

[REDACTED]

The evidence will show that NJOY indeed imports finished ACE products from its foreign contractors who manufacture and assemble such products, which are then shipped to NJOY's contracted third-party service providers for fulfillment and storage for meeting customer orders. *See, e.g.*, RX-1123C (Unangst Tr.) at 37:18-38:5, 41:20-43:3, 44:16-46:19, 48:13-49:18 (testifying that all components of ACE Pods [REDACTED]), 50:1-12 (testifying that [REDACTED] [REDACTED]), 157:11-158:22; RX-1130C (Silverman Tr.) at 23:15-23, 24:11-25:9 [REDACTED] [REDACTED] [REDACTED]; RX-1187C.55-56, .58; *see also* RX-1021C (Vander Veen Tr.) at 48:8-20 (acknowledging that [REDACTED] [REDACTED] 52:7-11 (admitting inability to [REDACTED] [REDACTED]). Notably, once sent to its third-party service providers, [REDACTED] [REDACTED] [REDACTED] *See* RX-1123C (Unangst Tr.) at 31:1-33:21.

Moreover, the specific line items included as alleged domestic industry investments for [REDACTED] [REDACTED] [REDACTED] *See* RX-0940C (Thomas Rpt.) at ¶ 76 (analyzing JX-0588C (NJOY_ITC Legal Request_Jan1_x270018-Dec31_x270023_2024.03.05 PM.xlsm)).

Therefore, NJOY fails to distinguish its supply chain, fulfillment, and storage activities from those of a mere importer to justify the inclusion of the resulting expenses. *See, e.g.,* RX-1022C (Thomas Tr.) at 60:22-61:4 (observing that [REDACTED]

[REDACTED]), 65:4-18.

d. Policy and Enforcement

Similarly, NJOY fails to demonstrate that its activities in the policy and enforcement category are cognizable domestic industry activities. *See* RX-0940C (Thomas Rpt.) at ¶¶ 78-79; RX-1022C (Thomas Tr.) at 70:3-23. NJOY asserts that its policy and enforcement activities

[REDACTED] NJOY has not provided any factual or legal support that such activities are not activities that a mere importer would be required to perform in order to legally sell products such as ACE in the United States. *See, e.g., In Vitro*, Inv. No. 337-TA-1196, Comm’n Op. at 20.

e. Customer Service

NJOY fails to present sufficient evidence to demonstrate that its claimed customer services expenses relate to cognizable activities for a domestic industry. *See* RX-0940C (Thomas Rpt.) at ¶¶ 81-83; RX-1022C (Thomas Tr.) at 76:20-77:4, 77:7-78:2, 78:22-79:5. The evidence will show at NJOY’s customer service activities are likely not technical in nature or otherwise qualifying but seem to only entail documenting customer inquiries and/or tied to sales support. *See, e.g.,* RX-1123C (Unangst Tr.) at 19:8-12, 20:16-21:16; RX-1022C (Thomas Tr.) at 71:23-24, 72:3-6; *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm’n Op. at 58 & 58

[REDACTED]

n.26 (Jan. 6, 2016) (crediting specifically “consumer technical service” and “warranty activities” that include “handling technical calls and facilitating the repair or replacement of any defective product or component under its warranty program” and not non-technical customer services).

For the five broad categories of expenses, NJOY has thus swept in a considerable amount of expenses for its alleged investments with no adequate evidentiary or legal support. With such improper over-inclusion, NJOY has grossly inflated its alleged investments, for the five categories of expenses also take up a considerable portion of the total investments claimed:

- [REDACTED]
- [REDACTED]

RX-0940C (Thomas Rpt.) at ¶¶ 84-86.

ii. NJOY Fails To Substantiate that Its Alleged Engineering and R&D Activities and Investments Are Related to ACE and/or [REDACTED]

NJOY’s unsubstantiated over-inclusion of expenses also taints its claimed engineering and R&D investments, especially when NJOY fails to show that the underlying engineering and R&D activities in fact relate in any way to ACE and/or [REDACTED] in the time periods considered, especially given that the ACE product has had no changes since NJOY purchased the [REDACTED] [REDACTED] and there is [REDACTED] product. *See id.* at ¶¶ 87-98. NJOY’s failure to meet its burden with respect to its alleged engineering and R&D investments is particularly problematic, for such investments pertain to all three subprongs and take up a sizeable share of the total domestic industry investments as alleged by NJOY:

[REDACTED]

[REDACTED]

Id. at ¶ 87.

To justify his inclusion of the engineering and R&D expenses as purportedly related to ACE and/or [REDACTED], Dr. Vander Veen relies almost exclusively on NJOY's own Complaint and contentions and from a "Conversation with Philippa Silverman." However, neither suffices for NJOY to meet its burden. *Id.* at ¶¶ 88-89. First, contentions are no substitutes for actual evidence. *See, e.g., Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) ("Attorney argument is not evidence."); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1284 (Fed. Cir. 2005) ("Attorney argument is no substitute for evidence."); *Certain Electronic Stud Finders, Metal Detectors and Electrical Scanners ("Electronic Stud Finders")*, Inv. No. 337-TA-1221, Order No. 42 at 4 (June 23, 2021) (precluding complaint from admitting and using its own "discovery responses and contentions" as substantive evidence). Second, at her deposition, Ms. Silverman made clear that she is not privy to the engineering and R&D activities at NJOY, including as to whether and how such activities might relate to ACE and/or [REDACTED], if at all. *See* RX-0940C (Thomas Rpt.) at ¶ 88; RX-1130C (Silverman Tr.) at 73:8-74:8, 74:20-75:13, 75:23-77:23. Yet Dr. Vander Veen is not able to justify his inclusion of various line items as [REDACTED] beyond parroting the barebone labels in JX-0588C (NJOY_ITC Legal Request_Jan1_x270018-Dec31_x270023_2024.03.05 PM.xlsm) designated by Ms. Silverman. *See, e.g.,* RX-1021C (Vander Veen Tr.) at 66:22-69:15, 73:15-74:12, 74:18-23, 75:20-77:1, 77:13-19. Among the line items claimed as investments without substantiation are, *e.g.*, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]”—for which Dr. Vander Veen was unable to provide any details of the testing described or how such testing could relate to R&D of ACE and/or [REDACTED]. *Id.*

Moreover, the evidence will show that NJOY has not in fact engaged in much R&D at least as to ACE since its acquisition of the design from [REDACTED]. RX-1123C (Unangst Tr.) at 86:14-87:1 (testifying *no knowledge* of [REDACTED] [REDACTED]); RX-1115C (Hawes Tr.) at 77:10-19, 84:12-25 [REDACTED] [REDACTED]); RX-1120C (Bonet Tr.) at 10:22-12:6, 204:11-18 (testifying that [REDACTED] as to ACE since NJOY [REDACTED] [REDACTED]; *see also* RX-1021C (Vander Veen Tr.) at 70:7-14 [REDACTED]

[REDACTED]

RX-0940C (Thomas Rpt.) at ¶ 90; RX-1491C (ACE Packaging Component Specification) (showing the [REDACTED]); RX-1488 (Vuse Overtakes Juul and Becomes the U.S Vaping Market Champion) (stating that NJOY Ace is [REDACTED] [REDACTED]. Similarly, the evidence will show that NJOY [REDACTED]

[REDACTED]

[REDACTED] *See, e.g.*, RX-1115C (Hawes Tr.) at 88:8-91:6 (noting that the only exception was [REDACTED]

[REDACTED]

[REDACTED] (noting that [REDACTED]

[REDACTED]

[REDACTED]”); *see also* CX-2327C (Vander Veen Rpt.) at ¶ 70 (expressly relinquishing any reliance on [REDACTED] In fact, NJOY’s

[REDACTED]

[REDACTED]

[REDACTED]. *See, e.g.*, RX-1112C (Feist Tr.) at 139:17-140:22, 144:25-145:12 (testifying that the e-liquids [REDACTED] now supplies to NJOY [REDACTED])

[REDACTED]

[REDACTED]

Likewise, NJOY fails to show that the specific [REDACTED] expenses claimed as [REDACTED] in fact relate to R&D activities in ACE and/or [REDACTED]. RX-0940C (Thomas Rpt.) at ¶¶ 93-95. For each of the three facilities underlying [REDACTED] [REDACTED] NJOY has failed to provide even basic information such as the addresses and square footage thereof, let alone explaining how such facilities are used for NJOY's R&D activities related to ACE and/or [REDACTED]. However, even public information casts strong doubts on the relevance of these three facilities: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] By contrast, NJOY's corporate deposition testimony suggest that its corporate designees, including Ms. Silverman, does not know what activities occur at any of Wisconsin facilities or how those activities are tied to ACE or [REDACTED]. *See, e.g.*, RX-1130C (Silverman Tr.) at 70:1-10, 70:22-71:9, 72:6-75:3 (testifying *inter alia* that she was [REDACTED])

[REDACTED]

[REDACTED]

[REDACTED]

Moreover, NJOY also appears to claim various asset costs without providing adequate, if any, support that such asset costs relate to its engineering and R&D activities. RX-0940C (Thomas Rpt.) at ¶ 96. For instance, NJOY's expert Dr. Vander Veen includes the following [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* (citing CX-2327C (Vander Veen Rpt.) at ¶ 80 and CX-2334C.4 (Vander Veen Rpt. Tab 7c)). Yet in Altria's profit and loss statement, Altria in fact categorizes many of NJOY's Engineering / R&D costs as part of the [REDACTED] *E.g.*, RX-1122C (Winch Tr.) at 94:4-18.

Furthermore, [REDACTED] of the claimed equipment expenses as set forth by Dr. Vander Veen relate to assets that have been disposed or fully depreciated. RX-0940C (Thomas Rpt.) at ¶ 97. The evidence will show that for NJOY, being disposed or fully depreciated means that the assets have [REDACTED]

[REDACTED] *E.g.*, RX-1130C (Silverman Tr.) at 133:10-134:12; RX-1123C (Unangst Tr.) at 135:2-16. Dr. Vander Veen fails to present any proper justification for his inclusion of such disposed or fully depreciated assets for the claimed domestic industry investments and instead simply ignores the disposal or depreciation status. RX-0940C (Thomas Rpt.) at ¶ 97; RX-1012C (Vander Veen Tr.) at 140:15-23 (admitting that he did not consider "[REDACTED]" [REDACTED] when evaluating equipment investments); RX-1022C (Thomas Tr.) at 90:10-19 [REDACTED]

iii. NJOY Fails to and Cannot Justify Its Reliance on E-Liquid Acquisition Costs and E-Liquid Exclusivity Acquisition Costs, or Its Severely Flawed and Unreliable Reliance on [REDACTED] Expenses in the Alternative

As part of its claimed capital investments, NJOY seeks to rely on expenses related to e-liquid either by (a) its own expenditures related to purchasing e-liquid from supplier [REDACTED] (b) its own expenditures to acquire IP rights to e-liquid formulations, or, alternatively, (c) the purported investments by e-liquid supplier [REDACTED] in manufacturing the same ACE e-liquids. NJOY fails to justify its reliance on any of the three categories of expenses, especially when the figures presented for these categories are themselves duplicative, flawed, and unreliable for the purpose of evaluating a domestic industry. *See* RX-0940C (Thomas Rpt.) at ¶¶ 99-115.

a. E-Liquid Acquisition Costs

NJOY relies on the [REDACTED] of its e-liquid purchase orders made to [REDACTED] for its claimed e-liquid acquisition costs. Case law abounds, however, holding that such generic purchase prices do not reflect relevant domestic industry investments. *See id.* at ¶ 107; CX-2335C.6 (Vander Veen Rpt. Tab 8c) (relying on the Tab [REDACTED] [REDACTED]); *Lelo Inc. v. Int’l Trade Comm’n*, 786 F.3d 879, 884 (Fed. Cir. 2015) (“These [generic] pricing data do not reflect the magnitude of labor expended to produce the components, or the amount the suppliers invested in their equipment to fulfill [complainant’s] orders. The record contains no data indicating the share of labor and capital costs attributable solely to purchases made by [complainant].”); *Certain Strontium-Rubidium, Radiosotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, Comm’n Op. at 40-41 (Dec. 11, 2019) (vacating “the FID’s findings with respect to the domestic industry under subsection 337(a)(3)(A)” based on

[REDACTED]

complainant’s payments to subcontractors, for which the FID “does not cite any evidence to support its finding that ‘a significance portion of the [said] payment represents a significant investment in plant and equipment” despite noting that such payment could also include payments for labor and for raw materials); *Collapsible Sockets*, Inv. No. 337-TA-1056, Comm’n Op. at 18-19 (refusing to credit complainant’s payments to third-party vendors and contractors “for assembly, as well as unidentified ‘other services’” where complainant fails to show “what portion of its payments ... pertains to labor or capital”).

b. [REDACTED] Purported Investments for Making ACE E-liquids

NJOY has not provided any basis for relying on the investments of [REDACTED] who is not a named complainant or a licensee to the Asserted Patents. *See, e.g.*, CX-0004C (Compl. Ex. 7C, Commission Rule 210.12(a)(9)(iii) Statement) [REDACTED]. Moreover, the evidence will show that the alleged e-liquid “manufacturing” of [REDACTED] itself largely resembles those of a mere importer, which should not qualify for domestic industry. *See, e.g.*, *Certain Vaporizer Cartridges and Components Thereof*, Inv. No. 337-TA-1211, Comm’n Op. at 7 n.13 (Mar. 1, 2022) (“Some portion of these activities may not be distinguishable from those of a mere importer and therefore may not be appropriate to credit in the economic prong analysis.”); *Certain Electronic Candle Products and Components Thereof*, Inv. No. 337-TA-1195, Comm’n Op. at 8 (Sept. 13, 2021) (“Congress did not intend to protect mere importers under section 337. ... Commission precedent requires that the evidence show qualifying investments in [the three statutory] categories with respect to the protected article.”) (citation omitted). Specifically, [REDACTED] so-called [REDACTED] [REDACTED] RX-1112C (Feist Tr.) at 51:23-52:2, 52:16-21 (admitting that [REDACTED] [REDACTED]; *see also id.* at 31:25-32:9, 32:12-33:2, 33:9-14, 35:18-36:18, 66:11-67:1,

75:16-76:17. Furthermore, it is undisputed that [REDACTED] only sells e-liquids and not ACE devices or ACE Pods. NJOY does not and cannot assert e-liquids to be “articles protected” by the Asserted Patents to qualify the investments in making e-liquids as relevant domestic industry investments and the asserted claims in this case. *See* 19 U.S.C. § 1337(a)(3) (requiring that the domestic industry be “with respect to the articles protected by the patent ...”); *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm’n Op. at 50 (Apr. 9, 2019) (“[T]he Commission has credited domestic investments when they are made with respect to an ‘essential,’ ‘necessary,’ and/or ‘integral’ part of the article covered by the patent claims and/or is ‘central to enabling’ exploitation of the article covered by the patent claims.”); *see also Certain Electronic Nicotine Delivery Systems and Components Thereof*, Inv. No. 337-TA-1139, Comm’n Op. at 7-8 (May 5, 2020) (“[T]he Commission declines to adopt the discussion of the quantitative significance of [complainant’s] *contract manufacturers’ investments*”) (emphasis added). Thus, even if any expenses related to e-liquids were to be considered (and they should not be), it is NJOY’s and not [REDACTED] purported investments that should be considered.

Moreover, [REDACTED] purported investments are unreliable. For its purported investments, [REDACTED] has only provided allocated figures that NJOY’s expert Dr. Vander Veen acknowledges to be based on [REDACTED]

[REDACTED] CX-2327C (Vander Veen Rpt.) at ¶ 74. However, [REDACTED] expressly refused to produce any of the underlying data, such as [REDACTED] which are maintained in [REDACTED] ordinary course of business, thereby insisting on keeping its allocation in black box and providing only documents specifically created for litigation. *See* RX-0940C (Thomas Rpt.) at ¶¶ 105-106; *see also, e.g.,* RX-1498C (Email from E. Heyer re: JLI Subpoena to [REDACTED] RX-

[REDACTED]

1112C [REDACTED] Tr.) at 46:8-24, 57:3-19, 60:8-61:6, 109:21-23, 150:17-150:17-25, 151:23-152:1; *see also id.* at 59:21-60:1 [REDACTED] *id.* at 114:2-5 (testifying that [REDACTED] does not [REDACTED] [REDACTED] in terms of tracking expenditures); *id.* at 123:23-124:9 (failing to provide [REDACTED] [REDACTED] *id.* at 126:2-6 (failing to provide [REDACTED] [REDACTED]); *see also* RX-1021C (Vander Veen Tr.) at 147:18-148:13, 149:5-150:23, 151:22-152:10; RX-1022C (Thomas Tr.) at 93:12-24 [REDACTED] [REDACTED] 94:12-18, 96:17-97:6, 97:10-24, 99:3-8, 139:25-140:23 (noting that [REDACTED] fails to provide even [REDACTED] [REDACTED] 141:2-17 (noting [REDACTED] refusal to provide [REDACTED]

The evidence will further show that as to the limited information that [REDACTED] did produce, many of [REDACTED] purported investments claimed by NJOY are expenses that plainly do not qualify for a domestic industry, including at least raw [REDACTED]. *See, e.g., Lelo*, 786 F.3d at 885 (“Though important, the ALJ’s analysis is incomplete as it does not account for the value expended on relevant domestic activities, as opposed to total profit or total general administrative costs.”); RX-1010C at ¶ 3; JX-0570C [REDACTED] RX-1123C (Unangst Tr.) at 53:9-16, 69:21-70:11; RX-1115C (Feist Tr.) at 32:12-33:2, 66:11-67:1, 75:16-76:17; RX-0815 (Website, Buy 100% Pure Menthol Crystals Usp Online - Mass Corporation). NJOY similarly fails to provide sufficient details to ascertain whether NJOY’s labor

[REDACTED]

expenses relate to activities and work by [REDACTED] employees that qualify for a domestic industry. The only job description produced by [REDACTED] contains merely aspirational statements about the desired skills, experience, and credentials of various positions and is not a description of what [REDACTED] current employees actually do. RX-1115C (Feist Tr.) at 42:13-17, 43:11-15. NJOY does concede, however, many of [REDACTED] [REDACTED]. CX-2327C (Vander Veen Rpt.) at ¶ 75 & n.217; RX-1021C (Vander Veen Tr.) at 154:6-155:9 (admitting the need to exclude more than a dozen line items under [REDACTED] [REDACTED] [REDACTED]; *see also* RX-0940C (Thomas Rpt.) at ¶¶ 109-110.

Notably, while already flawed and unreliable, [REDACTED] purported investments shows that from [REDACTED] [REDACTED] [REDACTED]. RX-0940C (Thomas Rpt.) at ¶ 108; JX-0570C [REDACTED] [REDACTED]; RX-1010C at ¶ 3; JX-0570C ([REDACTED] [REDACTED]); *see also, e.g.*, RX-1187C.55-56; RX-1492C.27 ([REDACTED] [REDACTED]) (noting that the [REDACTED] [REDACTED]); JX-0226 (Photo of 5 Pack NJOY Ace Pods Menthol) (“Liquid made in USA with domestic and imported ingredients.”); JX-0225 (Photo of 5 Pack NJOY Ace Pods Classic Tobacco) (same); JX-0490C (NJOY ACE PMTA, [REDACTED]; JX-0561C (NJOY ACE PMTA, [REDACTED]; RX-1021C (Vander Veen Tr.) at 111:12-112:17 (acknowledging that RX1010C, cited by his report, expressly indicate that the [REDACTED]); RX-1022C

[REDACTED]

(Thomas Tr.) at 142:2-24; *but see* CX-2327C (Vander Veen Rpt.) at ¶ 72. From 2018 to 2023,

[REDACTED]

[REDACTED]. JX-0570C ([REDACTED]); CX-2336C.10-11 (Vander Veen Rpt. Tab 9h) (compiling data set forth in JX-0570C); RX-1021C (Vander Veen Tr.) at 113:20-114:1

[REDACTED]; *see also* JX-0568 (Ma, Shaoying, et al., “The associations between e-liquid characteristics and its pricing: Evidence from online vape shops”). Indeed, about [REDACTED]

[REDACTED]. RX-0940C (Thomas Rpt.) at ¶ 108.

Therefore, NJOY’s alternative reliance on [REDACTED] purported investments in making the ACE e-liquids are legally unfounded and based on impermissible, unreliable, and overstated figures.

c. [REDACTED] Costs

NJOY seeks to also rely on a total of [REDACTED] for its [REDACTED] as part of its claimed domestic industry investments. NJOY does not and cannot provide any proper justification for including this irrelevant sum. *See, e.g.*, RX-1021C (Vander Veen Tr.) at 114:21-25. In fact, Dr. Vander Veen expressly conceded that such e-liquid exclusivity acquisition expenses may not be [REDACTED]

[REDACTED] *Id.* at 115:18-23.

Specifically, NJOY and [REDACTED] entered an [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. RX-0940C (Thomas Rpt.) at ¶ 114 (analyzing relevant line items on the Tab [REDACTED]

[REDACTED] To begin with, NJOY fails to establish that such [REDACTED] tied to invoices is not captured in full or in part within the [REDACTED] to assure no double counting. *Id.* In addition, there can be no dispute that this \$5 million sum does not tie to any manufacturing or R&D of ACE or [REDACTED] or other cognizable domestic industry activities. Instead, it appears to be merely a sum paid to secure [REDACTED] [REDACTED], which NJOY does not and cannot show to have resulted in any increase of investment of employment in the United States. *See Lelo*, 786 F.3d at 885; *see also, e.g.*, RX-1112C (Feist Tr.) at 146:24-147:2, 148:3-9 [REDACTED] [REDACTED]; *Certain Portable Battery Jump Starters and Components Thereof*, Inv. No. 337-TA-1256, Final ID at 362 (Apr. 29, 2022) (excluding “royalty payments ... based on product sales and not the hours of labor [the payees] performed”).

iv. NJOY Fails To Exclude Foreign Expenses from Its Alleged Domestic Industry Investments

The evidence will show that NJOY’s flawed and overstated domestic industry investments also include a considerable amount of expenses that appear to relate to foreign investments. The

Tab [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]), which NJOY asserts provide virtually all underlying data for its alleged domestic industry investments, indicates that for the claimed expenses, line items with at least the following foreign locations are included: [REDACTED]

[REDACTED] See JX-0588C

(Column AF marking as [REDACTED]

[REDACTED]; RX-0940C (Thomas Rpt.) at ¶ 123; *but see* CX-2327C (Vander Veen Rpt.) at ¶ 48 (stating that

the Tab [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED] More specifically, [REDACTED]

[REDACTED] and reflects products that are sent to or

warehoused outside of the United States (RX-1130C (Silverman Tr.) at 111:23-112:23); [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

NJOY fails to provide any proper justification for including such expenses tied to foreign locations as part of its alleged domestic industry investments. Such improperly included expenses are summarized as below, allocated to ACE and/or [REDACTED] according to NJOY's methodologies:

[REDACTED]

[REDACTED]

RX-0940 (Thomas Rpt.) at ¶ 124 & n.286 (analyzing [REDACTED]

[REDACTED].

3. NJOY Applies Flawed and Unreliable Allocation Methodologies To Allocate Its Expenses to ACE and/or [REDACTED]

As the evidence will show and as JLI's expert Mr. Thomas will opine, NJOY's allocation methodologies applied to its expenses to purportedly obtain investments allocable to ACE and/or [REDACTED] are flawed and unreliable, which further compounds NJOY's serious defects of including ineligible expenses from each of the selected categories of expenses. *See* RX-0940C (Thomas Rpt.) at ¶¶ 116-122; RX-1022C (Thomas Tr.) at 18:12-19:12, 20:10-21:2, 22:13-17, 22:21-23:2, 38:11-20. Because NJOY does not track its expenses on a product-specific basis in its ordinary course of business, for most of the expense categories considered, NJOY has to somehow allocate the recorded expenses to purportedly obtain domestic industry investments specific to ACE and/or [REDACTED]. *See* CX-2327C (Vander Veen Rpt.) at ¶¶ 50, 53, 59-60, 64-67; RX-1261C (Silverman Decl.) at ¶ 15 n.4 [REDACTED]

[REDACTED] For the myriad categories of expenses, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

i. Allocation Based on Unit Sales Volume

NJOY applies an allocation based on unit sales volume of ACE (and not [REDACTED]) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] See CX-2327C (Vander Veen Rpt.) at ¶¶ 50, 59, 64-65. While NJOY characterizes the allocated expenses in these categories as qualified domestic industry investments for both ACE and [REDACTED] a fundamental flaw of such a unit-based sales allocation exists when [REDACTED] is undisputedly not sold or on the market at any point during 2018 to 2023. See, e.g., CX-2327C (Vander Veen Rpt.) at ¶ 17 (alleging that [REDACTED] [REDACTED]); RX-1132C (Leistra Tr.) at 156:14-157:1 [REDACTED]). Thus, such a unit-based sales allocation cannot properly allocate any expenses in relation to [REDACTED] [REDACTED] RX-0940C (Thomas Rpt.) at ¶¶ 116, 118-119. As another fundamental flaw, NJOY also does not have any complete, reliable unit sales data to support its unit-based sales allocation. See RX-1130C (Silverman Tr.) at 196:20-197:22 (stating that the unit sales data underlying NJOY's belated allocation includes [REDACTED] beyond just wholesale); RX-1132C (Leistra Tr.) at 189:10-190:2, 192:8-20 (testifying that Altria does not have [REDACTED])

Moreover, the sales-based approach fails to properly reflect the reality with respect to any engineering and R&D activities (and the resulting investments). First, NJOY's purported allocation of its expenses under the categories [REDACTED] [REDACTED] capital contradicts the evidence that suggests there to be no further R&D

[REDACTED]

on ACE—NJOY’s sole domestic industry product that is commercially available, thus reflected in the unit sales data used for allocation—since NJOY’s acquisition of the ACE [REDACTED]

[REDACTED] *See, e.g.*, RX-1123C (Unangst Tr.) at 86:14-87:1 (testifying no knowledge of [REDACTED] RX-1115C (Hawes Tr.) at 77:10-19, 84:12-25 [REDACTED]

[REDACTED]); RX-1120C (Bonet Tr.) at 10:22-12:6, 204:11-18 (testifying that [REDACTED]

[REDACTED]

Second, NJOY’s use of a unit-based sales allocation fails to address any implicit time lag typically found between R&D activities and the actual product sales. Thus, by relying on a unit-based sales allocation, NJOY is implicitly but baselessly asserting that it is not involved in any new product development in the time periods considered that does not result in actual product sales—which again contradicts the evidence. For instance, NJOY’s expert Dr. Vander Veen alleges that [REDACTED]

[REDACTED]

[REDACTED] among other expenses. CX-2327C (Vander Veen Rpt.) at ¶ 36. In addition, the Tab [REDACTED]

[REDACTED]

[REDACTED] or non-domestic-industry products, a unit-based sales allocation cannot properly account for the relevant proportions of the recorded engineering and R&D expenses. RX-0940C (Thomas Rpt.) at ¶ 119.

Furthermore, a unit-based sales allocation serves to significantly skew the allocation in view of NJOY’s product mix, *i.e.*, allocating significantly more investments for the ACE Pods than both the ACE devices and non-ACE products. *Id.* at ¶ 120; RX-1022C (Thomas Tr.) at 40:24-41:7.

[REDACTED]

However, NJOY fails to justify this heavily skewed and inflated allocation towards ACE Pods, *e.g.*, by presenting any evidence to show that NJOY actually invests more heavily on the ACE Pods than any other products. RX-0940C (Thomas Rpt.) at ¶ 120; *cf.* RX-1130C (Silverman Tr.) at 192:12-193:9 (testifying that it [REDACTED] expenses between ACE Pods and ACE devices). As JLI's expert Mr. Thomas will opine, the unit-based sales allocation grossly inflates the allocated domestic industry investments, *e.g.*, [REDACTED]

[REDACTED]

ii. Allocation Based on Percentage Estimates

For other expense categories, NJOY applies an allocation based on percentage estimates of utilization and/or work time provided by certain employees. *See* CX-2327C (Vander Veen Rpt.) at ¶¶ 53, 60, 66-67. However, NJOY fails to provide any evidence to support or corroborate the reliability or reasonability of such seemingly arbitrary, individual-dictated percentage estimates. *See* RX-0940C (Thomas Rpt.) at ¶¶ 97, 121-122. As one specific example, for NJOY's asset costs claimed as equipment investments, NJOY applies the [REDACTED]

[REDACTED]

However, neither NJOY nor Dr. Vander Veen provides or is able to provide any insight as to the basis of these estimates, let alone attesting to their reasonability. *Id.* at ¶ 97; *see also, e.g.*, RX-1130C (Silverman Tr.) at 131:15-132:22 (testifying that she [REDACTED])

[REDACTED]

[REDACTED]

4. NJOY Fails To Establish a Nexus Between Its Alleged Domestic Industry Investments and the '864 Patent as to Subprong (C)

While NJOY asserts “substantial investments in the exploitation of the '864 Patent” as to ACE and [REDACTED] it fails to establish a nexus between the alleged investments and the '864 Patent. Having only acquired the '864 Patent on August 11, 2023, NJOY presents no justification to rely on its purported expenses before then as qualified [REDACTED] for a domestic industry. RX-1212C.27-28 (Patent Purchase Agreement between NJOY, LLC and Fuma International LLC); RX-0940C (Thomas Rpt.) at ¶ 127.

Moreover, NJOY relies solely on its expert Dr. Vallee’s conclusory opinions for alleging a nexus, which contradict both legal precedent and factual evidence. CX-2327C (Vander Veen Rpt.) at ¶ 79 (citing RX-1079C (Vallee Rpt.) at ¶¶ 2044-2048). First, Dr. Vallee’s ill-informed assertion that [REDACTED]

[REDACTED] does not suffice to establish the requisite nexus. *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm’n Op. at 49 (Aug. 22, 2014) (“[A]n investment in the article is not automatically an investment in the asserted patent. Were it so, it would impermissibly read out of subparagraph (a)(3)(C) the ‘its.’”). Second, as discussed in Section V.A.2.ii *supra* and as the evidence will show, NJOY fails to substantiate that its engineering and R&D investments (1) relate to ACE or [REDACTED] and (2) relate to cognizable activities. RX-0940C (Thomas Rpt.) at ¶ 128. For instance, even if any of the patented features are indeed practiced by ACE and/or [REDACTED] NJOY’s R&D efforts do not seem to be directed to such features. *See, e.g.*, RX-1115C (Hawes Tr.) at 79:5-10 (confirming that NJOY’s investments in the research and development of [REDACTED] *see also, e.g.*, RX-1120C (Bonet Tr.) at 215:7-11 (testifying that contrary to the '864 Patent, the heating element of the ACE Pod [REDACTED] In addition, the evidence

suggests that NJOY's engineers have [REDACTED]

[REDACTED] See, e.g., JX-0590C (NJOY Ace US Domestic Industry Summary 2018-2023) at Tab [REDACTED] RX-1130C (Silverman Tr.) at 154:4-18

[REDACTED] The evidence will also show that there does not seem to be any engineering and R&D on ACE since 2018, [REDACTED]. E.g., RX-1123C (Unangst Tr.) at 86:14-87:1; RX-1115C (Hawes Tr.) at 77:10-19, 84:12-25; RX-1120C (Bonet Tr.) at 10:22-12:6, 204:11-18.

5. NJOY Fails To Demonstrate that It Has Taken the Necessary Tangible Steps To Establish a Domestic Industry in the United States and Fails To Show that There Is a Significant Likelihood That The Domestic Industry Requirement for ACE and/or [REDACTED] Will Be Satisfied in the Future

As an alternative to its claim of an NJOY-based existing domestic industry, where the only relevant time period is merely eleven days, NJOY asserts that there exists a domestic industry in the process of being established based on its investments in [REDACTED]. See, e.g., CX-2327C (Vander Veen Rpt.) at ¶ 87. As a foundational defect, however, NJOY again fails to distinguish between the alleged activities and investments between ACE and [REDACTED] as discussed in Section V.A.1 *supra*; RX-0940C (Thomas Rpt.) at ¶ 137. NJOY's expert Dr. Vander Veen again seeks to improperly aggregate the alleged investments across ACE and [REDACTED], specifically (1) NJOY's 2023 year-end headcount; (2) its [REDACTED] and [REDACTED]; and (3) its projected expenses for the second half of 2023 and 2024 set forth in the Declaration of Lynn Winch (the "Winch Declaration" or "Winch Decl." RX-1324C)—all allegedly related to the "Domestic Industry Products" and not specifically ACE [REDACTED]. See CX-2327C (Vander

██████████

Veen Rpt.) at ¶¶ 83, 86; RX-0940C (Thomas Rpt.) at ¶ 137. The improper conflation of alleged investments between ACE and ██████████ defeats any meaningful evaluation of a domestic industry in the process of being established as to either product. More importantly, such conflation renders NJOY’s assertions as to ██████████ deficient and misleading, for the evidence will demonstrate that NJOY in fact has at best engaged in some limited activities in relation to ██████████ that neither amount to “necessary tangible steps” nor show “a significant likelihood that the industry requirement will be satisfied in the future.” *Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm’n Op. at 16-17.

To begin with, NJOY again relies on post-Complaint actual and projected expenses with no attempt to even justify such reliance, *e.g.*, through identification of any significant or unusual events after the filing of the Complaint. *Video Game Systems*, Inv. No. 337-TA-743, Comm’n Op. at 5 (“[A]s a general matter, the only activities that are relevant to the determination of whether a domestic industry exists or is in the process of being established are those that occurred before the complaint was filed.”); *Collapsible Sockets*, Inv. No. 337-TA-1056, Comm’n Op. at 14-15 (“The Commission has determined not to credit any of [complainant’s] expenditures that occurred after the filing of the complaint. [Complainant] ... does not identify any specific facts or circumstances, much less a significant and unusual development, to warrant considering expenditures after the filing of the complaint.”). Therefore, no alleged post-Complaint activities and investments should be credited for evaluating an NJOY-based domestic industry in the process of being established.

Even if any of the alleged post-Complaint activities and investments were to be considered (and they should not be), the evidence will show that such activities and investments are flawed and unreliable to support the showing of a domestic industry in the process of being established. As one example, NJOY’s expert Dr. Vander Veen appears to have merely summarized, but have

[REDACTED]

not analyzed or endorsed, the Winch Declaration that projects NJOY's expenses, indiscriminately for ACE and [REDACTED], through the second half of 2023 and 2024. CX-2327C (Vander Veen Rpt.) at ¶ 86. The evidence will show that the Winch Declaration is flawed and unreliable at least because: (1) it applies an abandoned, unreliable SKU-based allocation for the projected expenses, and not the unit-based sales allocation NJOY now relies on (*see, e.g.*, RX-1324C (Winch Decl.) at ¶ 5 n.1; RX-1388C.17-18, 20, 25, 38 (Complainant's Fifteenth Supplemental Objections and Responses to Respondent's First Set of Interrogatories)); (2) the Winch Declaration's projections are based on a [REDACTED] of already flawed allocation of actual expenses from the first half of 2023 without justification (*see, e.g.*, RX-1325C (NJOY ITC Legal Request Forecast for July 2023 through Dec 2024 (08/18/2023))); RX-1122C (Winch Tr.) at 126:13-128:12); (3) the Winch Declaration asserts various projected expenses and activities contradicted by the reality as shown by the evidence, including at least NJOY's continued failure to [REDACTED]

[REDACTED]

[REDACTED] (*see, e.g.*, RX-1130C (Silverman Tr.) at 65:3-67:7; RX-1123C (Unangst Tr.) at 40:21-41:11, 43:4-14, 62:15-21, 89:5-15); and (4) the Winch Declaration relies on sales forecast that has proven grossly inflated and unreliable. The evidence—including NJOY's multiple iterations of sales and demand forecasts and the deposition testimony of its corporate designees—will show that NJOY's sales and demand forecasts continue to drop drastically, rendering any projected expenses based thereon unreliable. *See, e.g.*, JX-0491C [REDACTED]

[REDACTED]

[REDACTED] with RX-1327C [REDACTED]

[REDACTED]); compare also JX-0491C [REDACTED]

[REDACTED]

[REDACTED]) and RX-1330C [REDACTED]

[REDACTED]

[REDACTED] with RX-1328C [REDACTED]

[REDACTED]

[REDACTED] compare also RX-1329C [REDACTED]

[REDACTED] with RX-1330C [REDACTED]

[REDACTED]

[REDACTED]; see also, e.g., RX-1123C (Unangst Tr.) at 143:13-146:5, 146:17-147:8, 148:17-149:3, 159:1-161:19; RX-1122C (Winch Tr.) at 159:15-160:7, 164:5-165:21, 167:1-13; *id.* at 29:17-30:13, 49:19-50:5, 160:16-161:24 (stating that Altria—and not NJOY—provides [REDACTED] in relation to NJOY’s financial plans); RX-1132C (Leistra Tr.) at 189:10-190:2, 192:8-20 (testifying that Altria does not have [REDACTED])

Apart from alleging activities and expenses improperly aggregated across ACE and [REDACTED] NJOY fails to present any evidence adequate to support a domestic industry in the process of being established for [REDACTED]. First, NJOY fails to show and indeed appears not to have taken necessary tangible steps to establish a domestic industry for [REDACTED] as the evidence will show and as JLI’s expert Mr. Thomas will opine. See RX-0940C (Thomas Rpt.) at ¶¶ 138-140. NJOY fails to present any evidence including, e.g., equipment orders, trial manufacturing runs, internal capex approvals, or board presentations, that may attest to whether NJOY has in fact committed to making any expenses for [REDACTED]. *Id.* at ¶ 138. Similarly, NJOY fails to present any evidence of actual expense that NJOY has made for [REDACTED] (if any at all), e.g., purchase of new equipment and custom components for manufacturing [REDACTED] custom tooling costs, or production line

planning costs. *Id.* In addition, despite acknowledging the importance of PMTA [REDACTED]
[REDACTED], NJOY's expert Dr. Vander
Veen concedes that [REDACTED]
[REDACTED]
[REDACTED] CX-2327C (Vander Veen Rpt.) at ¶ 84 n.230
(quoting RX-1130C (Silverman Tr.) at 65:3-17); *see also* RX-1261C (Confidential Declaration of
Philippa Silverman, "Silverman Declaration" or "Silverman Decl.") at ¶ 11. In fact, the evidence
will show that NJOY itself merely aspires to filing a [REDACTED]
[REDACTED]
[REDACTED]. RX-1132C (Leistra Tr.) at 151:3-153:3; RX-0940C
(Thomas Rpt.) at ¶ 140. Moreover, the evidence will show that NJOY is affirmatively holding off
any requests, let alone any investments, as to the commercial production of [REDACTED] pending this
indefinitely delayed PMTA process. *See, e.g.*, RX-1123C (Unangst Tr.) at 40:21-41:11 (testifying
on February 20, 2024 that NJOY does not anticipate to [REDACTED]
[REDACTED] within the next year), 43:4-14 (testifying that NJOY has not discussed selecting a [REDACTED]
[REDACTED], 62:15-21 (testifying that no component suppliers have been determined
for [REDACTED]), 89:5-15 (testifying that NJOY has not received a quote for
[REDACTED]), 110:11-18 (testifying that NJOY does not expect asking [REDACTED]
[REDACTED]
[REDACTED] (emphasis added). Indeed, NJOY admits that it does not anticipate
commercially launching [REDACTED]
[REDACTED]. RX-1132C (Leistra Tr.) at 156:14-157:11. For its latest iteration of financial
planning forecasts of January 2024, NJOY does not appear to even include [REDACTED] in its forecasts

that allegedly cover ten years into the future—through 2033 and include line items such as [REDACTED]
[REDACTED] RX-1122C (Winch Tr.) at 34:24-35:8, 41:23-42:4, 42:12-43:16.

Second, as to [REDACTED] the evidence will show that there does not seem to be a significant likelihood that the domestic industry requirement will be satisfied in the definite future either—and NJOY has not shown otherwise. *See* RX-0940C (Thomas Rpt.) at ¶¶ 141-146. NJOY fails to present any evidence on the likelihood of, *e.g.*, [REDACTED], which NJOY expressly concedes to be a crucial contingency, if not a prerequisite, for it to thereafter start planning the mass production and commercial launch of [REDACTED]. *See, e.g.*, RX-1123C (Unangst Tr.) at 40:21-41:11, 110:11-18.; RX-1132C (Leistra Tr.) at 156:14-157:11; *see also* RX-0940C (Thomas Rpt.) at ¶¶ 141-143. The evidence will show that even if NJOY were to [REDACTED]
[REDACTED]—a submission that itself has no reliable, definite timeline—the likelihood that it will receive the FDA approval thereof within the definite and near future is far from significant. *See, e.g.*, RX-0946.36 (Altria 2023 Form 10-K) (noting that four NJOY’s PMTAs submitted back in March 2020 remain “pending” now and that FDA has already “issued marketing denial orders (‘MDOs’) for four *NJOY ACE* and four *NJOY DAILY* flavored products”); RX-0940C (Thomas Rpt.) at ¶¶ 144-146.

Thus, NJOY fails to show that it “is taking the necessary tangible steps to establish such an industry in the United States” and that there will be “a significant likelihood that the industry requirement will be satisfied in the future.” *Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm’n Op. at 16-17. As JLI’s expert Mr. Thomas will opine, the evidence indicates just the opposite to NJOY’s claim of a domestic industry in the process of being established, especially as to [REDACTED]. *See* RX-0940C (Thomas Rpt.) at ¶¶ 136-146; RX-1022C (Thomas Tr.) at 132:15-25.

6. NJOY Fails To Demonstrate the Significance or Substantiality of Its Alleged Domestic Industry Investments for ACE and [REDACTED]

As the evidence will show and as JLI's expert Mr. Thomas will opine, NJOY fails to show through preponderance of evidence quantitative or qualitative significance and/or substantiality of its claimed investments. To begin with, NJOY's alleged domestic industry investments are already flawed, overstated, and unreliable, rendering any evaluation of such investments similarly flawed and unreliable—if not plainly meaningless. *See* RX-0940C (Thomas Rpt.) at ¶¶ 129-135; *see also*, *e.g.*, *Oil-Vaping Cartridges*, Inv. No. 337-TA-1286, Final ID at 101-102. Notably, even thus, NJOY's expert Dr. Vander Veen still fails to present any quantitative analysis of NJOY's alleged domestic industry investments under subprongs (B) or (C). *Id.* at ¶ 129; *see* CX-2327C (Vander Veen Rpt.) at ¶¶ 80, 108-109; CX-2338C (Vander Veen Rpt. Tab 11) (chart summarizing quantitative analysis as to [REDACTED] with no comparisons of total subprong (B) or (C) investments to any denominators at all); *see also*, *e.g.*, *Lelo*, 786 F.3d at 885 (holding that “qualitative factors alone are insufficient to show ‘significant investment in plant and equipment’ and ‘significant employment of labor or capital’ under prongs (A) and (B) of the § 337 domestic industry requirements” and that “[q]ualitative factors cannot compensate for quantitative data that indicate insignificant investment and employment”). Dr. Vander Veen has also admittedly but unjustifiably failed to perform any significance analysis in the context of the industry at large. RX-1012C (Vander Veen Tr.) at 176:22-177:5 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The significance and/or substantiality of alleged domestic industry investments ought to be analyzed [REDACTED] CX-2327C (Vander Veen

[REDACTED]

Rpt.) at ¶ 102; *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm’n Op. at 31 (Feb. 17, 2011) (“[T]he magnitude of the investment cannot be assessed without consideration of the nature and importance of the complainant’s activities to the patented products in the context of the marketplace or industry in question.”). However, Dr. Vander Veen fails to at all evaluate NJOY’s alleged domestic industry investments in the pertinent marketplace or industry. Instead, Dr. Vander Veen’s only reference to “marketplace” is a baseless and irrelevant statement that “NJOY’s engineering and R&D work is fundamental to the existence and continued competitiveness of the NJOY D.I. Products in the marketplace.” RX-0940C (Thomas Rpt.) at ¶ 131 (discussing CX-2327C (Vander Veen Rpt.) at ¶¶ 36 n.86, 107). While irrelevant to the significance of NJOY’s alleged investments relative to the marketplace, this statement is also a verbatim copy-and-paste from NJOY’s contentions that itself cites no evidentiary support whatsoever. *See* RX-1387C.40 (Complainant’s Sixteenth Supplemental Objections and Responses to Respondent’s First Set of Interrogatories); *see also Icon Health*, 849 F.3d at 1043 (“Attorney argument is not evidence.”); *Enzo Biochem*, 424 F.3d at 1284 (“Attorney argument is no substitute for evidence.”); *Electronic Stud Finders*, Inv. No. 337-TA-1221, Order No. 42 at 4 (precluding complaint from admitting and using its own “discovery responses and contentions” as substantive evidence). As JLI’s expert Mr. Thomas will opine, the evidence further undermines NJOY’s barebone and baseless assertion of any significance in view of the marketplace and the industry. As just one example, unlike NJOY [REDACTED]

[REDACTED], JLI has chosen to develop and assemble its products in the United States. *See, e.g., JX-0587C* (Inv. No. 337-TA-1368 Expert Report of Carla S. Mulhern).

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at ¶ 4; RX-0940C (Thomas Rpt.) at ¶ 131.

Similarly, NJOY's reliance on its domestic employee headcount in certain departments to allege significance is inapposite in the context of both the industry at large and NJOY itself. NJOY contends that as of 2023, it has a total of [REDACTED] working in the six departments allegedly relevant to the domestic industry, *i.e.* [REDACTED]

[REDACTED] CX-2327C (Vander Veen Rpt.) at ¶ 104. By stark contrast to the industry, however, this headcount appears to be at best trivial. For example, NJOY's parent company Altria employs around 6,000 employees (97% of whom are in the United States). RX-0947.5 (Corporate Fact Sheet - Altria). As another example, Philip Morris International, Inc. employs around 79,800 employees worldwide. RX-0814.3. Even in the much narrower context of NJOY itself, this total of [REDACTED] fails to establish significance. To begin with, as discussed in Sections V.A.2.i and V.A.2.ii *supra*, NJOY fails to substantiate that the six departments selected (and thus their employees) perform activities cognizable for a domestic industry. RX-0940C (Thomas Rpt.) at ¶ 130. In addition, NJOY's reliance on this total, unallocated headcount is without justification when NJOY itself does not and cannot allege that all these [REDACTED] exclusively work on ACE or [REDACTED]. *Id.* Thus, NJOY's comparison of this headcount to the number of its foreign employees is also plainly flawed. *Id.* Conspicuously missing from Dr. Vander Veen headcount analysis is any comparison to [REDACTED]

[REDACTED] *Id.*; RX-1021C (Vander Veen Tr.) at 171:2-21, 174:8-24 (admitting lack of knowledge as to [REDACTED])

[REDACTED] The omission is telling, for [REDACTED] alone employed [REDACTED] in [REDACTED] in 2022—many of which worked on manufacturing and assembling ACE. RX-1493C.25

[REDACTED]; *see also* RX-1012C (Vander Veen Tr.) at 174:15-176:9. Moreover, as conceded by Dr. Vander Veen, even this much overstated headcount has dropped considerably from [REDACTED] all while NJOY asserts a domestic industry in the process of being established. *Id.*; CX-2327C (Vander Veen Rpt.) at ¶ 104. Furthermore, generalized metrics such as this headcount not even tied to NJOY's alleged domestic industry investments cannot plausibly shed any light on the quantitative or qualitative significance or substantiality, let alone Dr. Vander Veen's baseless assertion that these employees "are critical to the success of [NJOY's] Domestic Industry Products." CX-2327C (Vander Veen Rpt.) at ¶ 104.

NJOY's comparison of the ACE sales to NJOY's domestic revenues also fails to establish the significance and/or substantiality of its alleged domestic industry investments. *See* RX-0940C (Thomas Rpt.) at ¶ 132; *see also, e.g., Certain Earpiece Devices and Components Thereof*, Inv. No. 337-TA-1121, Comm'n Op. at 18 (Nov. 8, 2019) ("[S]ales-based comparison of the [asserted] patent's contribution to the investments for [the] domestic industry products does not provide context of the company's operations, the marketplace, or the industry in question necessary to understand whether the relative value of [the] domestic activities and investments is significant or substantial."). Indeed, NJOY's expert Dr. Vander Veen precisely fails to consider the sales of ACE (and [REDACTED] if any at all) in the context of the marketplace or the industry. For instance, Altria's total revenue was \$24.5 billion in 2023, which plainly dwarfs the alleged total ACE sales. *See* RX-0940C (Thomas Rpt.) at ¶ 132 (citing RX-0946.58 (Altria 2023 Form 10-K)). Similarly, as Dr. Vander Veen himself asserts but fails to consider for his significance analysis, the e-cigarette market was \$22 billion in 2022 and the pod-based ENDS device market alone was \$2.5 billion in 2023. *Id.* (quoting CX-2327C (Vander Veen Rpt.) at ¶ 28; *see also* RX-1012C (Vander Veen Tr.)

[REDACTED]

at 176:22-178:11; JX-0566.1 (Yahoo Finance, “E-Cigarette Market Size is to be Worth \$168.96 Billion by 2030 with a CAGR of 28.9%, Says Beyond Market Insights”).

The few quantitative comparisons set forth by Dr. Vander Veen do not suffice to establish the requisite quantitative significance of NJOY’s alleged domestic industry investments either. *See* RX-0940C (Thomas Rpt.) at ¶ 133. First, as to the numerators (*i.e.*, the alleged domestic industry investments), the same defects that permeate NJOY’s quantification of its alleged investments as discussed above taint any quantitative significance analysis based thereon. *Id.* Relatedly, when limited the relevant time period of [REDACTED], despite NJOY’s improper inflation efforts, its alleged investments appear minimal and, in some cases, were plainly non-existent and cannot plausibly be considered significant by any measure. *See, e.g.*, CX-2327C (Vander Veen Rpt.) at ¶ 81; RX-1021C (Vander Veen Tr.) at 138:23-139:11 (evading opining whether a total of zero investments between [REDACTED] in fixed assets could be qualitatively or quantitatively significant). Second, as to the denominators, Dr. Vander Veen fails to set forth or analyze various relevant figures, including for example all foreign activities (and resulting investments) related to ACE and/or [REDACTED] and the time lag between e-liquid manufacturing and the subsequent manufacturing (and ultimate sale) of ACE ([REDACTED] *Id.*; RX-1022C (Thomas Tr.) at 123:25-124:2. When limited to the relevant time period of [REDACTED], Dr. Vander Veen further conceded that there can hardly be reliable significance analysis, especially if one is to limit the denominator(s) to the same [REDACTED]. RX-1021C (Vander Veen Tr.) at 164:11-

20 [REDACTED]

[REDACTED] Third, Dr. Vander Veen admittedly fails to perform any value-add analysis, which is especially relevant and probative [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. *See, e.g.*, RX-1012C (Vander Veen Tr.) at 171:12-21 (acknowledging that foreign third-party labor [REDACTED], 178:12-19 [REDACTED]
[REDACTED]); RX-1130C (Silverman Tr.) at 23:21-23, 24:16-23, 134:13-136:20 (testifying that NJOY’s total [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]; RX-1187C.55-56 (identifying [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]”); RX-1123C (Unangst Tr.) at 37:18-38:5, 41:20-43:3, 44:16-46:19, 48:13-49:18 ([REDACTED]
[REDACTED]), 50:1-12 [REDACTED]
[REDACTED]
157:11-158:22; RX-1130C (Silverman Tr.) at 23:15-23, 24:11-25:9 [REDACTED]
[REDACTED]
[REDACTED]
26:8-28:21 (testifying that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]; *see also, e.g., Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm’n Op. at 18 (Oct. 28, 2019) (“[T]he Commission has instead sought to place the value of domestic investments in the context of the relevant marketplace, such as by comparing

a complainant's domestic expenditures to its foreign expenditures or considering the value added to the product from a complainant's activities in the United States.”).

Lastly, NJOY's failure to break down its alleged domestic industry investments between ACE and [REDACTED] also defeats meaningful significance and substantiality evaluation, especially if one of the two shall be found relevant for a domestic industry in the process of being established. *See* RX-0940C (Thomas Rpt.) at ¶¶ 134-135; *see also, e.g., Certain Non-Volatile Memory Devices and Products Containing the Same*, Inv. 337-TA-1046, Comm. Op. at 41 (Oct. 26, 2018) (holding that “emergent industry must prove that it has significant or substantial investments or employment in the United States ‘with respect to articles protected by the patent’ as recited in the statute.”).

B. NJOY Fails to Show That a Domestic Industry Exists Based on RJR's Activities

NJOY does not claim any domestic industry as to the '881 Patent based on its own products. *See, e.g.,* CX-2327C (Vander Veen Rpt.) at ¶¶ 15, 18. Instead, NJOY relies exclusively on RJR's Vuse Solo products for claiming a domestic industry as to the '881 Patent. *Id.* at ¶ 18. NJOY relies on both Vuse Solo and Vuse Alto for its claim of a domestic industry as to the '864 Patent. *Id.*³⁶

However, the record is devoid of critical evidence specific to RJR's U.S. investments in Vuse Solo (or Vuse Alto) products, as NJOY itself admits. *See, e.g.,* Complainant's Motion to Certify a Request for Judicial Enforcement of a Subpoena (“NJOY's Motion to Enforce”), EDIS Doc. ID 816376 at 7 (Mar. 19, 2024) (“The documents produced by RJRV for expenditures from 2020 to 2023 are at such a high level that it is impossible to tell what the expenditures are for.”). NJOY's expert Dr. Vander Veen has given up on any attempt to quantify RJR's investments as to

³⁶ As to Vuse Solo, NJOY asserts that both generations (G1 and G2) practice the Asserted Patents—but as the evidence will show, NJOY fails to and cannot set forth relevant, quantified investments in Vuse Solo G1 or G2 in this Investigation, respectively, thereby failing to provide a basis to properly evaluate a domestic industry based thereon.

Vuse Solo or Vuse Alto on and after [REDACTED]

[REDACTED]. CX-0019C (Compl. Ex. 22C, Confidential Settlement and License Agreement); CX-2327C (Vander Veen Rpt.) at ¶¶ 88-101; RX-1012C (Vander Veen Tr.) at 23:19-25:1, 180:21-182:2. In fact, Dr. Vander Veen admitted that he has not “provid[ed] an analysis, other than summarizing the information” and has not “expressly assert[ed] the opinion that [RJR’s] investments are qualitatively and quantitatively significant.” RX-1012C (Vander Veen Tr.) at 24:14-23; CX-2327C (Vander Veen Rpt.) at ¶¶ 6, 121 (not mentioning RJR at all).

To obscure his failure to even provide a conclusive opinion as to—let alone establishing—an RJR-based domestic industry based on Vuse Solo and Vuse Alto products, NJOY’s expert Dr. Vander Veen quotes with zero analysis the aggregate, non-product-specific figures in the Declaration of Valerie Mras (the “Mras Declaration” or “Mras Decl.”) filed in Inv. No. 337-TA-1381. *See* CX-2327C (Vander Veen Rpt.) at ¶ 100 (quoting JX-0582C (Mras Decl.)). Dr. Vander Veen recounts at length the irrelevant and outdated financial figures allegedly related to Vuse Solo products in Inv. No. 337-TA-1199³⁷—all of which predate RJR’s entry into a license to the Asserted Patents. CX-0019C (Compl. Ex. 22C, Confidential Settlement and License Agreement); *see* CX-2327C (Vander Veen Rpt.) at ¶¶ 88-98 (acknowledging that the figures recited from Inv. No. 337-TA-1199 cover only through “June 2020”); RX-1012C (Vander Veen Tr.) at 184:2-5, 185:2-187:4 (testifying that he has no definitive knowledge of whether any of the activities relating to Vuse Solo discussed in Inv. No. 337-TA-1199 still existed as of August 21, 2023). Neither approach substitutes for a preponderance of evidence, specific to Vuse Solo and Vuse Alto and in relation to the Asserted Patents, which is required for NJOY to establish an RJR-based domestic industry in

³⁷ Vuse Alto was not at issue in Inv. No. 337-TA-1199. *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. at 12-13 (Oct. 19, 2021) (noting that Vuse Solo and Vuse Vibe are the only two domestic industry products).

[REDACTED]

this Investigation. *Electronic Candle*, Inv. No. 337-TA-1195, Comm’n Op. at 11; *Certain Replacement Automotive Lamps (II)* (“*Replacement Automotive Lamps*”), Inv. No. 337-TA-1292, Comm’n Op. at 29-31 (Mar. 22, 2024) (collecting Commission and Federal Circuit precedents in support of the long-standing principle that “[t]he economic prong of the domestic industry requirement must be shown on a patent-by-patent basis, and it is not appropriate to aggregate investments directed to different articles protected by different patents for determining significance”).

NJOY’s claim of an RJR-based domestic industry is thus neither supported by documentary evidence from RJR regarding its investments in the relevant period nor even backed by its own expert’s opinion and analysis—the epitome of baseless assertions. Therefore, for this reason alone, there can be no reasonable dispute that NJOY has plainly failed to satisfy its burden to establish an economic domestic industry based on RJR’s activities and investments in this Investigation.

1. NJOY’s Reliance on Inv. No. 337-TA-1199 Is Improper and Fails to Satisfy Its Burden to Prove an Existing Domestic Industry Based on RJR’s Activities

NJOY’s fixated emphasis on the Commission’s finding of a domestic industry in Inv. No. 337-TA-1199, based in part on RJR’s investments in Vuse Solo, is inapposite and irrelevant. *Certain Collapsible Sockets for Mobile Electronic Devices and Components Thereof*, Inv. No. 337-TA-1056, Comm’n Op. at 19 (July 9, 2018) (holding that as to domestic industry, “the analysis has always been conducted on a case-by-case basis”).

As a foundation defect, NJOY’s reliance on any domestic industry discussion from Inv. No. 337-TA-1199 is improper also in view of the irrelevant time period: as Dr. Vander Veen admits, the domestic-industry-related figures from Inv. No. 337-TA-1199 cover only [REDACTED]
[REDACTED]. CX-2327C (Vander Veen Rpt.) at ¶¶ 88-98 (acknowledging that the figures recited from Inv. No. 337-TA-1199 cover

only through [REDACTED] CX-0019C (Compl. Ex. 22C, Confidential Settlement and License Agreement); *see also* RX-0940C (Thomas Rpt.) at ¶ 151. In addition, at all times from 2012 through June 2020, *i.e.*, the time period discussed in Inv. No. 337-TA-1199, RJR remained an infringer as alleged by Fuma (then owner of the Asserted Patents), which renders its expenses unqualified for a domestic industry. *See, e.g., Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188, Comm’n Op. at 14 (finding that absent a license, a company “is nothing more than an infringer, which cannot be part of the industry”); *Power Semiconductors*, Inv. No. 337-TA-1308, Final ID at 116-117 (noting that “the Commission has consistently excluded such [pre-license] expenditures”).

Moreover, NJOY fails to provide any evidence that RJR’s activities and investments related to Vuse Solo, as discussed in Inv. No. 337-TA-1199, has continued after June 2020 and through at least the filing of the Complaint. NJOY’s expert Dr. Vander Veen asserts “[u]pon information and belief” and with no evidence that RJR has continued investing in Vuse Solo and Vuse Alto. The only specific “example” that Dr. Vander Veen presents—that RJR “continues to manufacture” Vuse Solo and Vuse Alto “at its 2 million square foot manufacturing plant located in North Carolina”—is based solely on NJOY’s own contentions that similarly lacks support. CX-2327C (Vander Veen Rpt.) at ¶ 98 & n.262 (citing RX-1388C.66 (Complainant’s Fifteenth Supplemental Objections and Responses to Respondent’s First Set of Interrogatories), which in turn cites CX-0022C); CX-0022C (Compl. Ex. 25C, Journal Now “Reynolds’ Vuse e-cigarette continues to expand market-share lead”) (public webpage dated December 14, 2022 with zero mention of Vuse Solo and Vuse Alto and where they are manufactured); *see also* RX-0940C (Thomas Rpt.) at ¶ 152. While absent from Dr. Vander Veen’s analysis, the RJR-produced evidence appears to show that RJR may have ceased investing in Vuse Solo, at least as to the category of [REDACTED]. RX-0945C [REDACTED]

[REDACTED]; RX-0940C (Thomas Rpt.) at ¶ 152.

2. NJOY’s Reliance on the Mras Declaration Filed in Inv. No. 337-TA-1381 Is Improper and Does Not Prove an Existing Domestic Industry

As a preliminary matter, NJOY should be precluded from relying on the Mras Declaration, for Ms. Mras has not sat for any deposition in this Investigation. *Certain Devices for Mobile Data Communication*, Inv. No. 337-TA-809, Order No. 58 at 5 (Oct. 11, 2012) (excluding a declaration where the declarant “was not deposed” and it was “agreed that he would not be called to testify at the hearing”); *Certain Raised Garden Beds and Components Thereof*, Inv. No. 337-TA-1334, Order No. 25 at 4-5 (May 19, 2023) (excluding declarations where the declarants had not been identified on a witness list or deposed).

Even if the Mras Declaration were to be considered, NJOY’s wholesale adoption of the aggregate figures therein—across four different Vuse products (including RJR products not alleged to practice the Asserted Patents in this Investigation), and the entire four-year period 2019 to 2022—fails to support any meaningful consideration of the relevant investments under Section 337. *See* JX-0582C (Mras Decl.); RX-0940C (Thomas Rpt.) at ¶¶ 154-156; *see also, e.g., Replacement Automotive Lamps*, Inv. No. 337-TA-1292, Comm’n Op. at 30 (“Commission precedent also demonstrates that aggregating investments in articles that *are* protected by a specific patent with investments in articles that *are not* protected by that patent precludes meaningful consideration of the relevant investments under section 337.”) (emphases in original). As NJOY’s expert Dr. Vander Veen conceded: “When you use aggregate numbers, it masks what’s going on in the underlying data ... it makes it hard to understand what’s going on.” RX-1021C (Vander Veen Tr.) at 144:6-12.

First, the Mras Declaration—which NJOY merely regurgitates without any analysis—only sets forth alleged aggregate expenses across the entire four-year period of 2019 to 2022. For the same reasons discussed above, at least RJR’s pre-license expenses [REDACTED]

[REDACTED] should not be considered. CX-0019C (Compl. Ex. 22C, Confidential Settlement and License Agreement). *Power Semiconductors*, Inv. No. 337-TA-1308, Final ID at 116-117; *Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188, Comm’n Op. at 14. However, NJOY fails to exclude such ineligible expenses and in fact even fails to present RJR’s expenses on a yearly basis. Instead, NJOY merely regurgitates RJR’s aggregate expenses, spanning 2019 to 2022, from the Mras Declaration that purportedly relate to [REDACTED]

[REDACTED] JX-0582C (Mras Decl.); CX-2327C (Vander Veen Rpt.) at ¶¶ 99-100; *see also* RX-0940C (Thomas Rpt.) at ¶ 156. NJOY’s expert Dr. Vander Veen fails to cite—let alone analyze—a single RJR document that RJR has identified as allegedly underlying the Mras Declaration. *See* CX-2327C (Vander Veen Rpt.) at ¶¶ 99-100; RX-1011 (identifying RJR-produced documents for “the data underlying the Mras Declaration from the 1381 Investigation). Moreover, the evidence will show that NJOY’s lumping of four-year expenses across four Vuse products serves to hide critical facts suggesting against an existing RJR-based domestic industry. [REDACTED]

[REDACTED] RX-0945C [REDACTED]

[REDACTED]; *see also* RX-0940C (Thomas Rpt.) at ¶ 152 & n.342. [REDACTED]

[REDACTED] may suggest actual or imminent discontinuation of the product, on which no domestic industry should be found. NJOY fails to present any contrary

evidence or any evidence as to whether the activities described in the Mras Declaration continued to exist from 2022 through at least August 22, 2023, *i.e.*, the filing of the Complaint. RX-1012C (Vander Veen Tr.) at 184:2-5, 185:2-187:4; *see also* RX-0940C (Thomas Rpt.) at ¶ 156.

Second, as NJOY's expert Dr. Vander Veen admits, the Mras Declaration only provides purported expenses related to the "VUSE Products" that collectively "refer to the VUSE Alto, VUSE Vibe, VUSE Ciro, and VUSE Solo." CX-2327C (Vander Veen Rpt.) at ¶ 100 n.264 (citing JX-0582C (Mras Decl.)). Such improperly aggregated expenses for all four of RJR's Vuse products present no meaningful basis for evaluating an RJR-based domestic industry covering only Vuse Solo and Vuse Alto as alleged by NJOY in this Investigation. RX-0940C (Thomas Rpt.) at ¶ 155; *Replacement Automotive Lamps*, Inv. No. 337-TA-1292, Comm'n Op. at 30.

Third, NJOY has failed to provide any details to demonstrate that such expenses exclude expenses tied to non-qualifying activities. The barebone descriptions in the Mras Declaration fail to show that the claimed expenses qualify, or whether and how such expenses are tracked in RJR's ordinary course of business and what they encompass. *See* JX-0582C (Mras Decl.). As just one example, NJOY fails to confirm whether any of the aggregate figures presented by Dr. Vander Veen covers foreign expenses (standalone or embedded in certain non-descriptive categories) or generic expenses that do not relate at all to Vuse Alto and Vuse Solo. Similarly, NJOY fails to furnish any substantive details regarding the activities associated with such expenses, when the Mras Declaration merely mentions generic categories of possible expenses, indiscriminately, for four Vuse products. *Id.*

3. NJOY Fails To Quantify and Substantiate RJR's Alleged Domestic Industry Investments Specific to Vuse Solo and Vuse Alto in This Investigation

The evidence will show that NJOY utterly fails to quantify any alleged domestic industry investments specific to Vuse Solo and Vuse Alto, in this Investigation, during the relevant time

period from November 29, 2021 to August 22, 2023. *See, e.g.*, CX-2327C (Vander Veen Rpt.) at ¶¶ 88-101; RX-0940C (Thomas Rpt.) at ¶¶ 157-158; *see also* RX-1387C.13-44 (Complainant's Sixteenth Supplemental Objections and Responses to Respondent's First Set of Interrogatories) (NJOY's contentions on domestic industry economic prong). Nor is NJOY able to, as its expert Dr. Vander Veen repeatedly emphasized. *See, e.g.*, RX-1012C (Vander Veen Tr.) at 181:14-182:2 ("I don't believe RJR has produced any information so far in this case. So other than what's cited here in the report, I don't believe I've seen any other RJR information."); 185:12-13 ("[T]here's a request to receive information from RJR. And I don't believe they've produced it so far."); 185:22-23 ("[W]ithout information provided by RJR, there's only so much you can do."); 187:3-4 ("Again, I believe RJR's been asked to provide information, and they've refused to do so."); *see also* NJOY's Motion to Enforce, EDIS Doc. ID 816376 at 7 ("The documents produced by RJRV for expenditures from 2020 to 2023 are at such a high level that it is impossible to tell what the expenditures are for.").

Among Njoya's unequivocally admitted failures to at all quantify RJR's domestic industry investments in this Investigation are, for example, failures to: (1) quantify under subprongs (A), (B), or (C), (2) quantify as to each of the two Asserted Patents, and (3) quantify as to Vuse Solo and Vuse Alto products, respectively. RX-0940C (Thomas Rpt.) at ¶ 157. NJOY also fails to present any nexus analysis for a domestic industry under subprong (C), and NJOY cannot do so when it does not and cannot even allocate any expenses to specific Vuse Solo and Vuse Alto products. *See, e.g., Integrated Circuit Chips*, Inv. No. 337-TA-859, Comm'n Op. at 38 ("[U]nder subparagraph (C), the complainant must establish that there is a nexus between the claimed investment and the asserted patent[.]"); *id.* at 49 ("[A]n investment in the article is not

automatically an investment in the asserted patent. Were it so, it would impermissibly read out of subparagraph (a)(3)(C) the ‘its.’”).

NJOY’s failure to allocate the claimed expenses to Vuse Alto and Vuse Solo is also fatal to its already deficient, if not non-existent, analysis of the significance and/or substantiality of an RJR-based domestic industry. *See, e.g., Oil-Vaping Cartridges*, Inv. No. 337-TA-1286, Final ID at 101-102. NJOY’s expert Dr. Vander Veen conceded that he has not “expressly assert[ed] the opinion that [RJR’s] investments are qualitatively and quantitatively significant.” RX-1012C (Vander Veen Tr.) at 24:14-23. NJOY’s contentions—not supported even by its own expert—fare no better with its conclusory assertions of significance. *See, e.g., RX-1387C.33* (Complainant’s Sixteenth Supplemental Objections and Responses to Respondent’s First Set of Interrogatories) (asserting, based on the Mras Declaration, qualitative significance “because [RJR’s investments in the Vuse Solo and Vuse Alto] relate to critical aspects of the products, including [REDACTED] [REDACTED]” and quantitative significance because such investments “[REDACTED] [REDACTED]”). Neither of NJOY’s two assertions comes even close to the requisite analysis. First, the sole apparent support NJOY has for its assertions, the Mras Declaration, does just the opposite by indiscriminately discussing activities and expenses related to four different Vuse products. In other words, NJOY precisely fails to any claimed expenses related to Vuse Alto and/or Vuse Solo “in the context of the company’s operations,” let alone in the context of “the marketplace, or the industry in question.” *Certain Solid State Storage Drives, Stacked Electronics Components, and Prods. Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at 33 (June 29, 2018). Second, having failed to quantify RJR’s expenses related to Vuse Alto and Vuse Solo and thus to provide even an “absolute value” of investments therein, NJOY baselessly asserts that RJR’s investments therein “[REDACTED].”

RX-1387C.33 (Complainant's Sixteenth Supplemental Objections and Responses to Respondent's First Set of Interrogatories). NJOY is alleging exactly an "abstract" figure that does not qualify for any significance or substantiality analysis. *See Printing and Imaging Devices*, Inv. No. 337-TA-690, Comm'n Op. at 26 ("[W]hether the complainant's investment and/or employment activities are 'significant' is not measured in the abstract or in an absolute sense."); *Certain Earpiece Devices and Components Thereof*, Inv. No. 337-TA-1121, Comm'n Op. at 19 (Nov. 8, 2019) ("[The] Commission has never 'determined the quantitative significance of a complainant's domestic industry investments based solely on the absolute value of those investments.'").

VI. REMEDY AND BONDING

A. Limited Exclusion Order

While JLI expects to prove that no remedy is appropriate, to the extent an LEO shall issue, it should contain a certification provision that would allow JLI to certify that imported products are not subject to the LEO, which is "necessary to minimize the possibility that non-infringing products will be excluded from entry into the United States" *Certain Digital Televisions and Products Containing Same and Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op. at 11 (Apr. 23, 2009) (citation omitted); *see also Certain Wearable Electronic Devices with ECG Functionality and Components Thereof* ("Wearable Electronic Devices"), Inv. No. 337-TA-1266, Comm'n Op. at 50 (Jan. 20, 2023) (agreeing that "the LEO should include the standard certification provision"); *Certain Composite Aerogel Insulation Materials and Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm'n Op. at 62 (Feb. 22, 2018) ("[T]he Commission's standard practice for the past several years [has been] to include certification provisions in exclusion orders to aid CBP."). Moreover, to the extent an LEO issues, it should contain a certification provision that would allow JLI to certify that imported products or components are for products that are not for sale in the U.S. market, but are only destined for sale in markets overseas, which would be

appropriate for products that are not sold in, or compete in, the United States. Such entry does not and is not likely to adversely affect NJOY, and NJOY has not shown and cannot show otherwise. *See Certain Devices for Connecting Computer via Telephone Lines* (“*Devices for Connecting Computer*”), Inv. No. 337-TA-360, Comm’n Op. at 10 (Nov. 18, 1994) (“A complainant that seeks exclusion of other types of entry [other than entry for consumption] should present evidence that activities by respondents involving other types of entry either are adversely affecting it or are likely to do so.”).

Furthermore, any LEO should include an exception for service, repair, and replacement, which will permit JLI to continue servicing its customers’ products. *See, e.g., CX2357.4*. Such an exception is necessary here to avoid impairing the utility of JLI products already imported and/or purchased prior to the expiration of the period of presidential review. *Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 50 (granting an exception under the LEO “for articles or components imported for use in servicing, repairing, replacing covered articles that were imported prior to the effective date of [the LEO] pursuant to existing service and warranty contracts”), 51 (finding that public interest factors warrant such an exception for service and repair). In addition, any LEO should also include an exception for compliance verification testing necessary for sales of JLI’s products overseas. *See, e.g., RX0320C.44; Magnetic Data Storage Tapes*, Inv. No. 337-TA-1012, Comm’n Op. at 132 .

B. Cease and Desist Order

For the same reasons stated above, any CDO should also include an exception for service, repair, and replacement for JLI products imported and/or purchased prior to the expiration of the period of presidential review, *i.e.*, prior to the effective date of any CDO. *See, e.g., Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, Comm’n Op. at 72-73 (granting a “service, repair, and replacement exemption for infringing

articles purchased prior to the expiration of the period of Presidential review”); *Certain Microfluidic Systems and Components Thereof and Products Containing the Same*, Inv. No. 337-TA-1100 (granting the same service and repair exception for the LEO and CDO).

In addition, any CDO should also include an exception for compliance verification testing necessary for sales of JLI’s products overseas. *See, e.g., Certain Magnetic Data Storage Tapes and Cartridges*, Inv. No. 337-TA-1012, Comm’n Op. at 132. As record evidence will demonstrate, NJOY has not shown and cannot show that such an exception for compliance verification testing would adversely affect it. *See id.* (citing *Devices for Connecting Computer*, Inv. No. 337-TA-360, Comm’n Op. at 10).

C. Bond

No bond should issue in this Investigation because NJOY has not shown and cannot show any injury from which they require protection in the form of a bond. *See, e.g., Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm’n Op., 2019 WL 2635509 at *44-45 (Apr. 9, 2019) (imposing zero bond during Presidential review period where Complainant failed to show bond is warranted). Moreover, NJOY fails to substantiate any support for a bond rate to apply in this Investigation. For example, in comparing prices of the (i) JUUL System and NJOY ACE System, (ii) JUULpods and NJOY ACE pods, and (iii) JUUL Device and NJOY ACE Device, NJOY either provides no comparison at all, or offers flawed comparisons, each of which is explained below. Thus, because NJOY has not met and cannot meet its burden to support a bond at any amount, no bond should issue in this Investigation. *See, e.g., Certain Coenzyme Q10 Products and Methods of Making Same*, Inv. No. 337-TA-790, Final ID at 380 (Sept. 27, 2012) (unreviewed in relevant part) (recommending no bond because complainant “failed in its burden to demonstrate the appropriate bond amount”).

First, as to comparing prices of the JUUL System and NJOY Ace System, NJOY fails to offer any price comparison at all. Instead, NJOY's comparisons only consider the prices of the devices and pods separately, and NJOY's expert, Dr. Vander Veen, fails to offer a bond rate for JUULpods. CX-2327C (Vander Veen Rpt.) at ¶¶ 119-120; *see also* RX-1021C (Vander Veen Tr.) at 189:12-15 (conceding that he is not recommending a bond rate for JUUL pods).

Second, as to comparing prices of the JUULpods and NJOY ACE pods, NJOY's expert, Dr. Vander Veen, conceded that NJOY is not recommending a bond rate for JUUL pods. RX-1021C (Vander Veen Tr.) at 189:12-15. In any event, publicly available information shows that the NJOY ACE pods are sold at a lower price than the JUULpods. As noted above, this evidence alone is sufficient to deny any bond. *See Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Comm'n Op. at 67 (June 20, 2019) (finding no bond for accused products priced higher than domestic industry products). For example, NJOY's menthol and classic tobacco ACE pods are each sold on the Electronic Tobacconist website for \$6.99 for a pack of one and \$9.99 for a pack of two. RX-0956 (NJOY ACE POD Classic Tobacco - Electric Tobacconist); RX-0957 (NJOY ACE POD Menthol - Electric Tobacconist); RX-0958 (NJOY ACE PODS Classic Tobacco - Electric Tobacconist); RX-0959 (NJOY ACE PODS Menthol - Electric Tobacconist); *see also* RX-0940C (Thomas Rpt.) at ¶ 163. These pods each contain 1.9 mL of e-liquid, implying a price for NJOY Ace pods per mL of \$3.68 for the pack of one and \$2.63 for a pack of two. *Id.* JUUL's menthol and Virginia tobacco pods, which each contain 0.7 mL of e-liquid, are sold on the Electronic Tobacconist as a 4 pack for \$20.99 and as a 2 pack for \$12.79, indicating a price per mL of \$7.50 and \$9.14, respectively. RX-0953 (JUUL Menthol Pods (4) - Electric Tobacconist USA); RX-0954; RX-0236 ("Virginia Tobacco," JUUL Shop); RX-0234 ("Menthol," JUUL Shop); *see also* RX-0940C (Thomas Rpt.) at ¶ 163. JUUL's menthol and Virginia tobacco

[REDACTED]

pods are sold on JUUL’s website as a 4 pack for \$19.99 and as a 2 pack for \$12.29, indicating a price per mL of \$7.14 and \$8.78, respectively. RX-0235 (4-pack of Menthol JUULpods); RX-0237 (4-pack of Virginia Tobacco JUULpods); RX-0234 (2-pack of Menthol JUULpods); RX-0236 (2-pack of Virginia Tobacco JUULpods).

These facts belie NJOY’s contentions that JLI “undercuts” NJOY’s pricing. RX-1402C.85-88 (Complainant’s First Supplemental Objections and Responses to Respondent’s First Set of Interrogatories). In those contentions, NJOY employed a price comparison of different quantity pod packs between NJOY and JUUL which was misleading and unreliable. *Id.* (e.g., alleging that a 4-pack of JUULpods is \$18.99 as opposed to \$20.99 (RX-0235 (4-pack of Menthol JUULpods); RX-0237 (4-pack of Virginia Tobacco JUULpods)) and ignoring the fact that the price of a 2-pack of JUULpods is typically \$12.79, which is *more* than a 2-pack of NJOY ACE pods. RX-0234 (2-pack of Menthol JUULpods); RX-0236 (2-pack of Virginia Tobacco JUULpods)).

In its second supplemental bond contentions, NJOY stated that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RX-1388C.94-96 (NJOY’s Fifteenth Supplemental Objections and Responses to Respondent’s First Set of Interrogatories). NJOY’s contentions failed to offer any support for the proposed revenue comparison.

Dr. Vander Veen set forth a flawed price differential methodology, claiming that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX-2327C (Vander Veen Rpt.) at ¶ 118. Dr.

[REDACTED]

Vander Veen claims that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].” CX-2327C (Vander Veen Rpt.) at ¶ 119. Dr. Vander Veen determines [REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at ¶¶ 119-120; *see also* RX-1021C (Vander Veen Tr.) at 189:12-15 (conceding that he is not recommending a bond rate for JUUL pods).

Furthermore, as even Dr. Vander Veen recognizes, his methodology does not take into account “many factors” such as “taxes,” “discounts, bundles and other promotions,” “clearance sales[,]” and “different product combinations such as bundles or other promotions.” *Id.* at ¶ 120; *see also* RX-0940C (Thomas Rpt.) at ¶ 161. Dr. Vander Veen’s comparison further does not take into account differences in the amount of e-liquid in the pods and the number of pods in a pack. Notably, NJOY analyzes price per pod based on the volume of liquid in the pods on a mL basis. RX-1132C (Leistra Tr.) at 108:9-22. JUULpods and NJOY ACE Pods are generally sold with 0.7 mL and 1.9 mL of liquid in each pod, respectively. RX-0953 (JUULpods); RX-0244 (NJOY ACE Pods); *see also* RX-0940C (Thomas Rpt.) at ¶ 163. Converting the per-pod average wholesale revenue to average wholesale revenue per mL, wholesale sales of NJOY ACE Pods generated [REDACTED] in revenue, compared with JUUL’s [REDACTED] per mL in Q3 2023. JX-0584C ([REDACTED] [REDACTED]); JX-0586C ([REDACTED] [REDACTED]); JX-0592C (NJOY Quarterly Sales Data 2020-2023); JX-0593C (NJOY Average Quarterly Pricing 2023).

[REDACTED]

Third, as to comparing prices of the JUUL Device and NJOY ACE Device, publicly available information shows that the NJOY ACE is sold at a price lower than (or, at most, equal to) the JUUL Device. For example, the Electric Tobacconist sells the NJOY ACE for \$9.99 and the JUUL Device for \$19.99. RX-0955 (NJOY ACE Device Kit, Electric Tobacconist); RX-0952 (JUUL Device, Electronic Tobacconist); RX-0952 (About Us, Electric Tobacconist USA); *see also* RX-0940C (Thomas Rpt.) at ¶ 163. This evidence alone is sufficient to deny any bond. *See Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Comm’n Op. at 67 (June 20, 2019) (finding no bond for accused products priced higher than domestic industry products).

NJOY’s first supplemental contentions were silent as to comparison of devices, likely because the JUUL Device typically sells for as high as \$19.99, which is *more* than the price of the NJOY ACE device (approximately \$9.99). RX-0952 (JUUL Device); RX-0955 (NJOY ACE Device). In NJOY’s second supplemental bond contentions, NJOY alleged that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RX-1388C.94-96 (NJOY’s Fifteenth Supplemental Objections and Responses to Respondent’s First Set of Interrogatories). NJOY’s contentions failed to offer any support for the proposed revenue comparison.

As with the JUULpods and NJOY ACE pods, Dr. Vander Veen set forth a flawed price differential methodology for the devices, based on his calculation of wholesale pricing during Q3 2023. CX-2327C (Vander Veen Rpt.) at ¶ 118. According to Dr. Vander Veen, in Q3 2023, [REDACTED]

[REDACTED] and “[t]he wholesale price of JLI’s JUUL

System device is [REDACTED] CX-2327C (Vander Veen Rpt.) at ¶ 119. Thus, Dr. Vander Veen opines,

[REDACTED] at ¶¶ 119-120.

To begin with, Dr. Vander Veen uses flawed source data and precisely fails to perform an apples-to-apples comparison: while he relies on NJOY's assessment of [REDACTED]

[REDACTED] he uses JLI's "Net Revenue" to purportedly calculate the JUUL System unit price. However, JLI's "Net Revenue" includes [REDACTED]

[REDACTED]. See JX-0584C; JX-0586C; *see also* CX-2327C (Vander Veen Rpt.) at ¶ 120 n.300

([REDACTED]). As the evidence will show and as JLI's expert Mr. Thomas will opine, Dr. Vander Veen's failure to conduct an apples-to-apples comparison renders his price differential analysis flawed and unreliable. RX-1022C (Thomas Tr.) at 149:9-17 ("For Juul [Dr. Vander Veen is] using [REDACTED] and for NJOY he's not ... he's simply just accepting the numbers that were provided without endeavoring to make any sort of adjustments one way or another."), 135:16-20 (noting that Dr. Vander Veen "acknowledges that he's relying on a price difference that isn't an apples-to-apples comparison," which is inappropriate), 136:22-25, 138:15-18, 148:5-15 (same).

Dr. Vander Veen's comparison similarly fails to account for evidence of discounting of the NJOY ACE. For example, NJOY has offered promotions during which the NJOY ACE was available at a retail price of \$0.99 and a wholesale price of \$0.66 (from Q1 2022 through at least

[REDACTED]

Q4 2023), which is significantly lower than the NJOY ACE's average wholesale revenue per unit of \$6.08 in Q3 2023 and significantly lower than JLI's average wholesale revenue per unit for the JUUL Device of [REDACTED]. CX-2327C (Vander Veen Rpt.) at ¶ 119. Notably, Dr. Vander Veen's own price comparison shows examples of [REDACTED]. For example, Dr. Vander Veen's analysis of the [REDACTED]

[REDACTED]

[REDACTED]

CX-2339C.1 (Vander Veen Rpt. Tab 12a) (referencing "JUUL – ACE Device Wholesale Price Differential" ranging from \$0.44 to \$2.67); RX-0940C (Thomas Rpt.) at ¶ 162; *see also* RX-1021C (Vander Veen Tr.) at 196:21-197:17 (conceding that "I've not reached an opinion on what the appropriate time period is. Certainly, I've laid out comparisons in this case, in my report here, for 2020 to 2023" despite relying exclusively on Q3 2023 for his recommended bond rate); *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Comm'n Op. at 67 (June 20, 2019) (finding no bond for accused products priced higher than domestic industry products).

Moreover, the failure to establish that a bond is necessary to protect NJOY from injury during Presidential review means that there should be no bond. *See e.g., Certain Electronic Devices with Multi-Touch Enabled Touch Pads and Touchscreens*, Inv. No. 337-TA-714, Initial Determination at 76-77 (Apr. 29, 2011) (no bond where complainant failed to provide any evidence of competitive injury). No bond is appropriate here because it is not necessary to "protect the complainant from any injury." 19 U.S.C. § 1337(j); 19 C.F.R. § 210.50.

VII. PUBLIC INTEREST

A. Harms Presented by Combustible Cigarettes and JLI's Innovations in Harm Reduction

As of 2021, there were an estimated *35.1 million combustible cigarette smokers* in the United States. JX-0254.1 (Cornelius et al., Tobacco Product Use Among Adults – United States, 2021 MMWR Morbidity and Mortality Weekly Report). The FDA has identified at least 250 chemicals in combustible cigarette smoke that are harmful to health. JX-0244 (CDC, Health Effects of Cigarette Smoking (2020)); JX-0095.13 (Amicus Brief of Abrams, Ballin, Bates, Jarvis, Sweanor (July 5, 2022)). As the FDA has explained, “[w]hile nicotine is what addicts and keeps people using tobacco products, it is not what makes tobacco use so deadly. Tobacco and tobacco smoke contain thousands of chemicals. This mix of chemicals—not nicotine—is what causes serious disease and death in tobacco users.” JX-0276.1 (Chemicals in Tobacco Products and Your Health); JX-0650C.11 (Madl Rpt.). As a result, combustible cigarette use is the leading preventable cause of death in the United States, and increases the risk of developing lung cancer in by 25 times in men, and 25.7 times in women. JX-0381.4 (How Tobacco Causes Disease); JX-0244.1 (CDC, Health Effects of Cigarette Smoking (2020)); *see also* JX-0650C.11 (Madl Rpt.).

JLI was founded in 2007 with the goal of designing a less harmful alternative to combustible cigarettes for current adult smokers. The JUUL System comprises the JUUL Device and JUULpods, and is a closed, cartridge-based product

. The JUUL Device is a battery-powered, rechargeable, user-activated device that . The JUULpods are pre-filled with nicotine-containing e-liquid formulation, which varies by flavor and/or nicotine concentration. *Id.*; JX-0647C.13 (Seth Rpt.) at ¶ 28.

Currently, JUULpods are available in the U.S. in two nicotine concentrations: 5.0%, which contains approximately 59 mg of nicotine per ml and 3.0%, which contains approximately 35 mg/ml. RX-0215.1 (Discover More About JUULPods & Flavors); JX-0647C.13 (Seth Rpt.) at ¶ 28. JUULpods are currently available in two flavors in the United States: Virginia Tobacco and Menthol. RX-0215.2 (Discover More About JUULPods & Flavors). The JUUL System has been subject of hundreds of studies, including clinical, nonclinical, and behavioral studies in connection with the FDA’s premarket tobacco application (“PMTA”) regulatory process. JX-0081C.1 (JUUL1 PMTA, Section B.1 Executive Summary).

As a result, the JUUL System does not involve combustion of tobacco. The JUUL System aerosol is less complex than cigarette smoke, and contains significantly fewer and lower levels of harmful and potentially harmful constituents (“HPHCs”), thereby significantly reducing the harms associated with smoking for adults who continue to use nicotine. *See* JX-0095.14-15 (Amicus Brief of Abrams, Ballin, Bates, Jarvis, Sweanor (July 5, 2022)); *see also* JX-0650C.81-94 (Madl Rpt.)).

At the time of JUUL’s founding, the existing alternatives in 2007—primarily other ENDS products—were overly complex to use and/or failed to provide users with a satisfactory experience. The JUUL System demonstrates a comparable, but lower, nicotine pharmacokinetic profile than combustible cigarettes. This demonstrates that the JUUL System provides an effective delivery of nicotine that provides adult smokers seeking to reduce or stop smoking with a potentially easier transition away from combustible cigarettes. *Id.*; RX-1019 (Madl Tr.) at 96:5-97:1 (“

(emphasis added)).

The JUUL System, through its many innovations in industrial design, technical engineering, and chemistry, revolutionized the stagnant ENDS industry. *See, e.g.*, JX-0626.55 (Altria and JLI’s Corrected Post-Trial Proposed Findings of Fact and Conclusions of Law, FTC Dkt. No. 9393 (Sept. 29, 2021)) (“JUUL [i]s [a]n [i]nnovative [b]reakthrough.”); JX-0626.56 at ¶ 216 (“By the end of 2016, JUUL’s ‘revolutionary design’ and ‘superior functionality’ had begun to attract a significant consumer following[.]” (citations omitted)); JX-0127C.16 (

).

B. Overview the Unique Effectiveness of the JUUL System

The evidence will show that the JUUL products are the “most effective product[s] for switching rates,” in successfully switching adult smokers away from combustible cigarettes, as compared to other ENDS products. *See, e.g.*, RX-1019 (Madl Tr.) at 83:6-84:7, 85:6-20 (“[S]o in my opinion, and when I evaluate the available products, I consider switching rates and the effectiveness of different products with different switching rates. JUUL has demonstrated to be *the most effective product for switching rates*[.]” (emphasis added)); RX-1127C, Deposition Transcript of Dr. Nicholas I. Goldenson (Feb. 28, 2024) (“Goldenson”) at 42:2-43:14, 89:14-21 (“From the data I’ve observed, the JUUL system is *uniquely effective at helping adults who smoke transition away from cigarettes*.”).

JUUL’s high complete switching rates, including rates of sustained abstinence from smoking of over 50% after 12 months, and an even higher percentage—58.6%—after 24 months, are well supported by several real-world observational studies, as set forth in JLI’s FDA submissions. *See, e.g.*, RX-1019 (Madl Tr.) at 250:1-251:25; RX-1127C (Goldenson) at 62:4-

63:25; JX-0368 (Shiffman, The Adult JUUL Switching and Smoking Trajectories (ADJUSST Study) (“ADJUSST Study”); JX-0108 (Kim, Switching Away From Smoking and Reduction in Cigarette Consumption Among US Adult Purchasers of the JUUL System across 24 months).

Additionally, even as to adult smokers who do not fully switch, but instead dually use JUUL with combustible cigarettes, a majority of such users still reduce their average daily cigarette consumption by at least 50%. *See, e.g.,* JX-0368 (ADJUSST Study); JX-0108 (Kim, Switching Away From Smoking and Reduction in Cigarette Consumption Among US Adult Purchasers of the JUUL System across 24 months); JX-0650C.20-22, Madl Report; JX-0081C.57-90 (

); JX-0084C (

; JX-0093C (

The evidence will further show, and expert witness testimony will opine, that while there are other ENDS and pod-based ENDS products available on the market in the U.S., none are as effective as the JUUL products because, *inter alia*, they do not have as high switching rates as JUUL, including for pod-based ENDS products like NJOY ACE and Vuse Alto. In particular, while the JUUL System exhibits switching rates of 58.6% after 24 months, NJOY’s studies have only shown [REDACTED] (leaving aside the FDA’s question over the reliability of NJOY’s studies and methodology), and RJR has reported the highest switching rate of Vuse Alto is 45% after 24 months. *Compare* RX-1019 (Madl Tr.) at 250:1-251:25 *and* JX-0368 (ADJUSST Study), JX-0108 (Kim), *with* JX-0461C (Updated NJOY User Study) and RX-0450 (R.J. Reynolds, Interim Results of Vuse Longitudinal Study).

Even presuming that JUUL and the ENDS product with the next-highest reported switch rates, Vuse Alto, were equal in all areas other than switching—and they are not—the differences

in these switching rates are significant. For example, the difference between 58.6% and 45% are significant, when taken into the context of the approximately 30 million cigarette users in the U.S., the millions people who are trying to quit by using ENDS devices in the U.S., the millions of users who prefer JUUL in the U.S. ENDS market, and the millions of users in the U.S. who have already switched by using JUUL. When taken into those contexts, the difference between 58.6% and 45% translates anywhere from *hundreds of thousands* to *millions* of people in the U.S. who, if JUUL were not available on the market, would be at risk of not switching away from combustible cigarettes. RX-1019 (Madl Tr.) at 237:20 - 238:16, 240:7 (“Q. Your point is if you have 2.3 million people who you want to take off of cigarettes, and you compare the switch rates [of JUUL and Vuse], *the difference would be 300,000 people not switched* if you assume the switch rates are ... accurate. A. Yes, correct. Q. Okay. You would actually – I’m going to help you out here. You get a better number if you multiply it against the 30 million [users of] combustible cigarettes. A. Yeah, I realize that.” (emphasis added)).

The evidence will also show that JUUL is preferable to other pod-based ENDS products like NJOY ACE and Vuse Alto, in terms of areas other than switching, for example, in terms of aerosol exposure of HPHCs. *See, e.g.*, RX-1019 (Madl Tr.) at 72:23-86:6, 83:6-84:7, 85:6-20, 112:9-119:11, 142:12-145:25, 160:10-163:13; RX-1127C (Goldenson) at 42:2-43:14, 89:14-21, 123:7-127:20, 61:10-90:23; RX-1020C (Seth Tr.) at 37:16-40:1; 66:18-80:19; JX-0650C.81-106 (Madl Rpt.). Further, with respect to potential alternatives that are unregulated, illegal disposable ENDS products (*e.g.*, Puff Bar, Esco Bar), to which JUUL users may turn if JUUL were taken off the market, those products also are not as effective or adequate alternatives to the JUUL System. *See, e.g.*, RX-1019 (Madl Tr.) at 142:12-145:25, 160:10-163:13; RX-1020C (Seth Tr.) at 79:17-25, 230:12-232:23, 233:23-235:7; JX-0387 (Yang, The Impact of a Comprehensive Tobacco

Product Flavor Ban in San Francisco Among Young Adults); JX-0650C.95-106 (Madl Rpt.); JX-0647C.50-57, 61 (Seth Rpt.) at ¶¶ 89-108, 115.

C. JLI's Extensive PMTA Filings Demonstrate That JUUL Products Have Superior Switch Rates and Are Appropriate for the Protection of Public Health

The evidence will show that NJOY's criticisms of the JUUL System, presently with an administrative stay over the FDA's previously-issued marketing denial order "MDO" are misplaced and unavailing.

1. PMTA Overview

As Dr. Madl explained, the FDA has regulated tobacco products (cigarettes, cigars, smokeless, pipe, and roll-your-own tobacco) since 2009 with the passage of the Family Smoking Prevention and Tobacco Control Act, which gave the FDA the authority to regulate the manufacturing, distribution, and marketing of tobacco products. JX-0650C.12 (Madl Rpt.); RX-0297C (Family Smoking Prevention and Tobacco Control Act of 2008).

Effective August 8, 2016, a final rule, known as the "Deeming Rule," gave the FDA regulatory authority over all tobacco products, including ENDS, setting forth review procedures for the FDA's Center for Tobacco Products ("CTP"). JX-0650C.12 (Madl Rpt.); JX-0272 (Final Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act);

JX-0650C.12-13 (Madl Rpt.); JX-0282 (FDA, A New Standard of Effective Regulation). The FDA codified its procedures for evaluating PMTAs and created postmarket reporting requirements for applicants that receive marketing granted orders (“MGOs”) in a recent final rule. JX-0650C.13 (Madl Rpt.); JX-0277 (FDA, Final Rule: Premarket Tobacco Product Applications and Record Keeping Requirements (2021)); RX-0371 (FDA, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems (Revised*) (2023)).

The Final Rule ensures that PMTAs contain sufficient information for the FDA to determine whether an MGO should issue for a new tobacco product. There are numerous areas of research, involving chemistry, toxicology, risk assessment, clinical observations, and behavioral outcomes, that are required by the FDA’s CTP to assess whether a product is appropriate for the protection of public health (“APPH”) and consistent with reduced harm. JX-0650C.13 (Madl Rpt.); JX-0277 (FDA, Final Rule: Premarket Tobacco Product Applications and Record Keeping Requirements (2021)); *see also* JX-0650C.12-16 (Madl Rpt.); RX-1019 (Madl Tr.) at 30:20-32:4, 37:14-42:1 (explaining PMTA regulatory process and evaluation of tobacco products); RX-1121C (Murillo) at 42:15-45:15 (describing APPH standard and FDA’s regulatory scheme for tobacco products).

2. JLI’s PMTAs Demonstrate That the JUUL Products Are APPH

To date, JLI has submitted four PMTAs with the FDA CTP: (1) July 2020, (2) December 2022, (3) July 2023, and (4) December 2023. As explained by Dr. Madl, each of JLI’s applications entailed thorough research demonstrating strong scientific evidence that the JUUL products are APPH. JX-0650C.17 (Madl Rpt.); RX-1019 (Madl Tr.) at 196:6-197:14 (“Based on the requirements that I’ve seen from the FDA, it’s my opinion that JUUL’s [PMTA filings] satisfied those – those requirements and has clearly demonstrated that those products are appropriate for the protection of public health.”).

i. JLI's July 2020 PMTA Demonstrated the JUUL System Is APPH

The July 2020 PMTA was for the JUUL System, which comprises the JUUL Device (currently on the US market), the JUUL Locked Device (not currently on the US market), and JUULpods in Virginia Tobacco and Menthol flavors in 5.0% and 3.0% nicotine concentration (currently on the US market). JX-0650C.17 (Madl Rpt.); RX-1121C (Murillo) at 78:19-79:11. The submission provided extensive evidence that the JUUL System is APPH. The July 2020 PMTA for the JUUL System included over 125,000 pages of data, information, and analysis from over 110 scientific studies across JLI's nonclinical (~75 studies), clinical (~13 studies), and behavioral (21 studies) research programs. JX-0090.5(JLI Request for 21 C.F.R. § 10.75 Supervisory Review); JX-0650C.17-18 (Madl Rpt.).

As Dr. Madl explained, the July 2020 PMTAs provided sufficient evidence for the FDA to conclude that the JUUL System is APPH. RX-1019 (Madl Tr.) at 196:6-197:14 ("Based on the requirements that I've seen from the FDA, it's my opinion that JUUL's [PMTA filings] satisfied those – those requirements and has clearly demonstrated that those products are appropriate for the protection of public health.").

Further, the July 2020 PMTA data supports JLI's expert testimony opining that the JUUL products are more effective and less harmful than other ENDS products for adult smokers seeking a less harmful alternative to combustible cigarettes. JX-0650C.81-106 (Madl Rpt.) (opining that JUUL products deliver far fewer harmful constituents than cigarettes and other ENDS products and describing adverse effects on public health resulting from exclusion of JUUL products); RX-1019 (Madl Tr.) at 250:1-251:25 (explaining that the switching rate for JUUL products is 58.6% after 24 months and 85% of dual-users reduced daily cigarette consumption by at least 50%); RX-1020C (Seth Tr.) at 37:16-40:1 ("JUUL is unique in terms of its effectiveness and its ability to

switch, the balance from abuse liability, the harmful chemicals that smoke – you know, its consumers are subjected to are significantly lower”).

For example, JLI used the nonclinical and clinical studies and risk assessments in its PMTA to characterize the potential individual health risks of both constituents of the JUUL products and JUUL products as a whole. demonstrated the significant reductions in certain HPHCs and classes of HPHCs in the JUUL System as compared to combustible cigarette smoke:

JX-0081C.42 (); *see also, e.g.*, RX-1019 (Madl Tr.) at 253:4-257:16, 256:3-14; JX-0650C.81-94 (Madl Rpt.); JX-0092C.10 (); *id.* at JX-0092C.11.

Additionally, JLI provided the FDA substantial and comprehensive

In total,

. JX-0091C; *see also* JX-0092C.29-39 (

); JX-0089C ().

- a. **The July 2020 PMTA's Scientific Data Demonstrates That the JUUL System Is Less Harmful Than Combustible Cigarettes and Adult Smokers Experience Positive Health Outcomes from Switching to the JUUL System**

In addition to the robust data regarding

JX-0081C.45-56 (); RX-0303C (

); JX-0650C.20 (Madl Rpt.).

As explained by Dr. Madl, the results of the July 2020 PMTA clinical studies demonstrated:

. JX-

0081C.18-19, 46-48 (); JX-0650C.20-21 (Madl Rpt.); RX-1019 (Madl Tr.) at 250:1-251:25, 253:4-257:16, 256:3-14.

As Dr. Goldenson's testimony explains, the JUUL System has a PK curve similar to that of a combustible cigarettes, demonstrating that it is delivering a sufficient amount of nicotine to satisfy cravings, which facilitates an adult smoker's ability to switch away from smoking combustible cigarettes more successfully. RX-1127C (Goldenson) at 46:17-50:3; *id.* at 46:12-20 ("Nicotine is the primary constituent that maintains dependence on cigarettes. So, yes, it is important to deliver a sufficient amount of nicotine in a manner that competes with a combustible cigarette in order to facilitate switching away from cigarettes"); *see also* RX-1019 (Madl Tr.) at 68:11-69 ("When you have delivery of nicotine products through oral products, the shape of that nicotine profile [PK curve] is different than combustible cigarettes, and so that can influence whether those products are appealing or not."), 83:6-84:7, 85:6-20 ("[S]o in my opinion, and when I evaluate the available products, I consider switching rates and the effectiveness of different products with different switching rates. JUUL has demonstrated to be the most effective product for switching rates,

.").

Similarly, the results of the clinical investigations demonstrate that the JUUL System facilitated positive health outcomes for its users, with respect to those who completely switch away from smoking and those who engage in dual use.

The behavioral studies in the July 2020 PMTA further support Dr. Madl's opinion that the JUUL System is APPH. JLI conducted 21 behavioral research investigations among more than 100,000 adults and 17,000 youth with support from literature reviews. JX-0650C.21 (Madl Rpt.); JX-0081C.18-19, 46-48 ().

JX-0650C.21 (Madl Rpt.); JX-0081C.18-19, 6-48 ().

As explained by Dr. Madl, the results of JLI's behavioral investigations demonstrated: (1)

. See JX-0081C.57-90

(
).

1. JLI's Extensive Efforts To Combat Youth Usage

While the July 2020 PMTAs provided extensive evidence supporting an APPH determination from the FDA, JLI also submitted evidence of its robust efforts to combat youth vaping. While the JUUL System revolutionized the ENDS market when it launched in 2015, one unintended, yet serious consequence was youth use of the JUUL System. JLI has emphasized that youth use of the JUUL System is unacceptable and has undertaken extensive measures to combat youth vaping.

. RX-0419C.2 (
); JX-0650C.22 (Madl Rpt.); RX-1019 (Madl Tr.) at
214:10-218:4 (discussing JLI's efforts to combat youth vaping). In order to further limit underage
appeal of the JUUL System,

. JX-0081C.12 (
); JX-0650C.22-23 (Madl Rpt.). Additionally, in order to further restrict underage access

to the JUUL System, JLI proposed

. JX-0081C.12 (
); JX-0650C.23 (Madl Rpt.).

The new measures announced in the July 2020 PMTA were in addition to the

These actions include:

. JX-0081C.13 (
); JX-0650C.23-24 (Madl Rpt.). Further, since November
2019, JLI suspended distribution of all flavored JUULpods other than Virginia Tobacco and
Menthol in the U.S. and fundamentally restructured the company to focus resources on the
development of technologies and strategies aimed at converting adult smokers and further
combatting underage use. JX-0104 (“Combating Underage Use,” Juul Labs). Finally, JLI has
committed to

. JX-0081C.13 (
); JX-0650C.24-25 (Madl Rpt.).

b. The FDA’s Marketing Denial Order of the July 2020 PMTA Is Administratively Stayed and Does Not Support a Finding That the JUUL System Is Not APPH

Despite JLI’s expansive July 2020 PMTA submission, the FDA issued market denial orders (“MDOs”) on June 23, 2022, finding that the applications “lack sufficient evidence to demonstrate that permitting the marketing of the products subject to these applications is appropriate for the protection of public health.” RX-0480C.1 (FDA MDO JLI PMTA); RX-0434 (CPT MDO List 2.4.24). The MDO identified four purported deficiencies regarding “potential toxicological risks,” including (1) leachable compounds, (2) *in vitro* genotoxicity, (3) *in vivo* genotoxicity; and (4) mutagenicity testing. RX-0480C.3-11 (FDA MDO JLI PMTA). Notably, the decision failed to assess the submission’s initiation, switching, and cessation data, and despite providing over 125,000 pages of information and data, the FDA’s Technical Project Lead (“TPL”) “found that [JLI] did not provide sufficient information for [the TPL] to assess the toxicological risks posed by the new products, and the information provided raised concerns.” RX-0481C.4 (FDA JLI TPL).

JLI responded to the MDO and the FDA’s subsequent public comments with a series of litigation and regulatory approaches to explain its disagreement with the MDO and TPL. JX-0650C.25-31 (Madl Rpt.); RX-1019 (Madl Tr.) at 41:7-20 (“Q. And if the FDA issues a market denial order, that means that the FDA has determined that the application was insufficient to show that the product is appropriate for the protection of public health, correct? A. Generally, yes, and I would say – one thing I would add to that is *with*

), 206:12-214-2 (

).

Immediately after the MDO and TPL issued, JLI petitioned the U.S. Court of Appeals for the DC Circuit for review of the MDOs on June 23, 2022, and JLI moved for an emergency temporary stay of the MDO on June 24, 2022, which was granted on the same day. RX-0451 (JLI’s

Petition for Review (DC Cir. June 23, 2022)); JX-0458C (JLI's Emergency Motion for Temp. Stay (DC Cir. June 24, 2022)); JX-0037 (FDA Press Release MDO); RX-0332 (D.C. Cir. Order Entering Temp. Stay).

In its motion, JLI explained its extensive, robust, and well-supported filing.

Subsequent motion practice³⁸ resulted in the FDA's July 5, 2022 conclusion that it would undertake an additional review of JLI's MDO because CPT determined that "there are scientific issues unique to this application that warrant additional review." RX-0449.1 (FDA Administrative Stay of JLI MDO). In connection with the FDA's decision to review, it administratively stayed the

³⁸ On July 27, 2022, JLI filed another emergency motion for a stay pending the DC Circuit's review of the FDA's MDO. JX-0459C (JLI's Emergency Motion for Stay Pending Review (June 27, 2022)). On July 6, 2022, JLI and the FDA jointly moved to hold the DC Circuit case in abeyance pending the FDA's administrative review, which was granted the next day. RX-0452 (Joint Motion for Abeyance (July 6, 2022)); RX-0459 (D.C. Circuit Order Granting Joint Motion for Abeyance (July 7, 2022)).

MDO and confirmed that “it would take no enforcement action against JLI.” *Id.* As a result of the administrative stay, the JUUL System remain on the market legally and under the FDA’s regulatory authority pending issuance of an MGO. JX-0650C.31 (Madl Rpt.).

Finally, on July 29, 2022, JLI requested supervisory review of the MDO from the FDA under section 10.75, arguing that the MDO was procedurally and substantively flawed. It explained that for each purported deficiency, “the MDO erred by overlooking key information, incorrectly analyzing the information it did consider, and inequitably holding [the JUUL System PMTAs] to a new and different standard compared to similarly-situated applicants.” JX-0090.15 (JLI Request for 21 C.F.R. §10.75 Supervisory Review).

. JX-0650C.25-31 (Madl Rpt.). The July 2020 PMTAs are currently still pending in supervisory review.

ii. JLI’s Subsequent PMTA Applications Further Demonstrate That JUUL Products Are APPH

While the July 2020 PMTA provides extensive evidence that the JUUL System is APPH, JLI’s three subsequent PMTAs introduced not only new products, but also additional data demonstrating the effectiveness of the JUUL products as a reduced harm alternative to combustible cigarettes that facilitates complete switching away from combustible cigarettes.

a. The December 2022 PMTA Provided Additional Support for a Finding That the JUUL System Products Are APPH

The December 2022 PMTA covered new Tobacco flavored JUULpods in 3.0% and 5.0% nicotine concentration for use in the JUUL System. RX-0472C (

). Data supporting the Dec. 2022 PMTA demonstrate that adult smokers who use tobacco-flavored JUUL System products achieved consistently high rates of switching completely

away from combustible cigarettes, nearly 59% at 24 months, but does not come at the cost of enticing underage users, as data show that tobacco-flavored ENDS are not popular among youth. *Id.* at RX-0472C.2.

The December 2022 PMTA was supported by at least 8 nonclinical studies to evaluate the

. RX-0428C (); RX-0429C ().

As explained by Dr. Madl,

RX-0429C (); JX-0650C.32-33 (Madl Rpt.).

The December 2022 PMTA was also supported by at least 5 clinical studies, which reinforced the conclusions of the July 2020 clinical studies, including that

RX-0428C (); RX-0429C (); JX-0650C.33-34 (Madl Rpt.).

The December 2022 PMTA did not directly evaluate the
 , but they can be bridged to the results of the behavioral studies in the July 2020
 PMTA, which provided strong evidence supporting high rates of complete switching from
 combustible cigarettes to the . RX-0428C (
); JX-0650C.34-35 (Madl Rpt.). Finally, in addition
 to JLI's robust evidence of continued efforts to combat youth use included in the Dec. 2022 PMTA,
 JLI also reported that due to these efforts,
 RX-
 0431C.19-20 (); RX-0432C.20-
 39 (. Dr. Madl opined that
 "based on my review of the FDA Final Rule and the information included in both the [July 2020]
 PMTA and the Dec. 2022 PMTA, this satisfies FDA requirements and should be determined
 APPH." JX-0650C.37 (Madl Rpt.).

. JX-0650C.32 (Madl Rpt.).

b. The July 2023 PMTA Introduced the JUUL2 System and the Robust Evidence in the PMTA Demonstrates That the JUUL2 System Is APPH

In July 2023, JLI submitted a PMTA for its

The July 2023 PMTA included multiple nonclinical studies, including targeted and non-targeted chemistry analyses, *in vitro* and *in vivo* toxicology studies, as well as clinical studies and a population health impact modeling study. RX-0319C.9. The submission also bridged data from studies conducted on similar JUUL System products to support the evaluation of the JUUL2 System. *Id.*

As Dr. Madl explained, the July 2023 PMTA “included extensive data, information, and analysis addressing each requirement [the FDA evaluates]. In my opinion, clinical and non-clinical data demonstrate that the JUUL2 System should be considered APPH, as it likely presents significantly less individual health risk than combustible cigarettes and does not present unique public health issues relative to ENDS that are currently marketed (and in some cases authorized).” JX-0650C.41 (Madl Rpt.); RX-0319C (July 2023 PMTA, Section 2.1 Executive Summary).

c. The December 2023 PMTA Provided Additional Data Supporting a Finding that the JUUL2 System Is APPH

JLI filed a PMTA for

Like the December 2022 PMTA and July 2023 PMTA, the December 2023 PMTA conducted studies using the [REDACTED] and bridged data from studies conducted on the JUUL System to support evaluation of the [REDACTED]. See RX-0470C ([REDACTED]); *id.* at RX-0470C.12-13.

JLI also conducted a standard set of *in vitro* tests for cytotoxicity, mutagenicity, and genotoxicity, and the resulting data demonstrate that t

Collectively, the behavioral studies and analyses provide a comprehensive picture of who is likely to use the

These studies show:

And further emphasizing JLI's commitment to combatting youth use, JLI's behavioral research also supported the conclusion that

Like JLI's prior PMTAs, the Dec. 2023 PMTA provides extensive evidence supporting a finding that JUUL products, and are APPH. Dr. Madl opined that the information contained in the Dec. 2023 PMTA, along with the prior JLI PMTA filings, "are in accordance and likely exceed FDA guidance. As such, the marketing of the should be determined APPH." JX-0650C.48 (Madl Rpt.).

D. There Is No Adequate Alternative for JUUL Products

The JUUL System is robustly adopted in the U.S. market, is uniquely effective, and is differentiated from other products based on the unique combination of

. See, e.g., RX-1020C (Seth Tr.) at 39:4-40:1; JX-0647C.53, 56 (Seth Rpt.) at ¶¶ 97, 104, and evidence cited therein. Because of such differentiation, no adequate alternative exists for JUUL products.

1. JLI's Switching Rates Are Amply Supported and Higher Than Other Tobacco Alternatives, Including Other Pod-Based ENDS

i. JLI's Switching Rates Are Above 50% Even After 24 Months

The evidence will show that JLI provided extensive research demonstrating that adults who smoke completely switch using JUUL products at consistently high rates. What is even more significant is that JUUL switching rates continue to rise the longer an adult uses the product; in fact, after 24 months, the rates of complete switching using JUUL is nearly 60%. See RX-1019 (Madl Tr.) at 150:22-151:6, 169:25-171:3; JX-0368 (ADJUSST Study); JX-0108 (Kim, Switching Away From Smoking and Reduction in Cigarette Consumption Among US Adult Purchasers of the JUUL System across 24 months); RX-1510 (Shiffman, Switching Away from Cigarettes across 24 Months Among US Adult Smokers who Purchased the JUUL System); *see also* JX-0456 (JLI's Supplement to Request for Supervisory Review of MDO). The July 2023 PMTA provided some of the most recent behavioral study data, which reinforces the high switching rates from the prior PMTAs. See, e.g., JX-0093C.25-32 (July 2023 PMTA,

The evidence suggests that the use of the JUUL System and JUUL2 System over time *increases* the likelihood of complete switching. For example, in the Adult JUUL Switching and Smoker Trajectories (ADJUSST) Study, changes in smoking behavior were prospectively assessed

in a cohort of approximately 18,000 US adult smokers (age ≥ 21) who purchased JUUL products in 2018 and were followed over the course of 24 months. JX-0093C.25-32 (

. Published analyses examined the prevalence of complete switching (i.e., no smoking, not even a puff in the past 30 days) over the initial 12-month follow-up period in the overall sample as well as subpopulations of interest, and subsequent analyses extended these analyses to 24 months of follow-up. JX-0093C.25-32 (

); JX-0368 (ADJUSST Study); JX-0108 (Kim, Switching Away From Smoking and Reduction in Cigarette Consumption Among US Adult Purchasers of the JUUL System across 24 months); RX-1510 (Shiffman, Switching Away from Cigarettes across 24 Months Among US Adult Smokers who Purchased the JUUL System). According to Figure 6 shown below from this study, among current established smokers at baseline, rates of past 30-day complete switching increased over time (Figure 6), from after purchasing JUUL System.

JX-0093C.22 ().

Id. at JX-0093C.26.

Further, while switching rates varied by smoking history (given that longer duration of smoking and greater frequency of smoking were associated with lower switch rates at each timepoint), even participants who were daily smokers and had been smoking for at least five years still reported complete switching to JUUL System at a high rate over time, reaching nearly

(Figure 7 as shown below from this study).

JX-0093C.27. Even smokers who reported not being ready to quit smoking in the next 30 days at the time they started using JUUL products in one study had high switching rates

at 12 months, which indicates that JUUL products may favorably impact the large portion of the adult smoker population that is not initially ready to stop smoking. *Id.* at 25.

JX-

0093C.25.

Data from a real-world study of adult

ii. JLI's Switching Rates Are Higher Than All Other Tobacco Alternatives, Including Vuse Alto and NJOY ACE

The evidence will show that rates of adult smokers completely switching away from combustible cigarettes using JUUL products is consistently higher than any other tobacco alternative, including pod-based ENDS like Vuse Alto and NJOY ACE.

For example, as noted above, the studies analyzing the JUUL System reported complete switching rates of 58% after 12 months and 58.6% after 24 months. *See, e.g., JX-0084C*

([REDACTED]); JX-0108 (Switching Away from Smoking and Reduction in Cigarette Consumption). Vuse Alto provided interim results from its Vuse Longitudinal Study, reporting switching rates between 37.2-45% for Vuse Alto after 24 months. RX-0450 (Interim Results of Vuse Longitudinal Study).

While Vuse Alto purports to have a switch rate of 45% over 24 months, the specifics of the study and the data relied on are unclear. *Id.* Notably, the participants in the study were registered current Vuse users with reported past 30-day use at baseline and the time of first use varied. RX-0454 (Measuring the Impact of Menthol and Tobacco-Flavored Vapor Product Use). It is unclear how long the participants in the study were using Vuse Alto before they completely switched. Additionally, Vuse's study suggests that it may not be representative of the larger population since it used a relatively small sample size (1,483). *Id.* By contrast, JUUL's studies included 17,986 adult smokers followed for 12 months and 18,420 adult smokers followed for 24 months. JX-0299 (Goldenson, Switching Away from Cigarettes Across 12 Months); JX-0108 (Kim, Switching Away From Smoking and Reduction in Cigarette Consumption).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

JLI's switching data is also substantially higher than the rates reported for ENDS generally, which range from 8.8-11% after 12 months. JX-0081C ([REDACTED]); RX-0308C (Coleman, Transitions in Electronic Cigarette Use); RX-0306C (Berry, E-Cigarette Initiation).

2. Toxicological Profile

As explained above, JLI's extensive scientific studies, including clinical and non-clinical investigations, demonstrate that JUUL products deliver [REDACTED] compared to combustible cigarette smoke. *See, e.g.*, RX-1019 (Madl Tr.) at 253:4-257:16, 256:3-14; JX-0650C.81-94 (Madl Rpt.).

This data show that are there substantive and measurable positive health benefits to switching from combustible cigarettes to JUUL products, and these findings were consistent

throughout JLI's clinical testing for all four of JLI's PMTA submissions for both the JUUL System and JUUL2 System.

3. Satisfaction

The evidence will show that the JUUL System has proven to satisfy its users' nicotine cravings, as demonstrated in the high switch rates, and JUUL is able to balance this satisfaction with the abuse liability, which ensures the JUUL System does not create dependence in its users. RX-1127C (Goldenson) at 123:7-127:20 (explaining JUUL study measuring subjective satisfaction and abuse liability of JUUL products and other pod-based ENDS products); JX-0017C ();
RX-1019 (Madl Tr.) at 112:9-119:11 (); RX-1020C (Seth Tr.) at 39:4-40:1.

One of the main factors that influence the abuse liability of a tobacco product is the bioavailability of nicotine and speed of uptake. JX-0650C.67 (Madl Rpt.). The FDA's Final Rule notes that "the abuse liability of a tobacco product is an important part of FDA's finding of whether permitting the marketing of a new tobacco product is APPH." JX-0277.66 (FDA Final Rule: PMTA and Record Keeping Requirements (2021)).

Variability of PK profiles following ENDS use demonstrates that nicotine intake and the abuse liability is not solely predicated by the e-liquid nicotine content, but are also highly dependent on behavioral use characteristics, such as puff topography and user experience. See RX-0311C.94 (). Nicotine pharmacokinetics can not only inform the abuse liability of a reduced harm nicotine product, but it can also inform the likelihood that the product can be used to reduce or quit smoking combustible cigarettes. Reduced cravings, withdrawal symptom relief, and subjective effects (e.g., satisfaction and

reward) are associated with the increased uptake of alternative nicotine products and reduction of or complete switching away from combustible cigarettes. JX-0293 (Goldenson, The Role of Subjective Responses in Electronic Cigarette Uptake and Substitution in Adult Smokers).

Several studies have compared JUUL to other ENDS products with respect to pharmacokinetic profile and subjective effects. JUUL delivered higher nicotine more efficiently, which was reflected in the subjective effects ratings where participants reported the JUUL relieved urges to smoke faster and was rated more pleasant than other ENDS products. *See, e.g.*, JX-0123 (Goldenson, Abuse Liability Assessment of the JUUL System (2020)); JX-0014C (

). Recent studies have compared JUUL products directly with Vuse Alto and NJOY ACE with respect to PK profile and/or subjective effects, and the results suggest that JUUL products may have similar abuse liability to other ENDS on the market, but may provide a more satisfying alternative to smoking. *See, e.g.*, JX-0123 (Goldenson, Abuse Liability Assessment of the JUUL System (2020)); JX-0014C (

s); JX-0015C

); JX-0073C (

).

[REDACTED]

Id.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dr. Goldenson's testimony
is supported by JUUL's sustained switching rates of nearly 60% after 24 months, which evinces
JUUL's satisfaction and abuse liability in the U.S. market.

4. Consumer Perception & Preference

A variety of factors inform consumer perception of and preference for JUUL products, including willingness to pay price premiums, brand loyalty, and market share. The evidence will show, and Dr. Seth will testify, that consumers perceive JUUL products as unique and different. RX-1020C (Seth Tr.) at 39:19-40:1, 40:22. The evidence will further show, and Dr. Seth will testify, that consumers strongly prefer JUUL products. *See, e.g.*, JX-0094C.25-37; RX-1020C (Seth Tr.) at 39:19-40:1, 40:22; JX-0647C.42 (Seth Rpt.) at ¶¶ 75-76, and evidence cited therein.

i. Price Premium

Consumer's willingness to pay a price premium is one factor that indicates consumer preference and acceptance of JUUL products. RX-1020C (Seth Tr.) at 136:6-9; JX-0647C.42-44 (Seth Rpt.) at ¶¶ 76-78 and Table 1, and evidence cited therein. "Price premium" refers to the maximum price consumers are willing to pay for one brand or product over another. *See, e.g.*, RX-0288 (Raj Sethuraman and Catherine Cole, "Factors influencing the price premiums that consumers pay for national brands over store brands," *Journal of Product & Brand Management*, Vol. 8, Issue 4, 1999); RX-0291 (Kusum L. Aliawadi et al., "Revenue Premium as an Outcome Measure of Brand Equity," *Journal of Marketing*, Vol. 67, October 2003); RX-0289 (Richard G. Netemeyer, Balaji Krishnan et al., "Developing and validating measures of facets of customer-based brand equity," *Journal of Business Research*, Vol. 57, Issue 2, February 2004); JX-0647C.42 (Seth Rpt.) at ¶ 76, and evidence cited therein.

Record evidence will establish, and Dr. Seth will opine, that JUUL products have enjoyed a price premium compared to other pod-based ENDS products. JX-0647C.42-44 (Seth Rpt.) at ¶¶ 77-78 and Table 1, and evidence cited therein; RX-1020C (Seth Tr.) at 142:21-24, 143:9-22. A comparison of the retail price of JUULpods to the retail price of other pod-based, cartridge-based,



or tank-based ENDS products with comparable specifications, including nicotine concentrations,³⁹ is summarized in Table 1⁴⁰ of Dr. Pallavi's Expert Report:

39

Consumers' willingness to pay a price premium for JUUL products is indicates that consumers consider certain other pod-based ENDS alternatives inferior. JX-0647C.42 (Seth Rpt.) at ¶ 76, and evidence cited therein; RX-1020C (Seth Tr.) at 132:12-18; *see also* RX-1020C (Seth Tr.) at 135:14-16 16 ("The willingness to pay for JUUL consistently across other products indicates consumers' preferences in terms of, you know, their wiliness to pay"). It is also notable that, despite the higher price of JUUL products, JUUL has continuously commanded a high market share. RX-1020C (Seth Tr.) at 139:10-13.

ii. Customer Loyalty

In addition, a consumers' willingness to pay a price premium is a strong measure of brand loyalty. RX-1020C (Seth Tr.) at 117:9-13.

iii. Market Shares

Market shares also indicate consumer acceptance of a product, as consumer acceptance drives market share. RX-1020C (Seth Tr.) at 49:10-12, 49:23-24. There are in the United States in 2023. *See, e.g.*, RX-0470C.3; JX-0118; ; JX-0647C.46 (Seth Rpt.) at ¶ 81, and evidence cited therein. Based on , JUUL sales have consistently exceeded each quarter. ”

As of the fourth quarter of 2023, JLI held the market share of the tobacco flavored segment of the ENDS market . JX-0035C; *see also, e.g.*, RX-1119C, Deposition Transcript of Jonah Joselow (Feb. 23, 2024) (“Joselow”) at 52:21-25; RX-1020C (Seth Tr.) at 50:3-5; *see also, e.g.*, JX-0647C.17-23 (Seth Rpt.) at ¶¶ 35-38, and evidence cited therein.

See, e.g., RX-1119C (Joselow) at 133:1-7, 134:10-12, 192:7-13 ().

Nevertheless, for the overall ENDS market (including non-tobacco and non-menthol flavors), as of the , JLI held the . JX-0035C (listing Vuse’s market share of the tobacco flavored segment of the ENDS market as 39% as of the fourth quarter of 2023, which includes its Vuse Alto, Vuse Ciro, Vuse Solo, and Vuse Vibe product lines); *see also, e.g.*, RX-1119C (Joselow) at 134:18-23, 135:3-8, 135:21-25; RX-

[REDACTED]

1020C (Seth Tr.) at 50:3-5; JX-0647C.17-23 (Seth Rpt.) at ¶¶ 35-38, and evidence cited therein.

[REDACTED]

[REDACTED] NJOY's spike in sales in 2019 was a direct result of its decision to (1) continue selling Blueberry and Watermelon ACE pods after JLI had voluntarily removed non-tobacco and nonmenthol flavored JUULpods from the market and (2) reduce the price of the Ace device to \$0.99 for retail purchasers. JX-0103.2-3 ("Late last year, NJOY started selling its Ace e-cigarettes for 99 cents in stores, compared with the \$7.99 it currently charges online. A Juul device runs for \$34.99 online. NJOY's attempts appear to be working. The company has captured 11.6% of dollar share, a 10.2% year-over-year increase. Dollar sales surged 34.4% from the prior period and an eye-popping 1,141.2% from the year-ago period ... NJOY also sells flavors that Juul does not in stores, including watermelon twist and blueberry. Critics say fruity flavors attract teens.").

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Complainant also seems to argue that its allegedly recent increase in presence of NJOY ACE in more stores will result in NJOY ACE being more successful. However, adding a product into more stores does not necessarily result in increased market share. In fact, Altria previously promoted products such as MarkTen and GreenSmoke, and neither product has gained market share levels that would indicate that either could be adequate alternatives to JUUL products. Finally, to the extent any of the increase in storefronts occurred in 2023, the market share data has [REDACTED], indicating that NJOY's allegations of the significance of their alleged increases in stores are unavailing.

E. Public Interest Factors

It is in the public interest to have JUUL's ENDS products—with the highest effectiveness and switching rates on the market today—available to the millions of U.S. adult smokers who are trying to completely switch off of combustible cigarettes.

Combustible cigarette use is the leading preventable cause of death in the U.S., with more than **480,000 deaths annually**, and contributes to about 90% of all lung cancer deaths. *See* JX-0650C.11, Expert Report of Dr. Amy K. Madl (Mar. 19, 2024) ("Madl Report"); JX-0243.1 (Tobacco-Related Mortality); JX-0381.4 (How Tobacco Causes Disease); JX-0244.1 (CDC, Health Effects of Cigarette Smoking (2020)). As compared to cigarettes, the JUUL System a [REDACTED] compared to combustible cigarette smoke. JX-0650C.81-94, Madl Report.

The JUUL System is the ENDS device on the U.S. market with the highest proven complete switching rates. The evidence will show that **58.6%** of users have sustained abstinence from smoking after 24 months of using the JUUL System. RX-1019C, Deposition Transcript of Dr. Amy Madl (April 9, 2024) (“Madl”) at 102:5-104:10.

The evidence will show that at least **2 million** adult former smokers in the United States have already completely switched from combustible cigarettes using the JUUL System. *See* RX-1121C, Deposition Transcript of Jose Luis Murillo (Mar. 12, 2024) (“Murillo”) at 98:5-17 (“I can tell you that ...the current JUUL product in the United States has already converted over two million people away from smoking[.]”). The JUUL System is already and has been robustly adopted in the U.S. marketplace, consistently maintaining a stabilized and high market share in the United States. For example, JLI had approximately between _____ of the U.S. market for all ENDS devices between Q4 2022 and Q4 2023, and between _____ of the U.S. market for all tobacco-flavored ENDS devices between Q4 2022 and Q4 2023. JX-0035C (_____).

The evidence will also show, and Dr. Seth will opine, that NJOY’s arguments that the NJOY Ace can replace the excluded JUUL products are unavailing. For one thing, the NJOY Ace’s consistently low market share demonstrates its lack of consumer adoption and acceptance, underscoring its lack of effectiveness as an alternative product to JUUL. *See, e.g.*, RX-1020C, Deposition Transcript of Dr. Pallavi Seth (April 9, 2024) (“Seth”) at 49:4-24 (explaining connection between market share and consumer acceptance), 115:5-116:8, 183:17-22, 202:16-204:8 (noting NJOY’s low market share). For another, NJOY has not shown it has the production capacity to produce enough articles to replace JUUL, even if NJOY were as effective as the JUUL System. If JUUL were taken off the U.S. market, consumers would be deprived of this product

with high consumer acceptance, and would be deprived of the NDS device with the highest proven complete switching rates on the U.S. market.

Simply put, because of the significantly adverse impacts that would result upon exclusion of the JUUL products from the U.S. market, the evidence and expert testimony will show that each of the four public interest factors weigh against issuance of the requested relief in this investigation should the ALJ find a violation of section 337.

Alternatively, due to these public interest concerns as set forth herein, any relief should be delayed in its enforcement for at least months, or as many as months, to allow for alternatives that are as effective as JUUL to gain regulatory approval and come onto the U.S. market, such as JUUL 2, the JUUL products, or other alternatives. Such a tailoring of the remedial orders would minimize the adverse effects on the public interest, and mitigate harm to public health. *See, e.g.*, RX-1019 (Madl Tr.) at 59:1-19, 62:5-64:1; JX-0650C.106-107 (Madl Rpt.) (opining the ALJ should delay enforcement of any remedy for at least months and as much as months to enable ; JX-0647C.61-62, Expert Report of Dr. Pallavi Seth (Mar. 19, 2024) (“Seth Report”) at ¶¶ 118-122 (opining that delaying the requested remedial orders would mitigate harm to the public interest allowing alternative JUUL products to come onto the market); *Certain Personal Data & Mobile Comm’n Devices*, No. 337-TA-710, Comm’n Op. at 81 (Dec. 29, 2011) (fashioning remedy to include a transition time for consumers to transition from HTC phones to other products, in light of public interest concerns including regulatory issues).

1. The Requested Relief Would Have An Adverse Impact On the Public Health and Welfare

The evidence will show, and the experts will opine, that removing JUUL products from the market would have a significant and detrimental impact on public health and is significantly

against the public interest. JX-0650C.9-10, 95-106 (Madl Rpt.); JX-0647C.52-53 (Seth Rpt.) at ¶¶ 92-93. If JUUL products are not available to smokers, consumers will either: return to smoking cigarettes, use dangerous and illegal products, and/or use other less effective and/or more harmful ENDS devices. *Id.*

Notably, smokers do not consider smokeless tobacco products a viable alternative to combustible cigarettes and NRT results in very low rates of cessation. *Id.*; *see also* JX-0647C.55 (Seth Rpt.) at ¶ 103; JX-0035C. Thus, exclusion of the JUUL products would result in fewer current smokers switching away from combustible cigarettes; increasing numbers of JUUL users who will switching back to combustible cigarettes, less effective and safe ENDS products like NJOY or VUSE, and/or illegal, unregulated, and unsafe disposable ENDS products; and ultimately increased smoking-related deaths. JX-0650C.9-10, 95-107 (Madl Rpt.), and evidence cited therein.

i. JUUL Users May Return to Smoking Cigarettes

Excluding JUUL products from the U.S. market would likely result in increased consumption of more harmful alternatives, including combustible cigarettes. *See, eg.*, RX-1019 (Madl Tr.) at 142:12-145:25, 160:10-163:13; RX-1020C (Seth Tr.) at 79:17-25, 230:12-232:23, 233:23-235:7; JX-0387 (Yang, The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults); JX-0650C.95-106 (Madl Rpt.); JX-0647C.52-55 (Seth Rpt.) at ¶¶ 94-103.

As Dr. Madl will opine, numerous studies have been published exploring the influence of hypothetical and actual flavor restrictions on behavioral changes of ENDS users at the national, state and local level. JX-0387 (Yang, The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults); JX-0388 (Response to Flavored Cartridge/Pod-Based Product Ban Among Adult JUUL Users: “You Get Nicotine However You Can Get It”); JX-0320 (Cigarette and E-Cigarette Use Among Smokers after a Statewide E-Cigarette Sales Ban); JX-0374

(Discussions of Flavored ENDS Sales Restrictions: Themes Related to Circumventing Policies on Reddit); JX-0650C.101-106 (Madl Rpt.), and evidence cited therein. Several common themes were identified in the literature, including off-label use, stockpiling, making do-it-yourself (DIY) e-liquid, purchasing illicit products, and/or returning to combustible cigarette smoking.

Dr. Madl will opine that, in response to hypothetical or actual ENDS restrictions and bans, adults in almost every study indicated that they would increase their combustible cigarette consumption or revert to combustible cigarettes if their preferred products were unavailable. JX-0650C.104-105 (Madl Rpt.), and evidence cited therein. JX-0240; JX-0350; JX-0266; RX-0489; JX-0386. For example:

- When adult current or former smokers were presented with the scenario where FDA bans all menthol and fruit/sweet flavors of ENDS products in a discrete choice experiment, there was an 8.3% increase in cigarette choice shares and an 11.1% decrease in ENDS choice shares. JX-0240.1.
- When adult ENDS users were asked how they would react to an FDA ban on flavors, 9.7% of them reported that they would return to smoking traditional cigarettes. JX-0266.6.
- In a survey of adult users (aged 18-29) dual users of combustible cigarettes and ENDS, 44.6% indicated that they would maintain or increase their cigarette consumption if there was a ban on flavored ENDS. JX-0350.6.
- In a cross-sectional analysis of data collected in 2020 on 2,169 young adults (aged 18-34) from Atlanta, Boston, Minneapolis, Oklahoma City, San Diego, and Seattle, when young adult ENDS users in the US (n=550) were asked about potential flavor

bans, 33.2% of them indicated that they would be very or somewhat likely to switch to smoking cigarettes. RX-0489.6.

- Among adult users (aged 18-34) current or former tobacco product users, cigarette use increased after the flavor ban in San Francisco compared to before the flavor ban. JX-0387.1 (Yang, The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults).
- Using state-level commercial sales data, another study examined the impact of these state-level short-term bans of ENDS on cigarette sales by comparing three study groups: treatment (n=3 states that instituted bans on all ENDS products (n=1) or flavor-specific products (n=2); halted (n=3 states); and control (n=33 states with no ban and data available). JX-0386. Cigarettes sales were higher than expected in the full ban state (7.5% increase) and in the states that banned non-tobacco flavored ENDS (4.6% increase). JX-0386; *see also* RX-0486C.36-37.

ii. JUUL Users May Turn to Illegal, Unregulated Disposable Products

Moreover, adults in the aforementioned studies also reported purchasing illicit, generic, or third-party products in response to flavor bans and restrictions. JX-0266; JX-0387 (Yang, The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults); JX-0388 (Response to Flavored Cartridge/Pod-Based Product Ban Among Adult JUUL Users: “You Get Nicotine However You Can Get It”); JX-0320 (Cigarette and E-Cigarette Use Among Smokers after a Statewide E-Cigarette Sales Ban); JX-0650C.102-104 (Madl Rpt.), and evidence cited therein. Notably, JUUL users reported experiencing issues with purchasing genuine pods after the FDA flavor ban. JX-0388 (Response to Flavored Cartridge/Pod-Based Product Ban Among Adult JUUL Users: “You Get Nicotine However You Can Get It”); *see also* JX-0387 (Yang,

The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults); JX-0374 (Discussions of Flavored ENDS Sales Restrictions: Themes Related to Circumventing Policies on Reddit). An analysis comparing third-party pods to genuine JUUL pods found that the third-party pods had more chemical constituents at higher concentrations than genuine JUUL pods. JX-0264 (Removal of Mango-Flavoured Juul Pods Created Opportunity For Adulterated Mango Juul-Compatible Pods with Altered Chemical Constituents). Thus, as Dr. Madl will opine, by restricting the availability and use of regulated the JUUL System ENDS products, with its large market share, unregulated and illicit products are available in the marketplace, posing significant and detrimental effects on public health. JX-0650C.102-104 (Madl Rpt.), and evidence cited therein.

Dr. Madl will opine that, if the JUUL System is removed from the market, consumers may start to use one of the hundreds of unregulated e-cigarette brands in the United States, particularly disposable e-cigarettes, such as Puff Bar. JX-0650C.95-106 (Madl Rpt.), and evidence cited therein. The evidence will show, and Dr. Madl will explain, that following major ENDS-related regulatory events, the google search volume for JUUL dropped significantly, while Google search volume for Puff Bar significantly increased. JX-0275; JX-0281; RX-0438; JX-0333; JX-0259; JX-0239; JX-0650C.95-106 (Madl Rpt.), and evidence cited therein; RX-0225; JX-0647C.56 (Seth Rpt.) at ¶ 106.

Notably, a flavor ingredient comparison between JUUL and Puff Bar demonstrated that total flavor ingredient concentrations of JUUL were below 0.35 mg/mL, whereas the Puff Bar products had more flavor ingredients at higher concentrations with total flavor concentrations being about 34.4 mg/mL, suggesting a higher potential for exposure and health risk of the Puff Bar products. JX-0349. As Dr. Madl will explain, risks associated with the use of DIY or illicit products

[REDACTED]

was fully realized in July 2019 with the outbreak of a lung disease, known as E-cigarette or Vaping Product Use Associated Lung Injury (EVALI). JX-0650C.104 (Madl Rpt.), and evidence cited therein. Although the majority of EVALI cases reported use of THC containing e-liquids obtained from informal sources, Dr. Madl will opine that similar health effects could occur following the use of illicitly purchased or DIY nicotine-containing e-liquids. JX-0650C.104 (Madl Rpt.), and evidence cited therein.

In sum, as Dr. Madl will opine, these unregulated disposable products have not been studied as extensively as JUUL, contain flavors that are oriented more towards youth and non-smokers, and may pose greater risk to consumers. JX-0650C.95-106 (Madl Rpt.), and evidence cited therein.

iii. JUUL Users May Turn to Less Effective and More Harmful ENDS Products

Further, removing JUUL products from the market may cause some JUUL consumers to use other ENDS products, none of which have proven to be as effective at switching smokers away from combustible cigarettes as JUUL products. *See, e.g.*, JX-0650C.95-106 (Madl Rpt.), and evidence cited therein. [REDACTED]

[REDACTED]

[REDACTED]

); JX-0650C.95-106 (Madl Rpt.), and evidence cited therein.

Because other nicotine alternatives have lower or unknown rates of complete switching from cigarettes, removing JUUL from the market would mean that the remaining available products would switch fewer smokers away cigarettes and result in a greater individual and population health risk. JX-0650C.95-106 (Madl Rpt.), and evidence cited therein; *see also* RX-1019 (Madl Tr.) at 231:8-241:8 (explaining that if JUUL is not on the market, at least 300,000 individuals would not switch away from combustible cigarettes that otherwise may switch away from combustible cigarettes if JUUL was on the market). This is the case whether JUUL 1, JUUL 2, or both were ordered to cease selling. RX-1019 (Madl Tr.) at 231:8-241:8.

2. The Request Relief Would Have An Adverse Impact on Competitive Conditions in the U.S.

The evidence will show, and Dr. Seth will opine, that the requested relief will have an adverse impact on competitive conditions in the US. As described above, the Dr. Seth will opine that there are no other products of other brands that are (i) currently not on the market, and (ii) would be as effective as JUUL products in effectiveness (meaning switching rates), consumer preferences, and abuse liability. Dr. Seth will further opine that even if NJOY were to identify a third party product, not yet on the market, that could potentially serve as replacements for JUUL products, there are significant regulatory barriers to lawful entry in the ENDS segment, at least due to FDA's regulatory requirements, *e.g.*, PMTA. Further, due to JLI's market share in the U.S., the requested remedial order would likely result in reduced competition in the ENDS market, particularly for regulated ENDS products. JX-0647C.57 (Seth Rpt.) at ¶ 107; JX-0647.57-58 (Seth Rpt.) at Section X.B.1.

Dr. Seth will opine that under the requested remedial orders, it is unlikely that any new products or firms would legally enter the ENDS market within a short time frame (*e.g.*, less than many months or even years of prior lead time), for a product as effective as the JUUL System,

without circumventing existing regulatory requirements. *See, e.g.*, RX-0961 (FDA, MGOs); JX-0368 (ADJUSST Study); RX-0476C (

s);

As Dr. Madl will opine, the average length of PMTA approval to MGO status is over 27 months.

The evidence will show and Dr. Seth will opine that an exclusion order removing JUUL products from the US market could result in increased market concentration given JLI's large market share of the ENDS segment, particularly for regulated products. Specifically, JLI has of the ENDS segment and of the tobacco-flavored ENDS sub-segment. *See* JX-0035C (); RX-1020C (Seth Tr.) at 239:1-25. Dr. Seth will opine that she estimates a portion of the demand for ENDS products will be diverted towards more harmful alternatives like cigarettes, and within the ENDS market, an even greater decrease in supply will occur as the over units sold by JLI will no longer be available for sale under the requested remedial order. RX-1020C (Seth Tr.) at 239:1-25; JX-0240; JX-0350; JX-0266; RX-0489; JX-0386.

Dr. Seth will opine that given that there would be a decrease in supply of JUUL products, with its market share, that is not offset by a comparable decrease in demand, there could be an in price for ENDS products in the short-term. Dr. Seth will opine that such a

This means that the requested remedial order would reduce approximately

. RX-1020C (Seth Tr.) at 239:1-25; JX-0035C (); JX-0647C.58-59 (Seth Rpt.) at Section X.B.2.

3. The Requested Relief Will Have An Adverse Impact On Production of Like or Directly Competitive Articles in the U.S.

The evidence will show and Dr. Seth will opine that the requested relief will have an adverse impact on production of like or directly competitive articles in the U.S. because there is no evidence that domestic manufacturers would be able to replace JLI's domestic production. JX-0647C.58-59 (Seth Rpt.) ¶ 110. JLI currently fills [REDACTED] in [REDACTED] numbers. For example, in 2020, JLI filled more than [REDACTED], in 2021 it filled [REDACTED], in 2022 it filled [REDACTED], and [REDACTED] s from January to July 2023. JLI-NJOY-ITC1368-01738679 ([REDACTED]). Dr. Seth will opine that these filling activities will decline steeply, as some activities may remain for overseas distribution, however, a [REDACTED] of JLI's revenues come from U.S. consumers. JX-0081C ([REDACTED]); JX-0118; JX-0035C ([REDACTED]).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

The evidence will show that past flavor bans indicate that an exclusion order in this Investigation may result in approximately 25 to 31 million fewer ENDS pods sold in the U.S. over one year. JX-0387 (Yang, The Impact of a Comprehensive Tobacco Product Flavor Ban In San Francisco Among Young Adults). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The reduced manufacturing activity would likely eliminate hundreds of jobs in ENDS manufacturing in the U.S. in the short term, including JLI's labor force in the U.S, in addition to third-party contractors supporting JLI's production operations. JX-0647C.59 (Seth Rpt.) ¶ 112.n.221 (and documents cited therein).

Another seller of ENDS products with U.S.-based manufacturing is R.J. Reynolds Vapor Company, which produces the Vuse ENDS products. Dr. Seth will opine that it may also have difficulty meeting the demand created from an exclusion order impacting the availability of JUUL products. R.J. Reynolds Vapor adopted a manufacturing process for Vuse wherein the e-liquid is produced in the U.S., while the pods are manufactured in China. JX-0467 (Vuse, Where Are Vuse Pods Made?). Dr. Seth will opine that due to Vuse's efficient manufacturing, it is unclear whether it would be able to meet the demand to replace JUUL products in the event of exclusion. RX-1020C (Seth Tr.) at 223:10-224:25. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, the evidence will show that it is likely that the requested remedial order will reduce manufacturing of like or directly competitive products in the U.S.

4. The Requested Relief Will Have An Adverse Impact on U.S. Consumers

The evidence will show and Dr. Seth will opine that an exclusion order directed to JUUL products would remove JUUL from the ENDS market and result in a significant portion of current JUUL users either switching back to combustible cigarettes or to other less effective and/or

unregulated, illegal alternatives. JX-0647C.52-61 (Seth Rpt.) at ¶¶ 94-115; RX-1020C (Seth Tr.) at 79:20-25, 252:20-253:20; see also RX-1019C (Madl Tr.) at 144:11-145:25. Under the requested remedial order, consumers will lose access to the ENDS brand on the market for tobacco-flavored e-liquid. JX-0035C). As discussed above, JUUL products have the highest switching rates, of nearly 60%, which evinces subjective satisfaction and balanced abuse liability. *See* Sections VII.E.i-iii *supra* (switching and satisfaction).

Given JUUL customers' revealed preferences, brand loyalty, and price premium, Dr. Seth will opine that the existence of the JUUL System provides a consumer welfare enhancing effect. JX-0647C.61 (Seth Rpt.) ¶ 116; *see* Section VII.F.1 *supra* (Public Health factor). Dr. Madl will opine that consumers who may switch to other noncombustible alternatives, such as NRTs, HTP, or smokeless tobacco, will use a less effective alternative than JUUL with respect to complete switching. *See, e.g.*, RX-1019 (Madl Tr.) at 73:25-74:20, 75:11-25, 76:13-18, 80:10-16, 81:6-12, 82:25-83:20; JX-0650C.9, 67, 80-81, 84, 95 (Madl Rpt.).

F. Declining To Implement or Delaying the Requested Remedial Orders Would Mitigate Harm to the Public Interest

The evidence and expert testimony will show that, if there is a finding of a violation of Section 337, the Commission should decline to issue any remedial orders given the public interest concerns as explained herein. Alternatively, delaying the requested remedial orders for at least months and as many as months to enable JLI's JUUL2 and/or pod products to enter the market would mitigate harm to the public interest. JX-0647C.61-62 (Seth Rpt.) at Section XI; JX-0650C.106-07 (Madl Rpt.). The Commission has "broad discretion in selecting the form, scope, and extent of the remedy" in a Section 337 proceeding. *Viscofan, S.A. v. ITC*, 787 F.2d 544, 548 (Fed. Cir. 1986). When crafting a remedy, the Commission balances the complainant's interest in obtaining relief against the disruption of legitimate trade. *See, e.g., Certain Personal Data &*

Mobile Comm'n Devices, No. 337-TA-710, Comm'n Op. at 81 (Dec. 29, 2011) (public version) (fashioning remedy to include delay to prevent disruption).

The evidence and expert testimony will demonstrate that the ALJ should exercise its discretion in fashioning a remedy should the ALJ find a violation of section 337, to delay enforcement of any remedial order where there is no evidence of adequate alternatives currently on the market, and where there is little evidence that any currently marketed ENDS manufacturers could replace the market in a commercially reasonable time. RX-1020C (Seth Tr.) at 261:5-236:3. Where JLI currently has pending regulatory applications for _____, a delay to allow _____ would mitigate the adverse impacts to public health, and would ensure that JUUL's ENDS products—with the highest effectiveness and switching rates on the market today—available to the millions of U.S. adult smokers who are trying to completely switch off of combustible cigarettes.

VIII. CONCLUSION

For the reasons set forth above, the evidence at the Hearing will demonstrate that JLI has not violated Section 337 because the Accused JLI Products do not practice any of the asserted claims; the asserted claims are invalid for multiple reasons; and NJOY does not satisfy the either the technical or economic prong of the domestic industry requirement. And even if it is determined that there has been a violation of Section 337, it would be against the public interest to exclude the Accused JLI Products from the market.

Dated: May 6, 2024

Respectfully submitted,

/s/ Michael T. Renaud

Michael T. Renaud

Adam S. Rizk

William Meunier

Marguerite McConihe

Samuel Davenport

Matthew A. Karambelas

Catherine Xu

James Thomson

Courtney Herndon

Paul Weinand

Meena Seralathan

Tianyi Tan

Hannah M. Edge

MINTZ LEVIN COHN FERRIS

GLOVSKY AND POPEO PC

One Financial Center

Boston, MA 02111

Tel: (617) 542-6000

Fax: (617) 542-2241

David Hollander

MINTZ LEVIN COHN FERRIS

GLOVSKY AND POPEO PC

555 12th Street NW, Suite 1100

Washington, DC 20004

Tel: (202) 434-7300

Fax: (202) 434-7400

Reza Dokhanchy

MINTZ LEVIN COHN FERRIS

GLOVSKY AND POPEO PC

3580 Carmel Mountain Road, Suite 300

San Diego, CA 92130

Tel: (858) 314-1596

Fax: (858) 314-1501

Mintz-JUUL-ITC-2@mintz.com

Counsel for Respondent

JUUL Labs, Inc.

CERTIFICATE OF SERVICE

I, Megan A. De Renzis, hereby certify that on May 24, 2024, true and correct copies of the forgoing document were served on the parties as indicated below:

The Honorable Lisa R. Barton Secretary to the Commission United States International Trade Commission 500 E Street SW, Room 112 Washington, DC 20436	☒ Via EDIS ☐ Via Hand Delivery ☐ Via Federal Express (Overnight) ☐ Via Electronic Mail
The Honorable Doris Johnson Hines Administrative Law Judge United States International Trade Commission 500 E Street SW, Room 317 Washington, DC 20436 JohnsonHines1372@usitc.gov	☐ Via EDIS ☐ Via Hand Delivery ☐ Via Federal Express (Overnight) ☒ Via Electronic Mail ☒ Via Box
Vu Bui, Esq. The Office of Unfair Import Investigations United States International Trade Commission 500 E Street SW, Room 317 Washington, DC 20436 Vu.Bui@usitc.gov	☐ Via EDIS ☐ Via Hand Delivery ☐ Via Federal Express (Overnight) ☒ Via Electronic Mail
<i>Counsel for Complainant NJOY, LLC</i> Elizabeth S. Weiswasser Anish R. Desai WEIL GOTSHAL & MANGES LLP 767 5th Avenue New York, NY 10153 Telephone: (212) 310-8000 W. Sutton Ansley Christopher M. Pepe Matthew D. Sieger WEIL GOTSHAL & MANGES LLP 2001 M Street NW, Suite 600 Washington, DC 20036 Telephone: (202) 682-7000 Adrian C. Percer WEIL GOTSHAL & MANGES LLP 201 Redwood Shores Parkway Redwood Shores, CA 94065 Telephone: (650) 802-3000 Beth Wilkinson Brian L. Stekloff	☐ Via EDIS ☐ Via Hand Delivery ☐ Via Federal Express ☒ Via Electronic Mail

The Honorable Lisa R. Barton Secretary to the Commission United States International Trade Commission 500 E Street SW, Room 112 Washington, DC 20436	☒ Via EDIS ☐ Via Hand Delivery ☐ Via Federal Express (Overnight) ☐ Via Electronic Mail
James Rosenthal Alysha Bohanon Wilkinson Stekloff LLP 2001 M Street N.W., 10th Floor Washington, DC 20036 Telephone: (202) 847-4000 <u>NJOY.JUUL.ITC.1372@weil.com</u> NJOY-JUUL-ITC@wilkinsonstekloff.com .	

/s/Megan A. De Renzis
 Megan A. De Renzis
 Legal Specialist
 Mintz, Levin, Cohn, Ferris
 Glovsky and Popeo, P.C.
 555 12th Street NW, Suite 1100,
 Washington, DC 20004
 +1.202.434.7406
MADeRenzis@mintz.com