given Thorens’ detection of inhalation using an airflow sensor, which it calls a “puff detection system.”

83. In Thorens, heating coil 209 operates by being “in contact with the electrical contacts 113 on the shell,” which themselves are in electrical contact with battery 103 via electrical connections 111. Ex. 1016, ¶¶42, 44. Thorens also

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discloses a disk-shaped programmable circuitry 105 “used to manage the device operation” (labeled “control circuit” in the above) including “sens[ing] the user taking a puff” (via the puff detection system 107) and then “suppl[y]ing a current pulse of a pre-determined time to the heating coil 209.” Ex. 1016, ¶46.

84. Petitioners’ proposed combination replaces Thorens’ “puff detection system” with a differential pressure sensor. The two are not the same. Differential pressure sensors detect a user’s draw through the reduced pressure in the device compared to ambient is an indicator of airflow, but does not measure airflow itself. If, for example, the air inlets become clogged or blocked, a user could draw on the device and the pressure sensor would indicate to the controller that there is airflow when there is not. This could be dangerous as the device may overheat. Also, some differential pressure sensors can be tricked by blowing into the mouthpiece increasing the pressure in the device. When the pressure later drops, it is incorrectly detected as a puff.

85. As I discussed above, the pressure drop through a device will be very dependent on the configuration of the air pathway and requires careful design and manufacturing. Thorens, on the other hand, discloses a “puff detection system” through which the air passes. This allows for the direct measurement of airflow. Thorens describes the puff detector may be an electro-mechanical device, a

86. Thus, there is really no reason to replace Thorens's sensor with Weigensberg's differential pressure sensor.

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88. Yet this modification results in exposed wiring where the cartridge is inserted, as shown in Petitioners' own images of the proposed combination. In my opinion, a POSITA would find such exposed wiring highly undesirable due to the likelihood that repeated insertion would cause damage to the wiring, rendering the device inoperable.

89. This modification also exposes the leads of the pressure sensor on the inside of the device, which is inferior to the electrically connected disks from Thorens. In the proposed combination, there are loose wires that have to be displaced by the cartridge when inserted. A POSITA would never make this design change and would consider it a poor design.

90. Petitioners' proposed modification also removes Thorens's programmable circuitry 105, which is "used to manage the device operation," such as the control of the heating coil upon detecting a puff. Ex. 1016, ¶46. Petitioners do not propose any suitable replacement. In my opinion, a POSITA would understand that removing said circuitry would leave the device inoperable for its intended purpose—that is, detecting a puff and activating the heating coil to form vapor.

91. In my opinion, these significant and undesirable modifications outweigh Petitioners' alleged motivations to incorporate a differential pressure sensor that is unnecessary in view of Thorens's airflow sensor for detecting a puff.

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See Ex. 1016, ¶¶15, 34. In particular, Thorens discloses that its device “comprises a sensor to detect air flow indicative of a user taking a puff,” which will then “provide an electric current pulse to the at least one heating element.” *Id.*, ¶15. There really is no benefit to replacing Thorens’s airflow sensor with a pressure sensor that, at best, provides the same result, especially not when it involves the dramatic changes proposed by Petitioner which, in my opinion, would result in a fundamental change in Thorens’s principle of operation.

92. Below, I address each of Petitioners’ reasons for making these drastic modifications.

93. *First*, Petitioners argue that “a differential pressure sensor is simply a design choice that was conventionally used in e-cigarettes.” Pet. 68. Yet as I show above, adding Weigensberg’s pressure sensor to Thorens requires significant, undesirable changes that are more than just a design choice. Petitioners’ proposed modifications are certainly not a design that a POSITA would choose in view of Thorens’s extant airflow sensor.

94. *Second*, Petitioners argue that “a differential pressure sensor open to ambient air can better accommodate external pressure changes,” such as “the device would not accidentally activate at high altitude due to the decrease in pressure.” Pet. 68. However, this alleged advantage is merely a potential advantage over non-differential pressure sensors. And, even a non-differential

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pressure sensor can easily address this issue by establishing a running average baseline pressure with software. Thorens uses an airflow sensor which does not have this high altitude issue.

95. *Third*, Petitioners argue that “because Weigensberg’s sensor outputs pressure values, that can be used to add features to the device,” such as “changing heater parameters based on airflow rate.” Pet. 68. As an initial matter, I note it would likely be difficult to implement such features given that the proposed combination removes Thorens’s control circuit. Moreover, Thorens’s sensor detects “air flow indicative of a user taking a puff,” and therefore can already detect different airflow rates. Ex. 1016, ¶34.

96. *Finally*, Petitioners argue that in the combination “space where the puff sensor was located is freed up” which “permits, for example, a larger battery.” Pet. 68-69. The opposite is true. The proposed combination adds at least a pressure sensor to the tip of the e-cigarette, leaving less space for a larger battery.

B. Petitioners’ combination does not render obvious “a gasket around the pressure sensor”

97. The independent claims of the ’123 patent recite a “gasket around the pressure sensor.” Weigensberg does not disclose a gasket around its pressure sensor. Instead, Petitioners point to a “plastic LED cap 207,” which Petitioners contend “acts as a gasket that isolates the ambient air pressure path from the device path to allow the pressure sensor to detect differences from ambient air.” Pet. 81

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(citing Ex. 1006, ¶107). Below, as I have annotated from Figure 24, is Weigensberg's plastic LED cap.

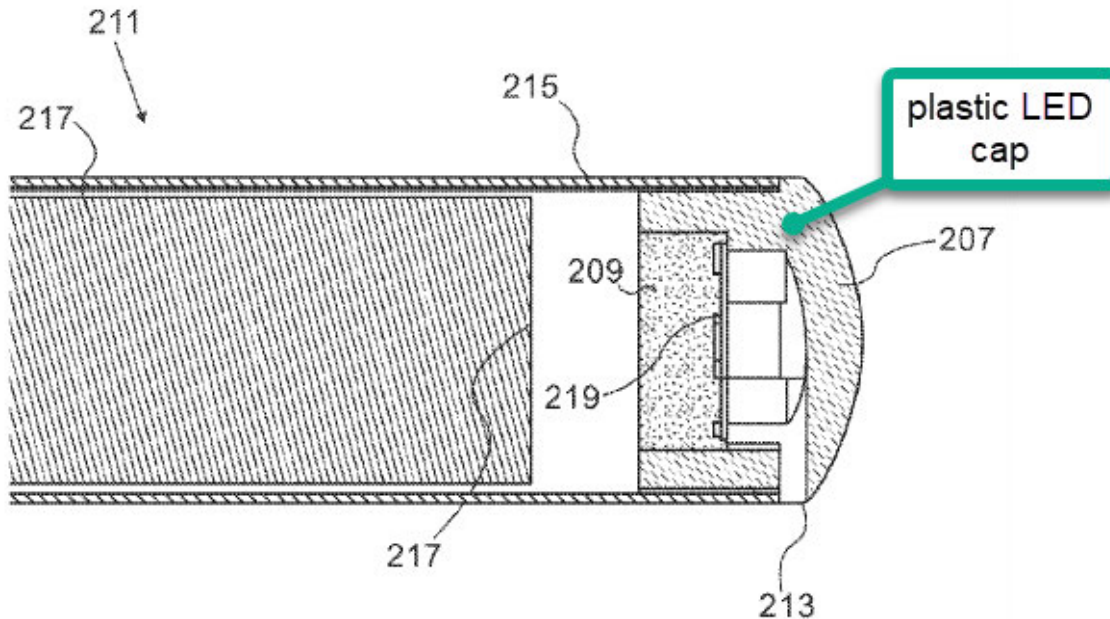


FIG. 24

98. However, Weigensberg does not disclose that the plastic LED cap is a gasket. It is, as its name indicates, a cap over the LED. In my opinion, no POSITA would consider a plastic LED cap to be a gasket. A POSITA would understand a gasket to be a flexible material surrounding the sensor that can form a seal between the ambient pressure side and the sealed airflow path. There is no disclosure in Weigensberg that the plastic LED cap provides such a seal, and a POSITA would understand that plastic is not a suitable material for a gasket because it does not provide an airtight seal that a gasket provides.

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99. I think Petitioners recognize the issue with Weigensberg's plastic LED cap. Thus, they argue that "a POSA would have recognized that, consistent with common practice, Weigensberg's pressure sensor would have a surrounding gasket to isolate the ambient side of the pressure sensor from the other side that senses the negative pressure." Pet. 82. However, Weigensberg's depictions do not have any space for a gasket. Nor would a gasket be needed since the plastic LED cap, while not a perfect seal, provides enough separation for the differential pressure sensor to work.

100. I understand that in its Institution Decision, the Board rejected the above argument because Weigensberg's plastic LED cap provides "enough of a seal for the differential pressure sensor to work." Institution Decision, 43.

However, I disagree with the Board's conclusion because a POSITA would understand that a gasket must provide an airtight seal. The '123 patent itself makes this clear, disclosing that the gasket is "configured to *seal* the device air path from the sealed air flow path" and states in the specification that the gasket "forms an *air-tight* seal." Ex. 1001, 42:28-30

VIII. GROUNDS 5-8 FAIL FOR THE SAME REASONS AS ABOVE

101. In Grounds 5 through 8, Petitioners propose combining Grounds 1 through 4 with Lamb as an alternative argument for the claimed "pressure sensor configured to output sensor readings" and "gasket around the pressure sensor...to

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seal the device air path from the sealed air flow path,” as well as several dependent claims reciting limitations with respect to the pressure sensor. Since these grounds rely on Grounds 1-4 for the claimed air flow path, air inlet and channel, in my opinion, they also fail for the same reasons discussed above. For Ground 8, Petitioners argue that Thorens and Weigensberg in further view of Lamb renders obvious “a gasket around the pressure sensor.” Pet. 95-97. However, Petitioners do not contend that Lamb discloses a gasket. Instead, Petitioners argue that “Lamb incorporates by reference Newton766,” and that Newton766 has a sealing member around its pressure sensor. Pet. 96 (citing Ex. 1005, ¶41).

102. But Petitioners do not provide any motivation to combine Thorens and Weigensberg with Newton766’s alleged sealing member. In the motivation to combine for Grounds 5-8, neither Newton766 nor a gasket is mentioned. Instead, the section is directed to incorporating Lamb, which does not teach a gasket.

IX. SECONDARY CONSIDERATION OF NON-OBVIOUSNESS

103. In my opinion, there is strong, objective evidence that the ’123 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, at least claims 14 and 27 of the ’123 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.

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104. 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

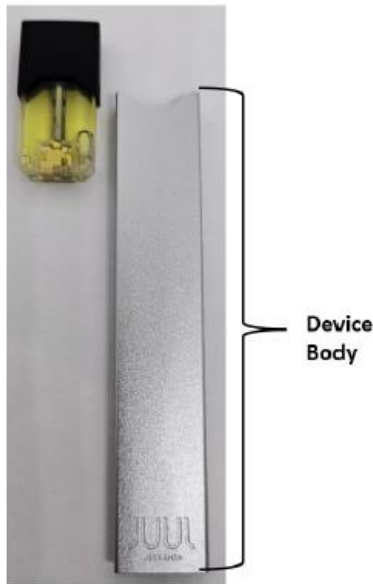
105. In my opinion, the JUUL System is coextensive with at least claim 14 of the '123 patent and therefore I understand it is assumed there is a nexus between the '123 patent and the objective evidence relating to the JUUL System. As I show below, the JUUL System embodies claim 14 of the '123 patent, including its main device body and the removable cartridge. Claim 14 is not simply a subcomponent of the JUUL System.

106. The JUUL System practices every limitation of claim 14 of the '123 patent, and in fact, several of the '123 patent's figures are similar to the actual JUUL System product.

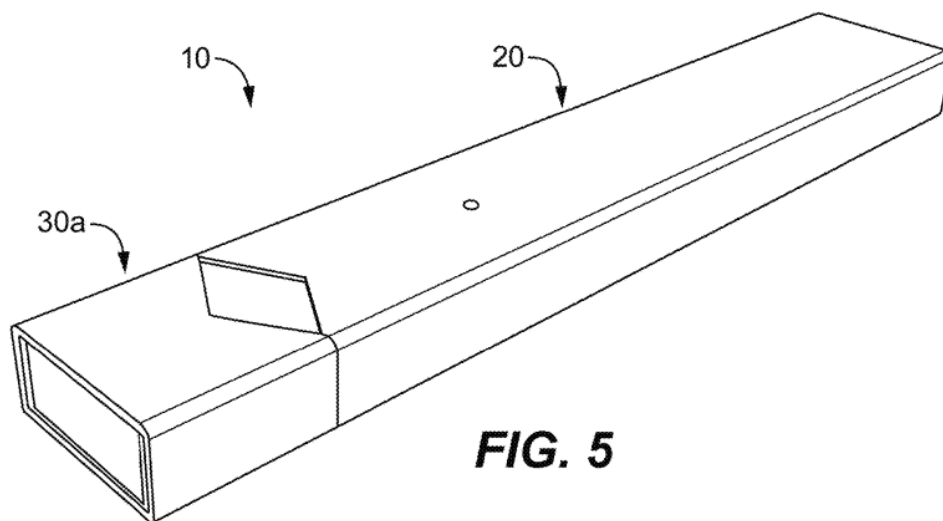
1. 14[pre]: A vaporizer device body comprising:

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107. In my opinion, as shown in the photograph below of the JUUL System, the JUUL System comprises a vaporizer device body. Ex. 2007.



108. This apparatus is consistent with the apparatuses described in the '123 patent and depicted in its figures. See, e.g., Fig. 5.



2. 14[a]: a cartridge receptacle configured to insertably receive a cartridge containing a vaporizable material;

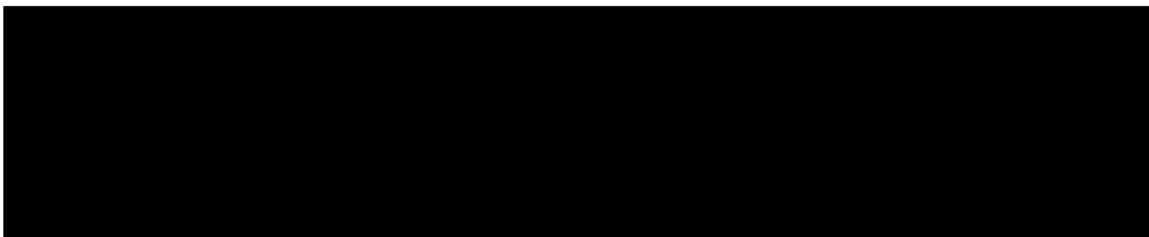
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109. In my opinion, as shown in the below photo, the JUUL System comprises a JUUL Device that has a cartridge receptacle configured to insertably receive a cartridge containing a vaporizable material (specifically a JUULpod).

Ex. 2007.



110. JLI documentation states that the cartridge contains a vaporizable material. Ex. 2003, 9.



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111. The JUULpod cartridge and JUUL Device's receptacle is consistent with the cartridges and receptacles described in the '123 patent and depicted in its figures. *See, e.g.*, Fig. 12.

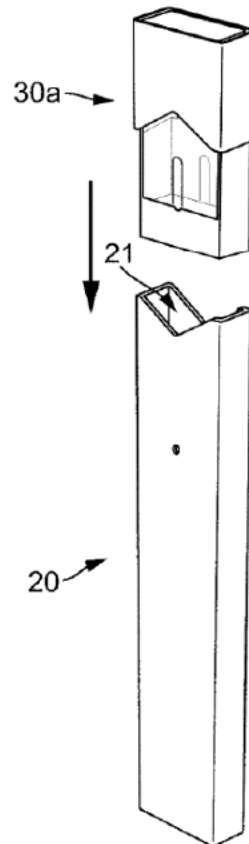
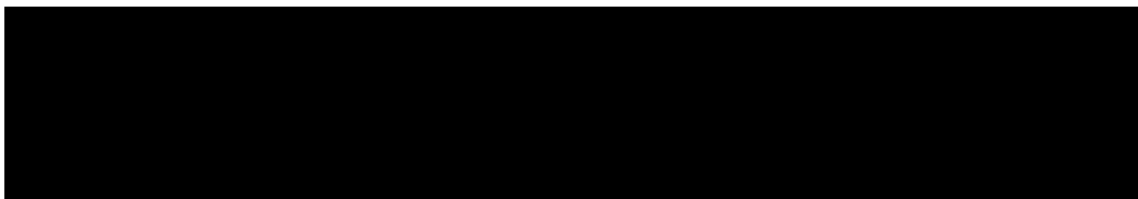


FIG. 12

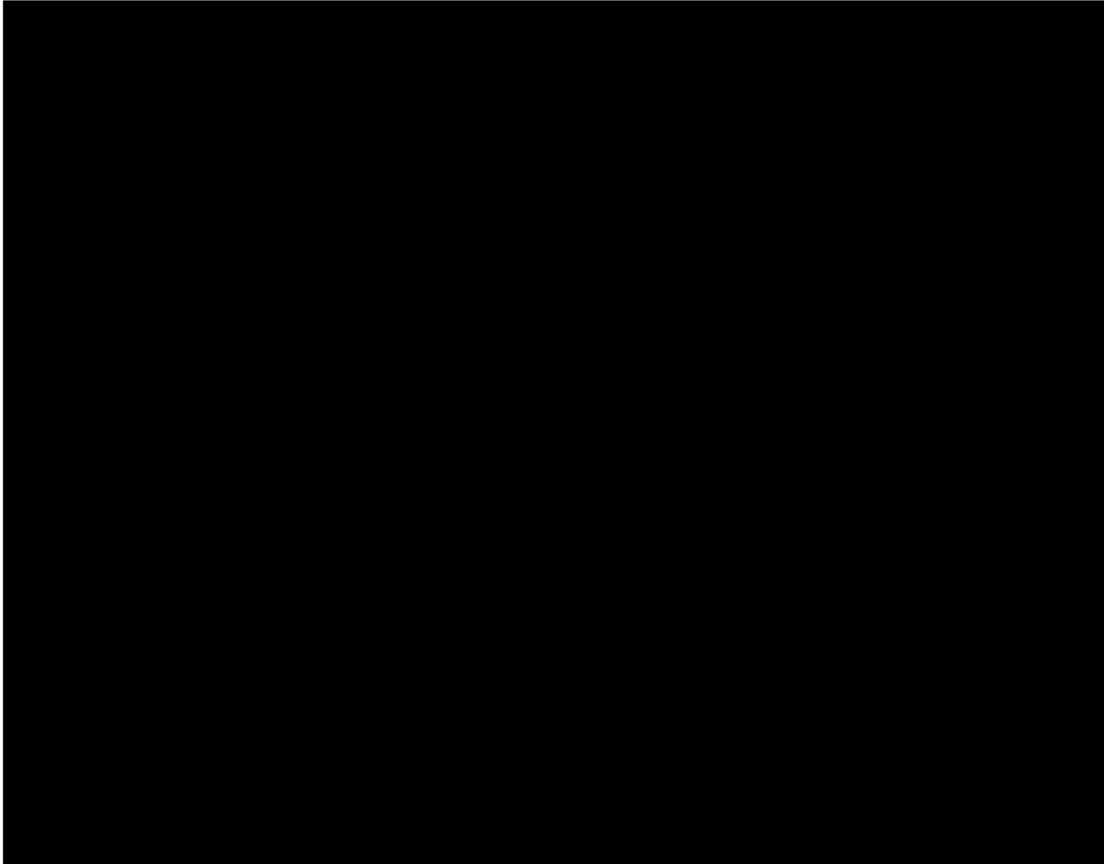
3. 14[b]: a pressure sensor configured to output sensor readings

112. In my opinion, JLI documentation describes that the JUUL System has a pressure sensor configured to output sensor readings. Ex. 2003, 11.



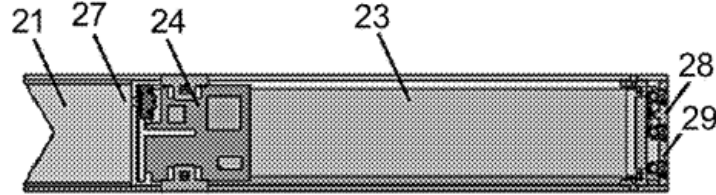
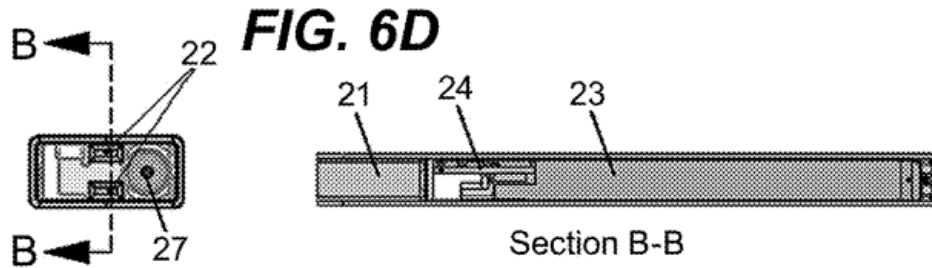
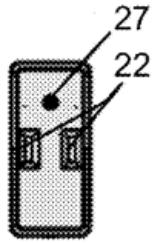
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113. The below diagram from the same document also shows a pressure sensor. *Id.*, 13.



114. The pressure sensor of the JUUL System is consistent with the pressure sensor described in the '123 patent and depicted in its figures. *See, e.g.*, Fig. 6B, 6C, 6D (element 27).

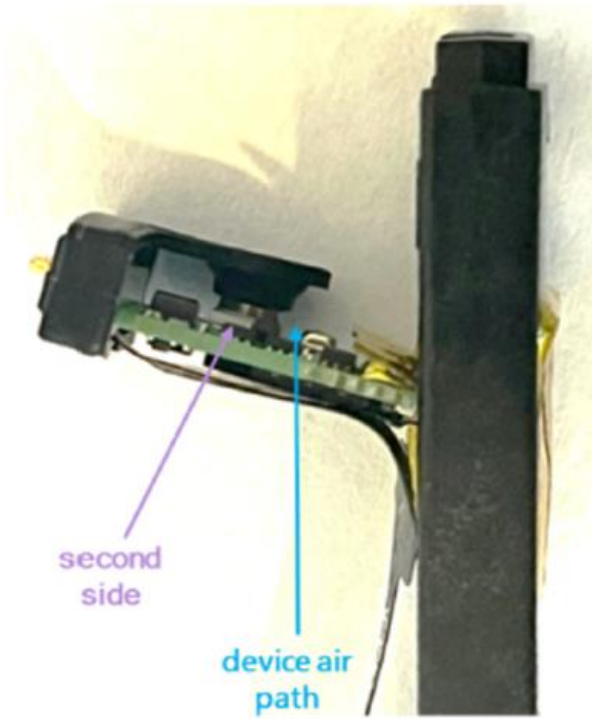
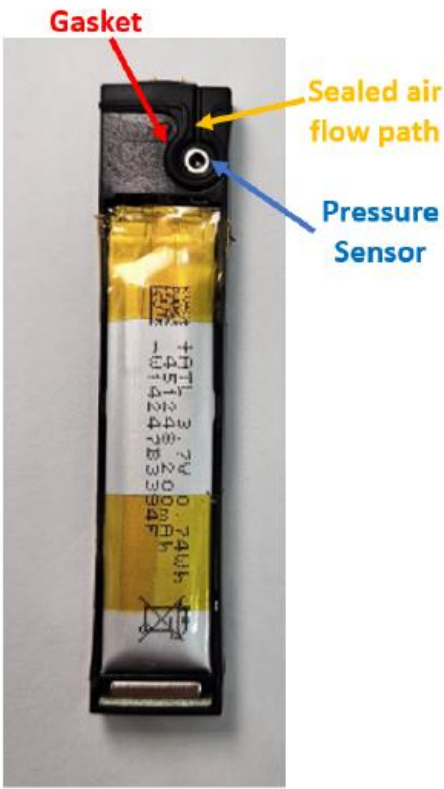
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FIG. 6A**FIG. 6B****FIG. 6C**

4. 14[c] wherein a first side of the pressure sensor is exposed to a sealed air flow path and a second side of the pressure sensor is exposed to a device air path open to ambient pressure,

115. In my opinion, the below annotated photographs of the JUUL System show that pressure sensor in the JUUL System has a first side exposed to a sealed air flow path and a second side exposed to a device air path open to ambient pressure. This is a “sealed” airflow path because the air in this airflow path is sealed by a gasket from ambient pressure. Exs. 2045, 2046, 2048, 2049.

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116. JLI documentation states that inhalation is detected “

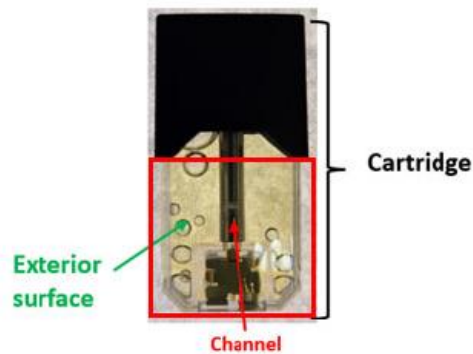
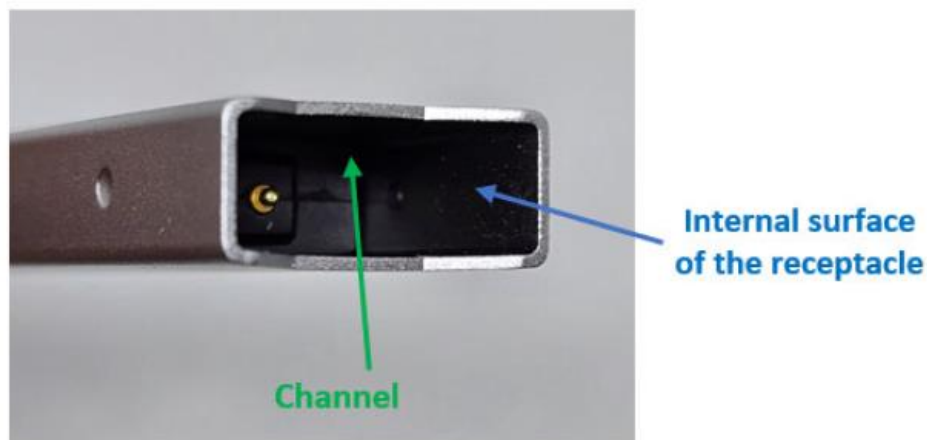
.” Ex. 2003, 11.

117. The ambient and negative pressure sides of the JUUL Systems pressure sensor are consistent with the ambient and negative pressure sides of a pressure sensor in the ’123 patent. *See, e.g.*, Ex. 1001, 4:38-43.

5. 14[d]: the sealed air flow path comprising a channel formed between an interior surface of the cartridge receptacle and an exterior surface of the cartridge.

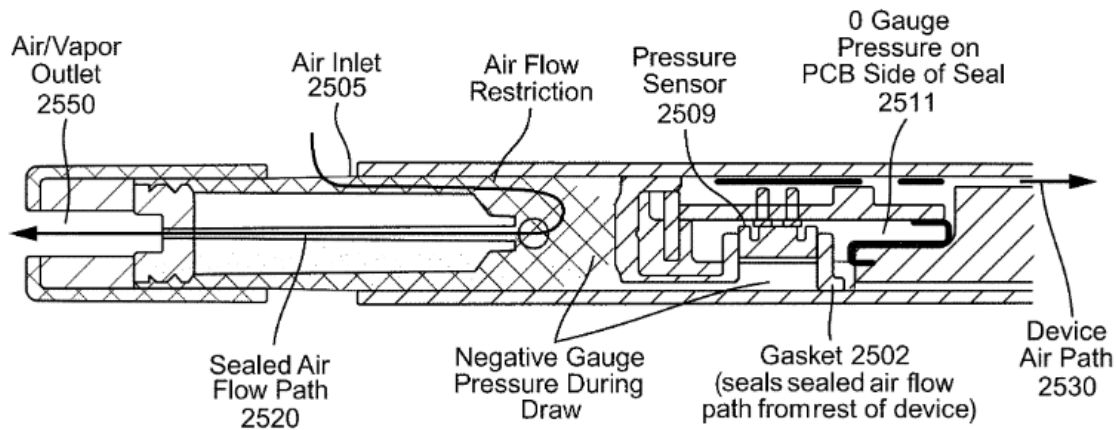
PUBLIC VERSION

118. In my opinion, in the JUUL System, air enters via an air inlet at the interface between the cartridge and the receptacle, on the sides of the device. It then flows downward, between the cartridge and the receptacle, to the base of the inserted cartridge, and up into the heating chamber. This channel is depicted in the below photographs. Ex. 2008, Ex. 2004.



119. The JUUL System's channel is consistent with the channel described and depicted in the '123 patent. *See, e.g.*, Fig. 25.

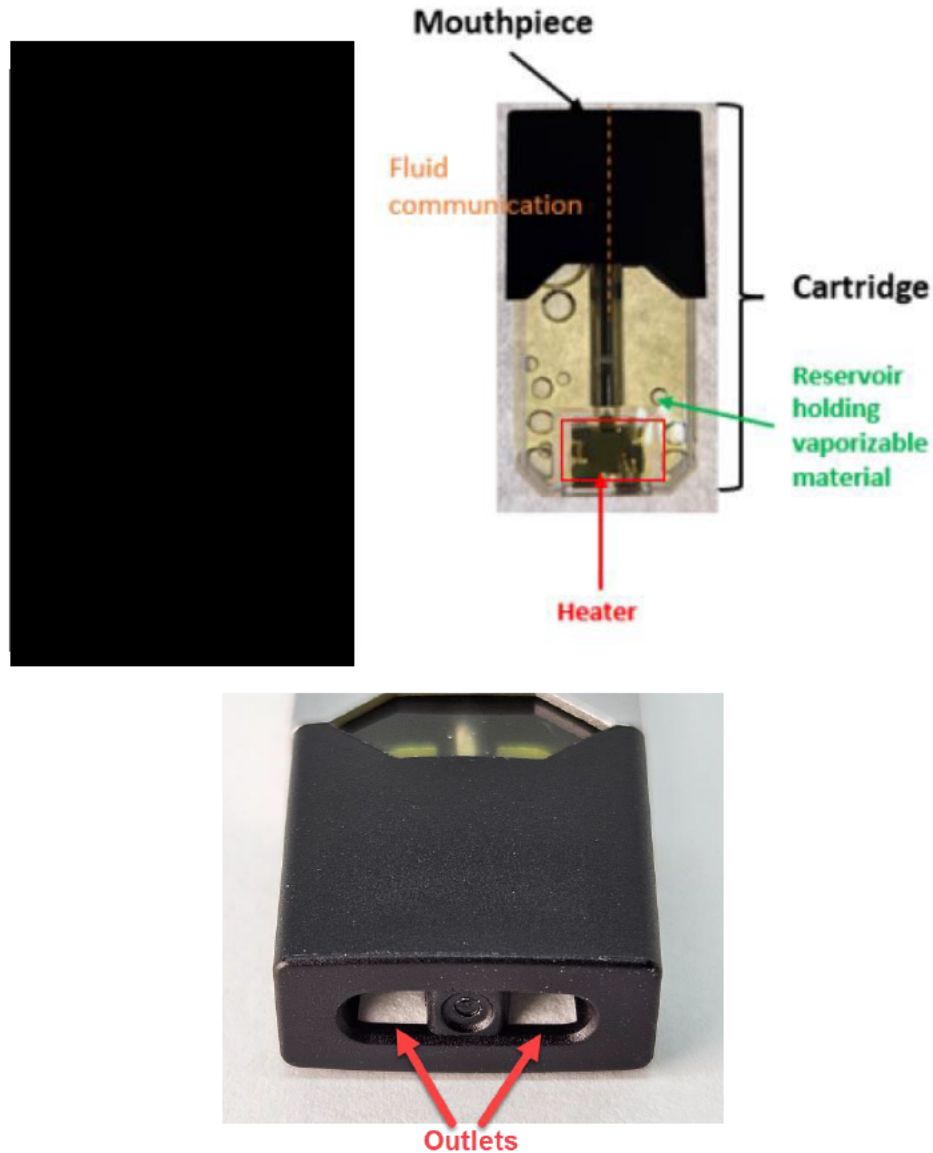
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**FIG. 25**

6. 14[e]: the sealed air flow path passing from an air inlet, through the channel and to a heater and an outlet of a mouthpiece within the cartridge; and

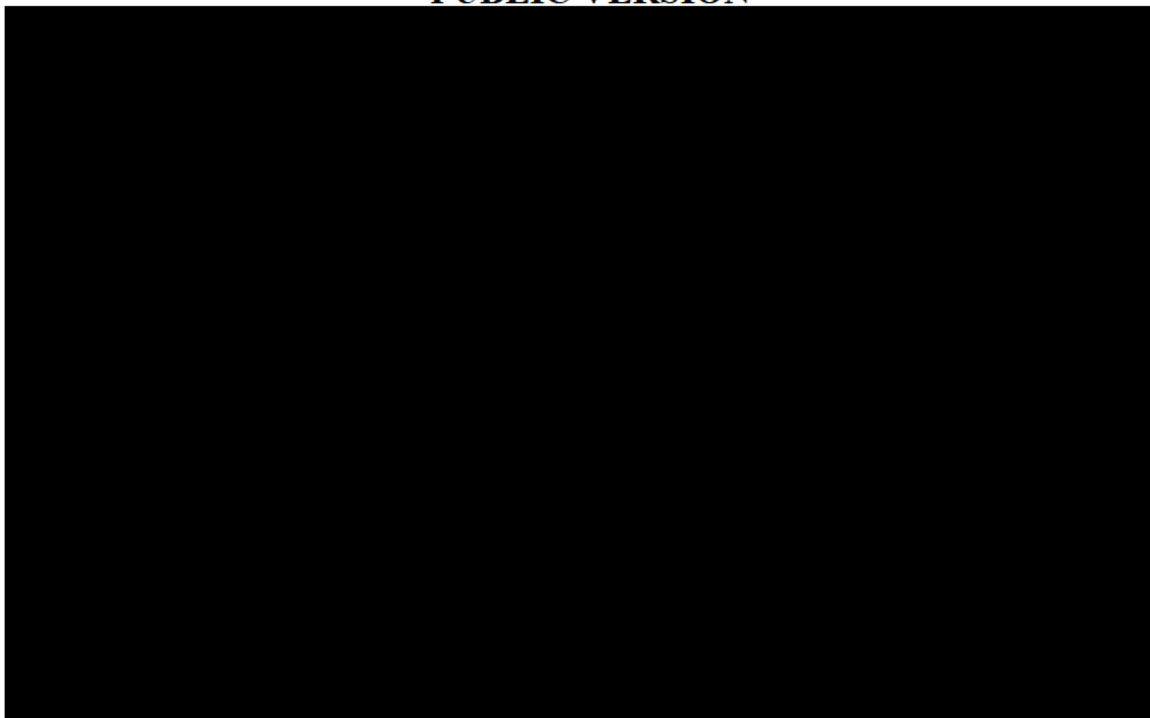
120. In my opinion, in the JUUL System, air enters at the interface between the cartridge and the receptacle, on the sides of the device. It then flows downward, between the cartridge and the receptacle, to the base of the inserted cartridge, and up into the heating chamber. The air path continues to outlets of a mouthpiece within the cartridge. This is shown in the below photographs. Ex. 2003, 9; Ex. 2004; Ex. 2050.

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121. The below figure from JLI documentation also depicts that the air flow path of the JUUL system passes through a heater and out of outlets of a mouthpiece within the cartridge. Ex. 2003, 26.

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122. The JUUL Device has a sealed air flow path consistent with the air flow paths described in the '123 patent and depicted in its figures. *See, e.g.*, Fig. 25.

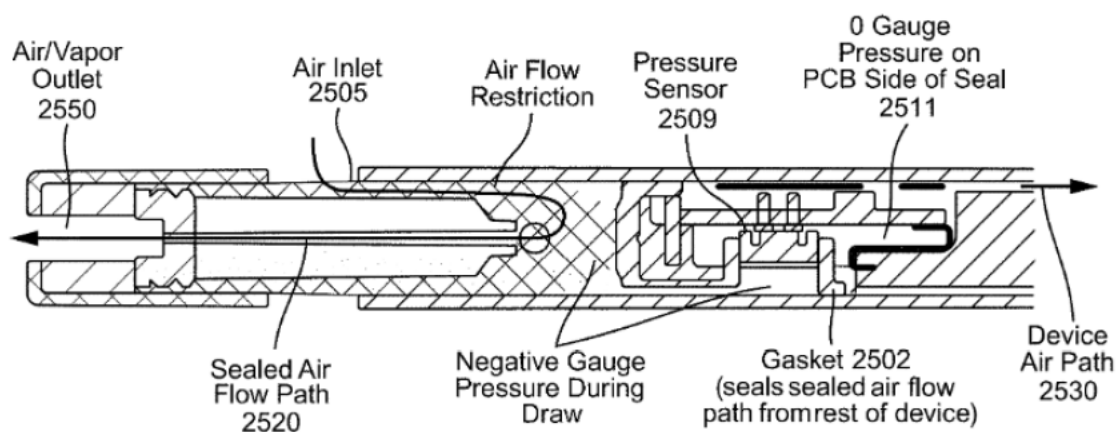
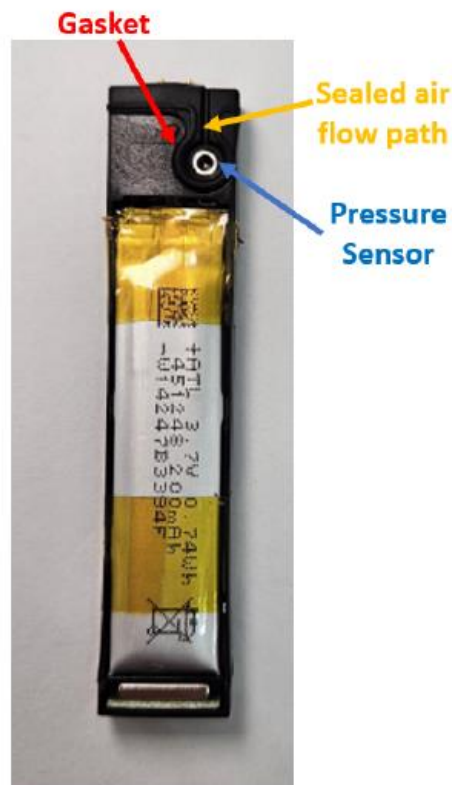


FIG. 25

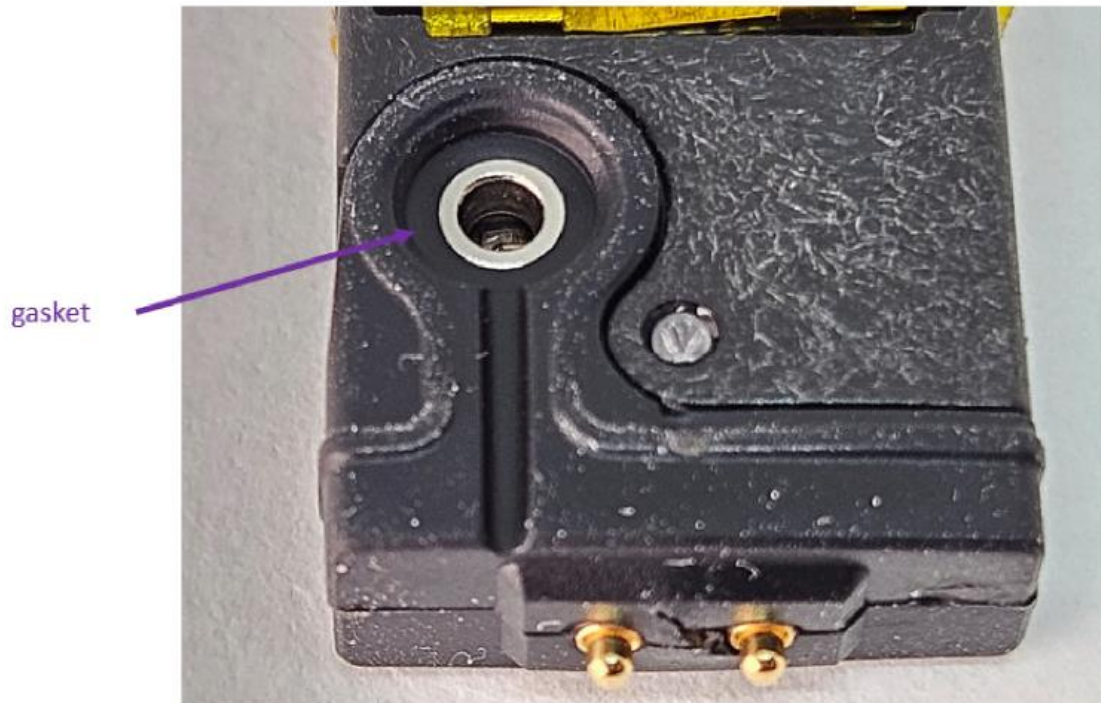
7. 14[f]: a gasket around the pressure sensor, the gasket configured to seal the device air path from the sealed air flow path.

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123. In my opinion, in the JUUL System, the gasket surrounds the perimeter of the pressure sensor, and is compressed between the enclosure and skeleton of the JUUL Device, isolating the sealed airpath pressure readings from the sensor readings of ambient pressure. The below photographs depict the gasket. Ex. 2045; Ex. 2051.

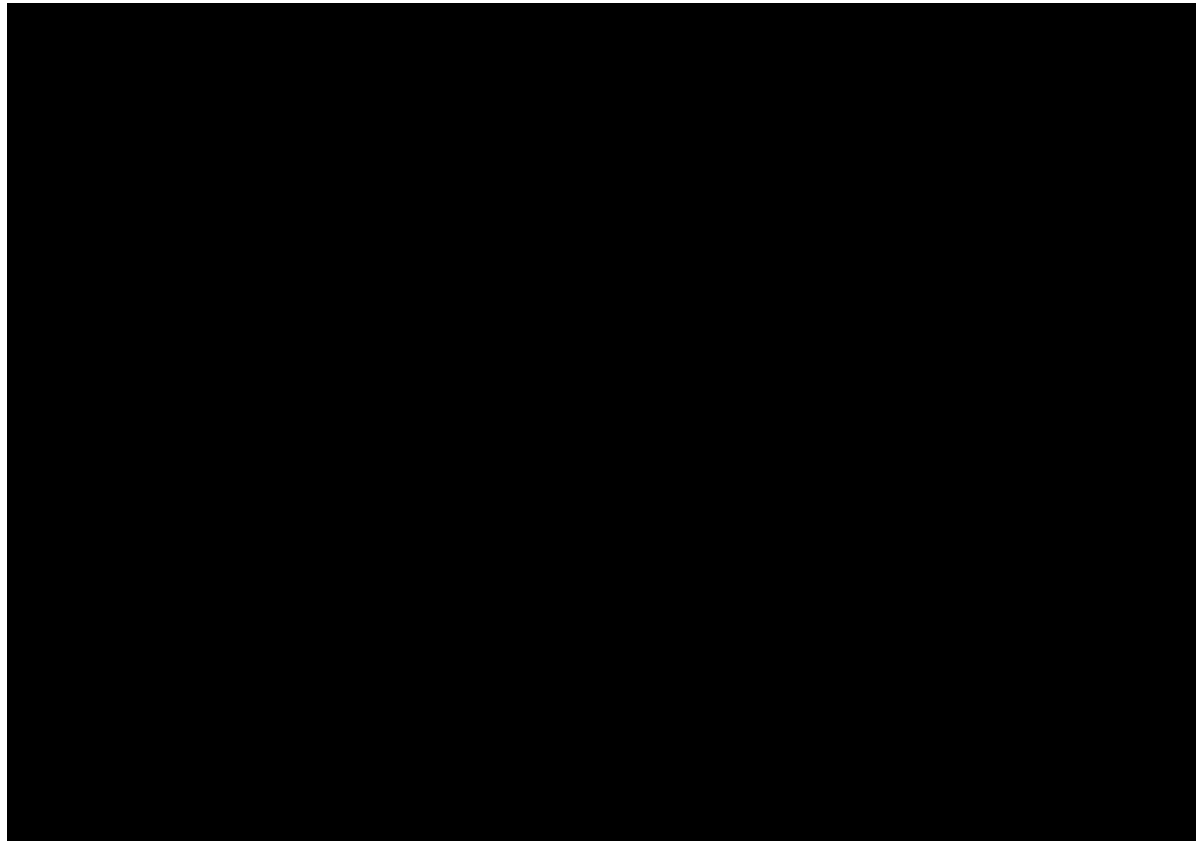


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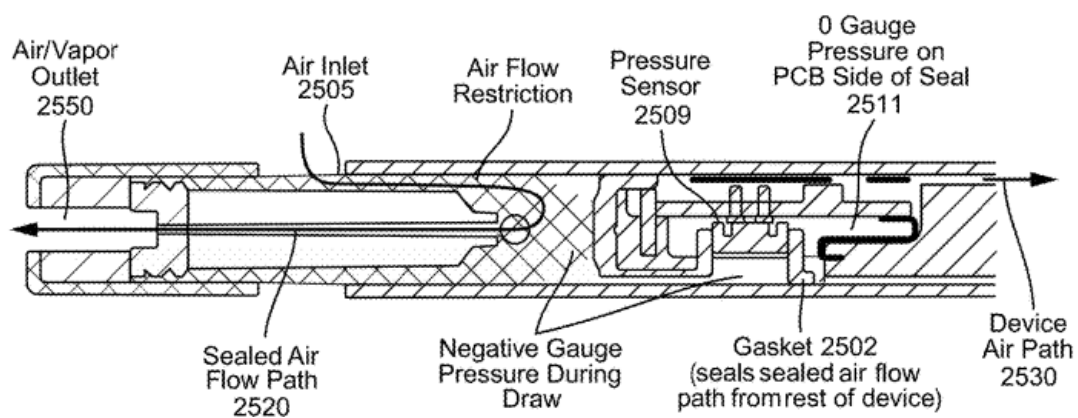


124. JLI documentation also identifies the gasket as part of the JUUL System. Ex. 2003, 13.

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125. The JUUL System's gasket is consistent with the gasket described and depicted in the '123 patent. *See, e.g.*, Fig. 25.



PUBLIC VERSION**B. Long-felt Need**

126. 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.

127. 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.

128. 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 non-smokers 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).

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129. 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.

130. 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.

131. 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

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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).

132. 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.

133. 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 ’123 patent. Ex. 2025, 39:8-41:5 ([REDACTED]

[REDACTED]); Ex. 2026, 25:6-30:8

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]); *id.*, 137:23-143 ([REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]; *id.*, 33:24-35:6 ([REDACTED])

[REDACTED]

[REDACTED]”); *id.*, 116:15-117:14. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Ex. 2025, 39:8-41:5, 65:9-66:19, 81:22-82:18, 84:8-85:4, 87:21-88:2.

134. 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 ’123 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.

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

PUBLIC VERSION**C. Unexpected Results**

136. 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.

137. 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 ([REDACTED]

[REDACTED]); Ex. 2026, 25:6-30:8 ([REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]); *see also id.*, 137:23-143 ([REDACTED])

[REDACTED]

[REDACTED]

[REDACTED]); *id.*, 33:24-35:6 ([REDACTED])

[REDACTED]

[REDACTED]”); *id.*, 116:15-117:14.

138. 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

139. 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.

140. 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-

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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 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

141. 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

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(“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.”).

142. 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.

143. 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.

144. Altria also recognized the commercial success of the JUUL System in its offers to potentially license JLI’s intellectual property. [REDACTED]

[REDACTED]

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

F. Copying

145. 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.

146. 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.

147. 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

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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).

148. Altria has also represented that it began “working on an internal pod-based 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.

149. 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

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any pod products that were available.” *Id.* ¶302. Internally, Altria referred to this project as “Project Mule.” *Id.* ¶303.

150. 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.

151. 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, in-house 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.

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152. 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.

X. CONCLUSION

153. 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 cross-examination within the United States during the time allotted for cross-examination.

154. 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: September 4, 2024

/s/ John Collins

John Collins, Ph.D.