IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Adam Bowen et al.	
U.S. Patent No.:	12,156,533	Attorney Docket No. 58718-0002IP1
Issue Date:	December 3, 2024	
Appl. Serial No.:	17/171,976	
Filing Date:	February 9, 2021	
Title:	NICOTINE SALT FORMULATIONS FOR AEROSOL DEVICES AND METHODS THEREOF	

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PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 12,156,533 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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LISTING OF CLAIMS

Claim 1	
[1.pre]	An electronic cigarette comprising…
[1.a]	a cartridge,
[1.b]	wherein the cartridge comprises a nicotine salt liquid formulation, wherein: (a) the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier,
[1.c]	wherein the organic acid is benzoic acid or lactic acid;
[1.d]	(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;
[1.e]	(c) the liquid carrier comprises glycerol and propylene glycol; and…
[1.f]	(d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.
Claim 2	
[2]	The electronic cigarette of claim 1, wherein the liquid carrier further comprises water.
Claim 3	
[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.
Claim 4	
[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.

Claim 5	
[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.
Claim 6	
[6]	The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises a flavorant.
Claim 7	
[7]	The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises one or more additional organic acids.
Claim 8	
[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.
Claim 9	
[9]	The electronic cigarette of claim 1, wherein the organic acid is benzoic acid.
Claim 10	
[10]	The electronic cigarette of claim 1, wherein the organic acid is lactic acid.

I. INTRODUCTION

NJOY LLC and NJOY Holdings (collectively, "Petitioner") petition for *inter partes* review ("IPR") of claims 1-10 ("the Challenged Claims") of U.S. Patent No. 12,156,533 ("the '533 patent"), assigned to Juul Labs, Inc. ("Patent Owner"). By revealing that the '533 patent claims recite an electronic cigarette ("e-cigarette") formulation that is comprehensively disclosed within a single prior art reference, and further exposing disclosure of features promoted as novel during prosecution by at least two other complementary references, the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to each of the challenged claims.

The '533 patent concerns the use of nicotine salt formulations in e-cigarettes to deliver nicotine to consumers, as opposed to using unprotonated nicotine, or what is commonly referred to in the industry as "free base" nicotine. During prosecution, Patent Owner proclaimed that it had discovered "surprising benefits of formulating nicotine as a nicotine salt liquid formulation for delivery in an electronic cigarette," and that its purported discovery defied the "[then]-conventional wisdom in the art…that optimum nicotine absorption" in an electronic cigarette occurred with "nicotine predominantly in the free base form." EX1002, 284. Specifically, Patent Owner claimed nicotine salts that used either benzoic acid or lactic acid in combination with the nicotine. EX1001, cl. 1.

But using nicotine salts instead of free base nicotine in electronic cigarettes

was far from new. And the superior properties of nicotine salts in delivering nicotine to consumers were far from unknown. Drawing on over twenty years of experience in the e-cigarette industry, Martin Wensley—Petitioner's expert—explains this with reference to various corroborating references. In detail, his testimony establishes that, in addition to being known in e-cigarettes, these properties had been known for ***decades*** in conventional cigarette formulations, to the point that a later publication called the rise of nicotine salts in e-cigarettes ***"déjà vu all over again."***[1] EX1008, 1.[2] And they were known using the very acids that Patent Owner claimed.

Indeed, a patent application filed by Sebastian in 2012 disclosed an e-cigarette with an "aerosol precursor" containing nicotine and lactic acid that meets every limitation of independent claim 1. As a matter of straightforward acid-base chemistry, when nicotine—a base—and an acid (like lactic acid) are combined, the result is certain—formation of a nicotine salt, i.e., nicotine lactate. Nothing more is required for anticipation. And yet, the necessary formation of a nicotine salt is documented in general chemistry textbooks and explained in record testimony offered by a reputed Ph.D. chemist—Dr. Steven Byrn—who has more than 50 years of experience.

[1] All emphasis added herein unless otherwise noted.

[2] Non-patent references cited herein cite to stamped page number.

While this evidence leaves no legitimate doubt that nicotine salt—and nicotine lactate in particular—was known as a desirable vehicle for the delivery of nicotine, Lechuga-Ballesteros further and independently discloses its favorable properties. In addition to empirically showing the formation of a nicotine lactate salt, Lechuga-Ballesteros reveals that, in 2006, "nicotine lactate solution had the most desirable combination of attributes" for delivering nicotine using a metered dose inhaler ("MDI"), as compared to both free base nicotine and a different organic acid. EX1005, [0084]. The benefits of nicotine salts were clearly known as early as 1988, as demonstrated by Lawson, for example, which credits a nicotine-organic acid salt within a conventional cigarette for "provid[ing] improved tobacco taste, strength and smoking satisfaction…while avoiding undesirable off-tastes during use." EX1006, 3:25-27. The '533 patent's claim to "surprising" findings are instead ***déjà vu all over again***, and certainly nothing new or non-obvious.

Without doubt, the core concepts described in the '533 patent—including the specific nicotine salt formulations Patent Owner now claims as its invention—were known by the critical date. Petitioner therefore respectfully requests that the Board institute IPR and cancel the Challenged Claims.

II. REQUIREMENTS FOR IPR UNDER 37 C.F.R. §42.104

A. Grounds for Standing Under 37 C.F.R. §42.104(a)

Petitioner certifies that the '533 patent is available for IPR. Petitioner is not

barred or estopped from requesting review of the Challenged Claims on the below-identified grounds.

B. Challenge and Relief Requested—37 C.F.R. §42.104(b)

Petitioner requests IPR of the Challenged Claims on the grounds below. Additional explanation is provided in Martin Wensley's Declaration and Dr. Stephen Byrn's Declaration. *See* EX1003, ¶¶ 1-178; EX1009, ¶¶ 1-49.

Ground	Claims	Basis for Rejection
Ground 1	**1-8, 10**	§102 – Sebastian
Ground 2	**1-10**	§103 – Sebastian, Lechuga-Ballesteros

The '533 patent was filed February 9, 2021, and purports to claim priority to provisional applications Nos. 61/912,507 (filed December 5, 2013) and 61/820,128 (filed May 6, 2013). Despite failures of priority, because all relied-upon prior art pre-exists both provisional filing dates, each qualifies as prior art on at least the basis noted in the table below, based on post-AIA 35 U.S.C., which applies:

Reference	Date	Prior Art Under
Sebastian	6/28/2012	§102(a)(2)
Bauer	2010	§102(a)(1)
Lechuga-Ballesteros	6/28/2005	§§102(a)(1), 102(a)(2)

C. Claim Construction

Claim terms should only be construed to the extent necessary to resolve a controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868

F.3d 1013, 1017 (Fed. Cir. 2017). Here, Petitioner identifies no terms requiring construction. Instead, Petitioner applies the ordinary meaning ascribed to the words of the claims in view of the intrinsic evidence. Petitioner reserves the right to respond to any claim constructions advanced by Patent Owner.

While Petitioner intends to advance an indefiniteness argument regarding one limitation in claim 1 in the parallel ITC proceeding, this Petition demonstrates that "notwithstanding the alleged indefiniteness of the claim term, an ordinarily skilled artisan would understand that the asserted art satisfies the claim limitation," satisfying the test set forth in *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper No. 18 at 3-4 (PTAB Nov. 5, 2025) (informative). Where applicable in the analysis section below, Petitioner explains how—indefiniteness aside—the asserted prior art nevertheless satisfies the claim limitations. *See* §IV.A.2[1f], *infra*.

III. TECHNOLOGY BACKGROUND AND '533 PATENT SUMMARY

A. Technology Overview

1. E-Cigarettes

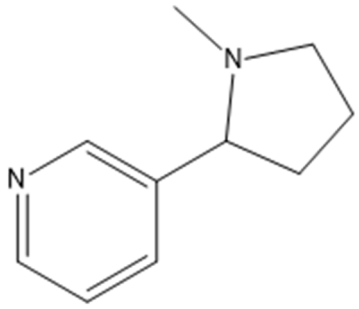
Like traditional cigarettes, e-cigarettes deliver nicotine and flavoring compounds to consumers through inhalation of a material created by heating. EX1012, 1; EX1013, 3; EX1003, ¶ 27. Traditional cigarettes deliver nicotine through combusting tobacco, producing smoke that contains nicotine and chemical byproducts, including tar and carbon monoxide. E-cigarettes, by contrast, were

developed to provide nicotine in an aerosol form by vaporizing nicotine rather than burning tobacco, thus negating many harmful byproducts associated with smoking. EX1013, 2; EX1014, 3; EX1003, ¶ 27. These devices generally use a heating element to aerosolize a nicotine-containing liquid. EX1013, 2-3; EX1012, 1; EX1004, [0010]-[0012], [0048], [0051], [0057]; EX1003, ¶ 28. The rise of e-cigarettes has been driven by both consumers seeking alternatives that pose less risk than combustible tobacco and by a desire for more customizable, convenient, and socially-acceptable nicotine delivery methods. *See, e.g.*, EX1014, 7; EX1015, 1; EX1003, ¶ 29.

In modern e-cigarettes, aerosolized liquids are known to include nicotine salts, produced by combining free base nicotine with an acid. EX1008, 2 (Fig. 1); EX1003, ¶¶ 30-31. The tobacco industry has known about nicotine salts for decades. Indeed, the benefits of nicotine salts have been appreciated not only in conventional combustible cigarette products, but also in early e-cigarette formulations, as discussed in more detail below. EX1006, 1:25-27; EX1008, 1, 5-6; EX1003, ¶¶ 30-31.

2. Nicotine Chemistry

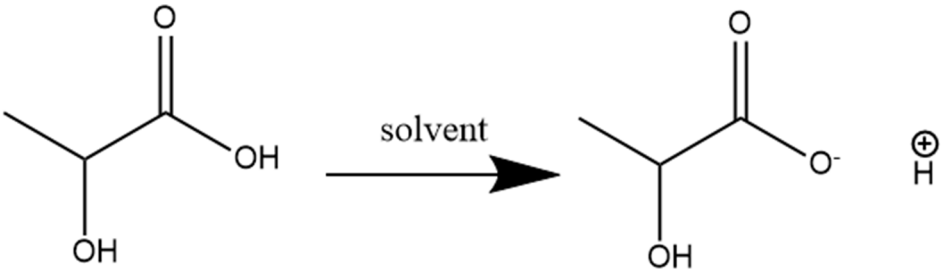
Nicotine is a naturally occurring alkaloid compound that is found primarily in tobacco plants. EX1007, 210; EX1008, 5; EX1003, ¶ 32. The chemical structure of nicotine is shown below:



"free base" nicotine

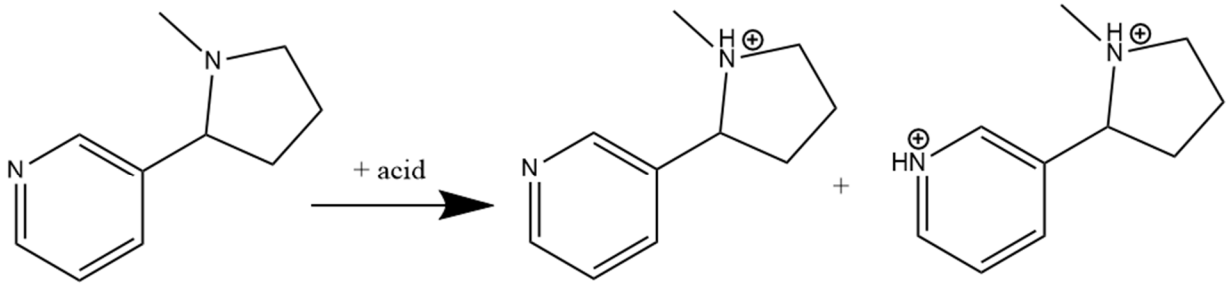
See EX1007, 210. Notably, nicotine has two nitrogen ("N") atoms that are capable of accepting protons, making it a base. *See* EX1022, 3-4. In the unprotonated form shown above, nicotine is colloquially referred to within the tobacco industry as "free base" nicotine, meaning it is "free" and not bound to an acid. EX1008, 1; EX1005, [0023]; EX1003, ¶ 32. In this form, nicotine is more volatile and more readily vaporized, but can be harsh when inhaled. EX1008, 1, 5; EX1005, [0062]; EX1003, ¶ 32.

A nicotine salt forms when nicotine is exposed to and reacts with an acid, such as benzoic acid or lactic acid. Taking lactic acid as an example, in polar solvents (e.g., water, glycerol, propylene glycol), lactic acid dissociates to some degree into its negatively-charged ionic form, yielding a lactate ion and a released positive hydrogen molecule:



lactic acid lactate ion

See EX1007, 206; EX1003, ¶ 33; EX1009, ¶ 33; *see also* EX1024. When nicotine is exposed to an acid, it reacts with the released positively-charged hydrogen molecules of the acid, creating positively-charged ionic forms:



"free base" nicotine monoprotonated nicotine diprotonated nicotine

See EX1008, 2; EX1003, ¶ 34; EX1009, ¶ 34; *see also* EX1023; *see also* EX1024. This is acknowledged by the ’533 patent itself, which recognized that protonated nicotine can exist with both a single charged nitrogen (“monoprotonated”) or two charged nitrogens (“diprotonated”). *See* EX1001, 12:65-13:2; EX1008, 2; EX1003, ¶ 34; EX1009, ¶ 34.

When lactic acid and “free base” nicotine are present together in a solvent, the lactic acid sheds a positively-charged hydrogen molecule, leaving a negatively-

charged lactate ion. The released hydrogen molecule reacts with the nicotine to produce a positively-charged nicotine ion. The negatively-charged lactate ion and the positively-charged nicotine ion interact electrostatically, due to their opposing charges. The result is a reaction between them that forms a salt, i.e., nicotine lactate. EX1003, ¶ 35; EX1009, ¶ 35; *see also* EX1008, 2 (Fig. 1) (showing reaction between nicotine and benzoic acid to form a nicotine salt).

Thus, salt formation occurs as a fundamental reaction between an acid and a base. As such, an acid interacting with a base to form a salt, like nicotine lactate, is nothing new or novel. Knowledge of this chemistry has been around for centuries. EX1007, 140-141; EX1003, ¶ 36; EX1009, ¶¶ 19-20.

3. History of Nicotine Salts in Cigarettes

The use of nicotine salts to deliver nicotine was so well-known that the transition from free base nicotine to nicotine salt (i.e. with protonated nicotine) in electronic cigarettes has been described as "déjà vu all over again," dating back to the 1900's in conventional cigarettes. EX1008, 5-6; EX1003, ¶ 37. Indeed, a 2019 article ("Duell") confirmed that it was appreciated that tobacco, in addition to containing nicotine, also contained "leaf sugars" that were "precursors of tobacco-smoke organic acids" and were "generally lost during slow air curing" performed in the 1600's, resulting in cigarettes containing a high fraction of free base nicotine ("α_{fb}"). EX1008, 5. When "flue-cured" tobacco was developed in the 1850's, it

produced "a noticeably milder smoke" because it "remain[ed] high in leaf sugars so that the resulting smoke contain[ed] numerous organic acids." *Id*.; EX1003, ¶ 38. Indeed, Duell confirmed that the "role of acids in converting nicotine to a ***protonated, 'salt' form*** in tobacco smoke has long been understood," citing an article ***from 1909*** stating:

> Apparently the only possible explanation of this pronounced effect on the sharpness of the smoke is that in the presence of the citric acid the nicotine ***enters the smoke in the form of a salt*** rather than in the free state, and thereby ***loses its pungency while still exerting the usual physiological effect***.

EX1008, 6; EX1003, ¶ 38.

Nor was that the only appreciation of the benefits of nicotine salts. In the 1980's, some conventional cigarette suppliers went one step farther, applying a salt solution to the "filler material" of the cigarette such that when it was smoked, the nicotine salt resulted in "improved tobacco taste, strength and smoking satisfaction…while avoiding undesirable off-tastes during use." EX1006, 3:25-27; EX1003, ¶ 39. Thus, the benefits of nicotine salts to deliver nicotine have been long appreciated.

Indeed, the parallels between the transitions to the use of nicotine salts in conventional cigarettes and e-cigarettes were so clear that Duell created a comparison graphic showing them, reproduced below. EX1008, 5 (Fig. 3). In this graphic, the top wavy line tracks the transition from the use of "air-cured" nicotine

in the 1600's on the right, associated with a higher fraction of free base nicotine (α_{fb} ~0.5-0.9), to "flue-cured" nicotine in the 1850's on the left, with a much lower fraction ($\alpha_{fb} < 0.1$), because the nicotine "leaf sugars" were preserved in the form of organic acid precursors.

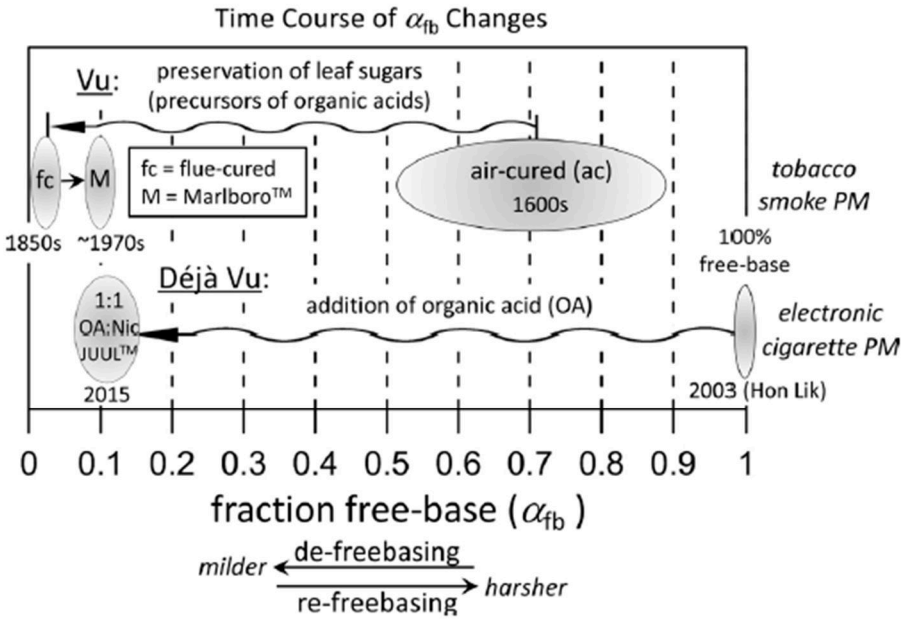


Figure 3 A visual representation of the historical changes in α_{fb} in tobacco smoke PM (top) in comparison to how electronic cigarette fluids and their associated aerosols have been changed (bottom). fc, flue-cured; α_{fb}, fraction of nicotine in the free-base form; M, Marlboro; Nic, nicotine; OA, organic acid; PM, particulate matter.

EX1008, 5; *see also* EX1003, ¶ 40. Similarly, the bottom wavy line tracks that same transition in electronic cigarettes. It shows the introduction of the e-cigarettes in 2003, showing on the right that they used exclusively free base nicotine ($\alpha_{fb} = 1$), and the transition to the "addition of organic acid (OA)," i.e. use of nicotine salts,

exemplified by the Juul product that used a "1:1" (or equimolar) ratio of organic acid ("OA") to nicotine ("Nic"), resulting in very little free base nicotine (α_{fb} ~0.1). EX1008, 5 (Fig. 3); EX1003, ¶ 40. Duell therefore concluded that "[t]he chemistry changes during the rapid evolution of e-cigarettes closely parallel the events that occurred during the centuries-long development of smoked tobacco." EX1008, 5; EX1003, ¶ 40.

Thus, the alleged "surprising benefits," (EX1002, 285), of using nicotine salts to deliver nicotine in cigarettes were neither new nor surprising. EX1003, ¶ 41.

B. Summary of the '533 Patent

The '533 patent is titled, "Nicotine Salt Formulations for Aerosol Devices and Methods Thereof." EX1001. It concerns nicotine-salt formulations used in e-cigarettes and other vaporizing devices, and it discloses a series of nicotine salt formulations and contrasts various properties of those formulations against free base nicotine. It states a fundamental fact known for decades that "formulations comprising a nicotine salt…cause faster and more significant rise [in heart rate] when compared with a nicotine free base formulation with the same amount of nicotine by weight." EX1001, 22:42-45; EX1003, ¶ 42. The '533 patent indicates that pharmacokinetic studies based on blood plasma testing support this conclusion by showing that nicotine salt formulations yield comparable or higher rates of nicotine uptake in the blood. *See, e.g.*, EX1001, 27:5-64, Figs. 4-6; EX1003, ¶ 42.

Further, the '533 patent stated that the "increased heart rate" was "theoretically approaching or theoretically comparable to that of a traditional burned cigarette," which purportedly "has not been demonstrated or identified in other electronic cigarette devices." EX1001, 22:58-61; *see also id.*, 24:14-22; EX1003, ¶ 43.

C. Prosecution History

The '533 patent issued on December 3, 2024, from prosecution of U.S. Patent Application No. 17/171,976 filed on February 9, 2021. *See* EX1002; *see also* EX1003, ¶¶ 44-49. What is now Claim 1 was initially presented during prosecution as claiming "a salt of nicotine and benzoic acid in a liquid carrier." *See* EX1002, 167. The Examiner rejected all claims as obvious over the combination of Sebastian (EX1004) in view of Lechuga-Ballesteros (EX1005). EX1002, 207-216.

The applicant overcame Sebastian by arguing that "Sebastian describes formulations that contain nicotine in the form of nicotine free base, which is consistent with the knowledge in the art at the time that nicotine free base was the preferred form for delivery of nicotine in an electronic cigarette." EX1002, 285. Further, the applicant argued that there was no motivation to modify the formulation in Sebastian based on Lechuga-Ballesteros "because the devices and the formulations are not interchangeable." EX1002, 286.

The Examiner withdrew the Sebastian-based rejection, finding applicant's arguments about the lack of motivation to modify "persuasive as it pertains to the

electronic cigarette claim," (EX1002, 314), but issued a new rejection of the ***cartridge*** claim over Lechuga-Ballesteros alone, finding it disclosed all of the features of the claimed cartridge, (EX1002, 308-313). The Examiner found the electronic cigarette claim allowable. *See* EX1002, 313. The applicant amended the cartridge claim to specify it was an "electronic cigarette cartridge," (EX1002, 377), and the Examiner subsequently issued a Notice of Allowance, (EX1002, 396-402).

After allowance, the applicant requested continued examination and broadened the relevant claims through amendment to read "a salt of nicotine and an organic acid in a liquid carrier, wherein the organic acid is benzoic acid ***or lactic acid***[.]" EX1002, 498. The Examiner reopened prosecution and newly rejected the "electronic cigarette cartridge" claim, this time over Lawson (EX1006; *See* EX1002, 519-523), but again found the "electronic cigarette" claim allowable. EX1002, 523. The applicant cancelled the "electronic cigarette cartridge" claim, (EX1002, 684), and a second Notice of Allowance issued, (EX1002, 692-696).

D. Level of Ordinary Skill

A person of ordinary skill in the art of the '533 patent at the time of invention would have at least (i) a bachelor's degree in chemistry, physics, or a related discipline and three years' experience in design and implementation of aerosol delivery systems and the formulation of their consumables, or (ii) an equivalent combination of education and/or work experience. EX1003, ¶¶ 22-23.

IV. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. [Ground 1] Sebastian Anticipates Claims 1-8, 10

1. Overview of Sebastian

Sebastian is titled, "Reservoir and Heater System for Controllable Delivery of Multiple Aerosolizable Materials in an Electronic Smoking Article." EX1004. Sebastian explains that it was "desirable to provide a smoking article that can provide the sensations of cigarette, cigar, or pipe smoking, that does so without combusting tobacco, that does so without the need of a combustion heat source, and that does so without necessarily delivering considerable quantities of incomplete combustion and pyrolysis products." EX1004, [0008]; EX1003, ¶ 50.

To that end, Sebastian discloses an "electronic smoking article" that can generate an inhalable aerosol. *See, e.g.*, EX1004, Abstract, [0009]-[0010]; EX1003, ¶ 51. Sebastian's electronic smoking article comprises a "cartridge" with "one or more reservoirs" that can store an "aerosol precursor composition" in liquid form. EX1004, [0069], [0116]; EX1003, ¶ 51. As will be discussed in more detail below, Sebastian further describes that its aerosol precursor composition can contain a combination of nicotine, organic acid, one or more liquid carriers (i.e., solvents), and other inhalable materials such as flavorants. EX1004, [0055]-[0057], [0059], [0061]; EX1003, ¶ 51. Sebastian contemplates using electrical energy to heat its liquid aerosol precursor until it is volatized (i.e., aerosolized) into an inhalable

aerosol used to deliver the nicotine formulation to a consumer. EX1004, [0031], [0065]; EX1003, ¶ 51.

2. Analysis

[1pre] An electronic cigarette comprising…

To the extent the preamble is found to be limiting, Sebastian discloses an electronic cigarette. EX1003, ¶¶ 52-59. Sebastian explains that the "electronic smoking article" of "[t]he present invention provides articles that use ***electrical energy*** to heat a material (preferably without combusting the material to any significant degree) to form an inhalable substance, the articles being sufficiently compact to be considered 'hand-held' devices." EX1004, [0029]; EX1003, ¶ 52. The term "smoking article" "is intended to mean an article that provides the taste and/or the sensation (e.g., hand-feel or mouth-feel) of ***smoking a cigarette***, cigar, or pipe without substantial combustion of any component of the article." EX1004, [0029]; EX1003, ¶ 53. Notably, "smoking" here does not refer to generation of smoke, but rather, "relates to the physical action of an individual in using the article—e.g., holding the article, drawing on one end of the article, and inhaling from the article." EX1004, [0029]; EX1003, ¶ 53.

Sebastian's "electronic smoking article" is consistent with the '533 patent's description of its claimed "electronic cigarette." Specifically, the '533 patent states that the term "electronic cigarette" "refers to an electronic inhaler that vaporizes a

liquid solution into an aerosol mist, simulating the act of tobacco smoking." EX1001, 11:24-27. As such, the claimed "electronic cigarette" is similar in purpose with Sebastian's "electronic smoking article" as both articles serve to generate an inhalable aerosol by vaporizing a liquid solution containing nicotine to provide an experience similar to that of smoking a conventional cigarette. EX1003, ¶ 54.

In addition, Sebastian's "electronic smoking article" is similar in structure to the '533 patent's "electronic cigarette." The '533 patent describes an electronic cigarette as having "three essential components: a plastic cartridge that serves as a mouthpiece and a reservoir for liquid, an 'atomizer' that vaporizes the liquid, and a battery." EX1001, 11:31-35. And, as will be discussed in more detail below, Sebastian's "electronic smoking article" also includes a cartridge that serves as both a mouthpiece and reservoir for liquid, an "aerosolization zone" within which the liquid is vaporized, and a battery. EX1004, [0011]-[0012], [0116]; EX1003, ¶ 55.

The similarity of these components is apparent from a comparison of Figure 7 of the '533 patent to Sebastian's Figure 3. Below, using annotations, both are shown to have a cartridge with a mouthpiece (red) and reservoir (blue), and a battery (yellow):

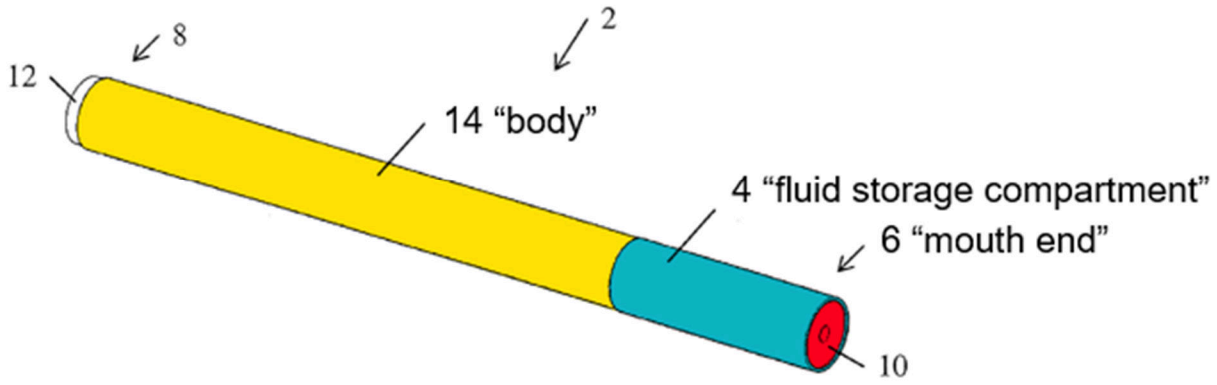


FIG. 7, ’533 Patent

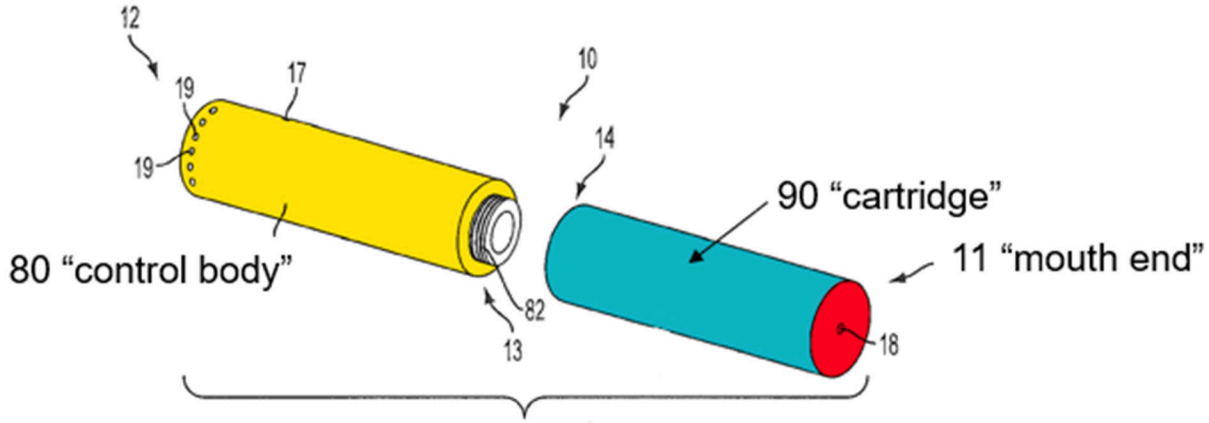


FIG. 3

FIG. 3, Sebastian

Specifically, Figure 7 of the ’533 patent (top) depicts a “fluid storage compartment 4” having a “mouth end 6.” EX1001, 17:10-15; EX1003, ¶ 56. The ’533 patent explains that “the fluid storage compartment 4 is replaceable ***as part of a replaceable cartridge***.” EX1001, 17:29-31; EX1003, ¶ 56. Figure 3 of Sebastian (bottom) similarly depicts a “cartridge 90” with a “mouthend 11.” EX1004, [0085],

[0088]; EX1003, ¶ 56. Likewise, Figure 3 of Sebastian depicts a "control body 80" that includes a "battery 40" (Figure 4, not shown). EX1004, [0087]. This structure is identical to the '533 patent's "body 14" that also contains a battery. EX1001, 17:21-23 ("the electronic cigarette comprises a rechargeable battery within a body 14 of the electronic cigarette"); EX1003, ¶ 56.

The prosecution history of the '533 patent further supports that Sebastian's "electronic smoking article" is an "electronic cigarette." EX1003, ¶¶ 57-59. The Examiner rejected the claims as obvious in part over Sebastian, finding that "Sebastian et al discloses an electronic smoking article (***i.e., electronic cigarette***) that provides for delivery of aerosolized components of a liquid aerosol precursor composition[.]" EX1002, 208. In addition, the Examiner cited the same Figure 3 shown above and highlighted Sebastian's "control body 80" as "detachably connected to a cartridge 90…which houses the liquid composition, a distal end of which is inserted into the mouth of [a] user," concluding that Sebastian teaches the claimed electronic cigarette. EX1002, 208-209; EX1003, ¶ 57.

Tellingly, in response, rather than contending that Sebastian somehow failed to disclose an electronic cigarette, the applicant expressly used the term "electronic cigarette" in connection with Sebastian, effectively conceding that Sebastian discloses an electronic cigarette. *See* EX1002, 285-286 (arguing that Sebastian disclosed use of "nicotine free base," "consistent with the knowledge in the art at the

time" that this "was the preferred form for delivery of nicotine ***in an electronic cigarette***"). EX1003, ¶ 58.

Thus, in view of Sebastian's express disclosures and the prosecution history, Sebastian teaches an electronic cigarette within the meaning of the '533 patent claims and specification. EX1003, ¶¶ 52-59.

[1a] a cartridge,

Sebastian expressly discloses a cartridge. Sebastian teaches that its electronic smoking article contains "a ***cartridge*** with a connecting end that engages the connecting end of the control body and with an opposing, mouthend." EX1004, [0068]; EX1003, ¶¶ 60-65. Further, Sebastian explains that its cartridge has a "mouth opening 18 at the mouthend 11 thereof to allow passage of air and entrained vapor (i.e., the components of the aerosol precursor composition in an inhalable form) from the cartridge to a consumer." EX1004, [0088]; *see also id*., Figs. 3-4; EX1003, ¶ 60.

Sebastian's "cartridge" is consistent with the '533 patent's description of a "cartridge." The '533 patent describes its cartridge "as a mouthpiece and a reservoir for liquid[.]" EX1001, 11:33-34; EX1003, ¶ 61. Similarly, Sebastian describes that "the interior cartridge space can include one or more reservoirs for storing a plurality of components of an aerosol precursor composition." EX1004, [0116]; EX1003, ¶ 61. The '533 patent further explains that "the fluid storage compartment 4 is

replaceable as part of a replaceable cartridge." EX1001, 17:29-31; EX1003, ¶ 62. Likewise, Sebastian explains that its "cartridge can comprise a shell containing one or more disposable components and having an end that removably attaches to the control body." EX1004, [0030]; *see also id.*, [0067], [0085], [0115]-[0116]. As such, Sebastian's "cartridge" is consistent with the claimed "cartridge." EX1003, ¶ 62.

As shown below, a comparison of annotated Figure 7 from the '533 patent and annotated Figure 3 from Sebastian illustrate this consistency:

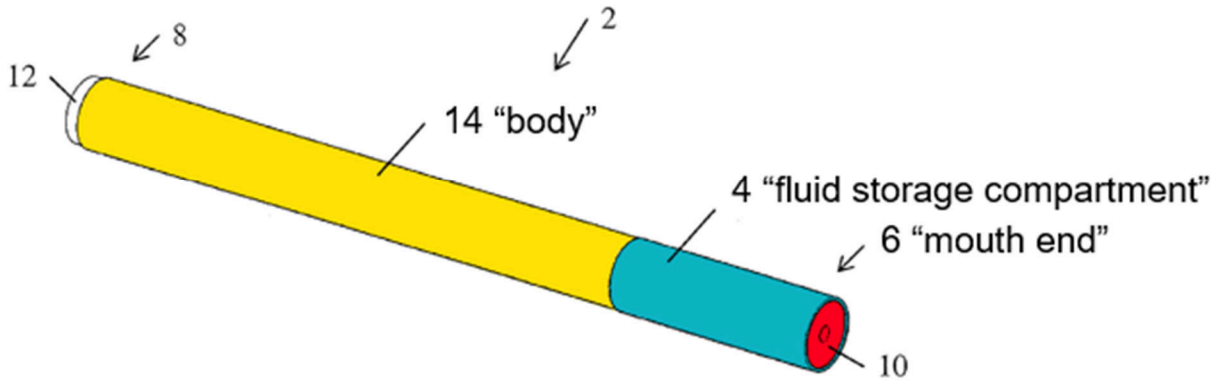


FIG. 7, ’533 Patent

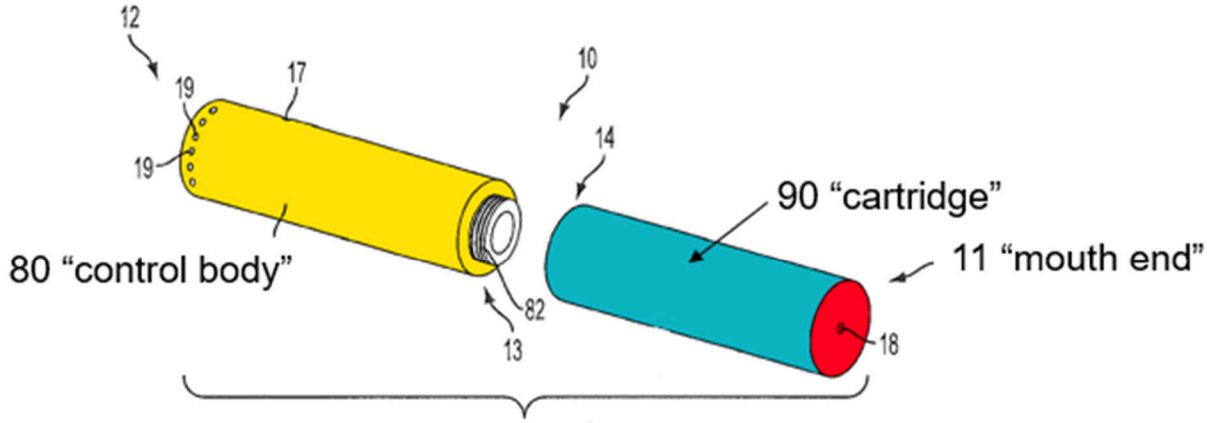


FIG. 3

FIG. 3, Sebastian

Sebastian discloses a “cartridge 90” with a “mouthend 11” that is consistent with the “fluid storage compartment 4” having a “mouth end 6,” as shown in annotated Figure 7 from the ’533 patent. EX1004, [0085], [0088]; EX1001, 17:10-15; *see also*

EX1001, 17:29-31 (explaining "the fluid storage compartment 4 is replaceable ***as part of a replaceable cartridge***."); EX1003, ¶ 63.

Additionally, during prosecution, as with "electronic cigarette," the Examiner found that Sebastian's "cartridge" corresponded to the claimed cartridge. EX1002, 208-09. In response, the applicant did not dispute that Sebastian disclosed a cartridge. EX1002, 285-86; EX1003, ¶ 64.

Thus, in view of Sebastian's express disclosures, Sebastian teaches a cartridge within the meaning of the '533 patent claims and specification. EX1003, ¶¶ 60-65.

[1b] wherein the cartridge comprises a nicotine salt liquid formulation, wherein: (a) the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier,

Sebastian discloses a nicotine salt liquid formulation comprised of "a salt of nicotine and an organic acid in a liquid carrier." EX1003, ¶¶ 66-90. As will be discussed in turn below, Sebastian discloses both "a salt of nicotine and an organic acid" and that the salt is "in a liquid carrier."

(a) Sebastian discloses "a salt of nicotine and an organic acid"

Sebastian discloses each part of this limitation, both separately and taken in combination—i.e., it discloses nicotine, the combination of nicotine with organic acid, and the necessary formation of a nicotine salt.

First, Sebastian expressly discloses the inclusion of nicotine. EX1004 [0057]; EX1003, ¶ 68. For example, Sebastian teaches that "liquid nicotine can be used" and further instructs that nicotine "can be included in the aerosol precursor or vapor precursor composition." EX1004, [0057]; *see also id*., [0056] [0061] ("[a]s a non-limiting example, an aerosol precursor according to the invention can comprise…nicotine[.]"); EX1003, ¶ 68.

Second, Sebastian also expressly discloses the combination of organic acids and nicotine. Specifically, Sebastian explains that "***[o]rganic acids particularly*** can be incorporated ***into the aerosol precursor*** to affect the flavor, sensation, or organoleptic properties of medicaments, ***such as nicotine***, that can be ***combined with the aerosol precursor***." EX1004 [0059]; EX1003, ¶ 69. Indeed, one of Sebastian's goals was to improve the "organoleptic properties" to "provide a smoking article that can provide the sensations of cigarette, cigar, or pipe smoking…without combusting tobacco," similar to the '533 patent's goal of achieving "satisfaction" that is "more comparable to the satisfaction in an individual smoking a traditional cigarette." EX1004, [0008], [0059]; EX1001, 8:1-5; *see also id.* 22:42-67; EX1003, ¶ 70.

Third, Sebastian discloses the creation of a "salt of nicotine and an organic acid" through its disclosure of a combination of nicotine and organic acid. *See* §III.A.2, *supra*. As the '533 patent itself discloses, "[n]icotine salts are formed by

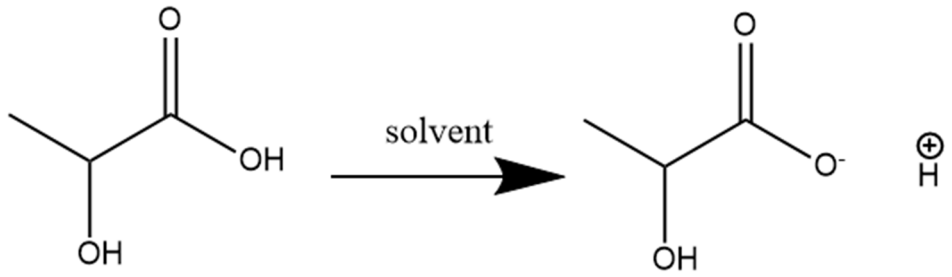
the addition of a suitable acid, including organic or inorganic acids." EX1001, 12:44-45; *see also id*., 13:3-7 ("Nicotine salt formulations may be formed by adding a suitable acid to nicotine"), 13:18-20 ("Nicotine salt formulations may be prepared by combining nicotine and a suitable acid in a carrier mixture, such as a mixture of propylene glycol and glycerin"); EX1003, ¶ 71. Notably, as these disclosures demonstrate, the '533 patent does not disclose any specific or novel method of generating a nicotine salt; rather, it implicitly recognizes that mere addition of organic acid to nicotine in solution leads to salt formation. EX1001, 12:44-45, 13:3-20; EX1003, ¶ 71.

Here, Sebastian discloses this "salt" limitation as a matter of fundamental chemistry because, consistent with the '533 patent's disclosures, the combination of acid and base will necessarily form a nicotine salt. As will be discussed below, this understanding is consistent with Federal Circuit precedent on inherent anticipation, and is further supported by textbook chemistry, as well as additional expert testimony from Dr. Byrn, a chemist with over fifty years of experience. EX1003, ¶¶ 72-89; EX1009, ¶¶ 4-15, 28-39. Finally, the prosecution history of the '533 patent provides context for how the claim was ultimately allowed.

(i) Chemical principles dictate that Sebastian's formulation includes a salt

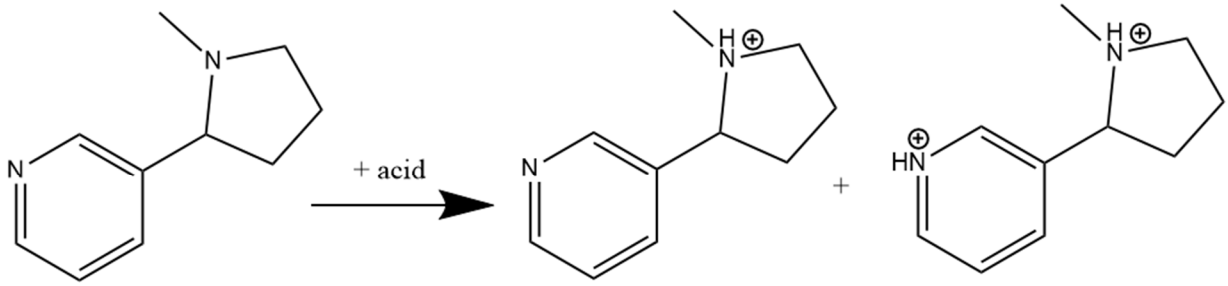
The formation of a salt in Sebastian is grounded in the inherent property of nicotine as a base and the necessary and inevitable reaction that occurs upon coming into contact with an acid such as lactic acid. EX1009, ¶¶ 19-20, 23-26, 32-35. In general, when an acid, such as lactic acid, and a base, such as nicotine, come into contact in a polar medium (i.e., water, propylene glycol, glycerol, etc.), the resulting reaction ***necessarily*** results in formation of a salt of the acid and the base. EX1009, ¶¶ 19-22, 32-39; EX1016, 15; EX1017, 3; EX1018, 1; *see also* §III.A.2, *supra*, incorporated by reference here.

To illustrate, Sebastian teaches a non-exhaustive list of organic acids that can be used as a component of the liquid aerosol precursor composition, including lactic acid. *See* EX1004, [0059]; EX1003, ¶ 74. As discussed above in Section III.A.2, in polar solvents, such as those disclosed by Sebastian, lactic acid dissociates into its negatively-charged ionic form—the lactate ion—with a corresponding positive hydrogen molecule, as shown below:



lactic acid lactate ion

EX1009, ¶ 33. When nicotine ($C_{10}H_{14}N_2$)—a base—is exposed to an acid, it will react with the free positively charged hydrogen molecules, creating a positively-charged ionic form:



EX1009, ¶ 34. As the '533 patent itself notes, nicotine can exist with both a single charged nitrogen ("monoprotonated") or two charged nitrogens ("diprotonated"). *See* EX1001, 12:65-13:2; EX1003, ¶ 74; *see also* EX1008, 1-2.

Therefore, simply as a result of being present in solution together, the negatively-charged lactate ions and the positively-charged nicotine ions will electrostatically interact, due to their opposing charges, and will necessarily react to form a salt, i.e., nicotine lactate. EX1009, ¶¶ 19-26, 32-39; EX1003, ¶ 75. As such, this reaction—and thus the formation of a salt—***necessarily*** occurs in Sebastian's aerosol precursor that contains lactic acid and nicotine in a liquid. EX1009, ¶¶ 28-39.

In addition to disclosing the presence of nicotine and organic acid together—which is all that is required to meet this claim limitation—Sebastian also specifically

discloses that in its formulations, "***organic acids***, such as levulinic acid, lactic acid, and pyruvic acid, ***can be included*** in the aerosol precursor ***with nicotine*** in amounts up to being ***equimolar*** (based on total organic acid content) with the nicotine." EX1004, [0059]; *see also id.* (disclosing ratio of "about 0.5 moles of lactic acid per one mole of nicotine[.]"). This statement is direct evidence that Sebastian disclosed a chemical reaction that occurs between nicotine and organic acid. EX1003, ¶¶ 76-77. "Equimolar" means present at equal molar concentrations, or amounts, i.e. a one-to-one (1:1) ratio. EX1003, ¶ 77; EX1009, ¶ 30. In other words, there is one molecule of acid for every molecule of nicotine—that is, every nicotine molecule has a corresponding organic acid molecule with which it can react. EX1003, ¶ 77; EX1009, ¶ 30. Thus, a POSITA would have understood that this disclosure of the specific ratios of organic acid to nicotine demonstrates express teaching by Sebastian of a chemical reaction between organic acid and nicotine. EX1003, ¶ 76-77.

In contrast, Sebastian does not reference molar ratios relative to nicotine when describing the concentration of other components of its aerosol precursor composition, such as water or propylene glycol—instead only describing their amounts by weight percentage. *See, e.g.*, EX1004, [0061] ("the glycerol can be present in an amount of about 70% to about 90% by weight… the water can be present in an amount of about 10% to about 20% by weight[.]"); EX1003, ¶ 78.

Thus, in the view of a POSITA, Sebastian's "up to equimolar" description distinctly contemplates a chemical reaction between nicotine and organic acid. EX1003, ¶ 78.

Thus, because the formation of a nicotine salt is the natural and necessary result flowing from the operation of at least one embodiment of Sebastian, Element [1b] is anticipated by Sebastian. EX1003, ¶ 79.

(ii) Precedent supports that Sebastian "necessarily and inevitably" forms a nicotine salt

Sebastian's inherent anticipation of the claimed salt of nicotine and organic acid is supported by binding Federal Circuit precedent. For example, in *Schering Corp. v. Geneva Pharms., Inc.*, the patent at issue claimed a metabolite of a particular drug that was formed in a patient's body after ingestion of the drug. 339 F.3d 1373, 1375 (Fed. Cir. 2003). The prior art, however, disclosed administration of that same drug without specifically disclosing the metabolite. *Id*. at 1376. The Federal Circuit found that the record showed the metabolite "necessarily and inevitably forms from [the drug] under normal conditions." *Id*. at 1378. Therefore, the Court held that the prior art's disclosure of administration of the drug inherently anticipated the claim to its metabolite. *Id*. at 1380. Similarly, here, Patent Owner's claim to a nicotine salt—which "necessarily and inevitably forms" as the product of the reaction between nicotine (an undisputed base), and organic acid—is anticipated by

Sebastian's express disclosure of both reactants and its clear instructions to combine them. *Id*.; EX1004, [0059]; EX1003, ¶¶ 67-79.

While a POSITA is not required to have recognized the inherent property under binding Federal Circuit precedent, here, as Mr. Wensley explains, it was well understood to him and to other POSITAs at the time of the invention that combining nicotine and lactic acid would indeed generate a nicotine lactate salt. EX1003, ¶¶ 67-79; *see Schering*, 339 F.3d at 1377 ("[R]ecognition by a person of ordinary skill in the art before the critical date of the ['533] patent is not required to show anticipation by inherency."); *see also Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1349 (Fed. Cir. 1999) ("Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation."). Regardless, for inherent anticipation, all that matters is that a salt necessarily and inevitably forms when organic acid is combined with a nicotine base. EX1003, ¶¶ 67-79.

It is also of no consequence that Sebastian does not expressly use the word "salt." *Adasa Inc. v. Avery Dennison Corp*., 55 F.4th 900, 910 (Fed. Cir. 2022) ("The reference need not satisfy an *ipsissimis verbis* test.") (quoting *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009)). Here, Sebastian anticipates the salt claim limitation because practicing Sebastian necessarily results in the formation of a nicotine salt by combining nicotine and organic acid.

(iii) Chemistry textbooks and chemistry expert further demonstrate that Sebastian necessarily discloses a "nicotine salt"

At bottom, the fundamental chemistry principles underlying this inherent anticipation analysis are supported by reputable chemistry textbooks. As just one non-limiting example, Bauer (EX1007) is a textbook titled "Introduction to Chemistry," published in 2010, designed for a freshman-level Introductory Chemistry course, which requires no chemistry prerequisite and targets non-physical science majors in disciplines that do not require the rigor of a science major's General Chemistry course.[3] Bauer sets forth general chemistry principles that underlie acid-base chemistry, including but not limited to the structures of lactic acid

[3] Because Petitioner does not rely on Bauer for the disclosure of a particular element or claim limitation—all elements are express or inherent in Sebastian—Bauer is not presented in combination with Sebastian, nor therefore is a specific motivation to combine articulated, per *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) ("[B]ecause the Board did not rely on Nelson for the disclosure of a particular element or teaching, the Board had no obligation to find a motivation to combine O'Brien and Nelson."). Simply, Sebastian anticipates claim 1; Bauer merely serves as an exemplary textbook demonstrating the fundamental principles that explain why Sebastian does so.

and nicotine, their properties as acids and bases, and how acids and bases react to form salts. EX1007, 61, 140-142, 206, 210; EX1003, ¶ 80.

Bauer explains acid-base chemistry in part using the "Brønsted-Lowry theory" which "defines an acid as any substance that can donate an H^+ ion to another substance" and "defines a base as any substance that can accept an H^+ ion from another substance." EX1007, 141; EX1003, ¶ 81; *see also* EX1019; *see also* EX1020. Notably, this is consistent with the definition of "organic acid" found in the '533 patent, which "refers to an organic compound with acidic properties (e.g., by Brønsted-Lowry definition, or Lewis definition)." EX1001, 11:6-8.

Bauer also discloses the structures of both nicotine and lactic acid. EX1003, ¶ 82. First, Bauer discloses that lactic acid is a carboxylic acid, and notes that its "reactions often involve loss of H^+." *See* EX1007, 206; EX1003, ¶ 82. Similarly, Bauer identifies nicotine as an "amine," and notes that "most amines act as bases due to the presence of an unshared electron pair on the nitrogen atom." EX1007, 210; EX1003, ¶ 82. Bauer also confirms that nicotine forms a base in the presence of water, and reacts with acids to form "salts." EX1007, 210; *see also* EX1005, Figs. 2A-2B (experimental results of a titration showing reaction of free base nicotine with organic acid in water to generate "ionized form"—i.e., salt—over pH range ~3.5-10); EX1003, ¶ 82; EX1009, ¶¶ 40-44; *see also* EX1011, 218-224.

To the extent there remains ***any*** question that a nicotine salt "necessarily and inevitably forms" in Sebastian, this finding is further confirmed by the opinions of Dr. Stephen Byrn, a Ph.D. scientist with over 50 years of chemistry experience. *See* EX1009, ¶¶ 4-15. Dr. Byrn—who is not relied upon in this proceeding for the views of a POSITA—explains the scientific basis underlying the inherent formation of the nicotine salt in Sebastian, in additional detail and with knowledge that a POSITA may or may not also possess (but in any event is certainly not required to possess). EX1009, ¶¶ 19-39.

Critically, the inclusion of Dr. Byrn's testimony is ***not*** a concession by Petitioner that knowledge of the inherent property is required to show inherent anticipation. *See Schering*, 339 F.3d at 1377. Nor is it a concession that a POSITA would not have understood that Sebastian disclosed the formation of a nicotine salt. Speaking from the perspective of a POSITA at the time of the invention, Mr. Wensley testified that a POSITA at that time would in fact have understood that combining lactic acid with nicotine as Sebastian disclosed would generate a nicotine salt. EX1003, ¶¶ 66-86.

(iv) Prosecution history shows Examiner did not contemplate Sebastian's "lactic acid" disclosure

If Patent Owner contends Sebastian should be dismissed because it was overcome during prosecution, such argument does not comport with the facts at issue

during prosecution. As discussed above, (*see* section III.C, *supra*), during prosecution, Patent Owner urged that Sebastian be distinguished on the basis it only described the use of "nicotine free base"—nicotine in its pure form—as a component of its formulation.[4] EX1002, 285 ("Sebastian describes formulations that contain nicotine in the form of nicotine free base, which is consistent with the knowledge in the art at the time that nicotine free base was the preferred form for delivery of nicotine in an electronic cigarette."); EX1003, ¶ 45. Patent Owner further argued that "Sebastian equates flavoring agents such as mint, nutmeg, clove, and lavender with organic acids as compounds that can affect the flavor and organoleptic properties of nicotine[,]" and therefore a POSITA "would not have been motivated ***to modify*** Sebastian to use the presently claimed nicotine salt liquid formulation." EX1002, 286.

Critically, at that time during prosecution, claim 1 required one specific organic acid—***benzoic acid***—which was not expressly called out by Sebastian. The Examiner withdrew the rejection, finding a POSITA "looking to improve the

[4] Notably, the applicant did not identify any paragraph in Sebastian to support its contention that the nicotine in Sebastian was free base nicotine. *See* EX1002, 285-286. Rather, Sebastian as a whole is ***silent*** as to the form of nicotine contemplated. EX1003, ¶¶ 50-51.

formulation of Sebastian…would not look to the formulation described in Lechuga-Ballesteros et al which has been optimized for delivery via a pressurized metered dosed inhaler." EX1002, 314. Thus, at that time, the applicant and the Examiner both understood that Sebastian's formulation had to be modified in some fashion to reach the claimed benzoic acid. After allowance, however, the applicant reopened prosecution and broadened the claims through amendment to require either benzoic acid ***or lactic acid***. EX1002, 498; EX1003, ¶ 48.

Specifically, this late amendment was broadening, expanding to cover formulations involving "lactic acid" in addition to those involving benzoic acid, and this brought the claim squarely within the four corners of Sebastian, with no modification needed. To this point and as recognized in early prosecution, Sebastian was comprehensive of the claim's limitations, other than benzoic acid. With lactic acid added through amendment as an alternative to benzoic acid, the one shortcoming of Sebastian was overcome. Indeed, as indicated by the Examiner during that early prosecution and as further demonstrated by this petition, Sebastian expressly discloses combining nicotine with lactic acid, which inherently forms a salt, just as the '533 patent contemplates. EX1004, [0059] ("For example, the aerosol precursor can include…about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine"); EX1003, ¶¶ 69, 91. Thus, this Petition presents different arguments related to Sebastian that were not considered during prosecution that

demonstrate how the formulation in Sebastian inherently anticipates this claim limitation.

(b) Sebastian discloses "in a liquid carrier"

Sebastian expressly discloses the nicotine salt in a liquid carrier. Specifically, Sebastian teaches that "the components for aerosolization (including aerosol formers and other inhalable materials) can be provided in liquid form in one or more reservoirs positioned sufficiently away from the resistive heating element to prevent premature aerosolization[.]" EX1004, [0051]; EX1003, ¶ 87. Additionally, Sebastian provides that the "aerosol precursor compositions can include other liquid materials, such as water." EX1004, [0055]; EX1003, ¶ 87. Specifically, Sebastian identifies that "aerosol precursor compositions can incorporate mixtures of glycerin and water, or mixtures of propylene glycol and water, or mixtures of propylene glycol and glycerin, or mixtures of propylene glycol, glycerin, and water," all of which are liquid in form. EX1004, [0055]; EX1003, ¶ 87.

Sebastian's disclosures are consistent with the '533 patent's description of a liquid carrier. The '533 patent states, "[s]uitable carriers (e.g., a liquid solvent) for the nicotine salts described herein include a medium in which a nicotine salt is soluble at ambient conditions, such that the nicotine salt does not form a solid precipitate," and that "[e]xamples include, but are not limited to, glycerol, propylene glycol, trimethylene glycol, water, ethanol and the like, as well as combinations

thereof." EX1001, 11:44-50; EX1003, ¶ 88. Furthermore, during prosecution, the Examiner likewise found that Sebastian's "aerosol precursor composition may include glycerol and/or propylene glycol (***read: liquid carrier***) in addition to a medicament, such as nicotine." EX1002, 209. Thus, the Examiner found these disclosures to read on the liquid carrier limitation. *Id*. In response, the applicant did not contend that Sebastian failed to disclose a liquid carrier. EX1002, 285-86; EX1003, ¶ 89.

Thus, in view of Sebastian's express, inherent, and implicit disclosures, Sebastian teaches "a salt of nicotine and an organic acid in a liquid carrier" within the meaning of the '533 patent claims, specification, and prosecution history. EX1003, ¶¶ 87-90.

[1c] the organic acid is benzoic acid or lactic acid;

Sebastian expressly discloses lactic acid. EX1003, ¶¶ 91-92. Specifically, Sebastian teaches that "organic acids, such as levulinic acid, ***lactic acid***, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine." EX1004, [0059]; *see also id*. (aerosol precursor can include "about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine"); EX1003, ¶ 91. Further, Sebastian makes clear the list of organic acids is non-exhaustive. EX1004, [0059] (identifying list of organic acids beginning with "e.g."); EX1003, ¶ 91. Nevertheless, express disclosure of

lactic acid is sufficient for anticipation here. "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001). Here, because the '533 patent claims benzoic acid or lactic acid in the alternative, Sebastian's disclosure of lactic acid anticipates this claim limitation. EX1004, [0059]; EX1003, ¶¶ 91-92.

Thus, in view of Sebastian's express disclosures, Sebastian teaches this limitation within the meaning of the '533 patent claims and specification. EX1003, ¶¶ 91-92.

[1d] (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;

Sebastian discloses nicotine concentrations within the claimed range. EX1003, ¶¶ 93-95. Specifically, Sebastian expressly discloses that "nicotine can be present in amount of about 0.1% to about 5% by weight." EX1004, [0061]; EX1003, ¶ 93. Sebastian further explains that "[f]lavors and the like (which can include medicaments, such as nicotine) can comprise up to about 10%, up to about 8%, or up to about 5% by weight of the aerosol precursor." EX1004, [0060]; EX1003, ¶ 93.

These disclosed ranges fall squarely within and around the claimed 5% to 20% range. A "range is anticipated by a prior art reference if the reference discloses a point within the range." *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015) (citing *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)). Even if Sebastian's disclosed ranges were found to only partially overlap with the claimed range, Sebastian still anticipates the claims. "A prior art reference that discloses an overlapping but different range than the claimed range can be anticipatory, even where the prior art range only partially or slightly overlaps with the claimed range." *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1338 (Fed. Cir. 2020). When "a range [is] disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence of teaching away, unexpected results or criticality[.]" *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018) (internal quotation omitted). Here, Patent Owner can point to no such evidence, as the highest concentration of nicotine used in its examples is 5%, which is an ***order of magnitude greater*** than the claimed lower end of the range—i.e., 0.5% nicotine. *See* EX1001, 20:33-36; EX1003, ¶ 94.

Thus, in view of Sebastian's express disclosures, Sebastian teaches "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" within the meaning of the '533 patent claims and specification. EX1003, ¶¶ 93-95.

[1e] (c) the liquid carrier comprises glycerol and propylene glycol; and…

Sebastian expressly describes the liquid aerosol precursor composition as comprising glycerol and propylene glycol. EX1003, ¶¶ 96-97. Specifically, Sebastian discloses that an "aerosol precursor according to the invention can comprise ***glycerol, propylene glycol,*** water, nicotine, and one or more flavors." EX1004, [0061]; EX1003, ¶ 96.

Thus, in view of Sebastian's express disclosures, Sebastian teaches this limitation within the meaning of the '533 patent claims and specification. EX1003, ¶¶ 96-97.

[1f] (d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.

Sebastian expressly teaches a liquid aerosol precursor composition comprised of a salt of nicotine that becomes an inhalable aerosol upon heating. EX1003, ¶¶ 98-100. Specifically, Sebastian expressly discloses that its electronic smoking article "can comprise a heating member that heats an aerosol precursor component to produce an aerosol for inhalation by a user." EX1004, [0048]; EX1003, ¶ 98. Sebastian further discloses that "[w]hen 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." EX1004, [0031]; EX1003, ¶ 98.

During prosecution, the Examiner concluded that Sebastian disclosed an electronic cigarette "that provides for delivery of aerosolized components of a liquid aerosol precursor composition to at least one heating element from which said aerosolized components are inhaled into the mouth of a user." EX1002, 208, 211-12. Notably, in response, the applicant did not argue that Sebastian failed to disclose either an electronic cigarette, as discussed above for Element [1pre], or the generation of an inhalable aerosol upon heating the liquid formulation in an electronic cigarette. EX1002, 285-86; EX1003, ¶ 99; *see supra* §IV(A)(2)[1pre].

Thus, in view of Sebastian's express disclosures, Sebastian teaches "the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette" within the meaning of the '533 patent claims and specification.[5] EX1003, ¶¶ 98-100.

[5] In the parallel ITC proceeding, Petitioner contends this limitation renders the claim indefinite because it recites both an apparatus and a method of using that apparatus. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (precedent makes clear that "because [a] claim [] recites both a system and the

method for using that system, it does not apprise a person of ordinary skill in the art of its scope, and it is invalid under section 112, paragraph 2"). Such a claim is indefinite because it is unclear whether infringement occurs by virtue of the very existence of the claimed electronic cigarette, or whether it occurs when the method of using the claimed electronic cigarette is performed. For the purposes of unpatentability, however, the definiteness of the claim is irrelevant, because Sebastian discloses ***both*** the apparatus and the method of using the apparatus. *See Samsung Elecs. Am., Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1355 (Fed. Cir. 2020) (remanding, finding indefiniteness does not preclude the Board from addressing section 102 and 103 grounds); *Prisua Eng'g Corp. v. Samsung Elecs. Am., Inc.*, No. 2021-1960, 2023 WL 4287194, at *4 (Fed. Cir. June 30, 2023) (upholding obviousness finding after remand). Because both the apparatus and method portions of the claim are disclosed by Sebastian, the claim is anticipated. *See Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper No. 18 at 3-4 (PTAB Nov. 5, 2025) (informative) (finding Petitioner's district court indefiniteness argument may not have precluded institution "for example, if Petitioner had shown that, notwithstanding the alleged indefiniteness of the claim term, an ordinarily skilled artisan would understand that the asserted art satisfies the claim limitation[.]").

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

Sebastian expressly describes that the liquid aerosol precursor composition further includes water. EX1003, ¶¶ 101-102. As discussed previously, Sebastian discloses that "the aerosol precursor compositions can include other liquid materials, such as water." EX1004, [0055]; *see also id.*, [0061] ("an aerosol precursor according to the invention can comprise glycerol, propylene glycol, ***water***, nicotine, and one or more flavors."); EX1003, ¶ 101.

[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.

Sebastian anticipates the claimed range of nicotine concentrations in claim 3 for the same reasons set forth for Element [1d]. EX1003, ¶ 103; *See* §IV.A.2.[1d], *supra*. By disclosing points within the claimed range, Sebastian anticipates claim 3. *See Ineos USA LLC*, 783 F.3d at 869. Additionally, even if Sebastian's disclosed ranges are determined to only partially overlap with the claimed range, these disclosures still anticipate for all of the reasons described above. *See Genentech*, 946 F.3d 1338.

[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.

Sebastian anticipates the claimed range of nicotine concentrations in claim 4 for the same reasons set forth for Element [1d]. EX1003, ¶ 104; *See* §IV.A.2.[1d],

supra. By disclosing points within the claimed range, Sebastian anticipates claim 4. *See Ineos USA LLC*, 783 F.3d at 869. Additionally, even if Sebastian's disclosed ranges are determined to only partially overlap with the claimed range, these disclosures still anticipate for all of the reasons described above. *See Genentech*, 946 F.3d 1338.

[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.

Sebastian anticipates the claimed range of nicotine concentrations in claim 5 for the same reasons set forth for Element [1d]. EX1003, ¶ 105; *See* §IV.A.2.[1d], *supra*. By disclosing points within the claimed range, Sebastian anticipates claim 5. *See Ineos USA LLC*, 783 F.3d at 869. Additionally, even if Sebastian's disclosed ranges are determined to only partially overlap with the claimed range, these disclosures still anticipate for all of the reasons described above. *See Genentech*, 946 F.3d 1338.

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

Sebastian expressly teaches that the aerosol precursor composition can comprise a flavorant. EX1003, ¶¶ 106-107. Specifically, Sebastian discloses that "an aerosol precursor according to the invention can comprise…***one or more flavors***" and teaches that "[a] wide variety of types of flavoring agents…can be

employed." EX1004, [0057], [0059]; *see also id.*, [0059] ("The flavoring agents can be combined with the aerosol-generating material if desired."); EX1003, ¶ 106.

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

Sebastian expressly teaches that more than one organic acid can be included in the aerosol precursor composition. EX1003, ¶¶ 108-109. Specifically, Sebastian discloses that "[a]ny combination of organic acids can be used."). EX1004, [0059]; EX1003, ¶ 108.

[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.

Sebastian expressly discloses a cartridge that is configured to serve as a mouthpiece and a reservoir for the aerosol precursor composition. EX1003, ¶¶ 110-111. As discussed above, Sebastian discloses that its cartridge includes "a mouth opening 18 at the mouthend 11 thereof to allow passage of air and entrained vapor (i.e., the components of the aerosol precursor composition in an inhalable form) from the cartridge to a consumer during draw on the article 10." EX1004, [0088]; EX1003, ¶ 110. Furthermore, Sebastian expressly teaches that "the interior cartridge space can include one or more reservoirs for storing a plurality of components of an aerosol precursor composition." EX1004, [0116]; EX1003, ¶ 110.

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

Sebastian expressly discloses lactic acid. EX1003, ¶¶ 112-113. As discussed above, Sebastian specifically identifies four organic acids, one of which is lactic acid. EX1004, [0059], *see id.* (identifying levulinic acid, lactic acid, pyruvic acid, and succinic acid); *see also* §IV.A.2.[1pre], *supra*; EX1003, ¶ 112.

B. [Ground 2] Sebastian in View of Lechuga-Ballesteros Renders Claims 1-10 Obvious

1. Overview of Lechuga-Ballesteros

Lechuga-Ballesteros is a patent application titled, "Aerosolizable Formulation Comprising Nicotine," published on January 26, 2006. EX1005. Lechuga-Ballesteros is directed to "Metered Dose Inhalers," or "MDIs," which are used to aerosolize and deliver nicotine to a consumer's lungs. EX1005, [0003], [0010]-[0012]; EX1003, ¶ 114. Lechuga-Ballesteros recognized that it was "desirable to be able to deliver the nicotine in a manner that simulates the nicotine delivery of a cigarette." EX1005, [0010]; EX1003, ¶ 114. To that end, Lechuga-Ballesteros describes an "aerosolizable formulation" that "comprises free-base nicotine; an organic acid, wherein (a) said organic acid is present in a mole ratio with said nicotine in a range of about 0.25:1 (organic acid:nicotine) to about 4:1 (organic acid:nicotine), (b) ***said organic acid and said free-base nicotine form a nicotine salt***, and (c) an equivalent mixture of free-base nicotine and organic acid in water has a pH between about pH 3.0 and about pH 9.0; and a hydrofluoroalkane

propellant." EX1005, [0012]; *see also id.* [0013]-[0014]; EX1003, ¶ 114. Notably, the primary organic acid that Lechuga-Ballesteros disclosed and tested was lactic acid, used to generate a nicotine salt, i.e., nicotine lactate. *See* EX1005, [0023], [0084]; EX1003, ¶ 115. In fact, Lechuga-Ballesteros found that the "nicotine lactate solution had the most desirable combination of attributes." EX1005, [0084]; EX1003, ¶ 115.

Through numerous experiments comparing its nicotine salt formulation to free base nicotine formulations, Lechuga-Ballesteros determined "that the formulation of the present invention provides a ***more palatable delivery*** of nicotine," which includes the findings that "nicotine salt forms are less harsh and have a less unpleasant taste" and that the nicotine salt formulation "provides nicotine in an inhalable form that is ***more biocompatible than delivery of the free base*** and provides delivery of the nicotine in a pH range more acceptable to a subject, for example, a human." EX1005, [0062], [0067]; EX1003, ¶ 116.

2. Motivation to Combine Teachings of Lechuga-Ballesteros to Sebastian

To the extent Sebastian alone is not found to disclose "a salt of nicotine and an organic acid"—it does, as discussed above—a POSITA would nevertheless have found it obvious to incorporate a nicotine salt into Sebastian's liquid aerosol precursor composition based on the express teachings of Lechuga-Ballesteros

regarding the benefits of nicotine salts, and specifically, the benefits of a nicotine lactate salt. EX1003, ¶¶ 117-140.

First, a POSITA reading Sebastian would have had the goal of being able to provide nicotine in an aerosol form to a consumer while offering the "***taste and/or sensation*** (e.g., hand-feel or mouth-feel) ***of smoking a cigarette***, cigar, or pipe ***without substantial combustion*** of any component of the article." EX1004, [0029]; EX1003, ¶ 118. That same POSITA would have been motivated to look to the teachings of Lechuga-Ballesteros when seeing that Lechuga-Ballesteros is also focused on providing nicotine in an aerosol form, and when observing that a stated objective of Lechuga-Ballesteros is "nicotine penetration into the lungs that ***simulates the sensation*** normally provided by nicotine when ***delivered by smoking a cigarette*** yet ***without the disadvantages of inhalation of combustion products from tobacco***[.]" EX1005, [0070]; *see also id.*, [0010] ("It is further desirable to be able to deliver the nicotine in a manner that ***simulates the nicotine delivery of a cigarette***"); EX1003, ¶ 118. In other words, a POSITA would have recognized that Sebastian and Lechuga-Ballesteros both wanted to simulate the sensation of smoking a cigarette through the inhalation of an aerosol which, in part, would replicate the delivery of nicotine similar to that of a combustible cigarette, while not including the combustion products that result from smoking cigarettes. EX1003, ¶ 119.

Second, a POSITA reading Sebastian would have looked to Lechuga-Ballesteros because Lechuga-Ballesteros has numerous express disclosures regarding the superior delivery properties and biocompatibility of a nicotine salt compared to the properties of nicotine in free base form. EX1003, ¶ 120. Lechuga-Ballesteros specifically discloses that the "nicotine/organic acid formulation of the present invention (e.g., ***Nicotine Lactate*** formulation) was shown to have ***superior performance*** for the evaluated attributes than the Nicotine Free Base formulation." EX1005, [0055]; *see also id.*, [0057] ("results suggested that ***all of the nicotine lactate formulations were preferable*** to the nicotine propionate formulations, which were ***more preferable than the nicotine free base formulation***"); EX1003, ¶ 120.

In addition, Lechuga-Ballesteros expressly discloses that "[i]t has also been discovered that the formulation of the present invention ***provides a more palatable delivery*** of nicotine," noting that "[f]ree-base nicotine has a harsh, unpleasant taste." EX1005, [0062], EX1003, ¶ 120. Elaborating further on the superior properties of nicotine salts, Lechuga-Ballesteros disclosed to a POSITA that "nicotine salt forms are ***less harsh*** and have a ***less unpleasant taste***" and do not lead to gastrointestinal upset as often as free base nicotine. EX1005, [0062], EX1003, ¶ 120.

Lechuga-Ballesteros's disclosures of nicotine lactate's superiority were not merely theoretical, but rather, were supported by empirical data. *See, e.g.*, EX1004, [0073]-[0100] (Examples 1-6); EX1003, ¶ 121. For example, in Example 3,

Lechuga-Ballesteros "evaluated properties related to aerosolized, pulmonary delivery of nicotine" including throat deposition of nicotine and the total nicotine dose delivered ("respirable dose"). EX1005, [0053], [0056]; EX1003, ¶ 122. The results showed that the "nicotine lactate formulation…had lower throat deposition…and provided a higher respirable dose…than the nicotine free base formulation." EX1005, [0087]; *see also id.* [0086] (Table 3); EX1003, ¶ 122. Lechuga-Ballesteros noted that less throat deposition is preferred, as it is associated with less irritation, as is a higher respirable dose of nicotine. EX1005, [0053]-[0054], [0056], [0087]; EX1003, ¶ 122. Further, Lechuga-Ballesteros also disclosed that its results "suggested better pulmonary delivery of nicotine by the nicotine lactate formulation versus the nicotine free base formulation." EX1005, [0088], EX1003, ¶ 122.

In Example 4, Lechuga-Ballesteros demonstrated that its aerosolized nicotine lactate formulation also provides nicotine in a more biocompatible form than free base nicotine. EX1005, [0067]; EX1003, ¶ 123. Specifically, through a titration experiment, Lechuga-Ballesteros found "that at an approximately 1.2:1 ratio (acid:nicotine) the majority of the nicotine free base was converted to the nicotine salt," meaning that "there is no dumping of strongly basic nicotine into the lungs, nor is there dumping of free acid into the lungs," but rather nicotine is "delivered as a salt comprising nicotine and the associated organic acid." EX1005, [0091]; *see*

also id. [0089]-[0090]; EX1003, ¶ 123. A POSITA would understand from Lechuga-Ballesteros that the "no dumping" property of nicotine delivery in salt form was "a highly desirable feature" as the salt form "provides nicotine in an inhalable form that is ***more biocompatible*** than delivery of the free base and provides delivery of the nicotine ***in a pH range more acceptable*** to a subject, for example, a human." EX1005, [0091]; EX1003, ¶ 123. Thus, a POSITA reading Lechuga-Ballesteros would have been further motivated to incorporate a nicotine salt into Sebastian's liquid aerosol precursor composition to deliver aerosolized nicotine in a more biocompatible form. EX1003, ¶ 124.

As such, in view of Lechuga-Ballesteros's extensive empirical findings demonstrating the superiority of nicotine lactate salt over nicotine in its natural free base form, a POSITA would have been motivated to incorporate a nicotine lactate salt in Sebastian's liquid aerosol precursor composition. EX1003, ¶¶ 121-124.

Third, the desirable delivery properties of Lechuga-Ballesteros's nicotine salts were long known in the industry. While Patent Owner contended during prosecution that it had "surprisingly discovered" "the surprising benefits of formulating nicotine as a salt for delivery in an electronic cigarette" when "the common knowledge in the art at the time" was allegedly that "free base nicotine was preferred," (EX1002, 285), the benefits of using a nicotine salt instead of free base

nicotine were long known in the industry, (EX1003, ¶ 125). Lechuga-Ballesteros is simply one example.

In fact, the superiority of nicotine salts for nicotine delivery was so well-known that the transition from free base nicotine to nicotine salt (i.e. protonated nicotine) was described in the industry as "déjà vu all over again," dating back to the 1900's. EX1008, 1; EX1003, ¶ 126. As discussed above in Section III.A.3, Duell commented that the "role of acids in converting nicotine to a protonated, 'salt' form in tobacco smoke has long been understood," citing an article ***from 1909*** stating:

> Apparently the only possible explanation of this pronounced effect on the sharpness of the smoke is that in the presence of the citric acid the nicotine ***enters the smoke in the form of a salt*** rather than in the free state, and thereby ***loses its pungency while still exerting the usual physiological effect***.

EX1008, 6; EX1003, ¶ 126. So stark were the parallels that the article's authors created a comparison showing the shift from free base nicotine to nicotine salts in both conventional cigarettes and electronic cigarettes:

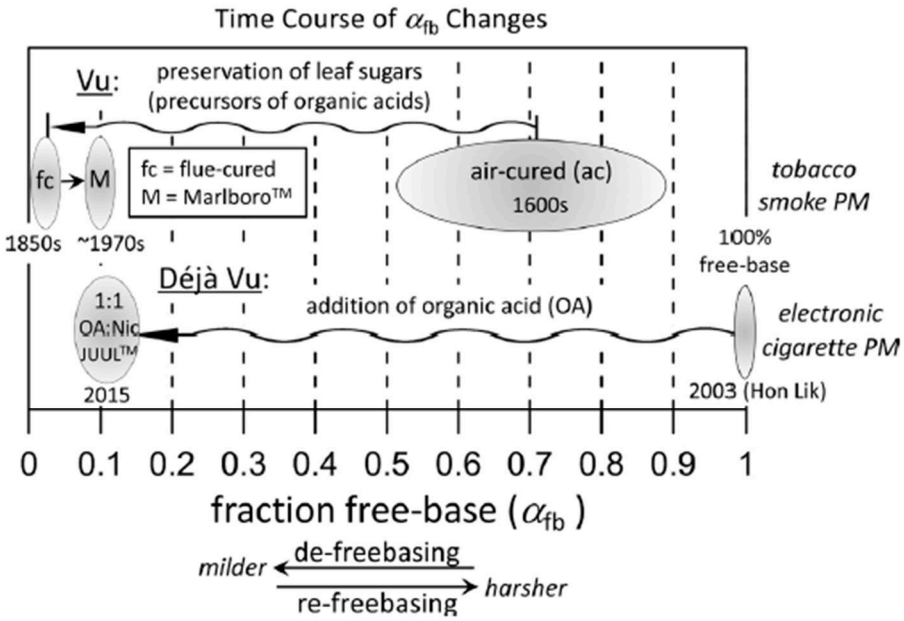


Figure 3 A visual representation of the historical changes in α_{fb} in tobacco smoke PM (top) in comparison to how electronic cigarette fluids and their associated aerosols have been changed (bottom). fc, flue-cured; α_{fb}, fraction of nicotine in the free-base form; M, Marlboro; Nic, nicotine; OA, organic acid; PM, particulate matter.

EX1008, 5; *see also id.* ("The chemistry changes during the rapid evolution of e-cigarettes closely parallel the events that occurred during the centuries-long development of smoked tobacco."); EX1003, ¶ 126. In this graphic, the top wavy line shows the movement from "air-cured" nicotine in the 1600's on the right, which had a higher fraction of free base nicotine, to "flue-cured" nicotine in the 1850's on the left, with a lower fraction of free base nicotine because the nicotine "leaf sugars" were preserved in the form of organic acid precursors. The bottom wavy line shows the same movement from free base nicotine to the addition of organic acids, i.e. use of nicotine salts. EX1008, 5; EX1003, ¶ 126.

Additionally, the Examiner recognized during prosecution that the claimed nicotine salt formulation was ***not*** novel. After the applicant added "lactic acid" to the claims, the Examiner rejected the claims as obvious over Lawson, a European patent related to conventional cigarettes that first published in 1988. EX1002, 519-523; EX1006, 1. Lawson explained that at that time, while it was possible to use tobacco with high nicotine content, "cigarettes having high nicotine contents…generally have the propensity to yield unpalatable mainstream smoke which may be perceived as harsh or irritating to the mouth, nose and throat of the user." EX1006, 2:33-36; EX1003, ¶ 127-128. To "improve the smoking character of such cigarettes so that their smoke is perceived as not being overly harsh or irritating," Lawson taught incorporating "at least one salt provided from nicotine and an organic acid," and could even include "nicotine lactate[.]" EX1006, 3:16-17, 6:38-41; EX1003, ¶ 129. Indeed, Lawson found that the presence of a nicotine salt "provides improved tobacco taste, strength and smoking satisfaction as well as improved or maintained flavor characteristics to the aerosol during use of the article while avoiding undesirable off-tastes during use." EX1006, 3:25-27; EX1003, ¶ 130.

The Examiner found—correctly—that Lawson, like Sebastian, disclosed every element of the claimed ***"cartridge"*** containing the nicotine salt formulation. EX1002; 519-523. Yet the Examiner allowed effectively the same claim that

expressly required an ***"electronic cigarette."*** *Compare id*., 498 (rejected claim 105 directed to "[a]n electronic cigarette cartridge"), *with id*., 499 (allowed claim 114 directed to "[a]n electronic cigarette comprising a cartridge").[6] The Examiner's rejection of the "cartridge" claim demonstrates that the only element of the claims missing from Lawson was not the formulation, but rather, the "electronic cigarette." Thus, the prosecution history further corroborates and supports that the nicotine formulation claimed in the '533 patent was well-known in the art long before the priority date of the '533 patent, as was the desirable properties of nicotine salts. EX1003, ¶ 131.

Fourth, to the extent Patent Owner may contend, as it did during prosecution (EX1002, 285-288, 382-384), that the ***manner*** of aerosolization (i.e., pressurized versus heated) would have dissuaded a POSITA from applying Lechuga-Ballesteros's express teachings regarding the superiority of aerosolized nicotine salt

[6] Notably, the allowed claim had an even ***broader*** disclosure of the nicotine salt formulation than the rejected claim, with no restrictions on the amounts of glycerol and propylene glycol. *Compare* EX1002, 498 (rejected claim 105 requiring "90% to 30% of glycerol and 10% to 70% of propylene glycol), *with id*., 499 (allowed claim 114 requiring only that the "liquid carrier comprises glycerol and propylene glycol").

over aerosolized free base nicotine to Sebastian, such a contention is unfounded. EX1003, ¶ 132. "[I]t is not necessary that the inventions of the references be physically combinable to render obvious" the invention. *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (citation omitted). "Rather, the test for obviousness is what the ***combined*** teachings of the references would have suggested" to a POSITA. *Id.* at 1333.

Petitioner does not contend here that a POSITA would have bodily incorporated Lechuga-Ballesteros's ***complete formulation*** in an e-cigarette. *Contra*, EX1002, 286-290, 382-384. Because Lechuga-Ballesteros's MDI used a pressurized inhaler to deliver nicotine, its formulation contained a propellant. *See, e.g.*, EX1005, [0049]; EX1003, ¶ 133. A POSITA would certainly have understood that propellants would be inappropriate to use in a device relying on heating to achieve aerosolization, as Sebastian does. EX1003, ¶ 133. That does not mean, however, that a POSITA would have ignored Lechuga-Ballesteros's explicit teachings of the superior performance and properties of aerosolized nicotine lactate over aerosolized free base nicotine to deliver nicotine to a consumer, as these teachings apply directly to e-cigarette chemistry. EX1005, [0012], [0084]. Whether the aerosolization was affected by pressure or by heat, the result is the same—aerosolized nicotine is delivered. EX1005, [0031] ("When the actuator is depressed a metered dose of the compound is aerosolized for inhalation"); EX1004, [0009]

("disclosed herein is a system that can transport and heat the various chemical compounds present in the aerosol precursor composition under controlled conditions so as to achieve a uniform puff chemistry."); EX1003, ¶ 134. Nothing in Lechuga-Ballesteros suggests or indicates that the propellant affected or drove the superior delivery properties of nicotine lactate salt over free base nicotine in any way. EX1003, ¶ 135.

Finally, to the extent Patent Owner may argue that a POSITA would not have looked to Lechuga-Ballesteros at all because it is not analogous art, such a contention is misguided. Prior art is analogous "if it either (1) is from the same field of endeavor, regardless of the problem addressed or (2) is reasonably pertinent to the particular problem with which the inventor is involved." *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000-01 (Fed. Cir. 2016) (citation omitted). Lechuga-Ballesteros satisfies both of these tests.

Lechuga-Ballesteros expressly describes the field of its invention as relating to "the delivery of alkaloids, such as nicotine, to the lungs of an individual." EX1005, [0002]; EX1003, ¶ 136. The '533 patent plainly falls within the same field of endeavor, stating that "described herein are nicotine salt formulations for use in an electronic cigarette, or the like, that provide a general satisfaction effect consistent with an ***efficient transfer of nicotine to the lungs*** of an individual[.]" EX1001, 8:22-26; EX1003, ¶ 136.

Additionally, other prior art from the same time period as Sebastian demonstrates that Metered-Dose Inhalers ("MDIs") like the one in Lechuga-Ballesteros were viewed hand-in-hand with electronic cigarettes when nicotine delivery by inhalation was analyzed. In a 2012 review article titled "A Systematic Review of Nicotine by Inhalation: Is There a Role for the Inhaled Route?," the authors "systematically reviewed clinical trials of nicotine inhalation devices to identify technical insights that might lead to more effective therapeutic nicotine inhalers." EX1010, 1. The authors found that nicotine particles in the relevant size range "can be made by (a) heating tobacco (by combustion [smoking] or electric heater)…(b) ***condensing and aggregating vaporized nicotine solutions by electric heater***…(c) aerosolizing nicotine solutions by bench-top nebulizer machines, (d) [pressurized metered-dose inhalers] pMDIs…(e) air classifiers…(f) capillary aerosol generators…and (g) novel devices[.]" *Id*., 5; *see also id.*, 4 (discussing MDIs immediately after electronic cigarettes); EX1003, ¶ 138. The authors found that "[o]f these devices, the pMDI is currently the cheapest, most portable, and relatively simple and economically practical to manufacture on a large scale." *Id*.; EX1003, ¶ 138. Thus, persons of skill in the art at the time of the invention actively considered MDI literature and electronic cigarette literature side by side. EX1003, ¶ 139.

In addition, Lechuga-Ballesteros is not only "reasonably pertinent to the particular problem with which the inventor is involved," but in fact addresses the

same problem that the '533 patent aims to address—improving the delivery of nicotine to the lungs. *Unwired Planet*, 841 F.3d at 1000-01. Lechuga-Ballesteros goes one step further, and even discloses the ***same solution*** to the problem; namely, the use of a nicotine salt. Thus, any contention by Patent Owner that Lechuga-Ballesteros is not analogous art is contradicted by Lechuga-Ballesteros' and the '533 patent's express disclosures. EX1003, ¶ 117-140.

3. Reasonable Expectation of Success in Applying the Teachings of Lechuga-Ballesteros to Sebastian

To the extent Sebastian is not determined to disclose a salt of nicotine and organic acid—it does, as discussed above—a POSITA nevertheless would have had a reasonable expectation of success of incorporating a nicotine salt—particularly nicotine lactate—into Sebastian's liquid aerosol precursor composition based on the similarities between the aerosol precursor compositions of Sebastian and Lechuga-Ballesteros. EX1003, ¶¶ 141-147.

First, Lechuga-Ballesteros expressly discloses a method of preparing a nicotine salt formulation that is consistent with Sebastian's disclosures. Specifically, in the titration experiment, Lechuga-Ballesteros describes that "comparable amounts of nicotine and organic acid [were] combined in water[.]" EX1005, [0066]; *see also id.*, [0089]; EX1003, ¶ 142. Nicotine, organic acid, and water are similarly components of Sebastian's aerosol precursor composition. EX1004, [0055], [0060]-

[0061]; EX1003, ¶ 142. As such, given that Lechuga-Ballesteros expressly describes the creation of a nicotine lactate salt by the addition of nicotine and lactic acid to water, a POSITA would have reasonably expected nicotine lactate to also form upon practicing Sebastian's disclosure of combining nicotine, lactic acid, and water together. EX1004, [0055], [0060]-[0061]; EX1003, ¶ 142.

Second, Lechuga-Ballesteros disclosed formulations in which the molar ratio of organic acid to nicotine is identical to that taught by Sebastian. For example, Sebastian teaches that "organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts ***up to being equimolar*** (based on total organic acid content) with the nicotine." EX1004, [0059]; EX1003, ¶ 143. In other words, the same number of molecules of nicotine are present as the number of molecules of organic acid. EX1003, ¶ 143. Similarly, Lechuga-Ballesteros discloses a molar ratio "preferably in a range of about 1:1," which likewise means that the nicotine and organic acid are present in equal amounts. EX1005, [0040]; EX1003, ¶ 143.

Third, Sebastian's liquid aerosol precursor composition and Lechuga-Ballesteros's nicotine/organic acid formulation contained many of the same components, including solvents like propylene glycol, glycerol, and/or water. *Compare* EX1004, [0061] ("an aerosol precursor according to the invention can comprise glycerol, propylene glycol, water, nicotine, and one or more flavors."),

with EX1005, [0045] (noting "[a] number of suitable co-solvents can be used in the formulations of the present invention including…propylene glycol…[and] glycerol," and further that "[m]ixtures of two or more co-solvents may be used as well."); EX1003, ¶ 144.

Fourth, at bottom, both Sebastian's liquid aerosol precursor composition and Lechuga-Ballesteros's nicotine lactate formulation were intended to be aerosolized and inhaled by a consumer. *Compare* EX1004, [0063] ("the article is configured with a sufficient amount of the individual components of the aerosol precursor composition to function at a sufficient temperature for a sufficient time to release a desired content of aerosolized materials over a course of use"), *with* EX1005, [0038] ("a formulation comprising nicotine and organic acid is aerosolized and delivered to the respiratory tract of a user"); EX1003, ¶ 145.

Finally, to the extent Patent Owner argues that the presence of a propellant in Lechuga-Ballesteros's cuts against a reasonable expectation of success, let Petitioner be clear—the obviousness combination proposed here is ***not*** bodily incorporation of Lechuga-Ballesteros's formulation into Sebastian's electronic smoking article; but rather, the ***application*** of Lechuga-Ballesteros's teachings regarding the superiority of nicotine lactate salt over free base nicotine in aerosolized delivery. EX1003, ¶ 146. The presence of the propellant is therefore irrelevant to the obviousness combination at issue.

Thus, in view of the common disclosures between Sebastian and Lechuga-Ballesteros, a POSITA would have a reasonable expectation of success in applying Lechuga-Ballestero's teachings regarding its nicotine lactate salt to Sebastian's aerosol precursor composition. EX1003, ¶¶ 141-147.

4. Analysis

[1pre] An electronic cigarette comprising…

To the extent the preamble is found to be limiting, Sebastian discloses an electronic cigarette for the reasons discussed previously. *See* §IV.A.2.[1pre], *supra*; EX1003, ¶ 148.

[1a] a cartridge,

Sebastian discloses a cartridge for the reasons discussed previously. *See* §IV.A.2.[1a], *supra*; EX1003, ¶ 149.

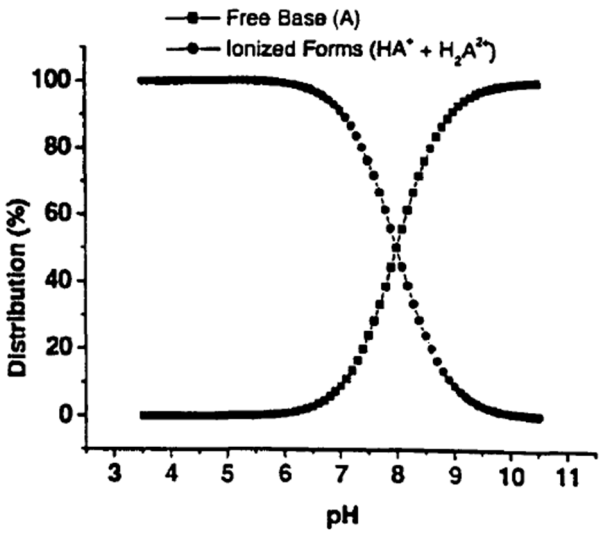
[1b] wherein the cartridge comprises a nicotine salt liquid formulation, wherein: (a) the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier,

Both Sebastian and Lechuga-Ballesteros disclose a nicotine salt liquid formulation comprised of "a salt of nicotine and an organic acid in a liquid carrier." EX1003, ¶¶ 150-158. As discussed previously, Sebastian inherently discloses a nicotine salt because it explicitly teaches combining nicotine and organic acid, which necessarily results in the formation of a nicotine salt. *See* §IV.A.2.[1b], *supra*; EX1003, ¶ 150. To the extent Sebastian is not found to disclose a nicotine salt,

Lechuga-Ballesteros explicitly discloses "an aerosolizable formulation [that] comprises ***free-base nicotine***; an ***organic acid***, wherein (a) said organic acid is present in a mole ratio with said nicotine in a range of about 0.25:1 (organic acid:nicotine) to about 4:1 (organic acid:nicotine), [and] (b) ***said organic acid and said free-base nicotine form a nicotine salt***[.]" EX1005, [0012]; *see also id.* [0013]-[0014]; EX1003, ¶ 151. Additionally, beyond simply disclosing the formation of a nicotine salt, Lechuga-Ballesteros extolls the "superior performance" of nicotine salts over freebase nicotine, as discussed at length in Section IV.B.2-3, above.

Moreover, at the very least, a POSITA would have appreciated based on Lechuga-Ballesteros's express disclosures that combining lactic acid and free base nicotine at a nearly one to one molar ratio necessarily generates a salt. *See* EX1005, [0091] ("[t]he results of this experiment indicated that at an approximately 1.2:1 ratio (acid:nicotine) the ***majority of the nicotine free base was converted to the nicotine salt***"); EX1003, ¶ 152. Lechuga-Ballesteros even includes titration data showing how the salt is generated in real time:

Figure 2B



EX1005, Fig. 2B; *see also* EX1009, ¶¶ 40-47. The "Free Base (A)" curve (squares) begins with 100% free base at pH 11. *See* EX1009, ¶¶ 41-43. At that point there is no salt, or "ionized form" present in the solution. As soon as the organic acid[7] is added to the solution, a salt is formed, either monoprotonated ("HA^+") or diprotonated ("H_2A^{2+}"), and the pH of the solution decreases. EX1009, ¶ 43; *see*

[7] While Lechuga-Ballesteros does not specify the organic acid shown in Figure 2B, it is either the propionic acid or the lactic acid that was used to generate the nicotine titration curves in Figure 2A. *See* EX1005, Figs. 2A-2B, [0089]-[0091]; EX1003, ¶ 152. Given the similarities of the two acids at the 1.2:1 molar ratio identified in Example 4, (*see* [0091]), a POSITA would expect the resulting percent distribution to likewise be highly similar. EX1003, ¶¶ 152-153.

also EX1011, 218-224. At "equimolar" distribution—i.e., 50% free base and 50% ionized salt form—the pH is ~8. When enough acid is added to the solution to decrease the pH of the solution to 7, less than 10% free base nicotine is left in solution. The other 90% of the solution is ionized, i.e., in salt form. *See* EX1003, ¶ 152; *see also* EX1009, ¶ 44.

Thus, because Sebastian disclosed including organic acids such as lactic acid "in the aerosol precursor with nicotine in amounts ***up to being equimolar*** (based on total organic acid content) with the nicotine," Lechuga-Ballesteros further corroborates that Sebastian requires no modification to reach claim 1. EX1004, [0059]-[0061]; EX1003, ¶ 153.

Additionally, regarding the "liquid carrier" limitation, Lechuga-Ballesteros discloses numerous examples of a "liquid carrier," referring to them as "co-solvents" or "excipients." *See* EX1005, [0035]; EX1003, ¶ 154. Lechuga-Ballesteros identifies "[a] number of suitable co-solvents" that include propylene glycol and glycerol—i.e., the claimed liquid carriers in the '533 patent. EX1005, [0045]; EX1003, ¶ 154.

To the extent that Patent Owner contends—as it did during prosecution, (EX1002, 288-290)—that its "liquid carrier" is somehow different from Lechuga-Ballesteros's disclosure of "co-solvents," Patent Owner's argument is undermined by its own specification which states that "[s]uitable carriers (***e.g., a liquid solvent***)

for the nicotine salts described herein include a medium in which a nicotine salt is soluble at ambient conditions, such that the nicotine salt does not form a solid precipitate," going on to identify "glycerol" and "propylene glycol" specifically. EX1001, 11:44-49; EX1003, ¶ 155. In addition to explicitly referencing its claimed liquid carrier as "a liquid solvent," this argument ignores that, as noted above, both Lechuga-Ballesteros and Sebastian ***teach the exact same components*** claimed by Patent Owner as liquid carriers, including glycerol, propylene glycol, and water. EX1002, 288-289; EX1003, ¶ 156.

In addition, to the extent Patent Owner attempts to differentiate Lechuga-Ballesteros on the basis that ethanol is the preferred co-solvent in Lechuga-Ballesteros, Patent Owner's argument is again undercut by the '533 patent's specification which states that "[e]xamples [of the liquid carrier] include, but are not limited to, glycerol, propylene glycol, trimethylene glycol, water, ***ethanol and the like***, as well as combinations thereof." EX1001, 11:47-50; *see also* EX1005, [0095]; EX1003, ¶ 157. As such, an ethanol "co-solvent" therefore falls squarely within the '533 patent's definition of a liquid carrier.

[1c] the organic acid is benzoic acid or lactic acid;

Both Sebastian and Lechuga-Ballesteros disclose either or both benzoic acid and lactic acid. EX1003, ¶¶ 159-160. Sebastian discloses lactic acid, as discussed previously. *See* §IV.A.2.[1c], *supra*; EX1003, ¶ 159. Lechuga-Ballesteros discloses

both lactic and benzoic acid. EX1003, ¶ 159. Specifically, Lechuga-Ballesteros provides a non-exhaustive list of "[n]umerous suitable organic acids…including…benzoic acid…[and] lactic acid[.]"[8] EX1005, [0042]; EX1003, ¶ 159.

[1d] (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;

Both Sebastian and Lechuga-Ballesteros disclose "a nicotine concentration of 0.5% (w/w) to 20% (w/w)." EX1003, ¶¶ 161-162. Sebastian discloses this limitation for the reasons discussed previously. *See* §IV.A.2.[1d], *supra*; EX1003, ¶ 161. Lechuga-Ballesteros similarly discloses the claimed range because Lechuga-Ballesteros teaches several concentrations of nicotine within the claimed range. EX1003, ¶ 161. Specifically, Lechuga-Ballesteros expressly discloses that "about 0.01 to about 5 weight percent of the three components is nicotine," which overlaps with the claimed range of 0.5% to 20%. EX1005, [0041]; EX1003, ¶ 161. "A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." *Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 272 (Fed. Cir. 2022) (quoting *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)). Additionally, Lechuga-Ballesteros explains that the "weight

[8] For this reason, this combination renders obvious claim 9 as well.

percent of nicotine can be varied, for example, to provide a range of MDIs that deliver difference[sic] nicotine concentrations (e.g., 0.01% w/w, 0.1% w/w, and 1% w/w)[.]" EX1005, [0060]; EX1003, ¶ 161; *see also* EX1005, [0012]-[0014]; EX1009 ¶¶ 45-47. Specifically, Lechuga-Ballesteros notes that "[t]ypically ***preferences and satisfaction*** with regard to harshness, strength, and similarity to cigarettes ***tend to increase proportionally with the percentage increase in nicotine***." EX1005, [0060].

[1e] (c) the liquid carrier comprises glycerol and propylene glycol; and…

Both Sebastian and Lechuga-Ballesteros disclose "glycerol and propylene glycol." EX1003, ¶¶ 163-164. Sebastian expressly discloses this limitation as discussed previously. *See* §IV.A.2.[1e], *supra*; EX1003, ¶ 163. Lechuga-Ballesteros similarly teaches the use of "glycerol and propylene glycol" in a nicotine formulation. Specifically, Lechuga-Ballesteros expressly discloses that co-solvents such as "propylene glycol…[and] glycerol" can be used and instructs that "[m]ixtures of two or more co-solvents may be used as well." EX1005, [0045]; EX1003, ¶ 163.

[1f] (d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.

Both Sebastian and Lechuga-Ballesteros expressly disclose a liquid aerosol precursor composition comprised of a salt of nicotine that becomes an inhalable

aerosol upon heating. EX1003, ¶¶165-166. As discussed previously, Sebastian expressly discloses this limitation. *See* §IV.A.2.[1f], *supra*; EX1003, ¶ 165. While Lechuga-Ballesteros teaches aerosolization through the use of a propellant, rather than heating, it would have been obvious to a POSITA to incorporate Lechuga-Ballesteros's disclosure of the benefits of incorporating a nicotine salt such as nicotine lactate into Sebastian's liquid aerosol precursor composition and electronic smoking article for the reasons discussed previously. *See* §IV.B.2., *supra*; EX1003, ¶ 165.

Thus, in view of Sebastian and Lechuga Ballesteros's express disclosures, taken together, the prior art teaches the claimed limitation within the meaning of the '533 patent claims and specification. EX1003, ¶ 166.

[2]-[10] Dependent Claims

For reasons stated above in Section IV.A.2[2]-[10] and IV.B.4[1c], Petitioner submits that the combination of Sebastian and Lechuga-Ballesteros anticipate or render obvious dependent claims 2-10. *See* §IV.A.2.[2]-[10], *supra*; EX1003, ¶¶ 167-178.

V. CONCLUSION

Petitioner respectfully requests institution of an IPR for the Challenged Claims of the '533 patent.

VI. PAYMENT OF FEES – 37 C.F.R. §42.103

Petitioner authorizes the Patent and Trademark Office to charge any fees to Deposit Account No. 06-1050.

VII. MANDATORY NOTICES UNDER 37 C.F.R §42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. §42.8(b)(1)

NJOY, LLC and NJOY Holdings, Inc. (collectively, Petitioner), Altria Group, Inc., Altria Group Distribution Company, Altria Client Services LLC, and Shenzhen Smoore Technology Limited are the real parties-in-interest. No other parties had access to or control over the present Petition, and no other parties funded the present Petition.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner is not aware of any disclaimers, reexamination certificates or petitions for *inter partes* review for the ’533 patent. The ’533 patent is the subject of *JUUL Labs Inc. v. NJOY LLC et al.*, 2-25-cv-02853 (DAZ) filed on August 8, 2025, and *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof (II)*; Inv. No. 337-TA-1460 filed on September 22, 2025.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel.

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D. Service Information

Please address all correspondence and service to the address listed above.

Petitioner consents to electronic service by email at IPR58718-0002IP1@fr.com.

Respectfully submitted,

Dated: 11/26/2025

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,930 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated: 11/26/2025

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on November 26, 2025, a complete and entire copy of this Petition for *Inter partes* Review, Power of Attorney, and all supporting exhibits were provided via Federal Express, to the Patent Owner by serving the correspondence address of record as follows:

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