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**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

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

Investigation No. 337-TA-1460

COMMISSION OPINION

I. INTRODUCTION

On May 29, 2026, the Commission determined to review an initial determination (“ID”) (Order No. 31) granting a motion for summary determination of invalidity and finding no violation in *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof (II)*, Inv. No. 337-TA-1460. On review, the Commission has determined to vacate the ID’s construction of the claim limitation “nicotine concentration” and to remand the investigation to the Administrative Law Judge (“ALJ”) for further proceedings. This opinion sets forth the Commission’s reasoning in support of that determination.

II. BACKGROUND

A. Procedural History

The Commission instituted this investigation on September 12, 2025, based on a complaint (the “Complaint”) filed by JUUL Labs, Inc. (“Complainant” or “JLI”) of Washington, DC. 90 Fed. Reg. 44238 (Sept. 12, 2025). The Complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vaporizer devices, cartridges used therewith, and components thereof by reason of the infringement of one or more of claims 1-8 and 10 of U.S. Patent No. 12,156,533 (“the ’533

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patent”). *Id.* The Complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337. *Id.* The notice of investigation names NJOY, LLC and NJOY Holdings, Inc., both of Scottsdale, Arizona; and Altria Group, Inc., Altria Group Distribution Company, and Altria Client Services LLC, all of Richmond, Virginia, as the respondents (collectively, “Respondents” or “NJOY”). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On March 25, 2026, the Commission terminated claims 7 and 8 of the ’533 patent from the investigation based on JLI’s withdrawal of allegations as to those claims. Order No. 22 (Mar. 3, 2026), *unreviewed by* Comm’n Notice (Mar. 25, 2026).

On March 20, 2026, NJOY filed a motion for summary determination of invalidity based on anticipation (“MSD”), which includes a memorandum in support (“MSD Memo.”) and numerous exhibits (“MSD Exhibits”). On April 1, 2026, JLI filed a response in opposition to the motion (“MSD Opp.”). On April 6, 2026, NJOY filed a reply in support of the motion (“MSD Reply”).

On April 14, 2026, the ALJ issued the subject ID (Order No. 31) granting the motion for summary determination and finding no violation of section 337. On April 24, 2026, JLI filed a petition for review, and on May 1, 2026, NJOY filed an opposition to the petition for review.¹

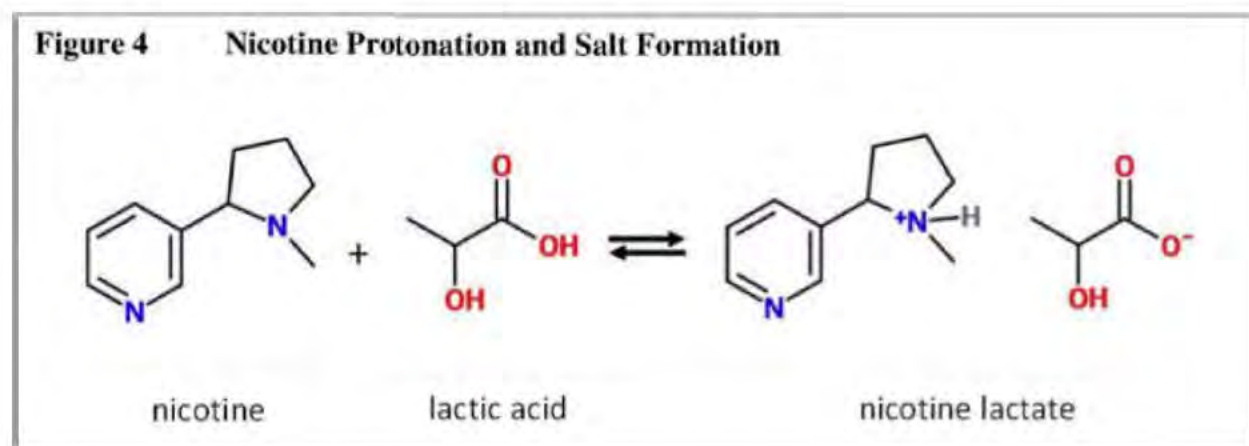
On May 29, 2026, the Commission determined to review the ID in its entirety. Comm’n Notice (May 29, 2026). The Commission solicited briefing from the parties addressing two questions regarding the ID’s claim construction for the term “nicotine concentration.” *Id.* The

¹ Complainant JUUL Labs, Inc.’s Petition for Review of the Final Initial Determination (Apr. 14, 2026) (“Pet.”); Respondents’ Response to Complainant’s Petition for Review of the Final Initial Determination (Apr. 24, 2026) (“Pet. Opp.”).

parties filed initial written submissions on June 12, 2026,² and reply submissions on June 22, 2026.³

B. Technology Background

The technology at issue relates to the vaporization of liquid solutions containing nicotine. *See* Complaint ¶¶ 46-47. Nicotine is a chemical compound that can exist in a “free base” form or as part of a “nicotine salt.” *See, e.g.,* ’533 patent at 7:52-65. A nicotine salt is formed when free base nicotine reacts with an acid that donates protons to nicotine molecules, forming “protonated” nicotine having a positive charge. *See* ID at 16-17.



Id. at 17 (citing MSD Opp., Exhibit 37 (Amiji Report) at ¶¶ 80-92). The salt comprises both the protonated nicotine (the positively charged “cation”) and the ionized acid (the negatively charged “anion”). *See* Comp. Pre-Hearing Brief at 13-16 (Apr. 3, 2026) (discussing the chemistry of nicotine salts).

² Complainant JLI’s Initial Submission Responding to Notice of Commission Determination to Review an Initial Determination (“Comp. Init. Subm.”); Respondents’ Initial Written Submission in Response to the Commission’s Notice of Review (“Resp. Init. Subm.”).

³ Complainant JLI’s Reply Submission Responding to Notice of Commission Determination to Review an Initial Determination (“Comp. Reply. Subm.”); Respondents’ Reply Written Submission in Response to the Commission’s Notice of Review (“Resp. Reply Subm.”).

C. The Asserted Patent

The '533 patent, titled "Nicotine Salt Formulations for Aerosol Devices and Methods Thereof," issued on December 3, 2024, from a continuation application that claims priority to several previous applications with the earliest priority date corresponding to a provisional application filed on May 6, 2013. MSD Exhibit 1 (the '533 patent) at 1-2.

1. Specification

The Abstract of the '533 patent states: "A nicotine salt liquid formulation for generating an inhalable aerosol in an electronic cigarette comprising nicotine salt that forms about 0.5% to about 20% nicotine is provided." '533 patent at Abstract. The specification describes a result that was "unexpectedly discovered," which is "that certain nicotine salt formulations provide satisfaction in an individual superior to that of free base nicotine, and more comparable to the satisfaction in an individual smoking a traditional cigarette." *Id.* at 8:1-5.

The specification provides many examples of nicotine salt formulations, which "have a nicotine concentration of about 0.5% (w/w) to about 20% (w/w), wherein the concentration is of nicotine weight to total solution weight." *Id.* at 1:31-35. The specification describes the preparation of several sets of nicotine formulations with different acids and appropriate amounts of nicotine to achieve a particular "final free base equivalent concentration." *Id.* at 17:57-21:61. The specification discloses sets of nicotine salt formulations having free base equivalent concentrations of 2% (w/w), 3% (w/w), and 4% (w/w). *Id.* at 17:57-21:41. The specification also discloses formulations with more than one type of nicotine salt, which are combined "to achieve a 5% w/w nicotine formulation." *Id.* at 21:42-61.

2. Asserted Claims

JLI asserts claims 1-6 and 10 in this investigation:

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1. An electronic cigarette comprising a cartridge, 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, wherein the organic acid is benzoic acid or lactic acid;
 - (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;**
 - (c) the liquid carrier comprises glycerol and propylene glycol; and
 - (d) the nicotine salt liquid formulation generates an inhalable aerosol upon heating in the electronic cigarette.
2. The electronic cigarette of claim 1, wherein the liquid carrier further comprises water.
3. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 1% (w/w) to 18% (w/w) in the nicotine salt liquid formulation.
4. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 3% (w/w) to 15% (w/w) in the nicotine salt liquid formulation.
5. The electronic cigarette of claim 1, wherein the salt is present in an amount that forms a nicotine concentration of 4% (w/w) to 12% (w/w) in the nicotine salt liquid formulation.
6. The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises a flavorant.
10. The electronic cigarette of claim 1, wherein the organic acid is lactic acid.

'533 patent at claims 1 (highlighting disputed limitation), 2-6, 10.

III. COMMISSION REVIEW OF THE ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Electronic Stud Finders, Metal Detectors and Electrical Scanners*, Inv. No. 337-TA-1221, Comm'n Op. at 9 (Feb. 15, 2022) (citations omitted), *aff'd*, *Zircon Corp. v. Int'l Trade Comm'n*, 101 F.4th 817 (Fed. Cir. 2024). Upon review, the

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“Commission has ‘all the powers which it would have in making the initial determination,’ except where the issues are limited on notice or by rule.” *Certain Electronic Devices, Including Streaming Players, Televisions, Set Top Boxes, Remote Controllers, and Components Thereof*, Inv. No. 337-TA-1200, Comm’n Op. at 7 (Nov. 10, 2021) (citations omitted), *aff’d*, *Roku, Inc. v. Int’l Trade Comm’n*, 90 F.4th 1367 (Fed. Cir. 2024). With respect to the issues under review, “the Commission may affirm, reverse, modify, vacate, or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any finding or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS

The Commission’s findings, conclusions, and supporting analysis follow. The Commission takes no position on the ID’s findings that are not addressed in this opinion.

A. Legal Standards

Claim terms are normally construed according to their ordinary and customary meaning in the art, as understood by a person of ordinary skill in the art in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). Claim construction focuses mainly on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *Id.* at 1313-1317. If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises, and it may be

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considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.* at 1317.

B. The ID's Claim Construction Findings

The ID addresses the meaning of “nicotine concentration” in the ’533 patent in the context of NJOY’s allegations that certain asserted prior art products meet the limitations of the asserted claims. ID at 23-26. The ID recognizes that the parties’ briefing did not fully address the construction of this term because NJOY had taken the position in its motion that the claim would be anticipated under any construction. *See id.* at 24-25. The ID therefore relies on the claim construction arguments in the parties’ pre-hearing briefs to determine the meaning of this term. *Id.*

The ID describes JLI’s proposed construction by quoting JLI’s pre-hearing brief: “the phrase ‘nicotine concentration’ in the context of the claims pertains to the concentration of the nicotine component of th[e] salt,’ not the concentration of nicotine in the nicotine liquid salt formulation overall.” *Id.* at 24-25 (quoting Comp. Pre-Hearing Brief at 49-53). The ID finds that JLI’s proposed construction is contradicted by the explicit claim language, which describes a nicotine concentration “in the nicotine salt liquid formulation” and not “in the salt.” *Id.* at 25. The ID thus adopts NJOY’s construction for this limitation, finding that the specification and prosecution history support construing “nicotine concentration” to mean the concentration of nicotine in the nicotine liquid salt formulation. *Id.* Based on prior art documents disclosing nicotine concentrations in the claimed range, the ID finds that the prior art meets the limitation under NJOY’s construction. *Id.* at 23-24.

C. Proposed Constructions

On review, NJOY continues to support the ID’s construction of “nicotine concentration” as the concentration of nicotine in the nicotine salt liquid formulation. *See* Resp. Init. Subm. at

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6-13. JLI contends that the proper construction of “nicotine concentration” is the percentage of nicotine formed from the amount of the claimed nicotine salt present in the nicotine salt liquid formulation. Comp. Init. Subm. at 1-2, 4-14.⁴

The ID rejects JLI’s construction because “[c]laim 1 plainly refers to the concentration of nicotine ‘in the nicotine salt liquid formulation’ (the claim language), not ‘in the salt’ alone (not the claim language).” ID at 25. But it is clear from the parties’ submissions on review that the ID misinterprets JLI’s proposed construction—JLI does not propose to measure the concentration of nicotine “in the salt alone” but to measure the amount of nicotine in the salt and to use that subset of nicotine to determine the claimed “nicotine concentration” in the nicotine salt liquid formulation. *See* Comp. Init. Subm. at 4-13. Both parties’ constructions thus measure a concentration of nicotine “in the nicotine salt liquid formulation” as a whole; the distinction is only whether that nicotine is limited to the nicotine contained in the claimed nicotine salt (*i.e.*, protonated nicotine) or whether the nicotine can be in any form (*e.g.*, free base nicotine).

To restate the issue, the dispute between the parties does not turn on whether the concentration of nicotine should be measured in the formulation or in the salt—it is whether all nicotine in the formulation should be counted when measuring the claimed concentration or whether only the nicotine in the claimed nicotine salt should be counted. In other words, if the claimed “nicotine concentration” is viewed as a fraction, the parties agree that the denominator is the total weight of the liquid formulation and dispute only the numerator: NJOY’s construction

⁴ The construction JLI now proposes is worded differently from the construction disclosed in JLI’s pre-hearing brief and considered in the ID: “the concentration of the nicotine component of [the] salt.” *Compare* Comp. Init. Subm. at 1 to ID at 24-25 (citing Comp. Pre-Hearing Brief at 49). The substance of JLI’s construction, however, has not changed—the parties recognize that under JLI’s construction the claimed “nicotine concentration” is measured by estimating the amount of protonated nicotine in the solution. *See* Comp. Init. Subm. at 13-14; *see also* MSD Memo. at 22-23; MSD Opp. at 25-30.

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would count the weight of all nicotine (in any form) in the formulation, while JLI's construction would count only the weight of nicotine that is in the claimed nicotine salt, *i.e.*, protonated nicotine.

D. Claim Construction Analysis

For the reasons discussed below, the Commission has determined to vacate the ID's analysis of the "nicotine concentration" limitation and to construe this claim language to mean "the amount of nicotine in the claimed nicotine salt, expressed as a percentage of nicotine weight to total solution weight."

1. Claim Language

The disputed limitation reads: "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." As discussed below, JLI's construction is more consistent with this claim language than NJOY's construction.

JLI's construction, which defines "nicotine concentration" as being based on nicotine from the amount of the claimed salt, gives meaning to the language in the first part of the limitation at issue, "the salt is present in an amount that forms." *See* Comp. Init. Subm. at 10-12; Comp. Reply Subm. at 2-4. NJOY contends that its construction also gives meaning to this claim language because it still requires that some amount of salt is present, and because the nicotine salt "forms" part of the overall amount of nicotine in the solution. *Resp. Init. Subm.* at 8-9. But under NJOY's construction the scope of the claim would be the same if the words "the salt is present in an amount that forms" were excised from the claim entirely, *e.g.*, "a nicotine concentration of 0.5% (w/w) to 20% (w/w) in the nicotine salt liquid formulation." *See* Comp. Init. Subm. at 11-12. That the claimed formulation has a salt is required by a preceding limitation ("the nicotine salt liquid formulation comprises a salt of nicotine and an organic acid in a liquid carrier"). '533 patent at claim 1. Accordingly, NJOY's construction cannot be

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correct as it would render the language “the salt is present in an amount that forms” entirely superfluous. JLI’s construction thus better aligns with the claim language because “[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (citations omitted).

NJOY argues that the language of the claim supports its proposed construction because the plain language “a nicotine concentration of 0.5% (w/w) to 20% (w/w) in the nicotine salt liquid formulation” requires that the “nicotine concentration” measure all of the nicotine in the formulation. Resp. Init. Subm. at 7-8; Resp. Reply Subm. at 2-3. But there is nothing in the claim language that requires all of the nicotine in the formulation to be counted. The claim merely requires “a nicotine concentration” that is “in the nicotine salt liquid formulation,” where that “nicotine salt liquid formation” comprises “a salt of nicotine and an organic acid.” ’533 patent at claim 1. JLI’s construction measures an amount of nicotine—the specific subset of the nicotine that is in the claimed nicotine salt—meeting these limitations. NJOY, by contrast, fails to identify any claim language requiring that all nicotine in the formulation be weighed in the claimed “nicotine concentration.”

NJOY argues that the claimed “nicotine concentration” is not limited to the nicotine salt recited in claim 1, pointing to dependent claim 7⁵ to argue that the invention could comprise “one or more additional organic acids” that form additional nicotine salts within the same “nicotine salt liquid formulation.” Resp. Init. Subm. at 18. Presumably, NJOY is arguing that JLI’s construction does not account for these additional sources of nicotine. But dependent

⁵ Unasserted claim 7 recites: “The electronic cigarette of claim 1, wherein the nicotine salt liquid formulation further comprises one or more additional organic acids.” ’533 Patent at 61:1-3.

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claim 7 does not state that the “additional organic acids” directly contribute to the “nicotine concentration” recited in claim 1. Rather, claim 7 allows for “one or more additional acids” beyond the “an organic acid” recited in claim 1.

2. Specification

JLI’s construction is more consistent with the specification’s overall description of the invention. Specifically, JLI’s construction aligns with the patent’s claimed advance over the prior art—the discovery that nicotine salts perform better than free base nicotine in aerosol devices. *See* Comp. Init. Subm. at 7-8. The detailed description of the invention begins by characterizing the state of the prior art, where “[s]ome reports have posited that nicotine free base should give rise to a greater satisfaction in a user than any corresponding nicotine salt.” ’533 patent at 7:65-67. The next paragraph describes a result that was “unexpectedly discovered,” which is “that certain nicotine salt formulations provide satisfaction in an individual superior to that of free base nicotine, and more comparable to the satisfaction in an individual smoking a traditional cigarette.” *Id.* at 8:1-5. The specification discloses extensive testing to demonstrate the superiority of the inventors’ nicotine salt formulations over free base formulations. *Id.* at 8:33-9:39, 9:49-10:66, 21:66-29:43. These disclosures show that the amount of nicotine salt is an important aspect of the invention that should not be read out of the claims. Accordingly, JLI’s proposed construction is more consistent with the specification’s emphasis on nicotine salt, and the Federal Circuit has held that the “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Phillips*, 415 F.3d at 1316 (Fed. Cir. 2005).⁶

⁶ NJOY argues that the alleged invention is not based on the quantity of nicotine salt in its formulations but on the choice of acid used to form the nicotine salt. *See* Resp. Init. Subm. at 3, 11-12. But this argument ignores the first paragraph of the specification’s detailed description of the invention, which clearly describes the problem to be solved in the prior art as a question of

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To support its construction, NJOY cites an explicit definition of “nicotine concentration” in the specification “wherein the concentration is of nicotine weight to total solution weight, *i.e.*, (w/w).” ’533 patent at 15:31-35; *see* Resp. Init. Subm. at 9-12; Resp. Reply Subm. at 3-6. However, both proposed constructions are measures “of nicotine weight to total solution weight” consistent with the definition in the specification—the difference being that the nicotine weight under NJOY’s construction is the weight of nicotine from any source while the nicotine weight under JLI’s construction is the weight of nicotine in the claimed nicotine salt.

The nicotine concentration would be the same under either proposed construction for all the example formulations in the specification made to have specific freebase equivalent concentrations used for comparison testing. *See* ’533 patent at 17:60-21:41 (describing formulations with 2%, 3%, and 4% concentrations). This is because the nicotine in these examples is either entirely in nicotine salt (in the example nicotine salt liquid formulations) or entirely free base nicotine (in the reference sample). *See* Comp. Resp. Subm. at 6-8.⁷ In one embodiment where the competing constructions would result in different measures of nicotine concentration, the specification describes the concentration in both ways. *See* ’533 patent at 21:47-53. In this example, the specification describes a formulation with two types of nicotine

whether users prefer nicotine salts or free base nicotine. *See* ’533 patent at 7:52-67. NJOY further argues that the specification’s testing of different nicotine salt liquid formulations compares and contrasts different acids rather than comparing nicotine salt to free base nicotine, Resp. Init. Subm. at 3, but this ignores the fact that all of the different formulations are compared against a baseline of free base nicotine. *See* ’533 patent at 18:1-21:41, 21:63-22:23, 22:42-55. NJOY’s argument that the invention is directed to the choice of acid rather than the use of nicotine salt therefore is not supported by the patent specification.

⁷ The specification explains why it would be advantageous to use an amount of acid in its nicotine salt formulations such that the nicotine content is entirely in a nicotine salt without any free base nicotine. In an example comparing different ratios of nicotine and acid, the specification provides that “[w]hen there is not enough [] acid to associate with all nicotine molecules, the free base nicotine left unprotonated in the formulation may reduce the satisfaction the formulation provides.” *Id.* at 14:31-41.

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salt: “0.43 g (2.5% w/w nicotine) of nicotine levulinate salt and 0.34 g (2.5% w/w nicotine) of nicotine acetate salt are added to 9.23 g of PG/VG solution, to achieve a 5% w/w nicotine formulation.” ’533 patent at 21:49-53. The final 5% nicotine concentration represents the total nicotine in the formulation by weight (consistent with NJOY’s construction), while the separate 2.5% nicotine concentrations represent the nicotine from each nicotine salt as a percentage of the total weight of the formulation (consistent with JLI’s construction). *See* Resp. Init. Subm. at 10-11; Comp. Reply Subm. at 5-6.

NJOY further argues that its construction should be adopted because the specification discloses using a UV spectrophotometer to measure the “nicotine concentration,” which NJOY asserts would not be able to distinguish between nicotine salt and other forms of nicotine like free base nicotine. Resp. Init. Subm. at 11 (citing ’533 patent at 26:7-20). NJOY submits that distinguishing between sources of nicotine in a formulation would require a more complex methodology that is not disclosed in the specification. *Id.* at 16. But as discussed above, the specification did not need to distinguish between nicotine salt and free base nicotine in its examples, because each formulation (save for the free base reference sample) includes enough acid to protonate all of the nicotine present in the formulation. *See* Comp. Reply Subm. at 7-8 n.4. Accordingly, the disclosed spectrophotometer would be able to measure a nicotine concentration in the disclosed examples that is consistent with either party’s proposed construction.⁸

⁸ Even if some different measurement would be required for formulations not disclosed in the specification, the methodology for making this measurement appears to be known in the art—both parties have offered expert analysis determining the amount of protonated nicotine to compute a “nicotine concentration” under JLI’s construction. *See* Resp. Init. Subm. at 16 (citing Exhibit G (Amiji Expert Report)); Comp. Init. Subm. at 13-14 (citing MSD Memo. at 22-23).

3. Prosecution History

The prosecution history for the '533 patent also supports JLI's proposed construction because it is consistent with the applicant's explanation for adding the claim language "the salt is present in an amount that forms."

In the parent application in the patent family of the '533 patent, the examiner rejected claims reciting a "nicotine salt concentration" because the disclosures of nicotine concentration in the specification "pertain to the amount of nicotine in the nicotine salt (liquid) formulation, as opposed to the amount of the nicotine salt in the nicotine salt (liquid) formulation." Resp. Init. Subm. at 12 (citing Exhibit H ('468 File History excerpts) at -.0104). In response, the applicant amended the claims to replace "nicotine salt concentration" with language reciting that "the salt is present in an amount that forms from about 3% (w/w) to about 15% (w/w) nicotine," similar to the "nicotine concentration" language in the '533 patent that is currently disputed. *Id.* (citing Exhibit H at -.0078). The applicant explained that "the concentrations now expressly refer to concentrations of nicotine, while also specifying that it is the nicotine salt [that] 'is present in an amount that forms' such nicotine concentration." Comp. Reply Exhibit 3 ('468 File History excerpts) at RX-2694.5716. The applicant further submitted that "the application clearly discloses nicotine concentrations resulting from amounts of nicotine salts present in the liquid formulation." *Id.*

NJOY reads this prosecution history as a disavowal of "nicotine salt concentration" and argues that the claimed concentration must measure nicotine rather than nicotine salt. Resp. Init. Subm. at 12-13. But as discussed above, both proposed constructions measure an amount of nicotine. The examiner merely noted that the specification's disclosures of nicotine concentrations represented "the amount of nicotine in the nicotine salt (liquid) formulation." *Id.* (quoting Exhibit H at -.0104). As discussed above, JLI's construction gives meaning to "the salt

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is present in an amount that forms” consistent with the applicant’s statements in the prosecution history, while NJOY’s construction fails to give any meaning to this claim language.

4. Extrinsic Evidence

NJOY argues that its construction is consistent with the ordinary meaning of “nicotine concentration,” but these arguments are not supported by credible evidence that outweighs the intrinsic evidence discussed above. NJOY relies on an expert opinion regarding the meaning of “nicotine concentration,” Resp. Init. Subm. at 7, Exhibit D (RX-0001C at ¶ 194), but this opinion is conclusory and addresses the phrase “nicotine concentration” outside the context of the patent. NJOY’s other extrinsic arguments are similarly untethered to the claim language at issue. *See* Resp. Init. Subm. at 16; Resp. Reply Subm. at 8. None of these arguments outweigh the intrinsic evidence discussed above that supports JLI’s construction. Because the intrinsic evidence is sufficient to establish the meaning of “nicotine concentration,” it is not necessary to consider the extrinsic evidence raised by NJOY. Nonetheless, even if the Commission were to consider the extrinsic evidence cited by NJOY, it does not raise a genuine issue of material fact. Thus, the Commission construes “nicotine concentration” based on the summary determination record. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1579 (Fed. Cir. 1989) (“Where no underlying fact issue must be resolved, claim interpretation is a question of law; thus, a mere dispute over the meaning of a term does not itself create an issue of fact.”).

5. Claim Construction Conclusion

For the reasons discussed above, the Commission has determined to construe “nicotine concentration” to mean “the amount of nicotine in the claimed nicotine salt, expressed as a percentage of nicotine weight to total solution weight.” This construction is consistent with JLI’s proposed construction, but it clarifies the appropriate concentration measurement such that

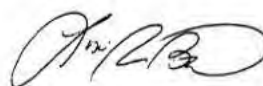
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the amount of nicotine being measured is only the nicotine in the claimed nicotine salt, and that the concentration percentage is expressed in comparison to the total weight of the solution.⁹

V. REMAND

In view of the foregoing, the Commission has determined to vacate the ID's construction of the "nicotine concentration" limitation. Accordingly, the Commission vacates the ID's grant of summary determination and remands the investigation to the ALJ for further proceedings consistent with this opinion.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: August 20, 2026

⁹ The wording of this construction is consistent with the definition of "nicotine concentration" in the specification "wherein the concentration is of nicotine weight to total solution weight, *i.e.*, (w/w)." '533 patent at 15:31-35.