

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NJOY, LLC and NJOY HOLDINGS, INC.,
Petitioner,

v.

JUUL LABS, INC.,
Patent Owner.

Case No. IPR2026-00161
U.S. Patent No. 12,156,533

**PETITIONERS' REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

LIST OF EXHIBITS

- EX1001 U.S. Patent No. 12,156,533
- EX1002 U.S. Patent No. 12,156,533 File History
- EX1003 Declaration of Martin Wensley
- EX1004 U.S. Patent Application Publication 2014/0000638 to Sebastian et al. (“Sebastian”)
- EX1005 U.S. Patent Application Publication 2006/0018840 to Lechuga-Ballesteros et al. (“Lechuga-Ballesteros”)
- EX1006 EP 0283672 to Lawson et al. (“Lawson”)
- EX1007 Bauer et al., “Introduction to Chemistry,” 2nd. Ed., The McGraw-Hill Companies, Inc. (2010) (“Bauer”)
- EX1008 Duell et al., “Nicotine in tobacco product aerosols: ‘It’s déjà vu all over again,’” *Tob. Control*, (2020) 29:656-662 (“Duell”)
- EX1009 Declaration of Dr. Stephen Byrn
- EX1010 Caldwell et al., “A Systematic Review of Nicotine by Inhalation: Is There a Role for the Inhaled Route?,” *Nicotine Tob. Res.*, (2012) 14(10):1127-1139
- EX1011 Blackman, et al., “Chemistry,” 2nd. Ed., John Wiley & Sons Australia, Ltd. (2012) (“Blackman”)
- EX1012 Goniewicz et al., “Nicotine Levels in Electronic Cigarettes,” *Nicotine Tob. Res.*, (2013) 15(1):158-166
- EX1013 Bertholon et al., “Electronic Cigarettes: A Short Review,” *Respiration*, (2013) 86:433-438

- EX1014 Modi et al., “US Tobacco,” *UBS Investment Research* (2012)
- EX1015 Cheng, “Chemical Evaluation of Electronic Cigarettes,” *Tob. Control*, (2014) 23:ii11-ii17
- EX1016 Stahl & Wermuth (Eds.), “Handbook of Pharmaceutical Salts: Properties, Selection, and Use: Chapter 7 – A Procedure for Salt Selection and Optimization,” (2002), 161-189
- EX1017 Gupta et al., “Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations,” *Molecules*, (2018) 23(7):1719
- EX1018 Cruz-Cabez, “Acid-base crystalline complexes and the pK_a rule,” *CrystEngComm*, (2012) 114:6362-6365
- EX1019 Kofoed et al., “Introductory Chemistry,” (available at <https://uen.pressbooks.pub/introductorychemistry/>)
- EX1020 Busch et al., “Universal Trends Between Acid Dissociation Constants in Protic and Aprotic Solvents,” *Chem. Eur. J.*, (2022) 28:1-12
- EX1021 RESERVED
- EX1022 Clayton et al., “Spectroscopic Investigations into the Acid-Base Properties of Nicotine at Different Temperatures,” *Anal. Methods*, (2013) 5:81-88
- EX1023 PubChem, “Lactic Acid,” *National Library of Medicine*, (available at <https://pubchem.ncbi.nlm.nih.gov/compound/Lactic-Acid>)
- EX1024 Subrahmanyam et al., “On the Road to Biopolymer Aerogels—Dealing with the Solvent,” *Gels* (2015) 1:291-313
- EX1025 U.S. Patent Application No. 14925968 File History

- EX1026 Right Claiming Document in CN201480025499.X, dated May 2, 2018
- EX1027 Translation of Right Claiming Document in CN201480025499.X (EX1027), dated May 2, 2018
- EX1028 Third Office Action issued in CN201480025499.X, dated November 5, 2018
- EX1029 Translation of Third Office Action issued in CN201480025499.X (EX1028), dated November 5, 2018
- EX1030 Email dated January 2, 2026 re: Stipulation
- EX1031 U.S. Patent Application No. 14/925,961 File History
- EX1032 USPTO Alert, “USPTO launches PTAB and Patents collaboration” bulletin, dated February 26, 2026
- EX1033 U.S. Patent Application No. 14/925,968 File History (excerpted)
- EX1034 U.S. Patent Application No. 14/271,071 File History
- EX1035 NJOY Opening Invalidity Report of Dr. Dean – Table of Contents (CBI Redacted), served in *Certain Vaporizer Devices, Cartridges Used Therewith, And Components Thereof II*, Inv. No. 337-TA-14601
- EX1036 Joint Stipulation for Discovery Cross-Use, *Juul Labs, Inc. v. NJOY, LLC et al.*, No. 2:25-cv-02853-JJT, D.I. 90 (D. Ariz. Feb. 27, 2026)
- EX1037 Excerpt from File History for EPO Opposition to EP 3073846 B1

Patent Owner (“PO”) knows full well that what it paints as a “simple failure of proof” in the Petition as to the “nicotine salt” limitation is actually a dispute as to its plain meaning and that under Petitioner’s understanding, the Petition fully addressed it.¹ Rather than explain this dispute to the Director and engage on the merits (using its ~10,000 unused words), PO instead pretends no such dispute exists. PO points to the word “salt” not appearing in the analysis for limitation [1d] and stops there. Paper 12, 7. That is a red herring. The Petition in fact devotes ten full pages and an entire *second* expert declaration for limitation [1b], which provides the foundation for [1d]. *See* Pet., 23-33; EX1009. Limitation [1b] requires the nicotine salt liquid formulation to comprise a salt of nicotine and organic acid, while limitation [1d] defines the % nicotine that must be present. The dispute hinges on whether the claims call for a *subset* of the nicotine in the formulation to be considered in the recited calculation as part of the salt (PO’s interpretation) or whether instead the claim omits such a constraint (Petitioner’s interpretation).

I. Petitioner Has Consistently Applied Its Interpretation of “Nicotine Salt,” While Patent Owner Remained Evasive

Petitioner has been clear from the beginning that it understands that limitation [1d] does not apply to only a subset of nicotine, and has applied that same meaning consistently across fora. *See* Pet., 38-40. PO has not alleged differently.

¹ This limitation is within claim 1(b) as recited in the ’533 patent but is referred to in the Petition as limitation [1d]. *See* Pet., 38-39.

At the time of the Petition's November filing, Petitioner believed PO to be in agreement. In December, however, Petitioner began to suspect the parties might be using that term differently and reached out to PO to clarify. PO refused to meaningfully engage, instead simply reiterating the claim language with emphasis. Despite requests for explanation, PO's silence necessitated Petitioner to seek and receive an Order *compelling* PO to provide such explanation. Even then, PO merely re-emphasized the same claim language. The analysis in PO's February expert report—served three months after the Petition's filing—finally provided the first articulation of its interpretation and tacit acknowledgment an actual dispute exists.

II. Patent Owner's Tortured Interpretation is Nevertheless Disclosed Within the Prior Art, as Petitioner's Evidence Demonstrates

PO's interpretation, as best Petitioner understands it, is tortured and finds no purchase in the '533 patent's claims, specification, or prosecution history. It is further at odds with the science. To clarify, in the parallel proceedings, PO has taken the position that the recited % nicotine "counts" only the nicotine that has interacted with (i.e., been "protonated" by) the claimed lactic or benzoic acid, and that it excludes nicotine from sources other than the salt of nicotine and benzoic or lactic acid (such as from freebase nicotine or a different nicotine salt), even if present within the liquid formulation.

But the '533 patent and its claims do not say that. Indeed, there exists no clear way to measure just the portion of nicotine solely attributable to that salt. PO

contends that calculations can be made through a previously undisclosed, multi-step process that includes (i) determining the amount of protonated nicotine, (ii) calculating the amount of unprotonated lactate or benzoate ion within that salt, (iii) adjusting the values to account for the molar ratio, (iv) determining which concentration was lower, and, finally, (v) comparing that concentration to the claimed range. But this is nowhere disclosed by the patent. And, in reality, every nicotine molecule is part of the salt, as every molecule will at times be protonated.

Nevertheless, to the extent PO's interpretation relies on a calculation of a *subset* of nicotine—i.e., nicotine that has received a proton—Petitioner has still met its burden. Petitioner's chemistry expert Dr. Stephen Byrn performed that calculation and found that the prior art nevertheless falls well within the claimed 0.5-20% nicotine range. *See* EX1009, ¶ 47. PO has not alleged otherwise. Thus, even under PO's new interpretation, Petitioner has met its burden to demonstrate a reasonable likelihood that the prior art invalidates the claims.

This latent claim construction issue should not preclude institution of the Petitioned grounds, which are meritorious and address material error previously identified. *See* Paper 13, 3-12. Petitioner has been open and consistent, while PO has disingenuously treated an ongoing claim construction dispute as a failure of proof.²

² The POPR repeats a discretionary denial argument. POPR, 9-17. Per the Board's guidance, Petitioner directs the merits panel to its rebuttal at Paper 13, 17-19.

Proceeding No.: IPR2026-00161

Attorney Docket: 58718-0002IP1

Respectfully submitted,

Date: March 26, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §42.6(e)(4), the undersigned certifies that on March 26, 2026, a complete and entire copy of this Petitioners' Reply to Patent Owner's Preliminary Response were provided via email, to the Patent Owner by serving the email correspondence addresses of record as follows:

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