

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436**

**Before the Honorable Doris Johnson Hines
Administrative Law Judge**

In the Matter of

**CERTAIN VAPORIZER DEVICES,
CARTRIDGES USED THEREWITH,
AND COMPONENTS THEREOF (II)**

Investigation No. 337-TA-1460

**ATTACHMENT G
RESPONDENTS' FINAL INVALIDITY CONTENTIONS**



I. INTRODUCTION

Respondents NJOY, LLC; NJOY Holdings, Inc.; Altria Group, Inc.; Altria Group Distribution Company; and Altria Client Services LLC (“Respondents” or “NJOY”) hereby submit the following Final Invalidation Contentions in accordance with Commission Rules 210.29 and 210.30, the Honorable Doris Johnson Hine’s Ground Rules (Order No. 2), and the agreed-upon Procedural Schedule.

Complainant Juul Labs, Inc. (“Complainant” or “JLI”) asserts U.S. Patent No. 12,156,533 (the “’533 patent”) against NJOY. These Second Amended Invalidation Contentions address the following claims of the ’533 patent:

Patent	Asserted Claims¹	Domestic Industry Claims
’533 Patent	1, 2–8 and 10	1, 9

The claims identified above are referenced as “the Asserted Claims.” Based on its investigation to date, NJOY hereby provides, in detail, the basis for its contention of invalidity or unenforceability for each of the Asserted Claim under 35 U.S.C. §§ 100 *et seq.* NJOY incorporates by reference its Verified Response to Juul Labs, Inc.’s Complaint and any amendments or supplements thereto.

II. SUPPLEMENTAL OVERVIEW OF THE TECHNOLOGY

NJOY incorporates by reference Section III of Attachment A to its Initial Invalidation Contentions, and any supplements or revisions thereto, as if fully set forth herein. NJOY provides additional background regarding information known to a POSITA.

¹ The independent claims are in bold.

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A. Historical Use of Nicotine Salts

Nicotine salts, including those formed from carboxylic acids, occur naturally in tobacco leaves. Leffingwell, *Basic Chemical Constituents of Tobacco Leaf* (1999) at 266, 280; Seeman, *The Form of Nicotine in Tobacco* (1999). To retain these salts and acids tobacco companies have been “flue-curing” tobacco leaves since 1850 to produce a “milder smoke” with a lower pH. Duell, *Nicotine Tobacco Product Aerosols* (2020) (“Duell”) at 660–61.

Indeed, for decades, skilled artisans have understood that lowering the pH of cigarette smoke makes it more palatable, and more easily and deeply inhaled due to nicotine protonation. *Id.* In application, tobacco companies have been using nicotine salt liquid formulations, including those from organic, lactic, and benzoic acids, in lit-end cigarettes since at least the 1990s. *See, e.g.,* U.S. Patent No. 4,836,224; Duell at 660; Keithly, *Industry Research* (2005); SCENIHR, *Tobacco Additives* (2010).

This knowledge and use of nicotine salts extended beyond lit-end cigarettes to include electronic nicotine delivery systems, inhalers, sprays, patches, and lozenges. *See, e.g.,* Potter ’486; Gonda ’474; Brinkley ’809; Rigas ’044; Hearn ’562; Rose ’567; Rose, *Pulmonary Delivery* (2010); Kosik ’203; Honeycutt ’348; U.S. Patent No. 8,322,350 (“Lipowicz”); Bullen, *Effect of an Electronic Nicotine Delivery Device* (2009); Duke University Medical Center, *New Smoking Cessation Therapy Proves Promising* (2010); SCENIHR, *Tobacco Additives* (2010); Caldwell, *Systematic Review of Nicotine by Inhalation* (2012).

JLI admits that “[t]he preparation and study of nicotine salts has been conducted by industry for some time (in particular, RJ Reynolds).” JLI-ITC1460_01152714 at JLI-ITC1460_01152726 (citing Perfetti, Thomas A. *Structural Study of Nicotine Salts*. *Beitrag Zur Tabakforschung International*, Vol. 12 - No 2, 1983). “The purpose was primarily to address

[REDACTED]

smoke harshness.” *Id.* Other documents confirm this. JLI-ITC1460_01046037 (“It is known to the industry that the use of organic acids or neat nicotine salts reduces the harshness of smoke.”); JLI-ITC1460_01165546 at JLI-ITC1460_011655469. While developing the ’533 patent family, Adam Bowen and Chenyue Xing looked specifically at the ingredients of cigarettes which include “lactic acid.” JLI-ITC1460_01043109; JLI-ITC1460_00228696; JLI-ITC1460_02714352.

B. Standards

Because of the above history, governments knew that nicotine devices that used nicotine salts would be sold. For example, well before the ’533 patent, Canada included in its Schedule F “nicotine *and its salts*, for human use.” https://web.archive.org/web/20110403173028/http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-293.html#h-161 (emphasis added). However, its schedule F exempted regulating “nicotine and its salts, for human use” “(d) in a form to be *administered orally by means of an inhalation device* delivering 4 mg or less of nicotine per dosage unit;” https://web.archive.org/web/20110403144057/http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-502.html (emphasis added). Therefore, it even outside of the industry, it was well known to lawmakers to include nicotine salts for this regulation and well known to anyone developing an electronic cigarette that may be sold in Canada to try to nicotine salts. JLI itself had to contend with these regulations for selling its products in Canada. JLI-ITC1460_02806522; JLI-ITC1460_02822609; JLI-ITC1460_02822599; JLI-ITC1460_02822602; JLI-ITC1460_02874112; JLI-ITC1460_02874118.

III. IDENTIFICATION OF PRIOR ART

NJOY also incorporates by reference Respondents’ Notice of Prior Art. Claim charts identifying the relevant invalidity disclosures NJOY is relying upon from the references identified

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in the tables below as to the Asserted Claims of the '533 Patent are provided in attached Exhibits A1 through A30.

Table 3-A: Claim Charts for the '533 Patent

Exhibit No.	Prior Art Reference/System
A1	Rigas '044
A2	Buchberger '185
A3	Buchberger '236
A4	Collett '554
A5	Hon '518
A6	Hon '803
A7	Kosik '203
A8	Rabinowitz
A9	2008 NJOY Tariff Classification Letter
A10	2008 Sailebao Liquid Component List
A11	2008 NJOY Products
A12	Smuke Products
A13	2008 Sailebao Products
A14	[REDACTED]
A15	Ruyan Products
A16	Novak '144
A17	Potter '486
A18	Sears '105
A19	Sears '781
A20	Chapman '487
A21	Ampolini '727
A22	Griffith '702
A23	Hearn '562
A24	Honeycutt '348
A25	Li '801
A26	Kane '490 and Kane '499
A27	Gonda '474
A28	Rose
A29	2007 NJOY Products
A30	Brinkley

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
JLI-ITC1460_01079596 (November 28, 2017 European Search Report). The claims which the European search report said were not entitled to the priority date included claim 16 which stated “wherein the organic acid is ... lactic acid.” JLI-ITC1460_01088412 (November 8, 2017 Amended Claims).

VI. INVALIDITY UNDER 35 U.S.C. §§ 102 AND 103

NJOY contends that certain prior art references below anticipate one or more Asserted Claims under 35 U.S.C. § 102 and that, to the extent the identified prior art references do not anticipate the Asserted Claims, those claims are invalid as obvious under 35 U.S.C. § 103. The prior art listed below anticipates or renders obvious the Asserted Claims under the proper construction of the claims and/or under Plaintiff’s apparent interpretation of the claims reflected by Plaintiff’s Complaint and Infringement Contentions. To the extent that JLI contends that any of the anticipatory prior art fails to disclose one or more limitations of the Asserted Claims, NJOY contends that any difference between the reference and the corresponding patent claims would have been obvious to one of ordinary skill in the art. Thus, all of the claim charts should be interpreted as both reflecting anticipation by the reference as well as invalidity due to single reference obviousness, to the extent that JLI contends that any limitation is missing.

A. Anticipation (35 U.S.C. § 102)

The Asserted Claims of the ’533 Patent are anticipated and/or rendered obvious by prior art. NJOY identifies the prior art references that anticipate or render obvious the ’533 Patent Asserted Claims in the claim charts of Exhibits A1 through A30 (collectively “Appendix A”), which are hereby incorporated by reference as if fully set forth herein. The claim charts of Appendix A show how these prior art references teach or suggest each and every element of the Asserted Claims of the ’533 Patent.

[REDACTED]

[REDACTED]

c. Potter '486

U.S. 2014/0261486A1 (“Potter ’486”) was published on September 18, 2014 and filed on March 12, 2013. Potter ’486 qualifies as prior art under at least 35 U.S.C. § 102(a)(2).

As set forth in Exhibit A-17 (incorporated by reference as if fully set forth herein) and below, claims 1–10 (the “Asserted Claims”) of U.S. Patent No. 12,156,533 (the “’533 patent”) are anticipated by Potter ’486.

Potter ’486 incorporates, *inter alia*, U.S. Patent and Application Nos. 4,830,028 (“Lawson ’028”), 4,836,224 (“Lawson ’224”), 5,056,537 (“Brown”), 4,924,888 (“Perfetti”), 5,159,942 (“Brinkley ’942”), 7,647,932 (“Cantrell”), 8,079,371 (“Robinson”), and 2007/0215167 (“Crooks”), 2008/0245377 (“Marshallet”). See *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

i. 1. An electronic cigarette comprising a cartridge, wherein the cartridge comprises a nicotine salt liquid formulation, wherein:

Potter ’486 discloses this limitation as shown below and in Exhibit A-17, Section 1, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

For example, Potter ’486 discloses a “vapor-enhancing apparatus ... provided for an electronic vapor smoking article.” Potter ’486 at Abstract, [0006], [0022]. The e-cigarette may “comprise a cartridge with a connecting end ... [and] an opposing mouth end.” *Id.* at [0059]–[0060], [0075]. Within the article, the “the aerosol precursor component [also called an “e-liquid”] can be located near an end of the article (e.g., with a cartridge which, in certain circumstances, can be replaceable and disposable.” *Id.* at [0022], Figs. 1–4. As explained below, Potter ’486 discloses a cartridge comprising a nicotine salt liquid formulation by virtue of disclosing an aerosol

[REDACTED]
[REDACTED]
precursor composition containing nicotine and organic acids in equimolar amounts. *See, e.g., id.* at [0049].

JLI admits that '486 discloses, *inter alia*, an electronic cigarette that comprises a cartridge. *See* JLI RFA Resp. Nos. 7–9, 13–15.

ii. (a) the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier, wherein the organic acid is benzoic acid or lactic acid;

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 1(a), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

For example, Potter e-liquids contain nicotine salts (nicotine benzoate and lactate) and organic acids (benzoic and lactic acids) by incorporating references with extensive discussions of salts, acids, and pH modification. Potter '486 discloses an electronic cigarette employing an “aerosol precursor composition” with nicotine and organic acids, as well as other “tobacco-derived material,” “including those described in “U.S. Pat. No. 4,836,224 to Lawson et al.” and “U.S. Pat. No. 7,025,066 to Lawson et al.,” which it incorporates fully. Potter '486 at [0041], [0049]. Potter '486 further discloses an electronic cigarette employing “tobacco additives ... used for the production of ... cigarettes” including “materials that can be added”—incorporating “U.S. Pat. No. 4,830,028 to Lawson et al.” Potter '486 at [0043].

The incorporated Lawson '224 discusses the purpose, effects, and mechanics of using nicotine salts, including pH modification via organic acids. It discloses the use of “nicotine/organic acid salt” to achieve “reduction of the pH of the mainstream aerosol” to ensure “fully bodied tobacco flavor, strength and satisfaction.” Lawson '224 at 10:35–45. It further

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discloses “incorporating an organic acid” into cigarettes with “high nicotine content tobacco ... to render[] smooth smoking and [a] palatable” experience. Lawson ’224 at Abstract. In further champions the use of “nicotine/organic acid salt within the cigarette [to] provide[] improved tobacco taste, strength and smoking satisfaction as well as improved or maintained flavor characteristics to the aerosol during use of the article.” Lawson ’224 at 3:28–32.

The incorporated Lawson ’224 further discloses the components and incorporation of nicotine salts and organic acids into a liquid formulation. It discloses possible organic acids to create nicotine salts, including “benzoic-type acids” and “monocarboxylic acids.” Lawson ’224 at 6:33–60. Lactic acid is a monocarboxylic acid. It also discloses “nicotine lactate,” which (along with the other acids) can be employed in a “liquid form ... in a suitable solvent ... includ[ing] water, ... glycerol, propylene glycol, and the like, as well as combinations thereof. Lawson ’224 at 8:31–9:21. These acids (and resulting nicotine salts) may be “applied to ... [or] incorporated within some or all of the filler material.” Lawson ’224 at 7:20–36. They may also be “be mixed with tobacco extracts ... and the resulting tobacco material/organic acid mixture can be blended with, mixed with, or otherwise used to treat other tobacco(s) or tobacco material(s).” *Id.*

The incorporated Lawson ’028 discusses the purpose, effects, and mechanics of using nicotine salts, including pH modification via organic acids. It discloses nicotine delivery devices using nicotine salts, and with high concentrations of nicotine, that provide “smoking satisfaction to the user,” but with a “smooth, palatable, flavorful taste” that does “not exhibit a harsh or irritating character.” Lawson ’028 at Abstract, 2:18–28, 6:62–7:7, 7:12–14, 7:15–25, Examples. It further teaches that the “presence of the salt within the article provides improved tobacco taste, strength and smoking satisfaction as well as improved or maintained flavor characteristics to the aerosol during use of the article.” Lawson ’028 at 2:30–44.

[REDACTED]

The incorporated Lawson '028 further discloses a nicotine-salt formulation combining nicotine and an organic acid (forming a nicotine salt) with carriers in a liquid formulation. It discloses a salt created from the combination of pure nicotine and organic acids: “salt provided from nicotine and an organic acid ... requires nicotine as a necessary component” which “can be naturally occurring nicotine which is obtained as an extract ... or synthetic nicotine.” Lawson '028 at 4:15–28. It also discloses useful acids, including “organic acids ... which form salts with nicotine in a 1:1 ... molar ratio, ... including benzoic-type acids and ... aliphatic monocarboxylic acids,” like lactic acid. Lawson '028 at 4:29–53. It further discloses that the “nicotine/organic acid salt” may be in “a liquid solution of the salt in a suitable solvent” which can be “spray[ed] or inject[ed],” and with a “concentration of the salt within the solution ... about 20 weight percent or more.” Lawson '028 at 6:9–17. “Suitable solvents for the salts include water, ethanol, glycerol, propylene glycol, and the like, as well as combinations thereof.” Lawson '028 at 6:18–31. This nicotine salt liquid formulation may be “applied within a region (e.g., a cavity) which is subjected to heat, or the like,” “applied to the filler material, [or] incorporated within some or all of the filler material.” Lawson '028 at 5:59–65.

Potter '486 adopts these teachings of the incorporated Lawson elsewhere too: discussing how acids “protonate nicotine and impart to the vapor a smoother vapor sensation or flavor characteristic.” Potter '486 at [0081]–[0088], [0102], [0100] (“[T]he vapor-enhancing element may comprise, for example, a liquid flavorant or other vapor enhancing substance contained or otherwise housed in a reservoir.”). Potter '486 further discloses an electronic cigarette operating at conditions suitable for use with nicotine lactate, nicotine benzoate, lactic and benzoic acid. Potter '486 at [0034].

Potter '486 incorporates additional references disclosing the use of organic acids to form

[REDACTED]
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nicotine salts.

Potter '486 at [0041]:

- U.S. Patent No. 5,056,537 (“Brown”) (“If desired, flavor additives such as organic acids can be incorporated into the cigarette as additives to the cut filler. For example, the levulinic acid, nicotine levulinate or levulinic acid/nicotine mixture can be added to the cut filler in amounts which typically range from about 0.5 to about 10 percent, based on the weight of the cut filler.”);
- U.S. Patent No. 4,924,888 (“Perfetti”) (“If desired, flavor additives such as organic acids can be incorporated into the cigarette as additives to the cut filler. In particular, levulinic acid, nicotine levulinate, or a mixture of levulinic acid and nicotine can be incorporated into the cigarette. For example, the levulinic acid, nicotine levulinate or levulinic acid/nicotine mixture can be added to the cut filler in amounts which typically range from about 1 to about 10 percent, based on the weight of the cut filler.”);
- U.S. Patent No. 5,159,942 (“Brinkley ’942”) (“If desired, certain other components can be incorporated into the concentrated liquid extract, preferably after that extract is contacted with the organic acid and/or organic acid salt. For example, compounds such as ... propylene glycol, glycerine, ... cocoa, licorice, carbon particles, and other casing, top dressing and particulate components can be incorporated into the liquid tobacco extract.”).

Potter '486 at [0042]:

- U.S. Pat. No. 7,647,932 (“Cantrell”) (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). Preferably, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of aerosol-generation segment, on a dry weight basis.”);

- [REDACTED]
- U.S. Pat. No. 8,079,371 (“Robinson”) (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). Preferably, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of tobacco, on a dry weight basis. The flavoring agents can be added to the tobacco material or to the aerosol-generating material or both.”);
 - US Pat. Pub. No. 2007/0215167 (“Crooks”) (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). In some embodiments, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of aerosol-generating segment, on a dry weight basis”);
 - Potter ’486 at [0043]: “The smoking article can incorporate tobacco additives of the type that are traditionally used for the manufacture of tobacco products.”);
 - US Pat. Pub. No. 2008/0245377 (“Marshallet”) at [0040] (“Typical casing materials include water... humectants (e.g. glycerin or propylene glycol), flavoring agents (e.g., cocoa and licorice), and C3-C20 organic acids such as levulinic acid, pyruvic acid, and lactic acid.”).

Potter ’486 at [0044]:

- U.S. Pat. No. 7,647,932 (“Cantrell”) (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). Preferably, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of aerosol-generation segment, on a dry weight basis.”); U.S. Pat. No. 8,079,371 (“Robinson”) (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). Preferably, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of tobacco, on a dry weight basis. The flavoring agents can be added to the tobacco material or to the aerosol-generating material or

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both.”);

- US Pat. App. Pub. No. 2007/0215167 (“Crooks”) at [0144] (“Flavoring agents also can include acidic or basic characteristics (e.g., organic acids, such as levulinic acid). In some embodiments, such flavoring agents constitute less than about 10 percent, and often less than about 5 percent of the total weight of aerosol-generating segment, on a dry weight basis.”).

Potter ’486 further discloses nicotine salt liquid formulations with its broad discussion of “flavoring agents” which are “materials that alter the sensory or organoleptic character or nature of the mainstream aerosol of the smoking article.” Potter ’486 at [0049]. Potter ’486 discloses that “Organic acids particularly may be incorporated into the aerosol precursor composition to affect the flavor, sensation, or organoleptic properties of ... nicotine, that may be combined with the aerosol precursor composition.” Potter ’486 at [0049]. These include “levulinic acid, lactic acid, and pyruvic acid ... included in the aerosol precursor composition with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine.” *Id.* These agents “can be employed as concentrates,” like the lactic acid concentrate added to formulations in the accused products. Potter ’486 at [0049].

The addition of organic acids or nicotine salts affects that flavor, nature, sensory, and/or organoleptic character of the aerosol by, *inter alia*, altering pH, vapor pressures, particle size, nicotine concentrations, nicotine forms, throat feel, palatability, ability to inhale deeply, and nicotine uptake. Potter ’486 recognizes this, discussing how acids “protonate nicotine and impart to the vapor a smoother vapor sensation or flavor characteristic.” Potter ’486 at [0102], [0100] (the vapor-enhancing element may comprise, for example, a liquid flavorant or other vapor enhancing Substance contained or otherwise housed in a reservoir). Further evidence of nicotine salts can be provided via testing. *See also* Section IV (Testing).

[REDACTED]

JLI admits that Potter '486 discloses, *inter alia*, organic and lactic acid. See JLI RFA Resp. Nos. 20, 25.

NJOY further incorporates the discussion of Potter '486, limitation 1(b), including that related to disclosed formulas, nicotine salt chemistry, and inherency, as if fully set forth herein.

- iii. **(b) the salt is present in an amount that forms a nicotine concentration of 0.5% (w/w) to 20% (w/w) in the nicotine salt liquid formulation; 3. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 1% (w/w) to 18% (w/w) in the nicotine salt liquid formulation; 4. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 3% (w/w) to 15% (w/w) in the nicotine salt liquid formulation; 5. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 4% (w/w) to 12% (w/w) in the nicotine salt liquid formulation.**

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 1(b), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussion for Potter '486, limitation 1(a), as if fully set forth herein.

Potter '486 discloses nicotine concentrations from 5–10% by weight with similar weight (or molar) concentrations of organic acids in liquid formulations. For example, it discloses an “aerosol precursor [“e-liquid”] material” with nicotine “up to about 10%, up to about 8%, or up to about 5% by weight of the aerosol precursor material.” Potter '486 at [0050]. It further discloses “flavors” at similar concentrations. More specifically, Potter '486 discloses an example formulation where the “aerosol precursor material ... comprises glycerol, propylene glycol, water, nicotine, and one or more flavors ... the nicotine ... present in an amount of about 0.1% to about 5% by weight, ... and the flavors can be present in an amount of up to about 5% by weight....”

[REDACTED]

Potter '486 at [0051]. Potter '486 also discloses the concentration of organic acids, stating that “organic acids, such as levulinic acid, lactic acid, and pyruvic acid, may be included in the aerosol precursor composition with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine.” Potter '486 at [0049].

Potter '486 incorporates Lawson which has similar concentration disclosures, including those for nicotine salt liquid formulations (around 20%). Lawson '028 at 6:9–17 (“the nicotine/organic acid salts ... form a liquid solution of the salt in a suitable solvent ... the concentration of salt within the solution is about 20 weight percent or more”); Lawson '224 at 5:36–44 and Examples (“nicotine contents of high nicotine tobacco materials oftentimes are above about 3 percent, frequency above about 4 percent, and in certain circumstances above about 5 percent”); Lawson '028 at 8:21–29 and Examples (the liquified levulinic acid is titrated 32.4 g (0.2 mole) of the purified 1-nicotine over about a 20 minute time period. It is preferred to introduce the nicotine to the organic acid in order to provide an environment of excess acid to nicotine and thus promote the formation of salt. A clear, viscous yellow colored material weighing about 100g results”); Lawson '224 at 2:42–55.

The combinations of nicotine and organic acids in the formulations disclosed above inherently form and disclose a nicotine salt which forms as part of the acid-base reaction between unprotonated nicotine and the disclosed organic acids. *See, e.g.*, 2025-11-04 JLI Infringement Contentions, Appx. A at 2–3 (“products utilize lactic acid to reduce e-liquid pH and protonate the nicotine to create a nicotine salt: nicotine lactate”); Bauer et al., “Introduction to Chemistry,” 2nd. Ed., The McGraw-Hill Companies, Inc. (2010) at 61, 140–149, 516; Blackman, et al., “Chemistry,” 2nd. Ed., John Wiley & Sons Australia, Ltd. (2012) (“Blackman”) at 96, 194–195; *Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991);

[REDACTED]
[REDACTED]
EMI Group North America, Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1349–51 (Fed. Cir. 2001). Further evidence of nicotine salt can be provided via testing. See also Section IV (Testing).

Indeed, the Lawson references (incorporated into Potter '486) contain extensive discussion about the creation of nicotine salts from the combination of nicotine and organic acids from formulations like those disclosed in Potter '486. They discuss that “nicotine/organic acid salts have a molar ratio of organic acid to nicotine of 1:1, 2:1 or 3:1” and that the “most preferred salts are totally ionized salts of nicotine and the organic acid.” Lawson '224 at 7:57–66, 3:12–18, 6:26–32; Lawson '028 at 2:30–44, 4:29–53, 4:58–64.

iv. (c) the liquid carrier comprises glycerol and propylene glycol; and

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 1(c), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). For example, Potter '486 discloses a nicotine-salt liquid formulation where the “aerosol precursor material ... comprises glycerol, propylene glycol, water, nicotine, and one or more flavors.” Potter '486 at [0051]. JLI admits that Potter '486 discloses, *inter alia*, a liquid carrier that contains both glycerol and propylene glycol. See JLI RFA Resp. Nos. 45–49.

v. (d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 1(d), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

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Potter '486 is directed, *inter alia*, to the problem of “a smoking article that employs heat produced by electrical energy to provide the sensations of cigarette, cigar, or pipe smoking, that does so without combusting tobacco to any significant degree.” Potter '486 at [0006]. In response, it discloses: “a heater component can be positioned sufficiently near that aerosol precursor component so that heat from the heater component can volatilize the aerosol ... and form an aerosol for delivery to the user. When the heating member heats the aerosol precursor component, an aerosol is formed, released, or generated in a physical form suitable for inhalation by a consumer.” Potter '486 at [0022], [0019] (“[A]n aerosol (i.e., a suspension of fine solid particles or liquid droplets in a gas ... is meant to include vapors, gases and aerosols of a form or type suitable for human inhalation.”).

Potter '486 further discloses representative e-cigarette products, including “NJOY,” “OneJOY,” “Ruyan,” and “Vuse” which generate an inhalable aerosol upon heating an in electronic cigarette. Potter '486 at [0005]. And explains that “the user of a smoking article of the present disclosure can hold that article much like a traditional type of smoking article, draw on one end of that article for inhalation of aerosol produced by that article, and take puffs at selected intervals of time.” Potter '486 at [0020]

JLI admits that Potter '486 discloses, *inter alia*, heating in an electronic cigarette as well as an inhalable aerosol. *See* JLI RFA Resp. Nos. 52, 54.

vi. 2. The electronic cigarette of claim 1, wherein the liquid carrier further comprises water.

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 2, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). For example, Potter '486 discloses a nicotine-salt liquid formulation where the “aerosol

[REDACTED]
[REDACTED]
precursor material ... comprises glycerol, propylene glycol, water, nicotine, and one or more flavors.” Potter ’486 at [0051]. JLI admits that Potter ’486 discloses, *inter alia*, a liquid carrier that water. *See* JLI RFA Resp. Nos. 50.

vii. 6. The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises a flavorant.

Potter ’486 discloses this limitation as shown below and in Exhibit A-17, Section 6, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). For example, Potter ’486 discloses a nicotine-salt liquid formulation where the “aerosol precursor material ... comprises glycerol, propylene glycol, water, nicotine, and one or more flavors.” Potter ’486 at [0051]. JLI admits that Potter ’486 discloses, *inter alia*, a flavorant. *See* JLI RFA Resp. No. 30.

viii. 7. The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises one or more additional organic acids.

Potter ’486 discloses this limitation as shown below and in Exhibit A-17, Section 7, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussion of limitations 1(a), 1(b), 9, and 10 as if fully set forth herein.

Potter ’486 discloses that for “Organic acids ... incorporated into the aerosol precursor composition ... For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, ... Any combination of organic acids can be used. For example, the aerosol precursor composition can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to

[REDACTED]

about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor composition.” Potter ’486 at [0049]. Further, throughout Potter ’486, it discloses several suitable organic acids for use in the nicotine salt liquid formulation. *See, e.g.*, Potter ’486 at [0049], [0102]; Lawson ’224 at 6:33–60, 8:31–41; Lawson ’028 at 4:29–53.

JLI admits that Potter ’486 discloses, *inter alia*, more than one organic acid. *See* JLI RFA Resp. No. 32.

ix. 8. The electronic cigarette of claim 1, wherein the cartridge is configured to serve as a mouthpiece and a reservoir, wherein the reservoir holds the nicotine salt liquid formulation.

Potter ’486 discloses this limitation as shown below and in Exhibit A-17, Section 8, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussion of limitation 1 as if fully set forth herein.

Potter ’486 discloses a cartridge “[a]s seen in the embodiment of FIG. 1, [wherein] the mouth end 11 of the article 10 is substantially an open cavity with the resistive heating element 50 and the reservoir 205 disposed therein.” Potter ’486 at [0069]. This “includes a mouthpiece (or simply the mouth end) with an opening at a proximate end thereof.” Potter ’486 at [0058]–[0060] (“exit the mouth end of the cartridge (and any optional mouthpiece present)”), [0075]–[0076]. The reservoir can be a container in which the aerosol precursor material is stored.” Potter ’486 at [0076].

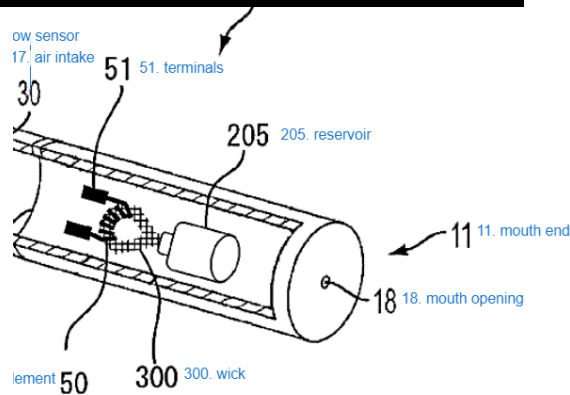


Fig. 1 (annotated)

Other Figures further show the cartridge is configured to serve as a mouthpiece and a reservoir, wherein the reservoir holds the nicotine salt liquid formulation.

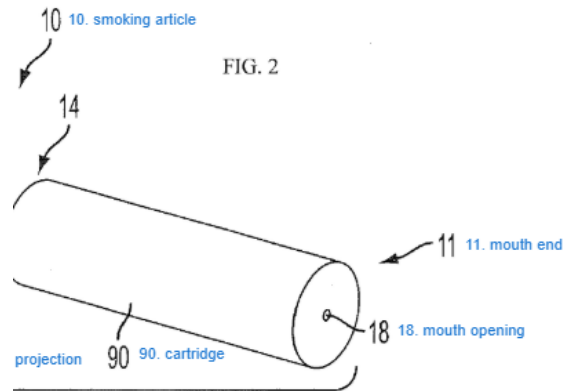


Fig. 2 (annotated)

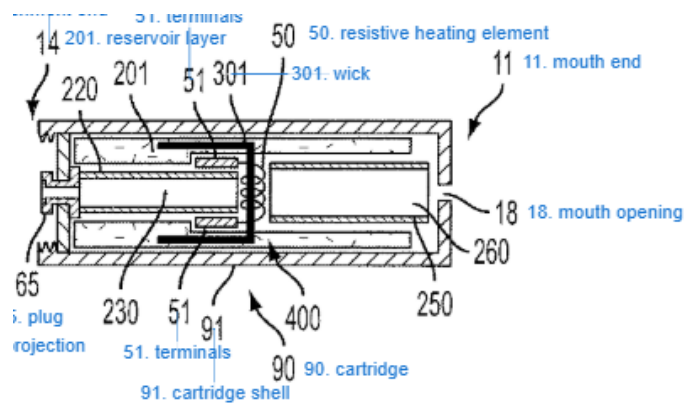


Fig. 3 (annotated)

[REDACTED]

Potter '486 further discloses representative e-cigarette products, including “NJOY,” “OneJOY,” “Ruyan,” and “Vuse.”

JLI admits that Potter '486 discloses, *inter alia*, an electronic cigarette, a cartridge, a mouthpiece, an electronic cigarette that comprises a cartridge, and a cartridge that comprises a mouthpiece. *See* JLI RFA Resp. Nos. 7–9, 13–15.

x. 9. The electronic cigarette of claim 1, wherein the organic acid is benzoic acid.

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 9, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussion of limitation 1(a) as if fully set forth herein.

xi. 10. The electronic cigarette of claim 1, wherein the organic acid is lactic acid.

Potter '486 discloses this limitation as shown below and in Exhibit A-17, Section 10, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussion of limitation 1(a) as if fully set forth herein.

xii. Evidence to Educate the Factfinder

NJOY incorporates by reference those references and documents in its First Invalidation Contentions (and any amendments or supplements thereto), NJOY discovery responses and document production, JLI discovery response and document production to educate the factfinder on the technology. *Sage Products, LLC v. Stewart*, 133 F.4th 1376, 1385–86 (Fed. Cir. 2025).

d. Hon '518

x. 9. The electronic cigarette of claim 1, wherein the organic acid is benzoic acid.

Rabinowitz '470 discloses this limitation as shown below and in Exhibit A-8, Section 9, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY incorporates by reference the discussion above of limitation 1(a) (nicotine salt liquid formulation) as if fully set forth herein, which discusses the presence of benzoic acid and salts in various nicotine salt liquid formulations. JLI admits that Rabinowitz '470 discloses, *inter alia*, discloses benzoic acid. JLI RFA Resp. No. 26.

xi. 10. The electronic cigarette of claim 1, wherein the organic acid is lactic acid.

Rabinowitz '470 discloses this limitation as shown below and in Exhibit A-8, Section 10, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY incorporates by reference the discussion above of limitation 1(a) (nicotine salt liquid formulation) as if fully set forth herein, which discusses the presence of lactic acid and salts in various nicotine salt liquid formulations. JLI admits that Rabinowitz '470 discloses, *inter alia*, lactic acid. JLI RFA Resp. No. 25.

xii. Evidence to Educate the Factfinder

NJOY incorporates by reference those references and documents in its First Invalidation Contentions (and any amendments or supplements thereto), NJOY discovery responses and document production, JLI discovery response and document production to educate the factfinder on the technology. *Sage Products, LLC v. Stewart*, 133 F.4th 1376, 1385–86 (Fed. Cir. 2025).

h. Brinkley '809

[REDACTED]

U.S. Publication No. 2011/0268809 (“Brinkley ’809”) was filed on April 28, 2010, and published on November 3, 2011. Brinkley ’809 qualifies as prior art under at least 35 U.S.C. § 102(a)(1), (a)(2). As set forth in Exhibit A-30 (incorporated by reference as if fully set forth herein) and below, claims 1–10 (the “Asserted Claims”) of U.S. Patent No. 12,156,533 (the “’533 patent”) are anticipated by Brinkley ’809. NJOY incorporates Exhibit A-30 as if fully set forth herein. Brinkley ’809 also incorporates by reference the disclosures of Hon ’803 and Hon ’518 (substantially similar disclosure) and their corresponding charts (A-5 and A-6) as if fully set forth herein.

i. 1. An electronic cigarette comprising a cartridge, wherein the cartridge comprises a nicotine salt liquid formulation, wherein:

Brinkley ’809 discloses this limitation as shown below and in Exhibit A-30, Section 1, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon ’803 and ’518 (substantially similar disclosure) by reference as if fully set forth herein.

Brinkley ’809 discloses that its nicotine salt liquid formulation is “capable of pulmonary delivery using various types of inhalation devices and vapor delivery systems designed to deliver an active agent to the lungs as opposed to buccal, sublingual, or nasal delivery. See, for example, the types of inhalable formulations and vapor delivery devices and systems set forth in U.S. Pat. No. 4,284,809 to Ray; U.S. Pat. No. 4,800,903 to Ray et al.; U.S. Pat. No. 5,167,242 to Turner et al.; U.S. Pat. No. 6,098,632 to Turner et al.; U.S. Pat. No. 6,234,169 to Bulbrook et al. and U.S. Pat. No. 6,874,507 to Farr; US Pat. Pub. Nos. 2004/0034068 to Warchol et al; 2006/0018840 to Lechuga-Ballesteros; 2008/0302375 to Andersson et al. and 2009/0005423 to Gonda; and EP

[REDACTED]
[REDACTED]
1,618,803 to Hon, which are incorporated herein by reference.” Brinkley ’809 at [0046], [0009]. These incorporated references disclose electronic cigarettes comprising a cartridge containing a nicotine salt liquid formulation. *See, e.g.*, discussion of Hon ’518, Section 1 (substantially similar disclosure to Hon ’803), incorporated as if set forth fully herein.

ii. (a) the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier, wherein the organic acid is benzoic acid or lactic acid;

Brinkley ’809 discloses this limitation as shown below and in Exhibit A-30, Section 1(a), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon ’803 and ’518 (substantially similar disclosure) by reference as if fully set forth herein.

For example, Brinkley ’809 discloses several nicotine forms for its nicotine salt liquid formulations, including “nicotine free base ... [or] a nicotine salt (e.g., as nicotine bitartrate). Brinkley ’809 at Abstract, [0013] (“as another form of nicotine salt (e.g., as nicotine bitartrate or another organic acid salt of nicotine)”). These salts include those formed from lactic and benzoic-like acids: “Exemplary pharmaceutically acceptable nicotine salts include nicotine salts of tartrate (e.g., nicotine tartrate and nicotine bitartrate) chloride (e.g., nicotine hydrochloride and nicotine dihydrochloride), sulfate, perchlorate, ascorbate, fumarate, citrate, malate, lactate, aspartate, salicylate, tosylate, succinate, pyruvate, and the like; nicotine salt hydrates (e.g., nicotine zinc chloride monohydrate), and the like. Additional organic acids that can form salts with nicotine include formic, acetic, propionic, isobutyric, butyric, alpha-methylbutyric, isovaleric, beta-methylvaleric, caproic, 2-furoic, phenylacetic, heptanoic, octanoic, nonanoic, oxalic, malonic, and glycolic acid, as well as other fatty acids having carbon chains of up to about 20 carbon atoms.

[REDACTED]
[REDACTED]
Brinkley '809 at [0023].

Brinkley '809 further incorporates, at [0024], U.S. Pat. No. 4,830,028 (“Lawson '028”). As discussed above, incorporated by reference as if fully set forth herein, the incorporated Lawson '028 discusses the purpose, effects, and mechanics of using nicotine salts, including pH modification via organic acids. It discloses nicotine delivery devices using nicotine salts, and with high concentrations of nicotine, that provide “smoking satisfaction to the user,” but with a “smooth, palatable, flavorful taste” that does “not exhibit a harsh or irritating character.” Lawson '028 at Abstract, 2:18–28, 6:62–7:7, 7:12–14, 7:15–25, Examples. It further teaches that the “presence of the salt within the article provides improved tobacco taste, strength and smoking satisfaction as well as improved or maintained flavor characteristics to the aerosol during use of the article.” Lawson '028 at 2:30–44.

The incorporated Lawson '028 further discloses a nicotine-salt formulation combining nicotine and an organic acid (forming a nicotine salt) with carriers in a liquid formulation. It discloses a salt created from the combination of pure nicotine and organic acids: “salt provided from nicotine and an organic acid ... requires nicotine as a necessary component” which “can be naturally occurring nicotine which is obtained as an extract ... or synthetic nicotine.” Lawson '028 at 4:15–28. It also discloses useful acids, including “organic acids ... which form salts with nicotine in a 1:1 ... molar ratio, ... including benzoic-type acids and ... aliphatic monocarboxylic acids,” like lactic acid. Lawson '028 at 4:29–53. It further discloses that the “nicotine/organic acid salt” may be in “a liquid solution of the salt in a suitable solvent” which can be “spray[ed] or inject[ed],” and with a “concentration of the salt within the solution ... about 20 weight percent or more.” Lawson '028 at 6:9–17. “Suitable solvents for the salts include water, ethanol, glycerol, propylene glycol, and the like, as well as combinations thereof.” Lawson '028 at 6:18–31. This

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[REDACTED]
nicotine salt liquid formulation may be “applied within a region (e.g., a cavity) which is subjected to heat, or the like,” “applied to the filler material, [or] incorporated within some or all of the filler material.” Lawson ’028 at 5:59–65.

The combinations of nicotine and organic acids in the formulations disclosed above inherently form and disclose a nicotine salt which forms as part of the acid-base reaction between unprotonated nicotine and the disclosed organic acids. *See, e.g.*, 2025-11-04 JLI Infringement Contentions, Appx. A at 2–3 (“products utilize lactic acid to reduce e-liquid pH and protonate the nicotine to create a nicotine salt: nicotine lactate”); Bauer et al., “Introduction to Chemistry,” 2nd. Ed., The McGraw-Hill Companies, Inc. (2010) at 61, 140–149, 516; Blackman, et al., “Chemistry,” 2nd. Ed., John Wiley & Sons Australia, Ltd. (2012) (“Blackman”) at 96, 194–195; *Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991); *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349–51 (Fed. Cir. 2001). Further evidence of nicotine salt can be provided via testing. See also Section IV (Testing).

Brinkley ’809 further discloses the use of more than one organic acid or nicotine salt: “For example, the nicotine can be employed within the composition as a mixture of at least two salts (e.g., two different organic acid salts including nicotine levulinate).” Brinkley ’809 at [0027].

- [REDACTED]
- [REDACTED]
- iii. (b) the salt is present in an amount that forms a nicotine concentration of 0.5% (w/w) to 20% (w/w) in the nicotine salt liquid formulation; 3. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 1% (w/w) to 18% (w/w) in the nicotine salt liquid formulation; 4. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 3% (w/w) to 15% (w/w) in the nicotine salt liquid formulation; 5. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 4% (w/w) to 12% (w/w) in the nicotine salt liquid formulation.

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 1(b), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. For example, Brinkley '809 discloses that the “concentration of the nicotine within the liquid spray formulation can vary, but typically is in the range of about 0.5 percent to about 5 percent ... based on the total weight of the liquid formulation and calculated as nicotine base.” Brinkley '809 at [0045]. NJOY further incorporates the discussion of limitation 1(a) as if fully set forth herein.

Brinkley '809 further incorporates, at [0022], the disclosure of U.S. Application 2004/0191322 (“Hansson”) which discloses that “the concentration of nicotine or the pharmaceutically acceptable salt, complex or solvate thereof [is] ... at the most about 20% w/w such as, e.g., at the most about 15% w/w, at the most about 12.5% w/w, at the most about 10% w/w....” Hansson at [0028]–[0029].

Brinkley '809 further incorporates, at [0024], U.S. Pat. No. 4,830,028 (“Lawson '028”). As discussed above, the discussion of which is incorporated as if fully set forth herein, the incorporated Lawson '028 discusses the purpose, effects, and mechanics of using nicotine salts,

[REDACTED]

including pH modification via organic acids. It discloses nicotine delivery devices using nicotine salts, and with high concentrations of nicotine, that provide “smoking satisfaction to the user,” but with a “smooth, palatable, flavorful taste” that does “not exhibit a harsh or irritating character.” Lawson ’028 at Abstract, 2:18–28, 6:62–7:7, 7:12–14, 7:15–25, Examples. It further teaches that the “presence of the salt within the article provides improved tobacco taste, strength and smoking satisfaction as well as improved or maintained flavor characteristics to the aerosol during use of the article.” Lawson ’028 at 2:30–44.

The incorporated Lawson ’028 further discloses a nicotine-salt formulation combining nicotine and an organic acid (forming a nicotine salt) with carriers in a liquid formulation. It discloses a salt created from the combination of pure nicotine and organic acids: “salt provided from nicotine and an organic acid ... requires nicotine as a necessary component” which “can be naturally occurring nicotine which is obtained as an extract ... or synthetic nicotine.” Lawson ’028 at 4:15–28. It also discloses useful acids, including “organic acids ... which form salts with nicotine in a 1:1 ... molar ratio, ... including benzoic-type acids and ... aliphatic monocarboxylic acids,” like lactic acid. Lawson ’028 at 4:29–53. It further discloses that the “nicotine/organic acid salt” may be in “a liquid solution of the salt in a suitable solvent” which can be “spray[ed] or inject[ed],” and with a “concentration of the salt within the solution ... about 20 weight percent or more.” Lawson ’028 at 6:9–17. “Suitable solvents for the salts include water, ethanol, glycerol, propylene glycol, and the like, as well as combinations thereof.” Lawson ’028 at 6:18–31. This nicotine salt liquid formulation may be “applied within a region (e.g., a cavity) which is subjected to heat, or the like,” “applied to the filler material, [or] incorporated within some or all of the filler material.” Lawson ’028 at 5:59–65.

The incorporated Lawson further ’028 discloses nicotine salt liquid formulations (around

[REDACTED]

[REDACTED]

20%). Lawson '028 at 6:9–17 (“the nicotine/organic acid salts ... form a liquid solution of the salt in a suitable solvent ... the concentration of salt within the solution is about 20 weight percent or more”); Lawson '028 at 8:21–29 and Examples (the liquified levulinic acid is titrated 32.4 g (0.2 mole) of the purified 1-nicotine over about a 20 minute time period. It is preferred to introduce the nicotine to the organic acid in order to provide an environment of excess acid to nicotine and thus promote the formation of salt. A clear, viscous yellow colored material weighing about 100g results”).

Further, Brinkley '809 recognizes the need to balance nicotine uptake with concentrations to “ameliorate the types of dissonant sensory and organoleptic effects attributed to the administration of nicotine. In essence, the levulinate moiety acts as a carrier or excipient for nicotine in a manner that reduces the harsh sensory characteristics sometimes associated with oral or nasal delivery of nicotine.” Brinkley '809 at [0026], [0049] (“By “effective amount”, “therapeutic amount” or “effective dose” is meant that amount sufficient to elicit the desired pharmacological or therapeutic effects, thus resulting in effective prevention or treatment of the condition”), [0050] (“For compositions of the present invention, the intended daily dose of the active ingredient can vary. The overall dose of active ingredient can depend upon factors such as the weight of the subject ingesting the composition, the type of condition, disease, or disorder being treated, the state or severity of the condition, disease, or disorder being treated, the desired pharmacological effect, or other such factors. Typically, the amount of nicotine active ingredient, calculated as nicotine base, administered to a subject per day is at least about 2 mg, often is at least about 4 mg, and frequently is at least about 10 mg”) (incorporating several nicotine dosing references).

[REDACTED]

[REDACTED]

iv. (c) the liquid carrier comprises glycerol and propylene glycol; and

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 1(c), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein.

For example, Brinley_ discloses that the “pharmaceutical compositions of the invention ... comprise combining (by various methods) an active agent with a suitable carrier or other adjuvant, which may consist of one or more ingredients ... (e.g., ... an aqueous suspension).” Brinkley '809 at [0029]. This includes “liquid solvents or carriers (e.g., water or water/ethanol mixtures).” Brinkley '809 at [0045]. Brinkley '809 further incorporates several references, at [0025], [0031] and [0045], which disclose the use of propylene glycol, glycerol, and water as carriers. For example, the incorporated Lawson '028 discloses acceptable carriers for nicotine salt liquid formulations: “Suitable solvents for the salts include water, ethanol, glycerol, propylene glycol, and the like, as well as combinations thereof.” Lawson '028 at 6:18–31; *see also* U.S. Pat./App. Nos. 6,676,959 (glycerin and propylene glycol), 7,025,983 (same), 2008/0286341 (same), 2009/0023819 at [0078] (“Nicotine,” “Glycerine,” “Peppermint oil,” and “Water”).

v. (d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 1(d), incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir.

[REDACTED]

2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. NJOY further incorporates by reference the discussion of limitation 1 and 1(a) above.

vi. 2. The electronic cigarette of claim 1, wherein the liquid carrier further comprises water.

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 2, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. NJOY further incorporates by reference the discussion of limitation 1(c) (carriers) above.

vii. 6. The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises a flavorant.

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 6, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. For example, Brinkley '809 discloses the addition of “an excipient ... employed in an amount sufficient to reduce the negative sensory characteristics sometimes associated with oral delivery of nicotine.” Brinkley '809 at [0011]. It further incorporates and discloses several references which disclose the addition of flavorants into nicotine solutions. For example, at [0072] it discloses that the preparation of “a nicotine-containing spray formulation designated as Composition A and set forth in Example 1 of

[REDACTED]
[REDACTED]
US Pat. Pub. No. 2009/0023819 to Axelsson ...” which contains, *inter alia*, “Nicotine,” “Glycerine,” “Peppermint oil,” and “Water.” U.S. Publication No. 2009/0023819 (“Axelsson”) at [0078]; *see also* [add research].

viii. 7. The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises one or more additional organic acids.

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 7, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein.

For example, Brinkley '809 discloses several nicotine forms for its nicotine salt liquid formulations, including “nicotine free base ... [or] a nicotine salt (e.g., as nicotine bitartrate).” Brinkley '809 at Abstract, [0013] (“as another form of nicotine salt (e.g., as nicotine bitartrate or another organic acid salt of nicotine)”). These salts include those formed from lactic and benzoic-like acids: “Exemplary pharmaceutically acceptable nicotine salts include nicotine salts of tartrate (e.g., nicotine tartrate and nicotine bitartrate) chloride (e.g., nicotine hydrochloride and nicotine dihydrochloride), sulfate, perchlorate, ascorbate, fumarate, citrate, malate, lactate, aspartate, salicylate, tosylate, succinate, pyruvate, and the like; nicotine salt hydrates (e.g., nicotine zinc chloride monohydrate), and the like. Additional organic acids that can form salts with nicotine include formic, acetic, propionic, isobutyric, butyric, alpha-methylbutyric, isovaleric, beta-methylvaleric, caproic, 2-furoic, phenylacetic, heptanoic, octanoic, nonanoic, oxalic, malonic, and glycolic acid, as well as other fatty acids having carbon chains of up to about 20 carbon atoms.” Brinkley '809 at [0023].

[REDACTED]

Brinkley '809 further discloses the use of more than one organic acid or nicotine salt: “For example, the nicotine can be employed within the composition as a mixture of at least two salts (e.g., two different organic acid salts including nicotine levulinate).” Brinkley '809 at [0027].

- ix. 8. The electronic cigarette of claim 1, wherein the cartridge is configured to serve as a mouthpiece and a reservoir, wherein the reservoir holds the nicotine salt liquid formulation.**

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 8, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. NJOY further incorporates the above discussion on limitation 1 as if fully set forth herein.

- x. 9. The electronic cigarette of claim 1, wherein the organic acid is benzoic acid.**

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 9, incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. NJOY further incorporates the above discussion on limitation 1(a) as if fully set forth herein.

- xi. 10. The electronic cigarette of claim 1, wherein the organic acid is lactic acid.**

Brinkley '809 discloses this limitation as shown below and in Exhibit A-30, Section 10,

[REDACTED]
[REDACTED]
incorporated as if fully set forth herein. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). NJOY further incorporates the discussions and charts (A-5 and A-6) of Hon '803 and '518 (substantially similar disclosure) by reference as if fully set forth herein. NJOY further incorporates the above discussion on limitation 1(a) as if fully set forth herein.

xii. Evidence to Educate the Factfinder

NJOY incorporates by reference those references and documents in its First Invalidation Contentions (and any amendments or supplements thereto), NJOY discovery responses and document production, JLI discovery response and document production to educate the factfinder on the technology. *Sage Products, LLC v. Stewart*, 133 F.4th 1376, 1385–86 (Fed. Cir. 2025).

i. Rigas '044

U.S. Publication No. 2014/0088044 (“Rigas '044”) was published on March 27, 2014, and claims priority to US. provisional application 61/703,999 (“Rigas '999”) filed on Sept. 21, 2012. The provisional application provides written description support for at least the specific portions of Rigas '044 identified in the chart below, examples of which are also included in the chart below. *See Penumbra, Inc. v. Rapidpulse, Inc.*, IPR2021-01466, 2023 WL 2605070, at *12 (P.T.A.B. Mar. 10, 2023), *aff'd*, 2025 WL 2911056 (Fed. Cir. Oct. 14, 2025). While not required under 35 U.S.C. § 102, the provisional also provides written description support for at least claims 1–15 of Rigas '044. *See In re Riggs*, 131 F.4th 1377, 1384 (Fed. Cir. 2025). Rigas '044 qualifies as prior art under at least 35 U.S.C. § 102(a)(2).

As set forth in Exhibit A-1 (incorporated by reference as if fully set forth herein) and below, claims 1–10 (the “Asserted Claims”) of U.S. Patent No. 12,156,533 (the “'533 patent”) are anticipated by Rigas '044.

[REDACTED]

D. Obviousness (35 U.S.C. § 103)

NJOY incorporates by reference Attachment E, including the combinations and motivations disclosed therein. NJOY provides additional details below.

As an initial matter, the below references disclose several problems and corresponding goals predating the priority date of the '533 patent. These include minimizing the health impacts of smoking, smoking cessation, tar reduction, and administering pharmaceutically sufficient quantities of nicotine of nicotine as a medicament. These shared goals would have motivated a skilled artisan to look to the below references and combine their teaching to achieve them.

[REDACTED]

The prior art reference accomplish these goals, providing solutions like e-cigarettes that aerosolize e-liquids to generate an inhalable aerosol that mimics the smoking lit-end cigarette experience, provides similar nicotine uptake as lit-end cigarettes, modulates throat irritation, limits throat irritation at higher nicotine concentrations, and provides a palatable smoking experience.

Underlying these pre-priority solutions are mechanisms based on well-known chemistry principles explained in detail in the prior art references. These solutions and explanations include controlling the concentration of nicotine in the aerosol to control nicotine uptake, controlling the phase of nicotine in the aerosol to control pulmonary deposition, controlling the particle size of the aerosol to control pulmonary deposition, controlling the pH of the aerosol or liquid to control throat irritation, and controlling the pH of the aerosol or liquid to mimic cigarette smoke. They are all related, demonstrated a consensus and well-known solution to the above goals before the priority date of the asserted patent. This shows a further motivation to combine these references, including between systems, and a reasonable expectation of success in applying these well-known solutions.

More specifically, the fundamental chemistry supporting these solutions had been known for decades before the priority date and deployed across different prior art references and system. This includes the addition of acidic compounds (like lactic and benzoic acid) to lower pH, the use of nicotine salts (including nicotine benzoate and nicotine lactate), and the protonation of nicotine in the aerosol all in liquid formulations.

o. Potter '486 i/v/o Gonda '474

Potter '486 in view of Gonda '474 renders obvious the claims of the '533 patent. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). NJOY incorporates Exhibits A-17 and A-

[REDACTED]

Additionally, Potter '486 discloses that the e-cigarette device, formulations, and processes described therein “may be embodied in many different forms,” which would motivate a skilled artisan to look to Gonda '474 with similar disclosures for additional information. Potter '486 at 2. The reference further discloses that the articles disclosed therein may be used as “medicament delivery articles,” which includes “pharmaceutical active ingredient” alongside tobacco derivatives, which recognizes the possibility of combination with other nicotine containing formulations, like those disclosed in Gonda '474. Potter '486 at 2, 7. A skilled artisan would, therefore, have been motivated to combine, with a reasonable expectation of success, Potter '486 with Gonda '474 which discloses detailed nicotine formulations. Further, a skilled artisan would have looked to Potter '486 from Gonda '474 for the reasons stated in Attachment E.

p. Potter '486 i/v/o Brinkley '809

Potter '486 in view of Brinkley '809 renders obvious the claims of the '533 patent. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). NJOY incorporates Exhibits A-17 and A-30 and the discussions of Potter '486 and Brinkley '809, *supra*, as if fully set forth herein. NJOY provides additional, exemplary discussion for this combination below.

i. Additional Motivations to Combine and Success

A skilled artisan would have been motivated to combine Potter '486 with Brinkley '809 with a reasonable expectation of success. NJOY incorporates the motivations to combine and success in Attachment E.

Potter '486 discloses and is directed to an electronic nicotine delivery system (an e-cigarette) with a cartridge, a heated liquid formulation, and an aerosol. It also discloses the use of nicotine salts, the addition of organic acids to the liquid formulation, which would inherently create a salt, with nicotine at various concentrations, in carriers like propylene glycol and glycerol. The

[REDACTED]

[REDACTED]

reference also discloses the addition of organic acids to protonate nicotine to alter the vapor sensation or experience. A skilled artisan would look to other references with similar disclosures, like Brinkley '809 which discloses a nicotine composition containing a nicotine salt, organic acid, and carriers to be administered in an aerosol via an electronic nicotine delivery system like that shown in Hon '803. *See, e.g.*, Brinkley '809 at Abstract. These similarities related to the asserted claims show that a skilled artisan would have a reasonable expectation of success combining these references.

While the disclosure of Potter '486, alone, is detailed and anticipatory, a skilled artisan would look to Brinkley '809 for additional information on the chemistry of the combination of organic acids and nicotine, additional organic acids to use in nicotine formulations, and additional information on nicotine salts. For example, Brinkley '809 discloses various forms of nicotine for use in a nicotine-containing composition, including lists of acceptable nicotine salts and lists of acids to form nicotine salts. *Id.* at [0011]–[0019], [0022]–[0024]. The reference also discusses nicotine concentrations sufficient to provide effective user experience. *Id.* [0049]–[0050]. The reference also discloses the problem and solution of using nicotine salts and organic acids to modify the sensory and organoleptic effects during the administration of nicotine. *Id.* at [0026].

A skilled artisan would further look to Brinkley '809 for information on how to replicate the nicotine experience of smoking, including by increasing the concentration of nicotine while retaining palatability and minimizing irritation. This would include information on alternative forms of nicotine, additives to solution to reduce irritation, mechanisms for nicotine absorption.

Additionally, Potter '486 is in the field of aerosol delivery articles, or uses thereof, to deliver inhalable forms of tobacco derivatives. Potter '486 at Field of Disclosure, Brief Summary of the Disclosure. This field is similar to that of Brinkley '809 which demonstrates a motivation

[REDACTED]

[REDACTED]

to combine with a reasonable expectation of success. Potter '486 is also directed to smoking alternatives that replicate the smoking experience without combustion products, including using electrical energy to heat liquids to form aerosols, replicating the “many sensations,” tastes, flavors, organoleptic affects, feel, rituals, and visual cues of smoking. Potter '486 at Description of Related Art, 2–3. A skilled artisan would look to Brinkley '809 disclosures in this field and those directed to similar goals of replicating the smoking experience without combustion products. For example, Brinkley '809 discusses the problem and purpose of effective the administration of nicotine for the purposes of nicotine replacement, smoking cessation, treatment of medical conditions, e.g., as a medicament, or reduction in negative effects or byproducts of smoking. *Id.* at Abstract, [001]–[0005], [0028]. This includes the use of nicotine salts or the addition of organic acid to modify the sensory and organoleptic effects during the administration of nicotine. *Id.* at [0026].

While the disclosure in Brinkley '809 is extensive and anticipatory, alone, a skilled artisan would look to Potter '486 for additional information, or more extensive discussion, on electronic nicotine delivery systems, acceptable nicotine concentration ranges, the nicotine uptake experience of a user, and acceptable carriers to be used in electronic nicotine delivery systems. Potter '486 provides this discussion.

Potter '486 discloses detailed information on the components, mechanism, and aerosolization processes in an e-cigarette, including a combined mouthpiece/reservoir, manner of aerosolization, power sources, power management, controllers, sensors, heat for aerosolization, indicators, heating elements, and vapor enhancing elements. Potter '486 at Abstract, Figs. 1–5, 3–6, 9–16. Indeed, Potter '486 provides that a skilled artisan would have a reasonable expectation of success in the combination of its systems with the formulations disclosed in Brinkley '809, when it discloses that the e-cigarette device, formulations, and processes described therein “may

[REDACTED]
[REDACTED]
be embodied in many different forms,” which would motivate a skilled artisan to look to other references with similar disclosures for additional information. Potter ’486 at 2. Further, Potter ’486 identifies several related systems, including various commercial e-cigarettes, Joytech eGO products, NJOY and ONEJOY products, Ruyan products, and R.J. Reynolds products (including VUSE). Potter ’486 at Description of Related Art.

Potter ’486 also discloses that various forms of tobacco, additives, carriers, flavors, medicaments, may be used in its electronic cigarette, further disclosing a reasonable expectation of success in combination. Potter ’486 at 6–8. This includes the addition of organic acids, which alter the acid/basic properties of the formulation and affect the flavor, sensation, or organoleptic properties of nicotine. *Id.* at 7–8. Potter ’486 discloses detailed formulation information for aerosol precursor material, including concentrations of nicotine, organic acids, carriers, and other components. *Id.* at 8. A skilled artisan would look to combine this reference with Brinkley ’809 because of its disclosure of acceptable concentration ranges and components, and higher nicotine concentrations to affect user nicotine uptake and experience.

Brinkley ’809 also discusses nicotine formulations that contain carriers so that the nicotine formulation is suitable for delivery, these formulations include liquid formulations with water or other acceptable carriers. *Id.* at [0029]–[0030]. A skilled artisan would look to the disclosures in Potter ’486 for additional information on acceptable carriers, including those for aerosolized delivery via heating.

q. Potter ’486 i/v/o Rigas ’044

Potter ’486 in view of Rigas ’044 renders obvious the claims of the ’533 patent. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). NJOY incorporates Exhibits A-17 and A-1,

Dated: January 6, 2026

Respectfully submitted:

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing document:

**ATTACHMENT G
RESPONDENTS' FINAL INVALIDITY CONTENTIONS**

have been served on January 6, 2026, on the following:

<p>Michael T. Renaud, Esq. MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. One Financial Center Boston, MA 02111 Email: Mintz-JUUL-ITC-3@mintz.com</p> <p>ATTORNEYS FOR COMPLAINANT JUUL LABS, INC.</p>	<p><input type="checkbox"/> Via First Class Mail <input type="checkbox"/> Via Hand Delivery <input type="checkbox"/> Via Federal Express <input type="checkbox"/> Via Electronic Filing <input checked="" type="checkbox"/> Via Electronic Mail</p>
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/s/ Tracy Haynes _____