

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

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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,’” <i>Tob. Control</i> , (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?,” <i>Nicotine Tob. Res.</i> , (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,” <i>Nicotine Tob. Res.</i> , (2013) 15(1):158-166
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- 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
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EX1037	Excerpt from File History for EPO Opposition to EP 3073846 B1

I. INTRODUCTION

Patent Owner JLI wants the Director focused on the clock. JLI's brief contends that the facts are stacked against Petitioner NJOY, and that discretionary denial is inevitable. It points to the ITC's speedy schedule and urges a *Fintiv* denial, as if speed alone can whitewash what happened at the Patent Office.

But the defining characteristic of this case is JLI's gamesmanship. JLI did not obtain these claims through innovation; it manipulated process to obtain them. After persuading the Patent Office to allow claims based on contentions that nicotine salts formed from benzoic acid achieve "unexpected superiority," JLI did an about-face. It filed a request for continued examination and quietly broadened the claims to alternatively cover lactic acid—the very feature the same Examiner had rejected *fifteen* times over three separate prosecutions between 2015 and 2018 based on Sebastian, the reference NJOY relies on here. Twice, JLI abandoned applications when it simply could not overcome those rejections.

Then, after a three-year hiatus, JLI returned with a new tactical plan: secure allowance on benzoic acid *first*, then slip lactic acid back into the claims through amendments, without calling attention to the prior rejections or its prior acknowledgement of lactic acid within the prior art. *See* EX1031, 365 (admitting that related art contained an "amount of lactic acid to an amount sufficient to protonate *only half* of the nicotine.") (emphasis added). JLI's tactics worked. The

Examiner—likewise failing to address her prior rejections or Sebastian—inexplicably allowed the expanded claims. It is hard to imagine a stronger case for material error than this.

Sebastian anticipated those broadened claims then, and it anticipates them now. The resulting allowance was not a considered change of course; it was material error. The Director should not permit *Fintiv* to be used as a shield for claims that never should have issued from the Patent Office. This error is a problem inherent to prosecution that the Patent Office has a duty to fix, since the ITC cannot. Indeed, this prosecution record could be the poster child for the Office’s new “Learning from Outcomes to Optimize Patents (LOOP)” program that seeks to create a feedback loop between errors discovered by the Board and reported to the examination corps. EX1032.

In short, yes, a co-pending ITC investigation is underway and will finish before a Final Written Decision would issue. But this case deserves an exception to discretion because of JLI’s gamesmanship during prosecution and the Examiner’s material error stemming directly from that gamesmanship. JLI knowingly broadened the scope after allowance to capture a configuration that JLI had already earlier acknowledged as within the prior art. A decision to deny substantive consideration based on discretion is a decision to disregard the clear examinational error, and to reward JLI for gamesmanship before the Examiner and its further tactics

in selecting a speedy litigation forum. Petitioner NJOY respectfully requests the Director to institute this IPR.

II. INSTITUTION IS NECESSARY TO CORRECT MATERIAL ERRORS THAT LED DIRECTLY TO ALLOWANCE

A. JLI Tried for Over a Decade to Obtain Claims Covering Lactic Acid in Nicotine Salts

NJOY, JLI, and their associated entities have a long history together in the e-cigarette industry. Today, NJOY and JLI directly compete in the marketplace. Among other differences, NJOY's products use an e-liquid containing nicotine and lactic acid to create a nicotine salt, nicotine lactate, while JLI's products instead use benzoic acid, creating nicotine benzoate. Claim 1 of the '533 patent is directed to an electronic cigarette containing in part a "nicotine salt liquid formulation" that "comprises a salt of nicotine and an organic acid in a liquid carrier, wherein the organic acid is benzoic acid or lactic acid," i.e., nicotine benzoate or nicotine lactate.

It took JLI *eleven years*, five applications, fifteen separate rejections, six interviews, and four declarations to secure a patent claim including "lactic acid" over Sebastian and related references. And JLI was only able to secure allowance after a five year gap in prosecution (with the Examiner taking two years to issue the first new substantive rejection after filing), after which JLI reintroduced lactic acid as an

alternative to benzoic acid (e.g., “benzoic acid or lactic acid”) in the claims.¹ Sebastian,² the central reference in NJOY’s Petition, discloses an “electronic smoking article” that can generate an inhalable aerosol. *See, e.g.*, EX1004, Abstract, [0009]-[0010]. Critically, Sebastian discloses 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.” *Id.*, [0059] (emphasis added). These disclosures served to thwart JLI’s efforts time and again to gain allowance of claims directed to an e-cigarette containing nicotine lactate.

1. Lactic Acid Was Recited Among Features Rejected Multiple Times by the Examiner During Prosecution of JLI’s ’961 and ’968 Applications

JLI filed three applications that each tried to secure an issued claim with NJOY’s “lactic acid” nicotine salt formulation. None succeeded. On October 28, 2015, JLI filed U.S. Pat. App. Nos. 14/925,961 and 14/925,968. The original claims of both applications included nicotine lactate in an e-liquid. *See* EX1031, 96 (cl. 2);

¹ At various points in prosecution “lactic acid” claims were also rejected over Griffith (US2013/0255702, EX2025) and Collett (US2014/0060554, EX2019), which contain similar disclosures as Sebastian with respect to the organic acid description, as Patent Owner acknowledges. Paper 11, 8-9 (comparing EX1004, [0059]-[0061] with EX2019, [0074]-[0077], EX2025, [0086]-[0088]). For clarity, they will be referred to herein collectively as Sebastian.

² U.S. Pat. App. Pub. No. 2014/0000638, filed June 28, 2012. EX1004.

EX1033, 95 (cl. 1). During prosecution of the '968 application, JLI introduced numerous claim amendments to try to overcome Sebastian, including by adding limitations with certain pharmacokinetic parameters, (EX1033, 369-372, 473-476), additional structural requirements to the e-cigarette itself, (*id.*, 473-476, 554-557), and the physiological response of increased heart rate, (*id.*, 746-749). After amendments failed to overcome the lactic acid disclosure in Sebastian, JLI³ submitted a declaration from its Head of Scientific and Regulatory Affairs, Dr. Gal Cohen, who testified to the commercial success of *NJOY's product* and long-felt but unsolved needs in support of secondary considerations of non-obviousness. *See id.*, 563-566, 568-593. Three months later, before it received another office action, JLI pre-emptively submitted additional amendments and another declaration related to secondary considerations, this time from one of the inventors, Adam Bowen, "providing additional experimental evidence in support of the heart rate effect of vaporizing nicotine lactate as well as providing evidence of unexpected results." *Id.*, 647-648, 650-654.

JLI's efforts failed again. The Examiner rejected that Mr. Bowen's results were "unexpected" in view of Sebastian because Sebastian disclosed nicotine and lactic acid in an e-liquid solution, and thus heating the same in an electronic cigarette

³ At this point in time JLI was operating as PAX Labs, Inc.

and being inhaled by a user was already known, and would inherently provide the then-claimed increases in heart rate comparable to inhaling a traditional burned cigarette. EX1033, 680-690. In a last ditch attempt to overcome Sebastian, JLI amended the claim with an additional narrowing limitation, and argued that the organic acids in Sebastian were merely “for the purpose of *altering flavor*.” *Id.*, 742 (emphasis in original). The Examiner rejected this too, noting that the ’533 patent describes organic acids the same way, i.e., as flavorants. *See id.*, 772 (“[I]t is to be noted that Applicant has also articulated that organic acids (including lactic acid) coupled with nicotine to produce nicotine lactate can be used to provide flavor (see instant published application para. [0131]).”); *see also* EX1001, 14:42-64 (corresponding to para. [0131] of published application). Thereafter, JLI abandoned the ’968 application. *See* EX1033, 795 (Notice of Abandonment dated January 10, 2018). Concurrently, JLI abandoned an additional application with claims to lactic acid. EX1034, 101 (cl. 22), 105 (cl. 70), 134-137 (cls. 110, 118, 126, 133), 463.⁴

2. *JLI Pivoted to Benzoic Acid to Overcome Sebastian in the ’961 Application*

While JLI was prosecuting the ’968 application, JLI sought to obtain “lactic

⁴ U.S. Pat. App. 14/271,071 was filed on May 6, 2014, (EX1034, 1) and abandoned after a single non-final rejection, (*id.*, 384-402) with Notice of Abandonment dated January 4, 2018 (*id.*, 463).

acid” claims during the prosecution of the ’961 application⁵ as well. *See* EX1031, 96 (cl. 2). The Examiner again repeatedly rejected claims with “nicotine lactate” or “lactic acid” over Sebastian. In a December 2016 rejection, the Examiner again acknowledged Sebastian’s inherent disclosure of a nicotine lactate salt, finding that “[s]ince the nicotine and lactic acid can be provided in equimolar ratios (i.e., 1:1), it is presumed, at this proportion, that ‘nicotine lactate’ is thereby formed (which, inherently, means that ‘the nicotine is protonated’), resulting in the claimed ‘nicotine lactate salt formulation that includes nicotine, lactic acid’.” *Id.*, 420-421. After four rejections and two unsuccessful requests for continued examination, on December 14, 2017 JLI cancelled all claims and pivoted to claiming “benzoic acid” instead, which covers JLI’s only products. *Id.*, 576 (cl. 26). After additional claim amendments, the Examiner eventually allowed the benzoic acid claims on November 25, 2020. *Id.*, 927-930.

B. JLI Invited Examiner Error Leading to Allowance of Claims to Lactic Acid

1. JLI Prosecuted Benzoic Acid Claims, Then Returned After Allowance to Recite Lactic Acid as an Alternative to Benzoic Acid

Three years after abandoning its attempts to claim an e-liquid containing nicotine and lactic acid, JLI filed a new application, U.S. Pat. App. No. 17/171,976,

⁵ The ’961 application is the parent of the ’533 patent. *See* EX1001, 1.

on February 9, 2021. After cancelling the original claims, JLI proposed new claims that started where it had previously left off, with claims to “a salt of nicotine and benzoic acid in a liquid carrier[.]” EX1002, 167. The Examiner rejected the claims as obvious over the combination of Sebastian and Lechuga-Ballesteros.⁶ *Id.*, 207-216. Lechuga-Ballesteros, the supporting reference in NJOY’s Petition, is directed to pressurized metered dose inhalers that are used to aerosolize and deliver nicotine to a consumer’s lungs. EX1005, [0003], [0010]-[0012]. Specifically, Lechuga-Ballesteros describes an “aerosolizable formulation” with nicotine and an organic acid, where “***said organic acid and said free-base nicotine form a nicotine salt[.]***” EX1005, [0012] (emphasis added); *see also id.* [0013]-[0014]. While Lechuga-Ballesteros disclosed a number of organic acids, including benzoic acid, the primary organic acid it disclosed and tested was lactic acid, finding that the “nicotine lactate solution had the most desirable combination of attributes.” *Id.*, [0023], [0084].

In rejecting the claims over the combination of Sebastian and Lechuga-Ballesteros, the Examiner relied on Sebastian’s e-cigarettes disclosures and Lechuga-Ballesteros’s benzoic acid disclosure. *See* EX1002, 208-211. In response, JLI argued (as it had unsuccessfully argued previously in the ’968 application) that Sebastian only describes formulations “that contain nicotine in the form of nicotine

⁶ U.S. Pat. App. Pub. No. 2006/0196518, filed on June 28, 2005. EX1005.

free base,” and “equates flavoring agents such as mint, nutmeg, clove, and lavender with organic acids as compounds that can affect the flavor” of nicotine. *Id.*, 284-286. Additionally, JLI submitted data purporting to show that nicotine benzoate salts had “unexpected superiority...over comparable freebase formulations.” *Id.* Regarding Lechuga-Ballesteros, JLI argued that a person of skill in the art would not have been motivated to combine Lechuga-Ballesteros’s formulation in Sebastian’s e-cigarette because it described formulations for a metered dose inhaler that were not interchangeable with an e-cigarette. *See id.*, 285-290.

Thereafter, the Examiner found the e-cigarette claim allowable but maintained the obviousness rejection to the claims directed to the “cartridge” within the e-cigarette over Lechuga-Ballesteros alone. *Id.*, 313-314. In finding the e-cigarette claim allowable, the Examiner found “persuasive” JLI’s argument that “the skilled artisan looking to improve the formulation of Sebastian for use in an electronic smoking article would not look to the formulation described in Lechuga-Ballesteros et al which has been optimized for delivery via a pressurized metered dosed inhaler.” *Id.*, 314. JLI subsequently amended the cartridge claims to reference an e-cigarette, (*id.*, 377-380), and the Examiner issued a Notice of Allowance, (*id.*, 400-402).

After the Examiner allowed the benzoic acid claims, however, JLI filed a Request for Continued Examination and amended the claims to ***add lactic acid*** as an alternative:

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

Id., 498 (emphasis in original). Rather than re-raise Sebastian or Lechuga-Ballesteros, which both plainly disclose lactic acid in combination with nicotine, the Examiner instead found the e-cigarette claims allowable but issued a new rejection of the cartridge claims over Lawson,⁷ a 1988 European patent describing traditional cigarette formulations. *Id.*, 519-523. JLI cancelled the offending cartridge claims, (*id.*, 681-684) and the Examiner issued a second Notice of Allowability without further rejection, (*id.*, 692-696).

2. The Examiner Erred by Maintaining Allowance Without Substantively Addressing the Sebastian Disclosure That She Earlier Relied Upon to Reject Claims Likewise Reciting Lactic Acid

In allowing the amended claims, the Examiner made a critical error. Adding “lactic acid” to the claim rendered Sebastian *anticipatory*. The Examiner had withdrawn the rejection over Sebastian because she was persuaded that a skilled artisan would not look to Lechuga-Ballesteros’s formulation “to *improve* the formulation of Sebastian.” EX1002, 314 (emphasis added). But now, Sebastian needed no improvement or modification; rather, Sebastian’s nicotine and lactic acid disclosures put it squarely within the scope of the claims, because it taught that

⁷ EP 0,283,672, filed on January 29, 1988. EX1006.

“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] (emphasis added).

The five-year gap between JLI’s abandonment of the ’968 application and the first office action in what issued as the ’533 patent certainly worked to JLI’s benefit. While the Examiner in 2023 indicated it was “not clear whether [Sebastian] teaches a nicotine salt liquid formulation,” (EX1002, 209, emphasis in original), that same Examiner earlier (in and before 2018) indicated no such ambiguity and she even corroborated her 2018 views by repeatedly referencing Sebastian’s teaching of “equimolar ratios” (or equal molar amounts) of nicotine and organic acids. *See, e.g.*, EX1031, 420-423 (2016 rejection); EX1033, 680-685 (rejecting JLI’s “unexpected results” argument over Sebastian in 2016); *id.*, 771-773 (2017 rejection).

JLI never effectively rebutted these arguments. In fact, JLI *admitted* its similar understanding of Sebastian, noting that Sebastian’s disclosure of nicotine and lactic acid would generate a nicotine salt (i.e., containing protonated nicotine). Specifically, during prosecution of the ’961 application, when JLI sought claims where “the lactic acid concentration is sufficient to protonate most of the nicotine,” JLI told the Examiner that “neither Griffith nor Collett suggests a liquid solution having a *lactic acid concentration is sufficient to protonate **most** of the nicotine*,” and that “[a]t best, Griffith and Collett limit the amount of lactic acid to an amount

sufficient to protonate **only half** of the nicotine.” EX1031, 365 (bold emphasis added). In other words, by JLI’s logic, lactic acid will protonate half the nicotine, forming a nicotine salt. As discussed above, (*see n. 1, supra*), Griffith and Collett have similar disclosures as Sebastian with respect to organic acid.⁸ Thus, contrary to the Examiner’s 2023 belief, it is clear that Sebastian “teaches a nicotine **salt** liquid formulation,” i.e., containing nicotine protonated by lactic acid. The Examiner issued these claims in error, and the Director should institute NJOY’s Petition to correct that error.⁹

⁸ Sebastian discloses that nicotine can be present in up to “about 5% by weight” in the “aerosol precursor” formulation. EX1004, [0061]; *see also id.*, [0060] (“Flavors and the like (which can include medicaments, such as nicotine) can comprise up to about 10%...”). Thus, even if only protonated nicotine is considered with respect to the claimed range (0.5% (w/w) to 20% (w/w)) in the claims—which NJOY disputes—JLI admitted that Sebastian at least discloses lactic acid sufficient to protonate 2.5% of the nicotine (or 5%, under 10% nicotine disclosure).

⁹ Secondarily, the Examiner also erred in finding a skilled artisan looking to improve Sebastian would not have looked to Lechuga-Ballesteros. EX1002, 314. JLI’s arguments on this point assumed that Lechuga-Ballesteros’s formulation must be bodily incorporated into Sebastian’s cartridge. *See id.*, 285-290. But that is not the law. *See In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious” the invention.) (citation omitted). As NJOY set forth in the Petition, a skilled artisan would have looked to 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. *See Pet.*, 46-62.

III. EXAMINER’S ERROR SUPERSEDES BOTH *FINTIV* CONCERNS AND JLI’S ADDITIONAL CONCERNS

JLI asserts a slew of *Fintiv* arguments and “other circumstances” favoring denial. None supersede the Examiner’s error and the importance of institution to enable error-free consideration of patentability by the Patent Office.

A. JLI’s Actions in the Parallel Proceedings Show Why Institution is Warranted

JLI acted strategically when the ’533 patent issued. It waited until the PGR window had nearly closed, and then it selected the fastest forum available to it—the ITC. JLI knew that choosing the ITC would create a situation where NJOY could not possibly seek an IPR Final Written Decision before the ITC investigation concluded. JLI knew it was lucky to finally get claims with the words “lactic acid,” that read on NJOY’s products, and it sought to exploit that luck by using the ITC’s accelerated schedule to discourage the Patent Office from reviewing and correcting its error.

NJOY does not dispute that the ITC investigation is likely to conclude prior to a Final Written Decision. Nor does NJOY dispute that NJOY did not request the optional §1659(a) stay in the District of Arizona available to ITC respondents and opposed JLI’s curious decision to move to stay its own case. JLI’s contention, however, that “[t]he Arizona district court sided with Petitioner on the stay,” (Paper 11, 7), is wrong. The Arizona court **granted** JLI’s stay in part; the court stayed “[a]ll

other disclosure, settlement, and dispositive motion deadlines that traditionally follow a *Markman* hearing” at least until a joint status report following the ITC *Markman* hearing stating the parties’ positions on “whether an extension of the partial stay is appropriate.” *See* EX2015, 6. There is therefore no guarantee that the Arizona case will proceed past that point, or that if it does, that trial will occur before a Final Written Decision.¹⁰

JLI would have the Arizona case stayed, the IPR Petition discretionarily denied, and the ITC be the sole arbiter of the patent’s validity. The Director should not reward JLI’s gamesmanship during prosecution. The ITC *cannot* correct the PTO’s material error in issuing the ’533 patent over Sebastian. At most, the ITC can determine that the claims are invalid or unenforceable for the purposes of that investigation, but the ’533 patent would nevertheless stand. *See Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996). The material error would remain, uncorrected, contrary to the Director’s strong stance against such outcome. Validity would have to be re-litigated in Arizona eventually regardless, creating additional inefficiencies. The Director should instead institute this IPR and correct the Patent Office’s error once and for all.

¹⁰ NJOY notes that if the Arizona case proceeds, the parties have entered into a cross-use agreement that permits document productions, discovery responses, and deposition testimony to be used across the forums, minimizing efficiency concerns. *See* EX1036.

B. Patent Owner's Other Concerns Do Not Warrant Discretionary Denial

1. NJOY Has Narrowed Its ITC Prior Art

JLI contends that NJOY “has advanced a kaleidoscope of defenses” against the ’533 patent in the ITC investigation, “including at least 30 different § 102 grounds and hundreds of different § 103 combinations,” and faults NJOY for not executing a “*Sotera*-styled” stipulation. Paper 11, 2, 5. NJOY has now served its opening invalidity expert report and narrowed its printed publication prior art challenges down to less than ten references; NJOY will likely assert even fewer at the evidentiary hearing. *See* EX1035. NJOY expects similar narrowing to happen in district court. Moreover, as JLI has acknowledged, the evidentiary hearing will likely occur before the Director’s institution decision, NJOY has confirmed it is not affirmatively relying on either Sebastian or Lechuga-Ballesteros before the ITC, and therefore any *Sotera* style stipulation would be functionally meaningless.

Additionally, JLI’s complaints about the numerous prior art references that all have the same “lactic acid” teaching as Sebastian only go to show how well known it was in the art that nicotine and lactic acid could be combined in an e-liquid to form a nicotine salt. *See* Paper 11, 1-2, 5, 8-10. The Examiner knew it, as did JLI. They tried to get claims to it anyway, all in a bid to come after NJOY. The Director should

not counsel such gamesmanship just because the Petition relies on disclosures widespread in the art.

2. *NJOY's Expert Provided Relevant, Specific Support for Petition*

JLI next takes aim at NJOY's expert but misses the mark. JLI points to the NJOY's Petition citing to its expert "at least **213** times," as if a Petition thoroughly supported by expert testimony is discouraged when it is anything but. Paper 11, 15. Further, JLI's criticisms are inconsistent. For example, JLI first criticizes NJOY's Petition for using "essentially identical" quotations of the art as its expert, ignoring that both necessarily rely on the same prior art disclosures.¹¹ *Id.* Yet in the next breath, JLI (notably without citation) accuses NJOY of relying on "broad-reaching, unfocused expert testimony." *Id.* Which is it?

In truth, the prior art here speaks for itself; NJOY's expert here needed little more than to present the plainly anticipatory prior art disclosures, just as the Petition did. NJOY's expert simply provided additional explanation to clarify that "the salt is present in an amount that forms" the claimed concentration ranges "in the nicotine liquid salt formulation." JLI ignores that testimony entirely. JLI argues that the

¹¹ Indeed, JLI's "exemplary comparison" of five paragraphs plucked from the two documents largely comprises quotes from the prior art, which would not be expected to change. *See* EX2033. Moreover, the redline appears erroneous, as it suggests that the expert declaration omitted quotation marks, when it did not.

Petition “essentially copies” its expert’s “conclusory testimony” on this limitation, but fails to acknowledge that NJOY submitted a second declaration from an expert chemist to explain the science behind what the Examiner already knew and what JLI admitted during prosecution. *See* Paper 11, 15 (no reference to EX1009, Declaration of Stephen Byrn); *see also* Section II.B.2, *supra*. Sebastian meets this limitation.

3. *JLI Mischaracterizes and/or Takes NJOY and Altria’s Prior Statements Out of Context*

Finally, JLI points to a number of statements made by NJOY that allegedly contradict statements in the Petition. None hold water. For example, JLI points to previous statements NJOY made regarding Sebastian’s “equimolar” disclosure, stating that “[t]he Petition contends that Sebastian inherently discloses ‘a nicotine lactate’ salt formed by an ‘equimolar’ (i.e., ‘1:1’ molar ratio) of nicotine *and lactic acid*.” *Id.*, 18 (emphasis added). Not so. JLI’s selective quoting misrepresents the Petition. The Petition states, for example, that “Sebastian’s ‘up to equimolar’ description distinctly contemplates a chemical reaction between nicotine *and organic acid*,” which is precisely the words Sebastian uses. *Pet.*, 29 (emphasis added); *see also id.* 28 (same), 60 (same), 65 (same); *compare with* EX1004, [0059]. Notably, no molar ratio is required by the claims here, and therefore not only are the statements from the prosecution of the Rabinowitz ’470 patent not relevant, but they are also not inconsistent.

With respect to NJOY's statements during the EPO Opposition to the Rabinowitz EP '846 patent, (*id.*, 16-18), JLI ignores that a more rigid "novelty" requirement applies in Europe than in the United States. In Europe, a claim lacks novelty only if *every* claimed feature is directly and unambiguously disclosed in a single embodiment, unless a combination has specifically been suggested within the reference. *See* T 305/87, para 5.3 (Sept. 1, 1989) ("It is not permissible to combine separate items belonging to different embodiments described in one and the same document merely because they are disclosed in that one document, unless of course such combination has been specifically suggested therein."). While Sebastian's reference to "[f]lavors" in [0060] is sufficient under U.S. law to combine with the more specific disclosures of what "flavors" are in [0059], the same is not necessarily true under Europe's more restrictive patent laws. Further, JLI's contention that "the EPO agreed with Petitioner that neither Sebastian nor Griffith anticipated the EP '846 claims" is misleading at best. In addition to suffering from the same legal standard discrepancy, JLI's quoted language was the EPO's "preliminary opinion" only. *See* EX2029, 85, 90. Because the EPO revoked the patent on other grounds (in an excerpt not included in JLI's exhibit), it made no final determination on this point. *See* EX1037.

JLI's arguments regarding NJOY statements made in another European proceeding regarding Lechuga-Ballesteros suffer similar deficiencies. Additionally,

the Petition does not propose bodily incorporation of Lechuga-Ballesteros's formulation, as the EPO did, but simply serves as additional motivation for a skilled artisan to try a nicotine lactate salt in an e-cigarette, and a reasonable expectation that a nicotine lactate salt would have benefits over freebase nicotine, as Lechuga-Ballesteros expressly concludes. *See* EX1005, [0084] (“the nicotine lactate solution (an example of nicotine in combination with an organic acid) appeared to overall have the most desirable properties[.]”); Pet., 47-62.

Finally, JLI touts statements that Altria (Petitioner's real-party-in-interest) made to the FTC in its final salvo, arguing that “Altria told the FTC how it failed for years to appreciate that Patent Owner's innovative nicotine salt liquid formulations were the ‘key’ for e-cigarettes to ‘provid[e] smokers the satisfaction necessary to replicate the nicotine experience.’” Paper 11, 20. As an initial matter, JLI fails to disclose that its quoted language is derived from a *joint filing with Juul Labs*, JLI's real-party-in-interest, and is not some independent endorsement. *See* EX2007, 1. Moreover, where *Altria* may have “failed” to appreciate the benefits of nicotine salts, *NJOY* (which was in no way associated with Altria at the time) did not. And, as detailed above, JLI spent over ten years trying to get claims to what NJOY perfected, even relying on NJOY's own commercial success to do so, rather than *JLI's* own success.

C. NJOY Acted Diligently to Challenge a Young Patent

The '533 patent issued on December 3, 2024. JLI waited until August 8, 2025 to file Complaints against NJOY in the ITC and District of Arizona, less than one month before the PGR window closed, effectively precluding NJOY from seeking the Director's preferred form of relief. *See LifeVac, LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11, 1 (PTAB July 11, 2025) (precedential) (explaining that "petitions for post-grant review are favored because they must be filed no later than nine months from the grant of the patent..., are close in time to examination, and occur before expectations in the patent rights are strongly settled.").

NJOY filed the instant Petition on November 26, 2025, less than four months after JLI filed its Complaints. JLI seeks to minimize that timing, stating that "[t]he timing of the Petition relative to the issuance of the '533 patent is not a significant factor here." Paper 11, 14. But it should be a significant factor. NJOY is bound within the constraints that JLI imposed through its choice of forum. JLI should not be allowed to wield the ITC's expedited schedule as a shield to protect its newly acquired, defective claims from Patent Office scrutiny and correction.

IV. CONCLUSION

The Director should grant institution to remedy the Patent Office's material error in allowing the '533 patent to issue with claims to "lactic acid" over known, admitted, anticipatory art.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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