

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NJOY, LLC and NJOY HOLDINGS, INC.,

Petitioner,

v.

JUUL LABS, INC.

Patent Owner.

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

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**PATENT OWNER'S REQUEST FOR DISCRETIONARY  
DENIAL OF INSTITUTION**

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**EXHIBIT LIST**

<b>Exh. No.</b>	<b>Description</b>
2001	Declaration of Thomas H. Wintner in Support of Patent Owner’s Notice of Intent to Designate a Provisionally Recognized PTAB Attorney Under 37 C.F.R. § 42.10(c)(2)
2002	Memorandum from Chief Administrative Patent Judge Boalick regarding Guidance on USPTO’s rescission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,” dated March 24, 2025
2003	U.S. Patent No. 9,215,895 to Bowen <i>et al.</i>
2004	Excerpts from File History of U.S. Patent Application No. 14/284,194 to Rabinowitz <i>et al.</i>
2005	Wayne <i>et al.</i> , “Brand differences of free-base nicotine delivery in cigarette smoke: the view of the tobacco industry documents,” <i>Tobacco Control</i> (2006) 15:189-198
2006	Shao <i>et al.</i> , “Nicotine Delivery to Rats via Lung Alveolar Region-Targeted Aerosol Technology Produces Blood Pharmacokinetics Resembling Human Smoking,” <i>Nicotine &amp; Tobacco Research</i> (2013) 15:1248-1258 (advanced publication Dec. 13, 2012)
2007	Excerpts from Post-Trial Brief of Respondents Altria Group, Inc. and JUUL Labs, Inc., <i>In the Matter of Altria Group, Inc. and JUUL Labs, Inc.</i> , Docket No. 9393, U.S. Federal Trade Comm’n (dated August 23, 2021)
2008	Complaint, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, Int’l Trade Comm’n (Aug. 8, 2025)
2009	Respondents’ Verified Response to JUUL Labs, Inc.’s Complaint, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, Int’l Trade Comm’n (Nov. 20, 2025)
2010	Redline Comparison of Sebastian (US 2014/0000638) ¶¶[0059]-[0061] to Potter (US 2014/0261486) ¶¶[0049]-[0051]

<b>Exh. No.</b>	<b>Description</b>
2011	Order No. 18: Construing Claim Term, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, Int’l Trade Comm’n (Jan. 22, 2026)
2012	Order No. 19: Amending Procedural Schedule, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, , Int’l Trade Comm’n (Jan. 30, 2026)
2013	Excerpts from Transcript for Markman Hearing and Case Management Conference, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, Int’l Trade Comm’n (Jan. 8, 2026)
2014	Defendants’ Response Memorandum to Plaintiff’s Motion to Stay (ECF No. 26), <i>JUUL Labs, Inc. v. NJOY, LLC, et al.</i> , Civ. Action No. 2:25-cv-02853-JJT, D. Az. (Oct. 24, 2025)
2015	Order (ECF No. 33), <i>JUUL Labs, Inc. v. NJOY, LLC, et al.</i> , Civ. Action No. 2:25-cv-02853-JJT, D. Az. (Nov. 20, 2025)
2016	Scheduling Order (ECF No. 36), <i>JUUL Labs, Inc. v. NJOY, LLC, et al.</i> , Civ. Action No. 2:25-cv-02853-JJT, D. Az. (Nov. 25, 2025)
2017	Excerpts from Attachment G, Respondents’ Final Invalidity Contentions, <i>In the Matter of Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof</i> , Inv. 337-TA-1460, Int’l Trade Comm’n (Jan. 6, 2026)
2018	U.S. Patent Application No. 2014/0261486 A1 to Potter <i>et al.</i> (publication date Sep. 18, 2014) (“Potter”)
2019	U.S. Patent Application No. 2014/0060554 A1 to Collett <i>et al.</i> (publication date Mar. 6, 2014) (“Collett”)
2020	U.S. Patent Application No. 2014/0253144 A1 to Novak <i>et al.</i> (publication date Sep. 11, 2014) (“Novak”)
2021	U.S. Patent Application No. 2014/0209105 A1 to Sears <i>et al.</i> (publication date July 31, 2014) (“Sears ’105”)
2022	U.S. Patent Application No. 2014/0096781 A1 to Sears <i>et al.</i> (publication date Apr. 10, 2014) (“Sears ’781”)
2023	U.S. Patent Application No. 2014/0261487 A1 to Chapman <i>et al.</i> (publication date Sep. 18, 2014) (“Chapman”)

Exh. No.	Description
2024	U.S. Patent Application No. 2014/0270727 A1 to Ampolini <i>et al.</i> (publication date Sep. 18, 2014) (“Ampolini”)
2025	U.S. Patent Application No. 2013/0255702 A1 to Griffith <i>et al.</i> (publication date Oct. 3, 2013) (“Griffith”)
2026	Redline Comparison of Sebastian (US 2014/0000638) ¶¶[0059]-[0061] to Griffith (US 2013/0255702) ¶¶[0086]-[0088]
2027	EP 3073846 B1 to Rabinowitz <i>et al.</i> (“Rabinowitz EP ’846”)
2028	WO 2014/004648 A1 to Sebastian <i>et al.</i> (publication date Jan. 3, 2014) (“Sebastian PCT”)
2029	Excerpts from File History for EPO Opposition to EP 3073846 B1
2030	Court Profile: International Trade Commission, “Motion Success – ITC Motion to Stay Pending IPR,” Docket Navigator (last accessed Feb. 2, 2026)
2031	WO 2006/004646 A1 to Lechuga-Ballesteros <i>et al.</i> (publication date Jan. 12, 2006) (“Lechuga-Ballesteros PCT”)
2032	Memorandum from USPTO Acting Director Stewart regarding “Interim Processes for PTAB Workload Management”, dated March 26, 2025
2033	Redline Comparison of Petition (Paper 2 at 23-25) to Wensley Decl. (Ex1003 ¶¶ 67-71)
2034	U.S. Patent No. 11,202,470 to Rabinowitz <i>et al.</i> (“Rabinowitz ’470”)
2035	International Trade Commission, “Section 337 Statistics: Average Length of Investigations” (Jan. 27, 2026), <i>available at</i> <a href="https://www.usitc.gov/intellectual_property/337_statistics_average_length_investigations.htm">https://www.usitc.gov/intellectual_property/337_statistics_average_length_investigations.htm</a>
2036	Pankow <i>et al.</i> , “Conversion of Nicotine in Tobacco Smoke to its Volatile and Available Free-Base Form through the Action of Gaseous Ammonia,” <i>Environ. Sci. Technol.</i> (1997) 31:2428-2433

## **I. Introduction**

If instituted, Petitioner's *inter partes* review ("IPR") request would initiate the third parallel proceeding involving the same patent claims and overlapping issues of validity. The most advanced of these proceedings is at the International Trade Commission ("ITC"), in which Patent Owner asserts the same patent against the same Petitioner and real-parties-in-interest. The ITC Evidentiary Hearing will be completed more than five weeks before the date for any potential IPR institution, and the ITC Final Initial Determination is scheduled for just one week after any Patent Owner Response would be due here. The Director's discretion to institute an AIA trial is informed by 35 U.S.C. § 316(b), which requires a consideration of "the economy, the integrity of the patent system, the efficient administration of the Office, and [its] ability ... to timely complete [IPR] proceedings." Adding yet another venue for Petitioner to assert redundant and largely duplicative §§ 102/103 challenges would not promote fairness or efficient administration of the Office. Accordingly, institution of the Petition should be denied on discretionary grounds.

Both of the references that Petitioner relies on to support its proposed Grounds, "Sebastian" (Ex1004) and "Lechuga-Ballesteros" (Ex1005), were before the Examiner and considered during prosecution of the '533 patent and related patents. Moreover, in the parties' parallel proceeding before the ITC, Petitioner currently asserts §§ 102/103 invalidity based on eight patent publications from the

*same* R.J. Reynolds Tobacco Co. (“RJR”) group as Sebastian – each of which are nearly identical to Sebastian in the main portions cited throughout the Petition. Likewise, Petitioner has disclosed the PCT publication of Lechuga-Ballesteros in the parallel ITC proceeding as allegedly invalidating art, and asserts §§ 102/103 invalidity based in part on the disclosures of Lechuga-Ballesteros. Thus, resolution of Petitioner’s art-based challenges will occur in the parallel ITC investigation far sooner than could occur in this PTAB proceeding. And, in an additional, parallel (and, at Petitioner’s election, unstayed) federal court proceeding in the United States District Court for the District of Arizona, Petitioner again challenges the ’533 patent on the same alleged art and same anticipation and obviousness arguments asserted in the ITC, plus more. It makes little sense for the PTAB to become the third tribunal to expend its time and resources adjudicating the validity of the ’533 patent on §§ 102/103 grounds, especially given the rapid pace and advanced stage of the ITC case, and Petitioner’s insistence on vigorously litigating the Arizona case in parallel.

Petitioner’s purported “stipulation” (Ex1030) would only further promote inefficiency. Instead of executing a *Sotera*-styled stipulation whereby a petitioner commits to forego *all* §§ 102/103 challenges in other proceedings that could have reasonably been raised in its petition (which would not shield the petition from discretionary denial, *see* Ex2002 at 2-3), Petitioner’s stipulation here would remove only “the prior art references *cited in this petition*” from the parallel proceedings,

and otherwise permits Petitioner to continue litigating §§ 102/103 invalidity in all proceedings – including based on similar patents and printed publications that Petitioner reasonably could have raised in the Petition. *See* Ex1030.<sup>1</sup> Petitioner’s watered-down stipulation only bolsters the case for a discretionary denial.

Finally, the Petition further merits discretionary denial because it rests on characterizations of the alleged prior art – including Sebastian and Lechuga-Ballesteros – that are directly contradicted by Petitioner’s past statements and representations made while trying to obtain its own patents on similar subject matter.

Accordingly, and as articulated further below, institution should be denied.

## **II. Background**

### **A. The Challenged ’533 Patent**

The ’533 patent, issued on December 3, 2024 claims priority back to U.S. Provisional App. No. 61/820,128, filed on May 6, 2013. The first U.S. patent in the family issued on December 22, 2015. Ex2003. Petitioner has been aware of this patent family since at least October 5, 2017. Ex2004 at 13 (citing US 2016/0044968).

The ’533 patent claims reflect Patent Owner’s novel concept of formulating the liquid that generates an inhalable aerosol upon heating in an electronic cigarette as a “*nicotine salt* liquid formulation” of nicotine and organic acid (benzoic acid or

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<sup>1</sup> Unless otherwise noted, all emphasis is added.

lactic acid) in a liquid carrier – such that the nicotine salt forms a substantial concentration of nicotine in the formulation (*e.g.*, 0.5% (w/w) to 20% (w/w)).

As of 2013, and even beyond, the conventional wisdom was that nicotine “free base” – *i.e.*, *un*protonated nicotine that is *not* in salt form – was critical to providing sufficiently satisfactory nicotine delivery, including from electronic cigarette devices that use heating to vaporize volatile liquids to produce inhalable aerosols. *See, e.g.*, Ex1001 at 7:52-8:8, 8:22-9:16; Ex2005 at 2; Ex2006 at 7; Ex2036 at 1-2.

Patent Owner, however, surprisingly discovered that nicotine salts of organic acids as claimed, when used in a liquid carrier to generate an inhalable aerosol upon heating in an electronic cigarette, provided pharmacodynamic and pharmacokinetic effects comparable to combustion cigarettes – resulting in comparable satisfaction of cravings. *See* Ex1001, 7:52-8:8, 8:22-9:16; *see also id.* 21:63-28:11 (Examples 2-8). Petitioner’s real-party-in-interest Altria Group, Inc. (“Altria”) has acknowledged the value of Patent Owner’s discovery before the U.S. Federal Trade Commission (“FTC”). Ex2007 at 14-15 (“[T]he ‘key’ to JUUL’s success was ‘its inclusion of nicotine salts’ (the product of nicotine mixed with an organic acid).”).

During prosecution, the ’533 patent Examiner initially issued rejections over Sebastian and Lechuga-Ballesteros, and ultimately found the claims patentable over the prior art. *E.g.*, Ex1002 at 283-290, 314, 382-384, 401, 523. For example, contrary to Petitioner’s positions here, the Examiner agreed that a POSA “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.” *See, e.g.*, Ex1002 at 314, 401.

**B. The Parallel ITC Investigation Soon Approaching Trial**

Patent Owner and Petitioner are parties to ITC Investigation No. 337-TA-1460 (the “Parallel ITC Investigation”), which Patent Owner initiated to stop Petitioner’s unlawful importation of products infringing the ’533 patent. Ex2008.

In the ITC, Petitioner has advanced a kaleidoscope of defenses against the ’533 patent, including at least 30 different § 102 grounds and hundreds of different § 103 combinations. Ex2009 at 25-26; Ex2017 at 4-6. Petitioner has reserved many grounds before the ITC that are redundant to the grounds proposed in the Petition. For example, Petitioner’s reliance here on the RJR patent application “Sebastian” is materially identical to how Petitioner relies on another RJR patent application, “Potter,” which serves as Petitioner’s primary §§ 102/103 reference in the ITC. *See* Ex2010; *infra* Section II.D. The portions of Potter and Sebastian central to Petitioner’s arguments are virtually identical, rendering meaningless Petitioner’s stipulation not to rely on Sebastian at the ITC if the Petition is instituted.

Petitioner’s ITC contentions also include seven additional RJR applications that are essentially identical to Sebastian and Potter in material portions, and at least six categories of “system art” (alleged prior products) that could not be asserted in

an IPR. Further, Petitioner challenges the '533 patent's priority date in the ITC (but not in the Petition) in an attempt to bring in even more purportedly invalidating art.

The Parallel ITC Investigation is already at an advanced stage, reflecting substantial investment by the parties. In particular,

- Claim construction proceedings are complete, and the ALJ has issued a claim construction order (siding with Patent Owner). Ex2011.
- The parties have produced ~475,000 documents; exchanged over 4,100 pages of contentions (including on §§ 102/103); served 48 interrogatories; and served nearly 2,600 requests for admission (over 1,800 by Petitioner).
- Initial expert reports will be exchanged in just over two weeks, and rebuttal expert reports will be complete around one month from today. *Id.*
- The evidentiary hearing is scheduled from April 22-28, 2026 – and the ALJ denied Petitioner's request to postpone that date. *Id.* at 3-4, 8; Ex2013 at 9. Post-trial briefing will be complete on May 28, 2026. Ex2012 at 8.
- The ALJ's Final Initial Determination is due September 11, 2026, and the ITC is scheduled to complete its investigation by January 12, 2027. *Id.*

The ITC thus outpaces this IPR proceeding at every stage. The Evidentiary Hearing and post-hearing briefing will be done *before* Institution (June 4, 2026). Paper 3; 35 U.S.C. § 314(b)(1). The ALJ's Final Initial Determination will issue one week after the Patent Owner Response (Sept. 4, 2026). 37 C.F.R. § 42.120(b)). The

Final Written Decision (“FWD”) would be due June 4, 2027 (35 U.S.C. § 316(a)(11)) – nearly *nine months after* the ALJ’s Final Initial Determination, and nearly *five months after* the ITC will have completed its Investigation. Ex2012 at 8.

**C. The Parallel District Court Action that Petitioner Refuses to Stay**

Patent Owner and Petitioner are also parties to a parallel proceeding captioned *JUUL Labs, Inc. v. NJOY, LLC et al.*, No. 2:25-cv-02853-JJT (D. Ariz.) (the “Parallel District Court Action”), in which Patent Owner asserts infringement of the ’533 patent, and Petitioner asserts defenses and counterclaims including invalidity.

Patent Owner filed simultaneous complaints in the Parallel District Court Action and the Parallel ITC Investigation, to preserve Patent Owner’s rights in each forum – including for money damages (not available in the ITC). Typically, defendants to district court proceedings that parallel an ITC investigation secure an automatic stay of the district court proceeding under 28 U.S.C. § 1659(a), which remains until the ITC’s determination becomes final. But Petitioner did the opposite – foregoing the automatic stay, and then *opposing* Patent Owner’s discretionary stay request made in the interest of efficiency and consistency. Ex2014; Ex2015.

The Arizona district court sided with Petitioner on the stay. Ex2016. As a result, the parties are actively litigating both at the ITC and district court – again involving similar if not identical issues. For example, in the Parallel District Court Action, Petitioner has served 157 written discovery requests; the parties have

exchanged detailed contentions on infringement and alleged invalidity (including Petitioner's re-assertion of its sprawling ITC positions); and Petitioner has served 19 subpoenas seeking documents from non-parties.

**D. The Art-Based Grounds Relied on in the Petition Are Substantially Duplicated in the Parallel Proceedings**

The Petition challenges the '533 patent on two Grounds: (1) § 102 anticipation of Claims 1-8 and 10 by the R.J. Reynolds Tobacco Co. ("RJR") patent application "Sebastian" (Ex1004) ("Ground 1"); and (2) § 103 obviousness of Claims 1-10 over Sebastian and Lechuga-Ballesteros (Ex1005) ("Ground 2"). *See* Paper 2 at 4.

The Petition substantially duplicates certain of Petitioner's extensive §§ 102/103 invalidity positions advanced in the Parallel Proceedings. For example, with respect to the "Sebastian" RJR application that is the cornerstone of Grounds 1 and 2, Petitioner intends to rely upon at least *eight other RJR patent applications* from the same RJR research group as Sebastian to support unconstrained § 102 and § 103 positions in the Parallel Proceedings. These other RJR references have disclosures *essentially identical* to the parts of Sebastian relied upon and central to the Petition. *See* Ex2017 at 4-6 (citing ITC Refs. A-4 and A-16 to A-22).

Paragraphs [0059]-[0061] of Sebastian (Ex1004) – which are central to Petitioner's contention that Sebastian "*inherently*" *discloses* the '533 patent's claimed nicotine salt liquid formulations of nicotine and lactic acid in the claimed

amounts/concentrations and liquid carriers (*see, e.g.*, Paper 2 at 15, 24, 26-30, 35, 37-38, 40, 43-46, 59-60, 65) – are nearly identical to the portions of the RJR applications Petitioner relies on in the Parallel Proceedings. *See* Ex2018 ¶¶[0049]-[0051]; Ex2019 ¶¶[0074]-[0077]; Ex2020 ¶¶[0043]-[0044], [0047]-[0048]; Ex2021 ¶¶[0105]-[0106], [0108]-[0109]; Ex2022 ¶¶[0051]-[0053]; Ex2023 ¶¶[0050]-[0051], [0054]-[0055]; Ex2024 ¶¶[0053]-[0055]; Ex2025 ¶¶[0086]-[0088].

Indeed, the “Potter” RJR application (Ex2018) is now Petitioner’s lead alleged §§ 102/103 reference in both the Parallel ITC Investigation and the Parallel District Court Action. *See, e.g.*, Ex2017 at 7-21, 35-40. As illustrated by a redline comparison of Sebastian ¶¶[0059]-[0061] to Potter ¶¶[0049]-[0051] – the substantive portions relied upon by Petitioner for its inherency argument are almost identical, and any differences in language (*e.g.*, replacing the word “can” with “may” in places) between them are minor and immaterial. Ex2010.

The same is true for the portions of the other seven RJR applications relied on by Petitioner – including, *e.g.*, Griffith (Ex2025). *See* Ex2026 (comparison of Sebastian to Griffith). In fact, during EPO Opposition in which Petitioner was defending its own EP patent claiming liquid formulations of nicotine and lactic acid (“Rabinowitz EP ’846,” Ex2027), the EPO disregarded the parties’ mix-up over whether the Opponent had challenged novelty based on Griffith (labeled “D8”) or the Sebastian PCT publication (Ex2028, labeled “D5”) – finding that Griffith and

Sebastian “have *very similar disclosures*,” and thus “*the assessment of novelty is not influenced* by” switching the two. Ex2029 at 84, 90.

With respect to Ground 2 (combining Sebastian with Lechuga-Ballesteros (Ex1005)), Petitioner relies on Lechuga-Ballesteros in the Parallel Proceedings as being allegedly incorporated by reference into “Brinkley” – another patent application relied upon by Petitioner for alleged §§ 102/103 positions in the Parallel Proceedings, including in combination with the RJR “Potter” application (Ex 2018). Ex2017 at 23-24; *id.* at 37-40. There is no reason to believe Petitioner would abandon Brinkley (or its purportedly incorporated references) upon Institution.

### **III. Argument**

#### **A. All *Fintiv* Factors Weigh Strongly in Favor of Denial**

The Petition should be denied in light of the Parallel ITC Investigation and Parallel District Court Action. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 2 (PTAB Mar. 20, 2020) (precedential, designated May 5, 2020).

Pursuant to 35 U.S.C. § 314(a), the Director has discretion to deny a petition based on parallel ITC or district court proceedings related to the same patent. *See* Ex2002 at 2; Ex2032 at 2. In *Fintiv*, the PTAB enumerated six non-dispositive factors to determine whether efficiency, fairness, and the merits support exercising discretion to deny institution. *Fintiv*, IPR2020-00019, Paper 11 at 5-6.

Here, assessment of the *Fintiv* factors in view of the Parallel ITC Investigation and Parallel District Court Action heavily weighs in favor of denying the Petition.

**1. Petitioner has not requested a stay from the ITC, and affirmatively opposes a stay in the District Court.**

Factor 1 weighs heavily against institution. With respect to the Parallel ITC Investigation, the ITC has not granted a stay, and Petitioner has not requested one, or said it would seek one. Also, it is highly unlikely that the ITC would issue a stay if the Director were to institute this Petition. *See* Ex2012 at 3-4; Ex2030. And in the District Court, Petitioner (1) intentionally abandoned its opportunity for an automatic statutory stay pending the ITC Investigation, and (2) successfully opposed Patent Owner's request for a discretionary stay. *See supra* Section II.C.

Thus, at Petitioner's insistence, the parties are actively litigating in two separate jurisdictions, over the same patent challenged in this Petition, and many of the same validity issues. Discretionary denial would prevent Petitioner from wasting the parties' and the Board's resources on issues being adjudicated elsewhere.

**2. The ITC Trial is scheduled for more than five weeks before the Institution date, and the ITC's Investigation will be completed nearly five months before the PTAB's FWD date.**

Factor 2 weighs heavily against institution because the Parallel ITC Investigation will be completed long before the FWD date. For example: (1) the ITC trial will be *more than thirteen months before* the FWD date; (2) the ALJ's Final Initial Determination will be *nearly nine months before* the FWD date; and (3) the

ITC will complete the Investigation *nearly five months before* the FWD date. Likewise, the upcoming trial (April 22, 2026) and post-hearing briefing will be complete before Institution. There is no reasonable likelihood that the ITC will reschedule these dates. Ex2012 at 3-4, 8; Ex2013 at 9; Ex2035; *supra* Section II.B.

The USPTO’s March 24, 2025 “Guidance on USPTO’s Recission of ‘Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation’” confirms that the *Fintiv* factors apply “when there is a parallel proceeding at the [ITC]” – especially “where the ITC has set a target date for completing its investigation ... to occur earlier than the Board’s deadline to issue a [FWD] in a challenge involving the same patent claims.” Ex2002 at 2.

That is the case here. Before potential institution, the parties and the ITC will already have completed all fact and expert discovery, claim construction, pre-trial submissions, the 5-day trial, and post-trial briefing. The only work left will be (1) the ALJ’s Final Initial Determination (*nearly nine months before* the FWD); and (2) the parties potentially seeking ITC review of the ALJ’s determinations, to be resolved by the January 12, 2027 Target Date (*nearly five months before* the FWD).

Factor 2 weighs heavily in favor of denying institution. *Milwaukee Elec. Tool Corp. v. Klein Tools, Inc.*, IPR2025-00724 *et seq.*, Paper 14 (Dir. Sep. 12, 2025).

- 3. By the date scheduled for Institution, the parties, the ITC, and the District Court will all have put substantial time and investment into the Parallel Proceedings.**

Factor 3, which considers “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision” (*Fintiv*, Paper 11 at 9), weighs heavily against institution. The parties, the ITC, and the District Court have already expended a great deal of time and resources in the Parallel Proceedings – and will expend substantially more before institution, including on the ITC trial and post-trial briefing. Ex2012 at 8; *supra* Sections II.B, II.C; *Milwaukee Elec. Tool Corp.*, IPR2025-00724 *et seq.*, Paper 14 at 3.

**4. The issues raised by the IPR substantially duplicate Petitioner’s defenses in the Parallel Proceedings.**

*Fintiv* Factor 4 weighs heavily against institution because, as detailed above, the Petition substantially duplicates Petitioner’s invalidity grounds in the Parallel Proceedings. *See supra* Section II.D; *Fintiv*, IPR2020-00019, Paper 11 at 12.

Moreover, in keeping with its toothless non-*Sotera* “stipulation” (Ex1030), Petitioner has shown every intention to pursue mirror-image invalidity challenges in the ITC, the district court, and the PTAB. There is no other way to understand Petitioner’s hollow promise to forgo only *Sebastian* in the Parallel Proceedings, while remaining free to rely on essentially identical disclosures from *Potter* (Petitioner’s lead §§ 102/103 reference in the Parallel Proceedings) and any of the seven other RJR applications that are interchangeable for purposes of Petitioner’s duplicative § 102 and § 103 arguments. *See* Ex2029 at 84, 90; *supra* Section II.D. Petitioner’s “stipulation” would also leave it free to rely on *Lechuga-Ballesteros* in

the Parallel Proceedings by citing to its PCT counterpart (Ex2031), or arguing that Lechuga-Ballesteros is “incorporated by reference” in other asserted patent publications. *See supra* Section II.D. Factor 4 weighs strongly in favor of denial.

**5. The parties are identical in the Parallel Proceedings.**

Patent Owner JUUL Labs, Inc. is Complainant in the Parallel ITC Investigation and Plaintiff in the Parallel District Court Action. Likewise, Petitioner NJOY, LLC and NJOY Holdings, Inc. (along with their real parties-in-interest Altria Group, Inc., Altria Group Distribution Company, and Altria Client Services LLC) are Respondents in the Parallel ITC Investigation and Defendants in the Parallel District Court Action. Factor 5 thus weighs heavily in favor of discretionary denial. *See, e.g., Apple Inc. v. Fintiv Inc.*, IPR2020-00019, Paper 15 (PTAB May 13, 2020) (informative, designated July 13, 2020), at 15.

**6. Other circumstances weigh in favor of denying Institution.**

Factor 6, considering other circumstances, likewise weighs toward denial.

**a. The timing of the Petition does not outweigh the other strong *Fintiv* Factors.**

The timing of the Petition relative to the issuance of the ’533 patent is not a significant factor here. In view of the Parallel Proceedings (*supra* Sections II.B-II.C., III.A.2), *Fintiv* considerations predominate to avoid significant duplication of effort, additional expense, risk of inconsistent decisions, and disregard for the parties’ substantial investment in the Parallel Proceedings. *See, e.g., Azurity*

*Pharms., Inc. v. Heron Therapeutics, Inc.*, PGR2025-00035 *et seq.*, Paper 11 (Dir. Aug. 14, 2025); *Milwaukee Elec. Tool Corp.*, IPR2025-00724 *et seq.*, Paper 14.

**b. Petitioner’s extensive reliance on conclusory expert testimony weighs in favor of denial.**

The Petition’s extensive reliance on expert testimony weighs toward discretionary denial of institution. *See* Ex2032 at 2. The Petition cites Dr. Martin Wensley’s declaration at least **213** times, and largely replicates Dr. Wensley’s declaration, including with (1) close paraphrasing or verbatim duplication, (2) parallel sentence-by-sentence structure, and (3) essentially identical characterizations and “quotations” of the alleged art, including emphasis. *See* Ex2033 (exemplary comparison of the Petition versus the Wensley Declaration). Such broad-reaching, unfocused expert testimony weighs in favor of denial.

The Petition likewise relies on conclusory assertions from Dr. Wensley to fill gaps in the alleged art. *See, e.g., Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, 15-17 (PTAB Aug. 24, 2022) (precedential, designated February 10, 2023). For example, the Petition essentially copies Dr. Wensley’s conclusory testimony that the alleged art discloses “nicotine” concentration ranges generally – but fails to explain how the art discloses that “***the salt is present in an amount that forms***” the claimed nicotine concentration ranges “***in the nicotine liquid salt formulation.***” Paper 2 at 38-40, 43-44, 67 (citing Ex1003 ¶¶93-95, 103-105, 161-162).

**c. The merits of the Petition are weak, and contradict Petitioner’s positions in prior proceedings.**

The Petition directly contradicts past statements made by Petitioner and its Real-Parties-in-Interest before the USPTO, the EPO, and in prior litigation.

**i. Petitioner’s IPR positions contradict positions previously taken at the USPTO and EPO.**

The Petition rests on characterizations of the alleged prior art – including Sebastian and Lechuga-Ballesteros – that are directly contradicted by Petitioner’s past representations while Petitioner was advocating to obtain its own patents purporting to claim liquid formulations of nicotine and lactic acid. *See, e.g.*, Ex2034 (“Rabinowitz ’470”), Claim 1; Rabinowitz EP ’846 (Ex2027), Claims 1, 5. Such double-speak further weighs in favor of denying institution. *See, e.g., Interactive Commc’ns Int’l, Inc. v. Blackhawk Network Inc.*, IPR2024-00465, Paper 40 at 3-4 (Dir. Oct. 9, 2025); *Sun Pharms. Indus. Inc. v. Nivagen Pharms., Inc.*, IPR2025-00893, Paper 18 (Dir. Sep. 19, 2025) (informative, designated Jan. 9, 2026).

**Petitioner’s Prior Arguments Regarding “Inherent Disclosure” of Lactic Acid in e-Liquids in the Claimed Amounts:** In the EPO Opposition to Petitioner’s Rabinowitz EP ’846 patent (Ex2027), the Opponent argued that Griffith ¶¶[0086]-[0088] (Ex2025, “D8”), and the mirror-image language in Sebastian PCT pp. 27-28 (Ex2028, “D5”), rendered the Rabinowitz EP ’846 claims not novel and obvious. *See, e.g.*, Ex2029 at 22, 31-32. In response, Petitioner admitted that Griffith

¶¶[0086]-[0088] (nearly identical to Sebastian ¶¶[0059]-[0061] asserted in the Petition) does not recite *any* liquid compositions with specific concentration ranges of nicotine in combination with lactic acid, propylene glycol, and glycerol:

*[T]he singling out of lactic acid from paragraph [0086] may not be combined with the specific composition described in paragraph [0088]. This is further demonstrated by ... paragraph [0087] ...:*

*“The aerosol precursor material may take on a variety of conformations based upon the various amounts of materials utilized therein.” (emphasis [by Petitioner])*

There is *nothing in [Griffith] that suggests* that one organic acid should be used or that *lactic acid should be the flavour* specified in the specific embodiment in paragraph [0088].

Ex2029 at 58-59 (emphasis added except where otherwise noted).

Thereafter, the EPO agreed with Petitioner that neither Sebastian nor Griffith anticipated the EP '846 claims directed to liquid formulations of nicotine and lactic acid in a liquid carrier. *Id.* at 90. Specifically, the EPO acknowledged: (1) “lactic acid is *not* directly and unambiguously disclosed in combination with the composition recited in [Sebastian PCT] p.28” (*i.e.*, Sebastian ¶¶[0061]; Griffith ¶¶[0088]), and (2) Petitioner’s claim reciting compositions of nicotine, lactic acid, and solvent was novel over the Sebastian PCT and Griffith. Ex2029 at 90.

Petitioner’s arguments advanced and accepted by the EPO regarding Sebastian and Griffith are the opposite of what Petitioner now says in order to allege

inherent anticipation over Sebastian in this proceeding. *See, e.g.*, Paper 2 at 15, 24, 26-30, 35, 37-38, 40, 43-46. Taking Petitioner at its word before the EPO, nothing in Sebastian supports Petitioner's new contention that "lactic acid" specifically can be read into Sebastian's every mention of generic "flavors."

**Petitioner's Prior Arguments Regarding Disclosure of "Equimolar"**

**Amounts of Nicotine and Acid:** The 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. *See* Paper 2 at 2, 26-29, 37, 60, 65. But during prosecution of its Rabinowitz '470 patent, Petitioner repeatedly said the opposite – arguing that *Sebastian does not teach an "equimolar" ratio of lactic acid to nicotine.*

For example, in defense of claims reciting "about 2:3 to about 1:1" lactic acid to nicotine, Petitioner argued that "Sebastian does **not** teach that the amount of lactic acid *alone* can range . . . up to an equimolar concentration." Ex2004 at 36, 46 (emphasis in original). Petitioner further presented a declaration from Dr. Walton Sumner, II, opining that: (1) "Sebastian **would not be understood by the [POSA]** as teaching that lactic acid may be present in a 1:1 molar ratio with nicotine"; and (2) "***There is little or no chance*** that a [POSA] would understand from Sebastian that any one or more ***organic acids in any concentration*** would favorably affect nicotine partitioning, deposition, or absorption." *Id.* at 66-68 (¶¶ 11, 15-16); *id.* at 98-102. Petitioner maintained these positions through allowance. *Id.* at 123-127, 149-150.

Petitioner again undermines its credibility by contradicting its own past positions before the USPTO, and by hiding those facts from the Petition.

**Petitioner’s Arguments Regarding the “Metered Dose Inhalers” of Lechuga-Ballesteros:** Petitioner’s Ground 2 asserts obviousness over Sebastian and Lechuga-Ballesteros, even though Lechuga-Ballesteros concerns an entirely different category of device: pressurized “metered dose inhalers” (“MDIs”) that disperse aerosol particles using a propellant. *See, e.g.*, Paper 2 at 3, 40-41, 46, 56, 59. But, when defending its own EP patent (Ex2027) against Opposition – Petitioner took exactly the opposite positions on Lechuga-Ballesteros that it takes here.

For example, Petitioner asserted in the EPO that the Lechuga-Ballesteros PCT (Ex2031, labeled “D3”) is “in a different technical field,” and that “the skilled person would not consider [Lechuga-Ballesteros] to be relevant prior art to vaping.” Ex2029 at 64, 67-68, 73. Petitioner further told the EPO that:

- “[N]othing in [Lechuga-Ballesteros] ... suggest[s] removing the essential propellant or to switch ... for a non-metered device”;
- “[Lechuga-Ballesteros] is *not related to the same purpose or effect* as the claimed invention in the patent”; and
- “[T]he skilled person *would not consider that [Lechuga-Ballesteros] is a relevant piece of prior art....*” *Id.* at 114-115.

Moreover, Petitioner told the EPO that (1) “[Lechuga-Ballesteros] refers to compositions for use in [MDIs],” (2) “[Sebastian] is not directed towards MDIs, and

does not require the use of a propellant,” and (3) [t]herefore, *the skilled person would not consider combining [Sebastian] with [Lechuga-Ballesteros].*” *Id.* at 70.

Again, Petitioner’s inconsistency and lack of candor merits denial of institution.

**ii. Petitioner’s IPR positions are contrary to those previously taken at the FTC.**

The Petition directly contradicts the past statements of Altria (Petitioner’s real party-in-interest) regarding the state of the art, which Altria made before the FTC while defending its 2018 investment of “\$12.8 billion to acquire 35 percent of [Patent Owner], the maker of JUUL, a leading e-vapor product.” Ex2007 at 6. For example, 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 provided by cigarettes.” *See, e.g.,* Ex2007 at 7, 14-15. Now, Petitioner argues that “using nicotine salts” in e-cigarettes was far from new. Paper 2 at 1-2. The Petition thus misleadingly ignores key “objective indicia” of nonobviousness – from a real-party-in-interest, no less. *See, e.g., LEO Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013). This is yet another reason discretionary denial is merited here.

**IV. Conclusion**

For at least the reasons above, Patent Owner respectfully requests that the Director and the Board exercise their discretion and deny institution of the Petition.

Respectfully submitted,

Dated: February 6, 2026

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**CERTIFICATE OF SERVICE**

I certify that a copy of Patent Owner's Request for Discretionary Denial of Institution was served by electronic mail on the following counsel of record:

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