

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN DISPOSABLE VAPORIZER
DEVICES

Inv. No. 337-TA-1410

ORDER NO 28: INITIAL DETERMINATION DENYING MOTION FOR
TEMPORARY RELIEF

Administrative Law Judge Monica Bhattacharyya

(November 19, 2024)

Appearances:

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Pursuant to the Notice of Investigation, ((EDIS Doc. ID 826182) (July 17, 2024); 88 Fed. Reg. 59158 (EDIS Doc. ID 826550 (July 22, 2024)), and Commission Rule 210.66, this is the administrative law judge's initial determination regarding the motion for temporary relief filed by Complainants RAI Services Company ("RAIS"), R.J. Reynolds Vapor Company ("RJRV"), R.J. Reynolds Tobacco Company ("RJRT"), and RAI Strategic Holdings Inc. ("RAISH") (collectively, "Reynolds") in the matter of *Certain Disposable Vaporizer Devices*, Inv. No. 337-TA-1410. 19 C.F.R. § 210.66.

The administrative law judge hereby determines that the motion for temporary relief is DENIED.

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The following abbreviations may be used in this Initial Determination:

Tr.	Temporary Enforcement Hearing Transcript
JX	Joint Exhibit
CX	Complainants' exhibit
CPX	Complainants' physical exhibit
CDX	Complainants' demonstrative exhibit
RX	Respondents' exhibit
RPX	Respondents' physical exhibit
RDX	Respondents' demonstrative exhibit
CPHB	Complainants' pre-hearing brief (EDIS Doc. ID 832809)
CIB	Complainants' initial post-hearing brief (EDIS Doc. ID 834043)
CRB	Complainants' post-hearing reply brief (EDIS Doc. ID 834570)
RPHB	Respondents' pre-hearing brief (EDIS Doc. ID 832831)
RIB	Respondents' initial post-hearing brief (EDIS Doc. ID 834065)
RRB	Respondents' post-hearing reply brief (EDIS Doc. ID 834591)
SIB	Commission Investigative Staff's initial post-hearing brief (EDIS Doc. ID 834053)
SRB	Commission Investigative Staff's post-hearing reply brief (EDIS Doc. ID 834576)
PMTA	Premarket Tobacco Product Application
ENDS	Electronic Nicotine Delivery Systems

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Complainants on June 11, 2024 (EDIS Doc. ID 823475). 89 Fed. Reg. 59158 (July 22, 2024). Supplements to the complaint were filed on June 12, 2024 (EDIS Doc. ID 823583) and on July 1, 2024 (EDIS Doc. ID 824868). The Complaint, as supplemented, alleges violations of § 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by forty-two Respondents based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain disposable vaporizer devices and components thereof alleged to infringe certain claims of U.S. Patent No. 11,925,202 (“the ’202 patent”). *See* Compl. (EDIS Doc. ID 823475) (June 11, 2024); First Supplement to Compl. (EDIS Doc. ID 823583) (June 12, 2024); Second Supplement to Compl. (EDIS Doc. ID 824868) (July 1, 2024). On the same day as they filed their Complaint, the Complainants filed a Motion for Temporary Relief (EDIS Doc. ID 823483) under 19 U.S.C. § 1337(e) and (f) and 19 C.F.R. § 210.52.

The Commission instituted this Investigation against thirty-five respondents on July 22, 2024. *See* 89 Fed. Reg. 59158 (July 22, 2024) (“Notice of Investigation”). The Commission ordered institution of this investigation to determine “whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain [disposable vapor devices] by reason of infringement of one or more of claims 1, 3, 4, 8-13, and 15 of the ’202 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.” *Id.* The Commission also “provisionally accepted” Complainant’s Motion for Temporary Relief and referred the same to the presiding administrative law judge for investigation. *Id.*

The Notice of Investigation named the following entities as Respondents: Breeze Smoke, LLC (“Breeze Smoke”); Dongguan (Shenzhen) Shikai Technology Co., Ltd. (“Shikai Technology”); Vapeonly Technology Co. Ltd.; iMiracle (Shenzhen) Technology Co., Ltd.; Guangdong Qisitech Co., Ltd. (“Guangdong Qisitech”); Guangdong Fewo Intelligent Manufacturing Limited (“Fewo Intelligent”); Nevera (HK) Ltd.; Guangdong Cellular Workshop Electronics Technology Co., Ltd. (“Guangdong Cellular”); Wonder Ladies Ltd.; Sailing South Ltd.; Marea Morada Ltd.; Social Brands, LLC; Zhuhai Qisitech Co., Ltd. (“Zuhai Qisitech”); Shenzhen Han Technology Co., Ltd. (“Shenzhen Han”); Palma Terra Ltd.; Shenzhen IVPS Technology Co., Ltd. (“Shenzhen IVPS”); Heaven Gifts International Ltd.; Maduro Distributors d/b/a The Loon (“Maduro”); Bidi Vapor, LLC (“Bidi Vapor”); Kimsun Technology (HuiZhou) Co., Ltd.; Shenzhen Yanyang Technology Co., Ltd. (“Shenzhen Yangyang”); Pastel Cartel, LLC (“Pastel Cartel”); American Vape Company, LLC (“American Vape”); Affiliated Imports, LLC (“Affiliated Imports”); Shenzhen LC Technology Co., Ltd.; LCF Labs, Inc.; Shenzhen Kangvape Technology Co., Ltd. (“Kangvape”); Flumgio Technology Ltd.; Shenzhen Pingray Technology (“Shenzhen Pingray”); SV3, LLC d/b/a Mi-One Brands (“SV3”); Price Point Distributors Inc. d/b/a Price Point NY (“Price Point”); Flawless Vape Shop Inc.; Flawless Vape Wholesale & Distribution Inc.; TheSy, LLC d/b/a Element Vape; and VICA Trading Inc. d/b/a Vapesourcing. *Id.* The Office of Unfair Import Investigations is also a party to the investigation. *Id.*

Pursuant to Order No. 6, the undersigned designated the temporary relief proceedings as “more complicated” pursuant to Commission Rule 210.60 and set the evidentiary hearing on the Motion for Temporary Relief for September 26-27, 2024. Order No. 6 (July 26, 2024).

On August 28, 2024, the undersigned issued an initial determination terminating the investigation as to Respondent Kimsun Technology (HuiZhou) Co., Ltd. based on the entry of a

consent order. *See* Order No. 10 (Aug. 28, 2024), *unreviewed by* Comm’n Not. (EDIS Doc. ID 832922). On September 3, 2024, the undersigned issued an order requiring Respondents Vapeonly Technology Co. Ltd.; iMiracle (Shenzhen) Technology; Nevera (HK) Ltd.; Wonder Ladies Ltd.; Sailing South Ltd.; Marea Morada Ltd.; Social Brands, LLC; Palma Terra Ltd.; Heaven Gifts International Ltd.; Shenzhen LC Technology Co., Ltd.; LCF Labs, Inc.; Flumgio Technology Ltd.; Flawless Vape Shop Inc.; Flawless Vape Wholesale & Distribution Inc.; and VICA Trading Inc. d/b/a Vapesourcing to show cause why they should not be found in default for failure to respond to the Complaint and Notice of Investigation. *See* Order No. 11 (Sept. 3, 2024). On September 16, 2024, the undersigned issued an initial determination finding those same Respondents in default. *See* Order No. 17 (Sept. 16, 2024), *unreviewed by* Comm’n Not. (EDIS Doc. ID 834276). On November 5, 2024, the undersigned issued an initial determination terminating the investigation as to Respondent Bidi Vapor, LLC based on the entry of a consent order. *See* Order No. 26 (Nov. 5, 2024). There are eighteen remaining respondents in the investigation (collectively, “Respondents”).

On August 12, 2024, Respondents jointly filed a memorandum in opposition to Complainant’s Motion for Temporary Relief (“Respondents’ TEO Opposition”). (EDIS Doc. ID 829336).

An evidentiary hearing on Complainant’s Motion for Temporary Relief was held on September 26 and September 27, 2024, with additional hearing testimony expert witnesses on the issue of Complainant’s bond on October 8, 2024. *See* Order No. 18 (Sept. 19, 2024). The parties filed initial post-hearing briefs on October 3, 2024, and filed reply post-hearing briefs on October 10, 2024.

The Initial Determination on Temporary Relief is due November 19, 2024. *See* Order No. 6 (July 26, 2024).

B. The Private Parties

1. Complainants

Complainants in this Investigation are RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, R.J. Reynolds Tobacco Company, and RAI Services Company (collectively, “Reynolds” or “Complainants”). Complainants are all are all North Carolina corporations and share the same principal place of business located at 401 North Main Street, Winston-Salem, N.C. 27101. CIB at 4; Compl. ¶¶ 7-10. RAI Strategic Holding is the assignee and sole owner of the Asserted Patent. CIB at 4; Compl. ¶ 7. R.J. Reynolds Vapor Company is a licensee of the Asserted Patent and is responsible for developing, distributing, and selling the DI Products. CIB at 4; Compl. ¶ 8. RAI Services Company provides research and technical support for the D.I. products. CIB at 4; Compl. ¶ 10. R.J. Reynolds Tobacco Company provided research and technical support for the DI products prior to February 2023. CIB at 4; Compl. ¶ 9.

2. Respondents

a. Breeze Respondents

Breeze Smoke LLC (“Breeze Smoke”) is a Michigan limited liability company with a registered address at 23999 West 10 Mile Road, Suite 200, Southfield, MI 48033. RIB at 10; Compl. ¶ 11.

Dongguan (Shenzhen) Shikai Technology Co., Ltd. (“Shikai Technology”) is a Chinese limited company located at No. 6, Shayong Road, Shajiao Community, Humen Town, Dongguan City, Guangdong Province, China. Shikai Technology manufactures Breeze-Smoke products. RIB at 10; Compl. ¶ 14.

b. Qisitech Respondents

Guangdong Qisitech Co., Ltd. (“Guangdong Qisitech”) is a Chinese limited company with an address at Room 201, Building 3, No. 36, Fuxing Road, Chang’an Town, Dongguan, Guangdong, China 523850. RIB at 11; Compl. ¶ 19.

Guangdong Fewo¹ Intelligent Manufacturing Limited (“Fewo Intelligent”) is a Chinese limited company with an address at 6th Floor Building A9, Zone A, Zhenghong High Tech Industrial Park, No. 243 Huiade Road, Dongguan City, Guangdong Province, China. RIB at 11; Compl. ¶ 20.

Guangdong Cellular Workshop Electronics Technology Co., Ltd. (“Guangdong Cellular”) is a Chinese limited company with an address at Room 201, Building 3, No. 216, Chang’an Bubugao Road, Chang’an Town, Dongguan City, Guangdong Province, China 523850. RIB at 11; Compl. ¶ 22.

Zhuhai Qisitech Co., Ltd. (“Zhuhai Qisitech”) is a Chinese limited company with an address at Room 201, Building 5, No. 16, Jinxing Road, Tangjiwan Town, High-tech Zone, Zhuhai, China. RIB at 11; Compl. ¶ 27.

c. Shenzhen Han

Shenzhen Han Technology Co., Ltd. (“Shenzhen Han”) is a Chinese limited company with an address at Qianwan Hard Technology Park, Bao’an District, Shenzhen, Guangdong Province, China 518126. RIB at 11; Compl. ¶ 28.

¹ An alternative spelling of “Fuwo” also appears in the record. *See* EDIS Doc. ID 831412.

d. Shenzhen IVPS

Shenzhen IVPS Technology Co., Ltd. (“Shenzhen IVPS”) is a Chinese limited company with an address at 101, Building B8, No. 2, Cengyao Industrial Area, Yuluv Community, Yutang Subdistrict, Guangming District, Shenzhen, China, 518001. RIB at 11; Compl. ¶ 30.

e. Maduro

Maduro Distributors Inc. d/b/a The Loon (“Maduro”) is a Minnesota corporation with a registered address at 3021 82nd Lane NE, Blaine, Minnesota 55449 and a principal executive office address of 7580 Commerce Lane NE, Fridley, Minnesota 55432. RIB at 12; Compl. ¶ 35.

f. Shenzhen Yangyang

Shenzhen Yangyang Technology Co., Ltd. (“Shenzhen Yangyang”) is a Chinese limited company with an address at No. 8 Taixiang Road, High-Tech Industrial Park, Huicheng Dist., Huizhou, Guangdong, China 516025. RIB at 12; Compl. ¶ 40.

g. Pastel Respondents

Pastel Cartel, LLC (“Pastel Cartel”) is a Texas limited liability company located at 5900 Balcones Drive, Suite 100, Austin, TX 78731-4298. RIB at 12; Compl. ¶ 42.

American Vape Company, LLC (“American Vape”) is a Texas limited liability company located at 13326 Immanuel Road, Pflugerville, Texas United States 78660. RIB at 12; Compl. ¶ 43.

Affiliated Imports, LLC (“Affiliated Imports”) is a Texas limited liability company located at 5900 Balcones Drive, Suite 100, Austin, TX 78731-4298. RIB at 12; Compl. ¶ 44.

h. Kangvape

Shenzhen Kangvape Technology Co., Ltd. (“Kangvape”) is a Chinese limited company with an address at Chuangxin Port, Hanyu Bay District, Fuhai Street, Bao’an District, Shenzhen, China. RIB at 12; Compl. ¶ 51.

i. Shenzhen Pingray

Shenzhen Pingray Technology (“Shenzhen Pingray”) is a Chinese limited company located at Building G, West Pioneer Park, Wangeng Community, Shajing Street, Bao’an District, Shenzhen City, China. RIB at 13; Compl. ¶ 55.

j. SV3

SV3 LLC d/b/a Mi-One Brands (“SV3”) is an Arizona limited company with a registered address of 2303 N. 44th Street Unit 2, Phoenix, Arizona 85008, USA. RIB at 13; Compl. ¶ 58.

k. Price Point

Price Point Distributors Inc. d/b/a Price Point NY (“Price Point”) is a New York corporation with its principal place of business at 500 Smith Street, Farmingdale, New York 11735. RIB at 13; Compl. ¶ 59.

l. Element Vape

Thesys, LLC d/b/a Element Vape (“Element Vape”) is a California limited liability company with a principal place of business at 10620 Hickson Street, El Monte, California 91731. RIB at 13; Compl. ¶ 62.

C. Products at Issue

Both the Accused Products and the DI Products are Electronic Nicotine Delivery Systems (“ENDS”). SIB at 4-5; CIB at xviii; RIB at 1. The Accused Products are disposable vaporizer devices, while the DI Products are rechargeable closed-system (“RCS”) devices. *See* SIB at 5; Tr. (Mras) at 74:24-75:1 (identifying the VUSE DI Products as a “pod-based rechargeable closed system vape product”); Tr. (Mooney) at 361:1-3 ([Q]: And all of the accused products are the disposable-type ENDS products? [A]: They are disposable-format ENDS products.”).

1. The TEO-Analyzed Accused Products

In the temporary enforcement proceedings, Reynolds identified fifty-one models of Accused Products (“the TEO-Analyzed Accused Products” or “Accused Products”). *See* CDX-0009.7; Tr. (Wensley) at 233:23-234:5. The Breeze Smoke Pro Edition; Funky Republic Ti7000; NOVO Bar AL9000; Hyppe Max Flow Mesh 2000 puffs; Lost Mary BM5000; Breeze Smoke Prime Edition; Elf Bar BC5000; Lost Mary MO5000; Posh Max 2.0; EBDesign BC5000; Off-Stamp SW9000; Esco Bars 2500 Mesh; EBCreate BC5000; Space Mary SM8000; Esco Bars Kilo 4000 puffs; KangVape ONEE Stick 5200 puffs; RABBEATS RC10000; EBCreate BC5000 Thermal Edition; KangVape SMOD ONEE Max 6000 puffs; RABBEATS RC10000 Touch; Elf Bar TE5000; Elf Bar TE6000; RAZ DC25000; Flum Float; EBDesign TE6000; RAZ TN 9000; Flum Gio; Elf Bar Pod King XC5000; Priv Bar Turbo; MORF Bar Touch 20K Kit; Funky Lands Ti7000; NOVO Bar AL6000; Funky Republic Fi3000; Geek Bar Pulse; Lost Mary OS5000; Hyppe Max Air 5000 puffs; Lost Mary MT15000 Turbo; Mr. Fog Switch; RAZ CA6000; Loon Air; Flum Pebble; Geek Bar B5000; and Flum UT Bar are accused of infringing claims 1, 4, 9 and 12 of the ’202 patent. CDX-0009.10; Tr. (Wensley) at 237:8-15. The Breeze Smoke Plus Edition; Loon Maxx; BIDI Stick Regal;² KangVape ONEE Max 5000 puffs; Hyppe Max 1600 puffs; KangVape ONEE Stick 1800 puffs; Mr. Fog Max; and Flum Mi are accused of infringing claims 1, 4 and 9 of the ’202 patent. CDX-0009.10; Tr. (Wensley) at 237:8-15.

² The undersigned notes that Bidi Vapor, LLC has been terminated from the investigation on the basis of a proposed consent order. *See* Order No. 26 (Nov. 5, 2024). However, there is not a one-to-one correlation between Respondents and Accused Product brands; that is, there is evidence that manufacturers may produce more than one brand of product and that distributors may sell more than one brand of product. *See, e.g.*, CIB at 18-19 (Shenzhen Han and Qisitech Respondents identifying various brands of Accused Products as relevant to their businesses); *id.* at 20 (SV3 and Element Vape identifying various brands of Accused Products as relevant to their businesses). The parties have not clearly identified which Accused Products—if any—are not longer at issue as a result of consent orders or defaults.

Mr. Wensley presented a “detailed” infringement analysis for 21 of the 51 products. Reynolds contends that the infringement analysis presented for “the 21 Accused Products analyzed in detail” at the hearing “extend to all 51 of the Accused Products.” CIB at 14 (citing Tr. (Wensley) at 237:4-19). Reynolds contends that Respondents have not identified any substantive or relevant differences among the Accused Products. CIB at 14 (citing Tr. (McAlexander) at 456:4-21; Tr. (Wensley) at 236:8-11).

Respondents, however, contend that Mr. Wensley “should be held to the scope of his testimony,” and contend that Mr. Wensley admitted that there were “differences” among the products. RIB at 39 (citing Tr. (Wensley) at 267:24-268:4).

Upon review of the arguments and record evidence, the undersigned finds that Reynolds has met its burden to establish representativeness as to the 51 TEO-Analyzed Accused Products. Mr. Wensley testified that he examined “teardown reports” for every such Accused Product, prepared claim charts for every such Accused Product, and reviewed and tested physical samples of 50 of these Accused Products. Tr. (Wensley) at 234:5-235:5. Based on this analysis, Mr. Wensley testified that all the products he examined had the same general structure and operation. Tr. (Wensley) at 235:17-19. Respondents have not identified any relevant differences in the 51 TEO-Analyzed Accused Products. *See, e.g., Certain Portable Battery Jump Starters & Components Thereof*, Inv. No. 337-TA-1256, Initial Determination, 2022 WL 1658137, at *132 (Apr. 29, 2022) (rejecting challenge to representativeness analysis where respondents failed to “argue specific material differences”). Based on Mr. Wensley’s testimony, and the lack of persuasive countervailing evidence, for purposes of the temporary relief phase of the investigation, Reynolds has shown that Mr. Wensley’s testimony as to the 21 TEO-Analyzed Accused Products is representative of the remaining 30 TEO-Analyzed Accused Products.

2. The Additional Accused Products

In addition to the 51 TEO-Analyzed Accused Products, Reynolds also references “remaining Accused Products,” and contends that those (unidentified) products are accused. *See* CIB at 14 (referring to the “remaining Accused Products” beyond the 51 products analyzed in detail); Tr. (Wensley) at 235:20-23 (“[Q]: Now, are you aware of any additional accused products, other than the ones you have identified here on slide 7? [A]: I’m aware there are additional accused products.”).

Respondents identified—in their pre-hearing brief and again in their opening post-hearing brief—a list of additional Accused Products for which Reynolds did not present an infringement analysis, which they term the “Ignored Products.” *See* RIB at 40-41; Compl. ¶¶ 71-89.³ Respondents contend that Reynolds ignored these products and did not meet their burden to establish representativeness. RIB at 41.

Reynolds does not address infringement of the Additional Accused Products in their opening or reply post-hearing briefing, except to assert that (1) “neither Respondents nor their experts identified a single difference between the dozens of Accused Products relevant to infringement”; and (2) that the Commission’s standard practice is that a remedial order “cover[s] products of the named Respondents that infringe the asserted claims” and is not limited to particular models. *See* CRB at 17-18; CIB at 14-15.

Staff asserts that the Accused Products for which infringement evidence was presented are limited to the 51 products discussed above, “plus any additional products covered by a Respondent’s representative product stipulation that might fall within the set of 51,” and that

³ The products identified by Respondents as “Ignored Products” appear to be identified in the Complaint as accused products.

“the Complainants failed to offer any proof of infringement regarding any other products.” SIB at 11 n.4.

Upon review of the arguments and record evidence, the undersigned finds that as to the accused products other than the TEO-Analyzed Accused Products above (“the Additional Accused Products”), Reynolds has not met its burden to establish representativeness or otherwise presented any evidence of infringement as to these products. Reynolds does not dispute that the Additional Accused Products were sufficiently disclosed or that Reynolds itself sought adjudication of the products by accusing them of infringement. RRB at 16 (“[The Additional Accused Products] were disclosed by Respondents; and they were accused initially by Complainants.”); CIB at 14 (referring to the “remaining Accused Products”). The Additional Accused Products, then, do not appear to be unaccused. To the extent Reynolds seeks to have the Additional Accused Products included within a remedial order provided in connection with the TEO proceedings, Reynolds bears the burden of establishing a likelihood of infringement. *See Certain LED Lighting Devices, LED Power Supplies, & Components Thereof*, Inv. No. 337-TA-1081, Comm’n Op., EDIS Doc. ID 682650, at 10 (July 23, 2019) (“*LED Lighting Devices*”) (“Complainants have the burden of proof to show infringement for each accused product.”); *Certain Lithium Metal Oxide Cathode Materials, Lithium-Ion Batteries for Power Tools, Products Containing Same, and Power Tool Products with Lithium-Ion Batteries Containing Same*, Inv. No. 337-TA-951, Order No. 19, EDIS Doc. ID 566036 at 11 (Sept. 14, 2015) (“*Lithium-Ion Batteries*”) (“Administrative Law Judges may grant summary determination of non-infringement where a Complainant fails to present evidence of infringement on a product, yet seeks to have the product covered by the exclusion order.”) (citing *inter alia Certain Flash*

Memory Circuits and Products Containing Same, Inv. No. 337-TA-382, Comm’n Op., EDIS Doc. ID 45523, at 18-25 (June 26, 1997).⁴

As to representativeness, although a complainant may rely upon analysis of a representative product, the complainant “cannot simply assume that the [analyzed products] are representative of the [unanalyzed products],” but rather “must show by a preponderance of the evidence that the products its expert[] analyzed are indeed representative of unanalyzed products.” *Id.* (quoting *Certain Semiconductor Devices, Semiconductor Device Packages, and Products Containing Same*, Inv. No. 337-TA-1010, Order No. 77 (Mar. 15, 2017), *not reviewed in relevant part*, EDIS Doc. ID 608676 (Apr. 14, 2017)). Reynolds’ expert, however, testified that he knew “nothing” about the products other than the 51 he specifically analyzed other than an “understanding” that they were “similar, if not the same.” Tr. (Wensley) at 235:25-236:1 (“[Q]: Do you know what kind of products [the additional accused products] are? [A]: My understanding is that they are similar, if not the same as these. But beyond that, *nothing*.”) (emphasis added)). Mr. Wensley’s testimony that he would expect the Ignored Products to be “fairly similar or very similar,” Tr. (Wensley) at 236:2-7, is not credible in view of his testimony that he knew “nothing” about the Additional Accused Products beyond an “understanding”—and for which no basis, source, or explanation was provided—that the Additional Accused Products were similar to those he analyzed. *See also* Tr. (Wensley) at 270:12-16 (“I haven’t seen them and I haven’t analyzed them, so I don’t know.”). Mr. Wensley’s unsupported and conclusory testimony does not satisfy Reynolds’ burden on representativeness.

⁴ Reynolds’ citations then, regarding the Commission’s practice as to unadjudicated products, CIB at 15, are inapposite. Moreover, Reynolds’ citation to Mr. McAlexander’s testimony regarding accused products (CRB at 18) is unpersuasive. Mr. McAlexander’s analysis was focused on rebutting the claim charts provided by Mr. Wensley, and Mr. Wensley testified that he had not analyzed products other than the 51 TEO-Analyzed Products. *See* Tr. (McAlexander) at 444:5-12; Tr. (Wensley) at 235:25-236:1, 270:12-16.

Reynold's post-hearing briefs contain no persuasive infringement arguments addressed to the Additional Accused Products. Accordingly, any such arguments have been waived and Reynolds has failed to meet its burden of proof. *LED Lighting Devices*, EDIS Doc. ID 682650, at 10; Ground Rule 13.1. Reynolds has failed to show a likelihood of success as to infringement of the Additional Accused Products.

3. The DI Products

The Reynolds DI Products are the VUSE Solo, the VUSE Vibe, the VUSE Ciro, and the VUSE Alto. Each of the DI Products are asserted to practice claims 1, 5, 9, and 14 of the '202 patent. CIB at 111-112; CX-0006C (Wensley WS) at Q20, Q26 ("I understand that Complainants have identified four products as the relevant Domestic Industry Products in this Investigation: VUSE Solo; VUSE Vibe; VUSE Ciro; and VUSE Alto.").

D. Witness Testimony

The parties presented testimonial evidence in the temporary enforcement phase of this investigation in the form of live testimony, deposition designations, and witness statements on discrete issues. *See* Order No. 12 (Sept. 3, 2024).

1. Party Witnesses

Reynolds presented live testimony from Ms. Valerie Mras, President of R.J. Reynolds Vapor Company (Tr. at 51:22-23); and Mr. Robert Ferris, Sr. Director of Strategy and Planning at Reynolds American Services Company (Tr. at 106:23-107:4). Reynolds also presented a witness statement from Mr. Ferris, CX-0007C, on economic domestic industry. Respondents did not present testimony from party witnesses.

2. Expert Witnesses

Reynolds' first expert witness was Mr. Ramon Alarcon, who was admitted as an expert in disposable vaporizer devices, tobacco products, and electronically powered smoking articles, including their components and underlying technologies. Tr. at 145:5-226:18 (expert qualification at 148:12-16). Reynolds also called Mr. Martin Wensley, who was admitted as an expert in vaporizer devices, tobacco products, and electrically powered smoking articles, including their components and underlying technologies. Tr. at 226:19-297:5 (expert qualification at 231:9-12). Mr. Wensley also presented testimony on technical domestic industry in a witness statement, CX-0006C. Reynolds also called Mr. Drew Mooney, who was admitted as an expert in an expert in accounting and economics, including intellectual property valuation. Tr. at 297:6-327:25, 346:12-391:6, 735:22-771:17 (expert qualification at 300:8-10). Mr. Mooney also presented testimony on economic domestic industry in a witness statement, CX-0004C. Finally, Reynolds called Dr. Edward Murrelle, who was admitted as an expert in the field of an expert in the field of public health as it relates to tobacco and potentially reduced risk products. Tr. 391:7-436:12 (expert qualification at 395:4-6). Dr. Murrelle also presented testimony as to the public interest in a witness statement, CX-0005C.

Respondents' first expert witness was Mr. Joe McAlexander, who was admitted as an expert in the field of electrical engineering.⁵ Tr. 437:4-477:24 (expert qualification at 443:17-23). Respondents also called Dr. Douglas Dean, who was admitted as an expert in the field of engineering, electronic nicotine delivery systems, and the scientific principles relating to the same. Tr. at 478:5-540:5 (expert qualification at 483:8-11). Respondents also called Dr. DeForest

⁵ The undersigned deferred the issue of whether Mr. McAlexander qualified as an expert in "the design and integration of components that are used in systems such as the smoking articles described in the '202 patent" for resolution on a full record. Tr. at 443:17-23. Mr. McAlexander's expert qualifications and whether he qualifies as one of skill in the art is addressed *infra* Part V.A.

McDuff, who was admitted as an expert in an economics. Tr. at 540:7-655:18, 689:8-735:18 (expert qualification at 542:25-543:1).

3. Deposition Designations

No designated deposition transcripts were received into evidence.

II. STATUTORY AUTHORITY AND LEGAL STANDARDS

A. Statutory Authority

The Commission has statutory authority over the present investigation, which includes the authority to investigate accused articles that are imported into the United States or sold after importation, and the authority to investigate the importation into the United States or the sale of such articles. *See Certain Video Security Equipment and Sys., Related Software, Components Thereof, and Prods. Containing Same*, Inv. No. 337-TA-1281, Comm’n Op., EDIS Doc. ID 794569, at 9-10 (Apr. 19, 2023); *Certain Portable Battery Jump Starters and Components Thereof (III)*, Inv. No. 337-TA-1360, Comm’n Notice, EDIS Doc. ID 826741, at 3 (July 22, 2024). Respondents have appeared and participated in the investigation, and Respondents do not dispute the Commission’s statutory authority, other than with respect to the importation issues detailed below. *See* CRB at 5; RIB at 22; *infra* Part IV.

B. Legal Standards for Temporary Relief

Commission Rule 210.52, which governs motions for temporary relief states, in pertinent part:

In determining whether to grant temporary relief, the Commission will apply the standards the U.S. Court of Appeals for the Federal Circuit uses in determining whether to affirm lower court decisions granting preliminary injunctions.

19 C.F.R. § 210.52(a); 19 U.S.C. § 1337(e)(3); *see also Rosemount, Inc. v. U.S. Int’l Trade Comm’n*, 910 F.2d 819, 821 (Fed. Cir. 1990) (“[T]he statute now requires that the exercise of

[the Commission’s] temporary relief authority should generally parallel that of the district courts.”). “When a patentee sues an alleged infringer for patent infringement and . . . moves . . . for the extraordinary relief of a preliminary injunction, the patentee’s entitlement to such an injunction is a matter largely within the discretion of the trial court.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375 (Fed. Cir. 2009) (citing *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). “To obtain a preliminary injunction, a party must establish likelihood of success on the merits, likelihood it will suffer irreparable harm absent preliminary relief, the balance of equities tips in its favor, and an injunction is in the public interest.” *Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024); see also *Certain Silicon Microphone Packages and Products Containing Same*, Inv. No. 337-TA-695, TEO ID, EDIS Doc. ID 422312, at 6 (Mar. 24, 2010) (“*Microphone Packages*”).

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *UATP IP, LLC v. Kangaroo, LLC*, No. 2022-2047, 2024 WL 658205, at *2 (Fed. Cir. Feb. 16, 2024) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)); see also *Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022) (characterizing a preliminary injunction as “rare and extraordinary relief”).

1. Likelihood of Success on the Merits

“A preliminary injunction cannot be granted unless the movant establishes **both** of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm.” *Certain Composite Wear Components and Welding Products*, Inv. No. 337-TA-644, Comm’n Op., EDIS Doc. ID 444172, at 10 (Feb. 10, 2011) (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis original)). With respect to the first factor, a patentee seeking preliminary relief “must show that it will likely prove infringement, and that it

will likely withstand challenges, if any, to the validity of the patent.” *Id.* (quoting *Titan*, 566 F.3d at 1372); *see also Natera, Inc. v. NeoGenomics Lab ’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (similar). In addition, in the Section 337 context, the complainant must show it is reasonably likely to establish the existence of a domestic industry. *See Certain Sulfentrazone, Sulfentrazone Compositions, & Processes for Making Sulfentrazone*, Inv. No. 337-TA-914, TEO ID, EDIS Doc. ID 541146, at 97 (Aug. 28, 2014) (“*Sulfentrazone*”).

The trial court’s decision requires “balancing of all the evidence” to determine whether the patentee has “succeeded in showing it is likely to succeed at trial on the merits.” *Titan*, 566 F.3d at 1378-79. The decision may be based “on less than a complete record or on disputed facts whose eventual determination will require trial.” *Id.* at 1379 (citations omitted). “The burden is always on the movant to show that it is likely to succeed on the merits.” *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022).

a. Likelihood of Success on Infringement

Section 337(a)(1)(B)(i) prohibits “[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17[.]” 19 U.S.C.

§ 1337(a)(1)(B)(i). The Commission has held that the word “infringe” in Section 337(a)(1)(B)(i) “derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement.” *Certain Elec. Devices with Image Processing Sys., Components Thereof, & Associated Software*, Inv. No. 337-TA-724, Comm’n Op., EDIS Doc. ID 467105, at 13-14 (Dec. 21, 2011).

At trial, infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). In the context of a request for preliminary relief, “a patentee must show that it will likely prove infringement of the asserted claims.” *ABC Corp. I v. P’ship & Unincorporated Ass’ns Identified on Schedule “A”*, 52 F.4th 934, 942 (Fed. Cir. 2022). “If [the defendant] raises a substantial question concerning . . . infringement . . . , i.e., asserts an infringement . . . defense that the patentee cannot prove ‘lacks substantial merit,’ the preliminary injunction should not issue.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001) (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). “[W]hether performed at the preliminary injunction stage or at some later stage in the course of a particular case, infringement and validity analyses must be performed on a claim-by-claim basis.” *Id.* at 1351; *see also Well Cell Glob. LLC v. Calvit*, No. 2023-1229, 2023 WL 6156082, at *4 (Fed. Cir. Sept. 21, 2023).

i. Claim Construction

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996) (internal citation omitted). “[T]he construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims.” *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000) (alterations in original) (quoting *Scripps Clinic v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991)). “[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.” *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200

F.3d 795, 803 (Fed. Cir. 1999). The words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in art” as of the date that the patent application was filed. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

In the context of preliminary relief, there is “no obligation to definitively construe claims.” *Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024).

ii. Infringement Analysis

A patent claim is directly infringed when a respondent “makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention” without consent of the patent owner. 35 U.S.C. § 271(a).

Literal infringement requires the patentee to prove that the accused device meets each and every limitation of the asserted claim(s).⁶ *Frank’s Casing Crew & Rental Tools, Inc. v. Weatherford Int’l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). “If even one limitation is missing or not met as claimed, there is no literal infringement.” *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (internal quotation marks omitted). Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008).

b. Likelihood of Success on Invalidity

At trial, “a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence[.]” *SRAM Corp. v. AD-II Eng’g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006); *see also* *Microsoft Corp. v. i4i Ltd. P’ship*,

⁶ Reynolds has not asserted a theory of infringement under the doctrine of equivalents. *See* RIB at 34 n.2; Tr. (Wensley) at 294:9-12.

564 U.S. 91, 100-114 (2011) (upholding the “clear and convincing” standard for invalidity). In considering temporary relief, however, the showing asked of the alleged infringers at this stage “is lower than what is required to prove invalidity at trial.” *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1006 (Fed. Cir. 2009). In particular, the burden of establishing a likelihood of success on the merits cannot be met “if the alleged infringer raises a ‘substantial question’ regarding invalidity, i.e., asserts an invalidity defense that the patentee cannot prove ‘lacks substantial merit.’” *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007); *see also Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1205 (Fed. Cir. 2017) (“If the trial court concludes there is a ‘substantial question’ concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.”). Thus, “[a] patent holder seeking a preliminary injunction bears the burden of establishing a likelihood of success with respect to the patent’s validity.” *Entegris*, 490 F.3d at 1351; *see also Low Temp Indus., Inc. v. Duke Mfg. Co.*, No. 2021-2137, 2021 WL 6124455, at *3 (Fed. Cir. Dec. 28, 2021) (“In seeking a preliminary injunction, the patentee has the burden to show a likelihood of success regarding the patent’s validity; if the accused infringer raises ‘a substantial question regarding validity,’ the district court should find that the patentee has not shown a likelihood of success on the merits.”).

At the preliminary injunction stage, a defendant may raise a substantial question of validity “on evidence that would not suffice to support a judgment of invalidity at trial.” *Amazon.com*, 239 F.3d at 1358. “Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.” *Low Temp Indus.*, 2021 WL 6124455, at *3 (quoting *Amazon.com*, 239 F.3d at 1359).

c. Likelihood of Success on Domestic Industry

In patent-based proceedings under section 337, a complainant must establish that an industry “relating to the articles protected by the patent . . . exists or is in the process of being established” in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of section 337 consists of a “technical prong” and an “economic prong.” *See, e.g., Alloc, Inc. v. Intl Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals & Components Thereof*, Inv. No. 337-TA-524, Order No. 40, EDIS Doc. ID 230409, at 17-18 (Apr. 11, 2005). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.” *Alloc*, 342 F.3d at 1375.

With respect to the “economic prong,” subsection (3) of Section 337(a) provides:

For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Expenditures may be counted toward satisfaction of the domestic industry requirement “as long as those investments pertain to the complainant’s industry with respect to the articles protected by the asserted IP rights.” *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, Comm’n Op., 2015 WL 6755093, at *36 (Oct. 30, 2015); *accord, e.g., Certain Marine Sonar Imaging Devices, Including Downscan &*

Sidescan Devices, Prods. Containing the Same, & Components Thereof, Inv. No. 337-TA-921, Comm’n Op., 2016 WL 10987364, at *40 (Jan. 6, 2016) (“Navico’s allocation methodology reasonably approximates the warranty and technical customer support expenditures relating to the LSS-1 product.”) (citing *Certain Ground Fault Circuit Interrupters & Prods. Containing Same*, Inv. No. 337-TA-739, Comm’n Op. at 74-75, 79-81 (June 8, 2012)). Subsections (A), (B), and (C) are listed in the disjunctive, and accordingly, the domestic industry investments in plant and equipment or labor and capital can include expenditures that relate to engineering or research and development. *Certain Solid State Storage Drives, Stacked Electronics Components, & Prods. Containing Same*, Inv. No. 337-TA-1097, Comm’n Op., EDIS Doc. ID 649139, at 14 (June 29, 2018) (“[T]he text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude non-manufacturing activities, such as investments in engineering and research and development.”).

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op., EDIS Doc. ID 279161, at 39 (Aug. 1, 2007). The decision is made on a case-by-case basis and requires “an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace.” *Id.* Although Section 337(a)(3) describes the economic activities as “significant” and “substantial,” a complainant does not need to show any “minimum monetary expenditure,” and a complainant does not “need to define or quantify the industry itself in absolute mathematical terms.” *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm’n Op., EDIS Doc. ID 300615, at 26 (May 16, 2008). “A precise accounting [of the complainant’s domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.” *Id.*

2. Irreparable Harm

A party seeking a preliminary injunction must show it is likely to suffer irreparable harm if the injunction is not granted and establish a causal nexus between the alleged infringement and the alleged harm. *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016); *see also Natera*, 106 F.4th at 1378. “Where the alleged injury is not quantifiable, the harm cannot be adequately compensated and is irreparable.” *Natera*, 106 F.4th at 1378. “Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are examples of possible grounds for finding irreparable harm.” *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, No. 2023-1058, 2024 WL 358136, at *3 (Fed. Cir. Jan. 31, 2024). However, “[t]he mere possibility or speculation of harm is insufficient.” *Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1380 (Fed. Cir. 2022).

As to nexus, “[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.” *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). “For example, a battery does not necessarily drive demand for a laptop merely because its removal would render the laptop ineffective as a portable computer.” *Natera*, 106 F.4th at 1380 (citing *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1376 (Fed. Cir. 2012)).

3. Balance of Equities & Public Interest

A party seeking a preliminary injunction must also establish that “the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1369 (Fed. Cir. 2017). The district court must weigh the harm to the moving party if the injunction is not granted against the harm to the non-moving party if the injunction is granted. *Hybritech Inc. v. Abbott Labys.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). It is

within the court’s discretion to balance the equities. *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1234 (Fed. Cir. 1985). As to public interest, “although there exists a public interest in protecting rights secured by valid patents, the focus of the district court’s public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.” *Sulfentrazone*, EDIS Doc. ID 541146 at 121 (quoting *Hybritech*, 849 F.2d at 1458).

III. THE ASSERTED PATENT

U.S. Patent No. 11,925, 202 (“the ’202 patent,” JX-0001) is titled “Tobacco-Containing Smoking Article” and names John Howard Robinson, David William Griffith, Jr., Billy Tyrone Conner, Evon Llewellyn Crooks, and Dempsey Bailey Brewer, Jr. as inventors. ’202 patent, cover. The patent issued from an application filed on March 31, 2023, and claims priority through a series of continuation applications to U.S. Patent App. No. 11/550,634 filed on October 18, 2006. *Id.* As a consequence of a terminal disclaimer, the ’202 patent will expire on October 18, 2026. *See* CIB at 92-93.

A. Ownership

The ’202 patent is assigned to RAI Strategic Holdings, Inc. *See* ’202 patent, cover; CIB at 7; SIB at 4. Respondents do not dispute that at least one Complainant is the owner and assignee of the ’202 patent. *See generally* RIB; RRB.

B. Specification

The ’202 patent is directed to “smoking articles” that “produce aerosols incorporating components derived from, or provided by, tobacco.” ’202 patent, 4:51-53. With reference to the embodiment depicted in Figure 1, below, the smoking article includes (1) “an outer container or housing 20” including “a mouth-end 15 and an end 13 distal to the mouth-end,” *id.* at 19:58-59,

20:4-6; (2) “an electric power source 36, such as at least one battery,” *id.* at 20:24-25; (3) “electrically powered control components 50” that “provide control of time of operation, control of current, control of electrical resistance heat generation, and the like,” *id.* at 20:45-52; (4) “at least one electrical resistance heating element 70, 72,” *id.* at 21:28-29; and (5) “a cartridge 85” which “contains tobacco in some form” and “also most preferably contains aerosol-forming material,” *id.* at 22:9-16.

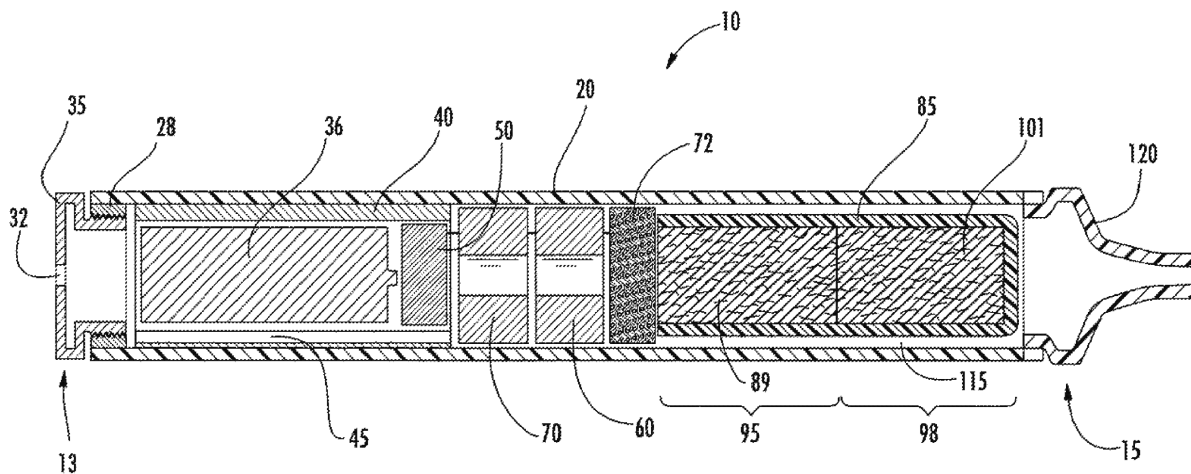


FIG. 1

C. Asserted Claims

For purposes of the temporary relief phase of the investigation, Reynolds asserts claims 1, 4, 9 and 12 of the '202 patent. CIB at 30. Reynolds relies on claims 1, 5, 9, and 14 of the '202 patent for purposes of the domestic industry requirement. *Id.* at 23, 44. The claims at issue of the '202 patent are reproduced below (with claim limitation identifiers added):

1. [1pre] An electrically-powered, aerosol-generating smoking article comprising:
 - [1a] an outer housing having two ends;
 - [1b] mouthpiece defined at one of the two ends;
 - [1c] an electrical power source arranged within the outer housing;

[1d] an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source

[1e] a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material;

[1f] an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece; and

[1g] a controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.

4. The electrically-powered, aerosol-generating smoking article of claim 1, wherein the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece.
5. The electrically-powered, aerosol-generating smoking article of claim 1, wherein the storage compartment is configured as a cartridge.
9. The electrically-powered, aerosol-generating smoking article of claim 1, wherein the electrical resistance heater is arranged in contact with the storage compartment.
12. The electrically-powered, aerosol-generating smoking article of claim 1, wherein the electrical resistance heater is configured to allow airflow therethrough.
14. The electrically-powered, aerosol-generating smoking article of claim 1, wherein the controller is configured to regulate the current flow through the electrical resistance heater during the draw on the electrically-powered, aerosol-generating smoking article.

'202 patent, cls. 1, 4, 5, 9, 12 and 14.

D. Level of Ordinary Skill in the Art

For purposes of the temporary relief phase of this investigation, Reynolds proposed the following level of ordinary skill in the art:

a bachelor's degree in mechanical engineering, electrical engineering, chemistry, or physics, and three to four years of industry experience. Or, a Master's degree in mechanical engineering, electrical engineering, chemistry, or physics, and one to two years of industry experience. Additionally, a POSA would have been familiar with electrically powered smoking articles and their components and underlying technologies or similar components and technologies.

CDX-0009.4; Tr. (Wensley) at 231:19-232:5; Tr. (Alarcon) at 148:18-149:4. Respondents' experts, Mr. McAlexander and Dr. Dean applied the same level of ordinary skill in the art. Tr. (McAlexander) at 452:21-25; Tr. (Dean) at 482:15-23. Staff does not dispute the proposed level of skill in the art. SIB at 7-8. Accordingly, for the purposes of the temporary relief phase of this investigation, the undersigned adopts Reynolds' proposed level of ordinary skill in the art.

E. Claim Construction

The parties have identified three claim construction disputes that require resolution:

(1) "smoking article"; (2) "storage compartment"; and (3) "controller." The identified terms are addressed below.⁷

1. "Smoking Article"

Claim Language	Reynold's Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"an electrically-powered, aerosol-generating smoking article"	Preamble is not limiting; plain and ordinary meaning	Preamble is limiting; "a smoking article that includes tobacco"	Plain and ordinary meaning ⁸

⁷ The parties also raised certain invalidity disputes that essentially—although not explicitly—raised claim construction disputes as to "ends" and "airflow." Those disputes are addressed in the context of the invalidity analysis, *infra*.

⁸ Staff does not appear to take a position as to whether the preamble is limiting.

Respondents propose a “contingent” construction of the term “smoking article” in the preamble of claim 1. That is, to the extent that the claims are not found to be invalid for insufficient written description,⁹ Respondents contend that the preamble of claim 1, “electrically-powered, aerosol-generating smoking article,” is limiting and limited to “a smoking article that includes tobacco.” RIB at 25. Respondents contend that the preamble is limiting because “many of the elements of claim 1 are triggered by or produce an output in relation to the electrically-powered, aerosol-generating smoking article,” and because the preamble provides antecedent basis for the term “electrically-powered, aerosol-generating smoking article,” which appears in the body of the claims. RIB at 26-27. Respondents contend that “smoking article” is limited to devices containing tobacco because “the Title, Summary of the Invention, and the Abstract all describe the invention as an article for smoking tobacco.” RIB at 27 (citing ’202 patent, Title, Abstract, 4:46-40). Respondents argue that it is not an embodiment that is described as limited to tobacco, but rather that “the invention as a whole is described as smoking articles that possess tobacco.” RIB at 28 (citing ’202 patent, 1:25-30, 4:30-44, 4:48-67, 5:5-17, 5:21-24, 5:41-43, 5:62-6:16, 6:30-35, 6:44-50, 6:53-58).

In opposition, Reynolds contends that the preamble is not limiting because “it simply provides a descriptive name for the structurally complete device described in the claims.” CIB at 12 (citing Tr. (Wensley) at 241:5-11). Reynolds argues that the preamble—and its usage elsewhere in the claims—can be deleted without altering the meaning or scope of the claim. CIB at 24-25. Moreover, even if limiting, Reynolds argues that the term “smoking article” is not limited to tobacco-containing devices. CIB at 25-26. Reynolds argues that the portions of the specification cited by Respondents describe preferred embodiments and that Respondents’

⁹ Respondents’ written description arguments are addressed *infra* Part VIII.C.

construction “improperly import[s] a limitation from the specification into the claims.” CIB at 27-28. Reynolds contends that the ’202 patent “incorporates by reference certain exemplary references describing entirely non-tobacco devices” and describes the use of liquid tobacco extracts. CIB at 28-29 (citing ’202 patent, 23:15-23; Tr. (Alarcon) at 155:5-9). Reynolds also argues that the ’202 patent specifically references—although denigrates as not preferred—pure nicotine extracts. CIB at 26-27 (citing ’202 patent, 23:30-24). These “unpreferred” embodiments, Reynolds argues, do not limit the scope of the term “smoking article.” RIB at 27 (citing *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.”)).

In response, Respondents renew their argument that the preamble is limiting because it provides “the antecedent basis for multiple instances of ‘smoking article’ in the body of the claim.” RRB at 6. As to the references incorporated into the specification, Respondents point out that such references were incorporated as “as “[e]xemplary types of tobacco extracts, tobacco essences, solvents, tobacco extraction processing conditions and techniques, and tobacco extract collection and isolation procedures.” RRB at 8 (citing ’202 patent, 13:1-21).

In Staff’s view, the phrase “smoking article” should be given its plain and ordinary meaning, which for purposes of the temporary relief phase of the proceeding, Staff believes “does not normally require the presence of tobacco.” SIB at 9.

Based on the current evidence and arguments of record, the undersigned first finds that the preamble is limiting. The preamble language provides antecedent basis for limitations in the body of claim 1 (e.g., “a controller configured to activate current flow through the electrical resistance heater in response to a draw on *the electrically-powered, aerosol-generating smoking*

article”). “When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.” *Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (quoting *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003)); *In re Fought*, 941 F.3d 1175, 1178 (Fed. Cir. 2019) (noting that “[w]e have repeatedly held a preamble limiting when it serves as antecedent basis for a term appearing in the body of a claim” and collecting cases).¹⁰

As to construction, for purposes of the temporary relief phase of the investigation and based on the current evidence of record, the undersigned finds that the specification reveals a clear disavowal of “smoking articles” that do not include some form tobacco, including tobacco-derived components (*e.g.*, tobacco or nicotine extracts that are derived from tobacco).¹¹ Accordingly, for purposes of the temporary relief phase of the investigation, the undersigned construes “smoking article” to necessarily incorporate tobacco or tobacco-derived components.

The Federal Circuit has explained that “the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (*en banc*). Disavowal “may be inferred from clear limiting descriptions of the invention in the specification or prosecution history.” *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012). Relevant here, “[i]t is axiomatic that, where the specification describes ‘the present invention’ as having [a] feature,’ that representation may disavow contrary embodiments.” *Techtronic Indus. Co. v. Int’l Trade Comm’n*, 944 F.3d 901, 907 (Fed. Cir.

¹⁰ Even if the preamble were not construed as limiting, the appearance of “smoking article” in the body of the claims means that the scope of the claims would be identical.

¹¹ Reynolds’ expert testified that tobacco extracts are “a form of tobacco.” Tr. (Alarcon) at 152:25-153:3.

2019); *see also Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016) (disavowal or disclaimer found based on statements such as “the present invention includes” or “the present invention is”). “An inventor may also disavow claim scope ‘by distinguishing the claimed invention over the prior art.’” *Techtronic Indus. Co. v. Int’l Trade Comm’n*, 944 F.3d 901, 907 (Fed. Cir. 2019) (quoting *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997)).

References to tobacco—including tobacco-derived components, such as tobacco extracts—are pervasive in the ’202 patent. The specification repeatedly uses the definitional language “the present invention” to limit the claimed articles to those that incorporate tobacco or tobacco-derived components. *See, e.g.*, ’202 patent, 1:28-29 (“The present invention relates to tobacco products, such as tobacco-containing smoking articles.”), 4:48-53 (“The present invention relates to smoking articles for providing tobacco enjoyment, as well as manners and methods for providing tobacco enjoyment using such smoking articles. That is, the present invention relates to articles that produce aerosols incorporating components derived from, or provided by, tobacco.”), 4:65-67 (“Thus, the present invention relates to smoking articles, and in particular, to smoking articles that incorporates tobacco in some form.”), 5:41-43 (“the present invention relates to a smoking article that is smoked by incorporating that tobacco within an electrically-powered, aerosol-generating device”), 8:66-67 (“A smoking article of the present invention incorporates tobacco. The type of tobacco can vary.”), 13:59-64 (“The smoking article of the present invention further includes an aerosol-generating material, which can be in intimate contact with the tobacco material (e.g., in the form of an intimate mixture), or can be carried by a non-tobacco substrate and segregated from the tobacco in the smoking article (e.g., positioned in an adjacent region of the device).”). Moreover, the title, abstract, background of the invention,

summary of the invention, and embodiments exclusively describe smoking articles containing tobacco in some form. *See, e.g.*, '202 patent, Title (“Tobacco-Containing Smoking Article”), Abstract (“The smoking article possesses at least one form of tobacco”).

The specification also specifically distinguishes the claimed invention over prior art “smoking articles that employ tobacco substitute materials”:

Smoking articles that employ tobacco substitute materials and smoking articles that employ sources of heat other than burning tobacco cut filler to produce tobacco-flavored vapors or tobacco-flavored visible aerosols have not received widespread commercial success. Thus, it would be highly desirable to provide a smoking article that provides a smoker with an ability to enjoy using tobacco without the necessity of burning any significant amount of tobacco. In particular, it would be highly desirable to provide a tobacco-containing smoking article, such as an article having the general appearance of a cigarette, cigar, or pipe, that possesses the ability to provide to a smoker many of the benefits and advantages of conventional tobacco smoking without necessarily delivering considerable quantities of incomplete combustion and pyrolysis products.

'202 patent, 4:30-44.¹²

The '202 patent thus repeatedly describes “the present invention” as incorporating tobacco or tobacco-derived components, disparages prior art employing “tobacco substitute materials,” and ties the stated benefits of the invention to the use of tobacco. This effects a disavowal. *See, e.g., Mosaic Brands, Inc. v. Ridge Wallet LLC*, 55 F.4th 1354, 1361 (Fed. Cir. 2022) (finding claimed “lip” limited to “extrudable plastic materials” where specification expressly stated “the device of the present invention is constructed of extrudable plastic materials” and “emphasize[d] the benefits of using extrudable plastic”); *Lydall Thermal/Acoustical, Inc. v. Fed.-Mogul Corp.*, 344 F. App’x 607, 613 (Fed. Cir. 2009) (“[W]hen a patentee consistently describes one embodiment as ‘the present invention,’ ‘[t]he public is

¹² Consistent with the intrinsic evidence, Reynolds’ expert Mr. Alarcon testified *inter alia* that “the patent specifically contemplates some form of tobacco.” Tr. (Alarcon) at 152:13-14.

entitled to take the patentee at his word.” (quoting *Honeywell Intern., Inc. v. ITT Industries, Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006)). Further, the title, embodiments, summary of the invention, and field of the invention—all of which are exclusively directed to smoking articles incorporating tobacco or tobacco-derived components—reinforce the conclusion of disavowal. *See, e.g., Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1137 (Fed. Cir. 2016) (“Every embodiment described in the specification has inwardly extended short seals and every section of the specification indicates the importance of inwardly extended short seals. These two facts provide together a proper reason to limit the claims in this way.”); *Wastow Enters., LLC v. Truckmovers.com, Inc.*, 855 F. App’x 748, 751 (Fed. Cir. 2021) (finding disavowal, in part based on the patent’s title, and noting that “[t]he title thus reinforces what the written description makes clear”); *Techtronic Indus. Co. v. Int’l Trade Comm’n*, 944 F.3d 901, 909 (Fed. Cir. 2019) (“Here, the entire specification focuses on enabling placement of the passive infrared detector in the wall console, which is both responsive to the prior art deficiency the ’319 patent identifies and repeatedly set forth as the objective of the invention. Thus, the ’319 patent disavows locating the detector elsewhere, even without an express concession to that effect.”).¹³

¹³ Reynolds—relying on Mr. Alarcon—has identified two places in the specification that allegedly describe “non-tobacco” embodiments. Mr. Alarcon identifies an embodiment described in column 26 that describes “non-tobacco aerosol components” and the incorporation of the Raymond reference in column 13, which he states describes non-tobacco plant extracts. Tr. (Alarcon) at 154:24-155:10. Mr. Alarcon’s testimony as to these embodiments, however, is contradicted by the specification. As to the column 26 embodiment, although “non-tobacco aerosol components” are disclosed as part of the cartridge, the embodiment includes “tobacco 89 located in another region of the smoking article 10 rather than from nicotine incorporation within the cartridge 85.” ’202 patent, 26:6-19. That is, the embodiment in column 26 expressly still includes tobacco. As to the Raymond reference, Raymond is incorporated by reference as disclosing “[e]xemplary types of tobacco extracts, tobacco essences, solvents, tobacco extraction processing conditions and techniques, and tobacco extract collection and isolation procedures.” ’202 patent, 13:1-21; *see Husky Injection Molding Sys. Ltd. v. Athena Automation Ltd.*, 838 F.3d 1236, 1248 (Fed. Cir. 2016) (“A host document incorporates material by reference if it identifies with detailed particularity what specific material it incorporates and clearly indicate[s] where that material is found in the various documents.”) (internal quotation omitted). Neither of these disclosures provide support for a claim scope that encompasses non-tobacco smoking articles.

The construction of “smoking article” as limited to such articles that incorporate tobacco or tobacco-derived components is not undermined by testimony from the parties’ experts about what the term “smoking article” may mean when read without reference to the specification. *See, e.g.,* Tr. (Dean) at 526:19-22 (“[Q]: And so you would agree that the plain and ordinary meaning of ‘smoking article,’ then, does not require tobacco, right? [A]: That’s correct, yes.”); Tr. (Wensley) at 286:18-20 (“certainly something that is used for cannabinoids or cloves or other illicit compounds would be a smoking article”); Tr. (Wensley) at 240:18-23 (“‘Smoking article’ is a term that could be used for cannabis, for clove, and other substances. So I don’t think it’s limited to tobacco.”). As the Federal Circuit has explained:

Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001).

Accordingly, “smoking article” is tentatively construed to be limited to devices incorporating tobacco, including tobacco-derived components.¹⁴

2. “Storage Compartment”

Claim Language	Reynold’s Proposed Construction	Respondents’ Proposed Construction	Staff’s Proposed Construction
“storage compartment being configured for storage of a liquid	Plain and ordinary meaning	“container configured for liquid storage, wherein the container	Plain and ordinary meaning, which “does not imply or require a

¹⁴ *See Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”). Moreover, to the extent the claims are interpreted to include smoking articles that do not incorporate tobacco or tobacco-derived components, and based on the arguments and evidence currently of record, the undersigned finds that Respondents have raised a substantial question of invalidity that Reynolds has not shown lacks substantial merit. *See infra* Part VIII.C.

aerosol-forming material”		is configured to permit replenishment of the liquid in the smoking article”	configuration that permits replenishment of the liquid”
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Respondents contend that the ’202 patent describes a “container” or “cartridge” when “referencing structures specifically configured to store aerosol-forming materials in liquid form,” and that such a “container” or “cartridge” is described as removable and/or replenishable. RIB at 30 (citing ’202 patent, 24:5-11, 5:57-61, 8:12-26, 24:11-13, 27:42-44); RRB at 9.

Reynolds submits that Respondents improperly attempt to import limitations from the “container” embodiment described in the specification, and separately claimed in dependent claim 8. CIB at 20-21. Reynolds argues that the specification describes various kinds of storage compartments that are not limited to the separately claimed “containers” or “cartridges,” including being “soaked withing absorbent fibrous materials or sponge-like materials” and “incorporated within, or carried by, a material that acts as a substrate.” CIB at 21 (quoting ’202 patent, 14:39-43). As to the requirement that the storage compartment be “replenishable,” Reynolds argues that “replenishable” does not appear in the specification and that the embodiments describing removable or refillable storage compartments use permissive language. CIB at 22-23 (citing ’202 patent, 24:11-13). Reynolds also points to the testimony of Respondents’ expert, Dr. Dean, who agreed that the plain and ordinary meaning of “storage compartment” is “something that is capable of holding consumable material that can be used by the device.” CIB at 23 (quoting Tr. (Dean) at 527:2-6); CRB at 10.

In Staff’s view, “the plain and ordinary meaning of ‘storage compartment’ controls, and it does not imply or require a configuration that permits replenishment of the liquid, and to so construe the limitation invites the impermissible importation of additional limitations into the claim.” SIB at 9.

For purposes of the temporary relief phase of the investigation and based on the current evidence of record, “storage compartment” is construed according to its plain and ordinary meaning to one of skill in the art, which is not limited to “containers” that are “configured to permit replenishment of the liquid in the smoking article.”

Although the specification does not use the term “storage compartment,” the ’202 patent describes a variety of different mediums for holding the aerosol-forming material, including “fibrous materials,” “sponge-like materials,” “substrates,” as well as refillable containers and removable cartridges.¹⁵ ’202 patent, 14:39-43, 24:5-11, 5:57-61, 8:12-26, 24:11-13, 27:42-44. The ’202 patent separately—in dependent claims 5 and 8—claims storage compartments that are “container[s]” and “cartridge[s].” *See* ’202 patent, cl. 5 (“wherein the storage compartment is configured as a cartridge”), cl. 8 (“wherein the storage compartment is configured as a container for holding liquid”). The doctrine of claim differentiation counsels against limiting the term “storage compartment” in the independent claim to a “container” or “cartridge,” or to storage compartments having the properties—e.g., that it is refillable or exchangeable—associated with the “container” or “cartridge” embodiments described in the specification. *InterDigital*, 690 F.3d at 1324. Although claim differentiation is merely a “presumption”—albeit an “especially strong” one in this context—Respondents have not submitted “strong contrary evidence” at this stage of the investigation to overcome the presumption, such as “definitional language in the patent” or a

¹⁵ The parties agree that “a cartridge” must be “removable” or “exchangeable.” *See* CIB at 68 (“Dr. Dean did not even suggest that the entirety of what he says is a storage compartment is removable, and thus a ‘cartridge’ under his interpretation of the term.”); RIB at 74 (“Because the ‘liquid container 32’ is ‘exchangeable,’ it is a removable liquid storage container and thus a ‘cartridge’”). This is consistent with the ’202 specification, which describes a “cartridge” as removable. *See* ’202 patent, 5:57-61 (“During use, a cartridge containing some form of tobacco is positioned within the smoking article, and after use, the used cartridge is removed from the outer housing of the device.”); Tr. (Dean) at 506:12-18, 522:12-21, 537:13-15 (“A cartridge is -- the definition of a cartridge is something that can, in this context, contain aerosol-forming material and that it can be exchanged.”).

“clear disavowal of claim scope.” *Id.* Rather, the language of the specification upon which Respondents rely is directed to particular embodiments and uses permissive language. ’202 patent, 24:11-13 (“The smoking article *can be configured* such that the cartridge 85 can be removed from the smoking article and replaced as needed.”) (emphasis added).

Moreover, testimony by experts on both sides confirmed that the plain and ordinary meaning of “storage compartment” is not limited to “containers” that are “replenishable.” Tr. (Dean) at 527:2-6 (“[Q]: And for storage compartment, you would agree that the plain and ordinary meaning of ‘storage compartment’ is something that is capable of holding consumable material that can be used by the device? [A]: Yes.”); Tr. (Wensley) at 252:8-13 (“[Q]: And why did you include both the bulk fibrous material and the wick as being part of the claimed storage compartment? [A]: Because those two components, combined, hold the liquid. They store the liquid, so that is the storage compartment.”).

Accordingly, based on the intrinsic evidence and the testimony of both sides’ experts, the undersigned construes “storage compartment” according to its plain and ordinary meaning, which is not limited to “containers” that are “configured to permit replenishment of the liquid in the smoking article.”¹⁶

3. “Controller”

Claim Language	Reynold’s Proposed Construction	Respondents’ Proposed Construction	Staff’s Proposed Construction
“a <i>controller</i> configured to activate current flow through the electrical	Plain and ordinary meaning	“a controller that is a separate and distinct component from a sensor and is	Plain and ordinary meaning

¹⁶ The undersigned notes that the construction of “storage compartment” is tentative and made based on the arguments and evidence presented in connection with the temporary relief phase of this investigation. Additional or different arguments or evidence may alter the construction. *See Natera, Inc. v. NeoGenomics Lab ’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”).

resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article”		not the puff-actuated controller of claim 18”	
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Respondents contend that the “controller” in claim 1 “is not synonymous with a puff-actuated controller,” and that the claimed “controller” must be a “separate structure from a sensor.” RIB at 32; RRB at 10-11. Based on the doctrine of claim differentiation, Respondents contend that claim 13—which requires “a sensor adapted for sensing the draw by a user on the electrically-powered, aerosol-generating smoking article”—means that the “controller” of claim 1 must be a separate structure from any “sensor.” RIB at 32-33; RRB at 9-10.

Reynolds argues that Respondents’ alleged claim construction is “a non-infringement argument” and “based on the flawed premise that a single structure cannot practice more than one claim limitation.” CIB at 17 (citing *Cannon Rubber Ltd. v. The First Years, Inc.*, 163 F. App’x 870, 876 (Fed. Cir. 2005) (finding that accused products having a single structure that meets more than one claim limitation “does not preclude a finding of literal infringement”)). Moreover, Reynolds argues, even if a “controller” and a “sensor” were construed to be separate structures, the Accused Products include a pressure sensor comprised of a “collection of components and circuitry” that satisfy the limitation. CIB at 19-20. As to Mr. Wensley’s testimony allegedly conflating the claim 1 “controller” and the “puff-actuated controller” in claim 18, Reynolds explains that Mr. Wensley did not testify that a “controller”—standing alone—was a “puff-actuated controller,” but rather that a “controller configured to activate current flow” “in response to a draw,” the full language of the claim, was a “puff-actuated controller.” CIB at 20 (citing Tr. (Wensley) at 278:9-18); CRB at 11-12.

Respondents, in reply, contend that the specification describes the “controller” and “sensor” as distinct and located separately from the controller components. RRB at 10 (citing ’202 patent, 20:45-21:8). Respondents also contend that the full claim language (e.g., “a controller configured to activate current flow” “in response to a draw”) cannot mean the same thing as “puff-actuated controller” because claim 18 recites similar functional language that the “puff-actuated controller” is “configured to regulate current flow . . . in response to a draw on the electrically-powered, aerosol-generating smoking article.” RRB at 10 (citing ’202 patent, cl. 18). Respondents argue that interpreting the functional language to make the controller of claim 1 “puff-actuated” would render the “puff-actuated” language in claim 18 superfluous. RRB at 10.

In Staff’s view, “the Staff is of the opinion that “controller” does not require construction beyond its plain and ordinary meaning and does not require further narrowing by importing any exclusionary language into the claim as Respondents seem to suggest.” SIB at 10.

For purposes of the temporary relief phase of the investigation and based on the current evidence of record, “controller” is construed according to its plain and ordinary meaning to one of skill in the art.

First, there is no real dispute that “controller”—standing alone—does not mean a “puff-actuated controller.” Respondents’ arguments that Reynolds sought such a construction appear to be based on misunderstandings of Mr. Wensley’s testimony and Reynolds’ arguments. CIB at 20 (“Mr. Wensley consistently testified that he was not simply construing the term ‘controller’ as a puff-actuated controller as defined in the specification of the ’202 Patent. Rather, Mr. Wensley was analyzing limitation 1[g] as a whole, which requires the controller to be specifically configured to ‘activate current flow’ to the heater ‘in response to a draw.’ As Mr. Wensley indicated, a controller so configured is, in fact, a puff-actuated controller.”). Mr. Wensley was

clear that in his opinion, a controller that responds to a draw, as required by the full language of Limitation [1g], is a “puff-actuated controller.” Tr. (Wensley) at 278:9-18 (“[Q]: So your testimony – your testimony today is that ‘puff-actuated controller’ is the plain and ordinary meaning of the term ‘controller’ in claim 1? Is that fair? [A]: No. I’m saying in claim 1 the controller is puff-actuated because in claim 1 it says a controller that responds to a draw.”).

As to Respondents’ remaining argument—that the “controller” must be a separate structure from any sensor that is “adapted for sensing the draw by a user”—the undersigned disagrees that the doctrine of claim differentiation is applicable. Reynolds has not argued that a sensor is claimed as part of the claim 1 “controller,” and is thus not attempting to import a limitation from a dependent claim into the independent claim. *See, e.g.*, Tr. (Wensley) at 284:4-15 (“[Q]: So claim 13 is claiming something that’s already in claim 1 from which it depends, right? [A]: No, because claim 1 does not claim a sensor. Claim 1 claims a controller that is activated as a response to a draw. It doesn’t—it does not claim a sensor in claim 1.”); Tr. (Wensley) at 284:18-21 (“I believe it makes sense or it’s common or certainly in all the accused products, there is a sensor that in effect triggers the controller to control current.”); *id.* at 284:24-285:2 (“Again, I think I’ve said this a number of times. What is within the scope of claim 1 is a controller that responds to a draw. How that happens is not claimed in claim 1.”). Although, in the Accused Products, it may be a sensor component that is used with a “controller” in order to meet the requirement that the “controller” “respond to a draw,” that does not violate the doctrine of claim differentiation, as claims are not construed in view of the Accused Products. *See, e.g.*, *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (“A claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, not in light of the accused device.”); *see also N. Am. Vaccine, Inc.*

v. Am. Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993) (“While it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog.”).

Accordingly, Respondents have not presented any reason to depart from the plain and ordinary meaning of “controller,” or to impose any particular narrower construction on the claimed “controller.”¹⁷

IV. IMPORTATION

A complainant generally need only prove importation of a single accused product to satisfy the importation requirement. *Certain Chem. Mech. Planarization Slurries & Components Thereof*, Inv. No. 337-TA-1204, Comm’n Op., EDIS Doc. ID 759875, at 10 (Jan. 6, 2022); *Certain DC-DC Controllers & Prods. Containing the Same*, Inv. No. 337-TA-698, Order No. 29, EDIS Doc. ID 428773, at 3 (June 18, 2010); *Certain Purple Protective Gloves*, Inv. No. 337-TA-500, Order No. 17, EDIS Doc. ID 215648, at 5 (Sept. 23, 2004).

Shenzhen Han and the Pastel Respondents dispute importation.¹⁸ See RIB at 41-43. The remaining Respondents entered into joint stipulations with Reynolds whereby they stipulated—at

¹⁷ The undersigned notes that the construction of “controller” is tentative and made based on the arguments and evidence presented in connection with the temporary relief phase of this investigation. Additional or different arguments or evidence may alter the construction. See *Natera, Inc. v. NeoGenomics Lab ’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”).

¹⁸ Price Point and Reynolds did not enter into a joint stipulation as to importation. Respondents’ post-hearing briefing, however, contains no challenge on behalf of Price Point as to whether the Accused Products sold by Price Point were imported. See generally RIB; RRB; CRB at 5. Any such challenge is waived, at least for purposes of the temporary enforcement phase of the litigation. See G.R. 13.1 (“The post-hearing brief shall discuss the issues and evidence tried within the framework of the general issues determined by the Commission’s Notice of Investigation and those issues that are included in the pre-hearing brief and any permitted amendments thereto. **All other issues shall be deemed waived.**” (emphasis added)). Moreover, the evidence of record shows that Price Point sold in the United States

least for purposes of the temporary enforcement phase of the investigation—as to importation and agreed not to contest importation. *See* EDIS Doc. ID 832291 (Joint Stipulation of Reynolds and Breeze Respondents); EDIS Doc. IDs 830763, 830761, 830765 (Joint Stipulations of Reynolds and Qisitech Respondents); EDIS Doc. ID 830507 (Joint Stipulation of Reynolds and Shenzhen IVPS); EDIS Doc. ID 832598 (Joint Stipulation of Reynolds and Maduro); EDIS Doc. ID 830509 (Joint Stipulation of Reynolds and Shenzhen Yangyang); EDIS Doc. ID 831100 (Joint Stipulation of Reynolds and Kangvape); EDIS Doc. ID 830505 (Joint Stipulation of Reynolds and Shenzhen Pingray); EDIS Doc. ID 832544 (Joint Stipulation of Reynolds and SV3); EDIS Doc. ID 832716 (Joint Stipulation of Reynolds and Element Vape). The Respondents disputing importation are addressed in turn below.

A. The Pastel Respondents

The Pastel Respondents and Reynolds entered into a stipulation whereby Respondent American Vape stipulated that “it has sold after importation into the United States, within the meaning of 19 U.S.C. § 1337(a)(1)(B)” certain Esco Bar-branded Accused Products, and agreed that American Vape would not challenge importation. EDIS Doc. ID 832728 (Joint Stipulation of Reynolds and Pastel Respondents) ¶¶ 2, 5. As to Affiliated Imports and Pastel Cartel, however, the stipulation states that “[p]rior to the publication of Import Alert 98-06 on or about May 17, 2023, Pastel Cartel and Affiliated Imports imported into the United States, within the meaning of 19 U.S.C. § 1337(a)(1)(B)” the Esco Bar Accused Products, but that as of [REDACTED], Affiliated Imports had not imported, sold for importation, or sold after importation the

Accused Products that other Respondents have admitted have been imported, *see* CIB at 10-11 (citing CX-1188C; CX-1189C; CX-1190C; CX-1191C), and sold in the United States Accused Products that are labeled as manufactured in China and delivered to addresses in the United States. CIB at 10-11 (citing EDIS Doc. ID No. 823475 (Compl. Ex. 4)). The un rebutted evidence of record, then, establishes that Price Point sold the Accused Products after importation. CRB at 5.

Esco Bar Accused Products, and that Pastel Cartel had not imported the Esco Bar Accused Products since May 17, 2023. *Id.* ¶ 2. Pastel Cartel and Affiliated Imports accordingly argue that “the importation requirement cannot be met with respect to Pastel Cartel or Affiliated Imports.” RIB at 42; RRB at 21-22.

Reynolds responds that the temporary cessation of importation is “irrelevant” as Pastel Cartel and Affiliated Imports have refused to enter into a consent order. CRB at 7; CIB at 10 n.1.

Staff argues that American Vape, a related company to Affiliated Imports and Pastel Cartel, admittedly sold Esco Bar Accused Products after importation in the relevant time period, and that “at this stage in the proceeding, given the relationships between the companies, it is enough that Complainants show a likelihood of being able to prove importation.” SRB at 4.

The undersigned finds that Reynolds is likely to be able to establish importation as to Pastel Cartel and Affiliated Imports. “[E]ven if [a respondent] has ceased to import the [accused products], they could nonetheless be subject to this investigation.” *See Certain Ground Fault Cir. Interrupters & Prods. Containing Same*, Inv. No. 337-TA-615, ID, EDIS Doc. ID 316261, at 22 (Sept. 24, 2008) (“*Certain CGFIs*”), *unreviewed by Comm’n Op.*, EDIS Doc. ID 321819. There, as here, importation was alleged to have ceased prior to the issue dates of the asserted patents. *Id.* The administrative law judge nonetheless found importation, citing longstanding precedent that “voluntary cessation of allegedly illegal conduct does not moot a case” and unrebutted evidence of sales after importation during the relevant time period by a distributor and other related entities. *Id.* at 22-23 (citing *inter alia Enercom GmbH v. United States Int’l Trade Comm’n*, 15 1 F.3d 1376 (Fed. Cir. 1998) (holding that the Commission properly exercised jurisdiction over accused wind turbines where the respondent made an offer for sale of an accused wind turbine two years prior to the commencement of the investigation))). As in

Certain GFCIs, there is unchallenged evidence of sales after importation by a related company since the '202 patent issued—*e.g.*, American Vape. *See* EDIS Doc. ID 832728 (Joint Stipulation of Reynolds and Pastel Respondents) ¶ 2; EDIS Doc. ID 829327 (Pastel Respondents' Response to the Complaint) ¶ 44 (stating that Affiliated Imports “is registered to AVC and acts as AVC’s and Pastel Cartel’s consignee and importer of record”). Although the suspension of importation pursuant to an FDA Import Alert is not strictly “voluntary,” the Import Alert permits the identified products to be removed and envisions “future shipments.” CX-0313 (Import Alert 98-06). Accordingly, based on the current record, Reynolds has shown they are likely to establish importation as to all of the Pastel Respondents.

B. Shenzhen Han

Shenzhen Han argues that it has [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

and thus “there is no basis for any finding that Shenzhen Han has committed any unfair acts under § 337.” RIB at 41-42; RRB at 20.

Reynolds argues that Shenzhen Han has sold Accused Products to a U.S. company and acknowledges that its Accused Products have been imported. CIB at 10; CRB at 5-6 (citing CX-0979C.4 (Shenzhen Han Interrog. Resps.)). Under Commission precedent, Reynolds submits that Shenzhen Han’s knowledge that the products are imported is sufficient to meet the importation requirement. CRB at 5-6 (citing *Certain Battery-Powered Ride-on Toy Vehicles*, Inv. No. 337-TA-314, Comm’n Op., EDIS Doc. ID No. 235431 at 4 (Apr. 10, 1991) (“Indeed, longstanding Commission precedent holds that a section 337 violation can be found when a foreign

manufacturer sells infringing goods to a foreign trading company with the knowledge that the goods will subsequently be exported to the United States, even if the manufacturer does not itself export or deal directly with U.S. importer.”); *Certain Wearable Monitoring Devices, Systems, and Components Thereof*, Inv. No. 337-TA-1190, Initial Determination, 2021 WL 823194, at *9 (Feb. 4, 2021), *not mod’d in rel. part*, Comm’n Notice (April 12, 2021) (“The importation requirement may be satisfied, however, where a respondent knew or should have known that the articles it sold to third parties would subsequently be imported into the United States.”); *Certain Inkjet Ink Cartridges with Printheads & Components Thereof*, Inv. No. 337-TA-723, Initial Determination, 2011 WL 3489151, at *12 (June 10, 2011), *aff’d in rel. part*, Comm’n Op. (Dec. 1, 2011) (To prove “a ‘sale for importation,’ a complainant must prove that a respondent sold infringing articles and knew or should have known that those articles would be subsequently exported to the United States.”).

In Staff’s view, because “Shenzhen Han has also sold accused products to a U.S. company,” “the importation requirement is satisfied.” SRB at 4.

The undersigned finds that Reynolds is likely to be able to establish importation as to Shenzhen Han. Shenzhen Han identified [REDACTED] [REDACTED] in response to an interrogatory requesting “all entities that distribute, sell or offer for sale each said Product for importation into the United States, import said Products into the United States, and/or offer for sale or sell said Products after they have been imported into the United States, and state the place of business of each entity and geographical location where each of the foregoing activities is or has been performed.” CX-0979C.4 (Shenzhen Han Interrog. Resps.). In similar situations, a manufacturer’s contract with a United States corporation has been found sufficient to establish that the manufacturer “should have known that such products

would be imported into the United States,” and thus sufficient to find the importation requirement satisfied. *See, e.g., Certain Wearable Monitoring Devices, Sys., & Components Thereof*, Inv. No. 337-TA-1190, Initial Determination, 2021 WL 823194, at *9 (Feb. 4, 2021) (“Here, Inventec and Maintek contracted with Fitbit, a United States corporation, to make Fitbit’s products, and they should have known that such products would be imported into the United States. The importation requirement has thus been satisfied with respect to Inventec and Maintek.”) *not mod’d in rel. part*, Comm’n Notice (April 12, 2021). Accordingly, based on the current record, Reynolds has shown they are likely to establish importation—based on the sale for importation to a U.S. company—as to Shenzhen Han.

V. INFRINGEMENT

As discussed *supra*, in the context of Reynolds’ motion for temporary relief, Reynolds “must show that it will likely prove infringement of the asserted claims.” *ABC Corp. I v. P’ship & Unincorporated Ass’ns. Identified on Schedule “A”*, 52 F.4th 934, 942 (Fed. Cir. 2022). “If [the defendant] raises a substantial question concerning . . . infringement . . . , i.e., asserts an infringement . . . defense that the patentee cannot prove ‘lacks substantial merit,’ the preliminary injunction should not issue.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001).

Reynolds contends that claims 1, 4, 9, and 12 of the ’202 patent are infringed by the Accused Products. CIB at 30. For the reasons discussed below, the evidence of record shows that Reynolds has not shown that it will likely prove infringement by the Accused Products under the tentative claim constructions adopted in this phase of the investigation.

A. Mr. McAlexander's Status as One of Skill in the Art

At the hearing, Reynolds objected to the qualifications of Mr. McAlexander—Respondents' expert on infringement issues—as an expert, alleging that he did not qualify as one of skill in the art. Tr. (Reynolds' Counsel) at 442:3-18. The undersigned qualified Mr. McAlexander as an expert in the “field of electrical engineering”—which was undisputed—but reserved the question of whether Mr. McAlexander qualified as an expert in “the design and integration of components that are used in systems such as the smoking articles described in the '202 patent” and whether Mr. McAlexander qualified as one of skill in the art for resolution on a full record. Tr. (ALJ Bhattacharyya) at 443:17-23.

In briefing, Reynolds renewed its contention that Mr. McAlexander did not meet the parties' definition of one of skill in the art because he “lacks the required three to four years of experience in the e-cigarette industry” or “vaporizer products industry.” CIB at 50-51. Reynolds argues that it would be “reversible error to admit or even consider” Mr. McAlexander's testimony. CIB at 51 (citing *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1362 (Fed. Cir. 2008) and *Kyocera Senco Indus. Tools Inc. v. Intl. Trade Comm'n*, 22 F.4th 1369, 1376–78 (Fed. Cir. 2022)). Reynolds argues that Mr. McAlexander's opinions should be “excluded in their entirety” or else be determined to “carry no weight.” CIB at 52.

Respondents argue that Mr. McAlexander meets the parties' definition—initially proposed by Reynolds, RRB at 18—of a person of ordinary skill, which requires only “industry experience,” without requiring that the “industry” be “e-cigarettes” or “vaporizer products.” RRB at 17. Rather, one of ordinary skill need only be “familiar with electrically powered smoking articles and their components and underlying technologies or similar components and technologies.” RRB at 16-17 (citing CDX-0009.4). Respondents contend that Mr.

McAlexander’s 52 years of electrical engineering experience (including 14 years of “industry experience” with similar “integrated circuits, sensors, controllers, and the like” at Texas Instruments) combined with his familiarity with ENDS devices as a result of expert consultant work (including the “opportunity to test, evaluate, disassemble, tear apart and evaluate various components, integrated circuits, ENDS systems”) qualify him as one of skill in the art.

Respondents argue that Reynolds “changed their definition” during the hearing to argue “for the first time that their [person of ordinary skill in the art] definition required ‘three to four years of experience in the e-cigarette industry.’” RRB at 16-18. Respondent argue that Reynolds should have raised objections to Ms. McAlexander’s credentials prior to his qualification as an expert, as Reynolds’ failed to file a *Daubert* motion, a motion *in limine*, a high priority objection, or to object to Mr. McAlexander as an expert when provided his CV on August 13, 2024. RRB at 18-19.¹⁹

In Staff’s view, “Mr. McAlexander certainly meets Complainants’ definition of a POSA as one who ‘possesses a Bachelor’s degree in mechanical engineering, electrical engineering, chemistry, physics, or a related field, complemented by three to four years of industry experience.’” SRB at 3. Staff submits that “Given the circuitry involved in the products at issue here, the Staff is of the view that there is nothing unique to the vaping industry when it comes to understanding the technology utilized in vaping products and resolving the disputes raised with respect to infringement. In view of Mr. McAlexander’s experience in electrical engineering, the Staff is of the view that Mr. McAlexander is qualified to offer the opinions on the issue of infringement that he provided at the Hearing.” SRB at 3.

¹⁹ In the particular context of a temporary enforcement proceeding, because Reynolds raised the challenge in its pre-hearing brief and preserved its challenge by objecting to Mr. McAlexander’s proffer, the undersigned does not find Reynolds’ challenge to Mr. McAlexander untimely.

For purposes of the temporary relief phase of the investigation and based on the current evidence of record, the undersigned finds that Mr. McAlexander meets the parties' definition of one of ordinary skill in the art. Accordingly, his testimony is admissible.

The parties' agreed-upon definition of one of ordinary skill in the art requires:

a bachelor's degree in mechanical engineering, electrical engineering, chemistry, or physics, and three to four years of industry experience. Or, a Master's degree in mechanical engineering, electrical engineering, chemistry, or physics, and one to two years of industry experience. Additionally, a POSA would have been familiar with electrically powered smoking articles and their components and underlying technologies or similar components and technologies.

See supra Part III.D. The definition does not specify that the required industry experience be in the "e-cigarette," "vaporizer products," "tobacco," or "designing smoking articles industry."²⁰

That the definition separately requires "familiarity with electrically powered smoking articles and their components and underlying technologies or similar components and technologies" indicates that the required "industry experience" is not limited to the "e-cigarette," "tobacco," "vaporizer products," or "designing smoking articles industry." This is true both because separate familiarity with "electrically powered smoking articles" would not be required if the industry experience was limited to such devices, and because the definition expressly permits familiarity with "*similar* components and technologies."²¹

²⁰ Reynolds has not asserted a consistent identification of the relevant industry. In its pre-hearing brief, Reynolds characterized the "relevant industry" as "designing smoking articles." EDIS Doc. ID 834111 (Reynolds' Pre-Hrg. Br.) at 67. At Mr. McAlexander's deposition, Reynolds asked about Mr. McAlexander's "industry experience working in the tobacco industry." *Id.* (citing McAlexander Dep. Tr. at 20:17-20). At the hearing, Reynolds objected to the proffer of Mr. McAlexander as an expert because the definition of one of skill in the art "requires three to four years of experience in the e-cigarette industry." Tr. (Reynolds' Counsel) at 442:8-11. In post-hearing briefing, Reynolds characterized the relevant industry as the "e-cigarette" or "vaporizer products" industries. CIB at 50-51.

²¹ The language of the definition of one of skill in the art distinguishes the present investigation from the precedent relied upon by Reynolds. CIB at 51-52. In *Kyocera*, for example, the agreed-upon definition of one of skill in the art explicitly required particular experience the expert undisputedly did not have: "at least two years of experience in power nailer design This experience in powered nailer design would

Given the language of the definition of one of ordinary skill, an evaluation of Mr. McAlexander's qualifications shows that he satisfies the agreed-upon definition of a person of ordinary skill in the art. Mr. McAlexander testified that he is an electrical engineer, with approximately 52 years of experience. Tr. (McAlexander) at 438:23-24. Mr. McAlexander testified that he had industry experience in the "design, not only of the integrated circuits, but the fabrication of those circuits, the packaging, the testing, the evaluation, the environmental studies, and the integration of those particular integrated circuits and systems" and that he held patents covering "for instance, capacitive sensors," "amplification of those sensing components," "pressure and pressure sensors," and "proximity sensors." Tr. (McAlexander) at 439:2-24. Accordingly, Mr. McAlexander's industry experience, albeit not in one of the four characterizations of the "relevant industry" offered by Reynolds, was in "similar components and technologies," for example, circuitry and pressure sensors. *See, e.g.*, Tr. (McAlexander) 447:18-21 (testifying regarding pressure sensors and circuitry in the Accused Products). Moreover, as to familiarity with ENDS devices, Mr. McAlexander testified that he had been retained and qualified as an expert witness in other proceedings to evaluate ENDS-type devices, including

include mechanical design, tool design, manufacturing, mechanics of materials, stress analysis, ergonomics, and human factor." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376 (Fed. Cir. 2022). The "industry experience" requirement here is not narrowly restricted to specific categories of devices or a particular aspect of industry experience (*e.g.*, "design"). In *Sundance*, the Federal Circuit found the district court abused its discretion in permitting a patent attorney to testify "in elaborate technical detail" as to infringement and validity despite the "absence of any suggestion of relevant technical expertise." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361-62 (Fed. Cir. 2008). In *Sloan Valve*, the parties disputed the definition of one of ordinary skill, and the district court found that "some experience designing, assembling, and/or repairing plumbing systems or devices" was required. *Sloan Valve Co. v. Zurn Indus., Inc.*, No. 10–CV–00204, 2013 WL 6068790, at *4 (N.D. Ill. Nov. 18, 2013). Moreover, the district court found the proffered expert was not qualified as one of skill in the art, *inter alia*, because he had "never consulted for a company that made" plumbing systems. *Id.* at *7. Here, the agreed-upon definition of one of skill in the art does not require a particular industry experience, and, moreover, Mr. McAlexander testified that he had experience in ENDS devices as a result of his expert consulting and witness work.

“nine or ten different PTAB matters,” three district court matters, and one ITC proceeding. Tr. (McAlexander) at 441:1-21. He testified that he had “the opportunity to test, evaluate, disassemble, tear apart, and evaluate various components, integrated circuits, ENDS systems.” Tr. (McAlexander) at 440:20-25.

Accordingly, Mr. McAlexander’s qualifications are consistent with the parties’ agreed definition of one of ordinary skill in the art. For purposes of this TEO proceeding, Mr. McAlexander is qualified as one of ordinary skill in the art, and his testimony is admissible. *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340 (Fed. Cir. 2024) (“All that is required ‘to be qualified to offer expert testimony on issues from the vantage point of an ordinarily skilled artisan in a patent case’ is that ‘an expert must at a minimum possess ordinary skill in the art.’ Our precedent is clear—nothing more is required.”).

B. Claim 1

1. Limitation [1pre]: An electrically-powered, aerosol-generating smoking article comprising:

The parties dispute whether the Accused Products meet this limitation. As discussed above, *supra* Part III.E.1, the undersigned holds the preamble to be limiting and tentatively construes “smoking article” as limited to devices incorporating tobacco, including tobacco-derived components. Respondents do not dispute that the Accused Products are “electrically-powered” or “aerosol-generating.” See RIB at 35; RRB at 12. The only dispute Respondents raise as to this limitation is under their construction of “smoking article” as limited to devices containing tobacco. RIB at 35; RRB at 12 (“As noted above in the claim construction section, the term ‘smoking article’ should be construed to require the presence of tobacco. With this proper construction, it is undisputed that Complainants have not established that any TEO Accused

Product practices any of the TEO Asserted Claims. Neither Complainants nor Mr. Wensley have alleged that any TEO Accused Products includes tobacco.”).

Reynolds has not identified evidence that the Accused Products incorporate tobacco, including tobacco-derived components.²² *See* Tr. (Wensley) at 291:22-24 (“I did not analyze the device to know whether there is tobacco in the device.”)²³; *see generally* CIB, CRB.

Accordingly, Reynolds has failed to show that it is likely to establish that the Accused Products meet Limitation [1pre].

2. Limitation [1a]: an outer housing having two ends;

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3. In addition, the undisputed evidence demonstrates that the Accused Products include an outer housing having two ends. *See* Tr. (Wensley) at 242:4-243:24; CDX-0009.13-20; CX-1052.2 (SMOD 6000); CX-1051.2 (ONEE Stick 5200); CX-1072.2 (ONEE Stick); CX-1048.2 (Posh Max 2.0); CX-1050.2 (Esco Bars Kilo); CX-1047.2 (Hype Max Flow); CX-1067.2 (BIDI Stick); CX-1070.2 (Loon Maxx); CX-1065.2 (Loon Air); CX-1074.2 (MORF Bar Touch 20K Kit); CX-1046.2 (NOVO Bar AL9000); CX-1045.2 (NOVO Bar AL6000); CX-1037.2 (Lost Mary MO5000); CX-1057.2 (Lost Mary MT15000 Turbo); CX-1028.2 (EBCREATE BC5000); CX-1042.2 (RAZ DC25000); CX-1062.2 (Geek Bar Pulse); CX-

²² Reynolds presented no evidence addressing whether the “liquid nicotine” contained in the Accused Products, including any “purely synthetic nicotine,” is tobacco-derived. *See, e.g.*, EDIS Doc. ID 830020 (Resps. Mem. in Opp. to Compls. Mot. for Temp. Relief) at 20 and n.11 (stating that the Accused Products “comprise purely isolated liquid nicotine” and that that the lack of tobacco is “even more the case” for Accused Products that “use purely synthetic nicotine”); CX-0005C (Murrelle WS) at Q127 (referencing “non-tobacco nicotine” and stating that synthetic nicotine “differs from tobacco derived nicotine”).

²³ Reynolds’ expert Mr. Alarcon testified that tobacco extracts are “a form of tobacco.” Tr. (Alarcon) at 152:25-153:3.

1066.2 (Breeze Plus); CX-1025.2 (Breeze Prime); CX-1024.2 (Breeze Pro); CX-1071.2 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet Limitation [1a].

3. Limitation [1b]: a mouthpiece defined at one of the two ends

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3. In addition, the undisputed evidence demonstrates that the Accused Products include a mouthpiece defined at one of the two ends. *See* Tr. (Wensley) at 243:25-246:3; CDX-0009.21-29; CX-1052.2 (SMOD 6000); CX-1051.2 (ONEE Stick 5200); CX-1072.3 (ONEE Stick); CX-1048.3 (Posh Max 2.0); CX-1050.3 (Esco Bars Kilo); CX-1047.2 (Hyppe Max Flow); CX-1067.3 (BIDI Stick); CX-1070.2 (Loon Maxx); CX-1065.3 (Loon Air); CX-1074.2 (MORF Bar Touch 20K Kit); CX-1046.2 (NOVO Bar AL9000); CX-1045.2 (NOVO Bar AL6000); CX-1037.2 (Lost Mary MO5000); CX-1057.2 (Lost Mary MT15000 Turbo); CX-1028.2 (EBCREATE BC5000); CX-1042.3 (RAZ DC25000); CX-1062.3 (Geek Bar Pulse); CX-1066.3 (Breeze Plus); CX-1025.2 (Breeze Prime); CX-1024.3 (Breeze Pro); CX-1071.2 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet Limitation [1b].

4. Limitation [1c]: an electrical power source arranged within the outer housing;

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3. In addition, the undisputed evidence demonstrates that the Accused Products include an electrical power source arranged within the outer housing, specifically, a battery. *See* Tr. (Wensley) at 246:4-248:2; CDX-0009.30-38; CX-1052.3 (SMOD

6000); CX-1051.3 (ONEE Stick 5200); CX-1072.4 (ONEE Stick); CX-1048.4 (Posh Max 2.0); CX-1050.4 (Esco Bars Kilo); CX-1047.3 (Hyppe Max Flow); CX-1067.4 (BIDI Stick); CX-1070.3 (Loon Maxx); CX-1065.4-5 (Loon Air); CX-1074.3 (MORF Bar Touch 20K Kit); CX-1046.3 (NOVO Bar AL9000); CX-1045.3 (NOVO Bar AL6000); CX-1037.3 (Lost Mary MO5000); CX-1057.3 (Lost Mary MT15000 Turbo); CX-1028.3 (EBCREATE BC5000); CX-1042.4 (RAZ DC25000); CX-1062.3 (Geek Bar Pulse); CX-1066.4 (Breeze Plus); CX-1025.3 (Breeze Prime); CX-1024.4 (Breeze Pro); CX-1071.3 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet Limitation [1c].

5. Limitation [1d]: an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3. In addition, the undisputed evidence demonstrates that the Accused Products include an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source, specifically, either a metal mesh heater or a coil wire wrapped into a helix. *See* Tr. (Wensley) at 248:17-251:11; CDX-0009.39-47; CX-1052.4-5 (SMOD 6000); CX-1051.4-5 (ONEE Stick 5200); CX-1072.5-6 (ONEE Stick); CX-1048.5-6 (Posh Max 2.0); CX-1050.5-6 (Esco Bars Kilo); CX-1047.5-6 (Hyppe Max Flow); CX-1067.5-6 (BIDI Stick); CX-1070.4-5 (Loon Maxx); CX-1065.6, 8 (Loon Air); CX-1074.4-5 (MORF Bar Touch 20K Kit); CX-1046.4-6 (NOVO Bar AL9000); CX-1045.5-7 (NOVO Bar AL6000); CX-1037.4-5 (Lost Mary MO5000); CX-1057.4 (Lost Mary MT15000 Turbo); CX-1028.4-5 (EBCREATE BC5000); CX-

1042.5-6 (RAZ DC25000); CX-1062.4-5 (Geek Bar Pulse); CX-1066.5-6 (Breeze Plus); CX-1025.4-5 (Breeze Prime); CX-1024.5-6 (Breeze Pro); CX-1071.4-5 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet Limitation [1d].

6. **Limitation [1e]: a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material;**

The parties dispute whether the Accused Products meet this limitation. As discussed above, *supra* Part III.E.2, the undersigned holds tentatively construes “storage compartment” as according to its plain and ordinary meaning to one of skill in the art, which is not limited to “containers” that are “configured to permit replenishment of the liquid in the smoking article.”

Reynolds, relying on Mr. Wensley, identifies a bulk fibrous material, in which e-liquid is stored, and a wick as the claimed “storage compartment.” CIB at 36 (citing Tr. (Wensley) at 251:20-252:13. Mr. Wensley explained that the wick is wrapped around the electric resistance heater, and is thus “wicked into contact” with the electrical resistance heater. CIB at 37 (citing Tr. (Wensley) at 252:14-253:5). Reynolds also points to testing conducted by Mr. Wensley, which confirmed that aerosol is generated by each Accused Products. CIB at 38 (citing Tr. (Wensley) at 253:9-18; CDX-0009.49). Reynolds argues that Respondents’ contention that the wick and bulk fibrous materials together cannot be the claimed “storage compartment” is unsupported by expert testimony, as Mr. McAlexander testified that he had no non-infringement opinion as to “storage compartment” except under Respondents’ proposed “replenishable” construction. CIB at 39 (citing Tr. (McAlexander) at 458:14-19); CRB at 13 (“[T]here is no actual evidence or testimony supporting this non-infringement argument, so Respondents are

relying entirely on attorney argument.”). Reynolds argues that both the bulk fibrous material and the wick are soaked in e-liquid, and thus both are arranged as a liquid storage compartment. CIB at 39-40.

Respondents argue that “the wick is simply not part of the bulk fibrous material,” and the fact that the wick also holds e-liquid is irrelevant as “under this rational [sic], a paper towel would be a storage compartment.” RIB at 36. Respondents point out the teardown reports that Mr. Wensley relied upon identify the wick as part of the heater assembly, not as part of the reservoir or the bulk fibrous material. RIB at 37 (citing JX-0003.8, JX-0004.8, JX-0005.16-17); RRB at 13-14.

In response, Reynolds submits that Dr. Dean—Respondents’ invalidity expert—also pointed to combinations of wicks and liquid storage containers as satisfying this claim language, and that Dr. Dean’s testimony as to the plain and ordinary meaning of “storage compartment” is consistent with the definition and approach adopted by Mr. Wensley. CRB at 14 (citing Tr. (Dean) at 527:2-6, 514:25-515:12).

In Staff’s view, “the evidence demonstrates that Complainants are likely to succeed in showing the charted Accused Products meet this limitation.” SIB at 13.

Upon review of the submissions and evidence of the current record, the undersigned finds that Reynolds has met its burden to show that it is likely to establish that the Accused Products include the claimed “storage compartment.” Respondents’ argument that the wick and the bulk fibrous material are separate components that would not be considered together as the claimed storage compartment is contradicted by the testimony of both parties’ experts. *See* Tr. (Dean) at 527:2-6; RDX-0201.037 (testifying that the plain and ordinary meaning of “storage compartment” is “something that is capable of holding consumable material that can be used by

the device”); *id.* at 514:25-515:12 and RDX-0201.037 (opining that the “storage compartment” in Takeuchi includes the “narrow space coming off” the “larger receptacle”)²⁴; Tr. (Wensley) at 252:8-13 (“[Q]: And why did you include both the bulk fibrous material and the wick as being part of the claimed storage compartment? [A]: Because those two components, combined, hold the liquid. They store the liquid, so that is the storage compartment.”). The expert testimony and evidence presented by Reynolds is sufficient to show that the Accused Products likely include the claimed storage compartment. *See* Tr. (Wensley) at 251:12-255:15; CDX-0009.48-57; CX-1052.7-8 (SMOD 6000); CX-1051.7-8 (ONEE Stick 5200); CX-1072.7-8 (ONEE Stick); CX-1048.8-9 (Posh Max 2.0); CX-1050.8-9 (Esco Bars Kilo); CX-1047.8 (Hyppe Max Flow); CX-1067.8-9 (BIDI Stick); CX-1070.6-7 (Loon Maxx); CX-1065.10-12 (Loon Air); CX-1074.7-8 (MORF Bar Touch 20K Kit); CX-1046.7-8 (NOVO Bar AL9000); CX-1045.9-10 (NOVO Bar AL6000); CX-1037.7-8 (Lost Mary MO5000); CX-1057.6-7 (Lost Mary MT15000 Turbo); CX-1028.7-8 (EBCREATE BC5000); CX-1042.8-9 (RAZ DC25000); CX-1062.7-8 (Geek Bar Pulse); CX-1066.8-9 (Breeze Plus); CX-1025.7-8 (Breeze Prime); CX-1024.8-9 (Breeze Pro); CX-1071.6-7 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet Limitation [1e].

²⁴ Respondents cite this portion of Dr. Dean’s testimony for the proposition that the “storage compartment” includes the “transport mechanism.” Dr. Dean did not indicate that his testimony was contingent upon any disputed construction.

7. **Limitation [1f]: an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece; and**

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3. In addition, the undisputed evidence demonstrates that the Accused Products include an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece, specifically, the air passageway goes through the bulk fibrous material. *See* Tr. (Wensley) at 255:16-257:19; CDX-0009.58-66; CX-1052.9 (SMOD 6000); CX-1051.9 (ONEE Stick 5200); CX-1072.9 (ONEE Stick); CX-1048.11-12 (Posh Max 2.0); CX-1050.10-11 (Esco Bars Kilo); CX-1047.10-11 (Hyppe Max Flow); CX-1067.11 (BIDI Stick); CX-1070.8 (Loon Maxx); CX-1065.15-16 (Loon Air); CX-1074.9-10 (MORF Bar Touch 20K Kit); CX-1046.9-10 (NOVO Bar AL9000); CX-1045.11-12 (NOVO Bar AL6000); CX-1037.9 (Lost Mary MO5000); CX-1057.8 (Lost Mary MT15000 Turbo); CX-1028.10 (EBCREATE BC5000); CX-1042.10-11 (RAZ DC25000); CX-1062.10 (Geek Bar Pulse); CX-1066.11-12 (Breeze Plus); CX-1025.10 (Breeze Prime); CX-1024.10 (Breeze Pro); CX-1071.8 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet the additional limitations of Limitation [1f].²⁵

²⁵ For the same reasons as discussed above, *supra* Part V.B.1, however, Reynolds has failed to meet its burden to show that the Accused Products are a “smoking article.”

8. Limitation [1g]: a controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.

The parties dispute whether the Accused Products meet this limitation. As discussed above, *supra* Part III.E.3, the undersigned holds tentatively construes “controller” according to its plain and ordinary meaning to one of skill in the art, and did not impose any particular narrowing construction on the claimed “controller.”

Reynolds, relying on Mr. Wensley, identify what is “colloquially referred to” as a pressure sensor in the Accused Products as satisfying this limitation. CIB at 44 (citing Tr. (Wensley) at 286:1-5). Reynolds contends that Mr. McAlexander and Mr. Wensley had nearly identical testimony confirming that the Accused Products detect a draw and activate a current to the heater in response to that draw. CIB at 41-42 (citing Tr. (Wensley) at 258:18-22; Tr. (McAlexander) at 459:15-17, 460:1-4); CRB at 15. Reynolds argues that even if a “sensor” and a “controller” had to be separate structures, the “pressure sensor” structure in the Accused Products separately contains control circuitry—e.g., an integrated circuit—and sensor components. CIB at 45 (citing Tr. (McAlexander) at 468:4-14; CX-1144; CX-1145; CX-1146). Reynolds also relies upon product documentation for certain Accused Products, which expressly refers to the “pressure sensors” as “controllers.” CIB at 45 (citing, *e.g.*, CX-1151C (“The S085S1 sensor adopts ASIC design to prevent the halt that happens in the current MCU solution, and also to avoid being unable to reset when the controller is used under threshold voltage.”))

Respondents argue—as they did in claim construction—that identification of the pressure sensor in the Accused Products is insufficient to show infringement because “[t]he patent describes a sensor that sends signals to a controller – two distinct structures.” RIB at 38-39. Respondents argue that the evidence of the teardown of the pressure sensors in the Accused

Products was created by counsel and “should be entitled to little weight.” RRB at 14.

Respondents also argue that the product literature describing the “pressure sensors” as “controllers” are “unauthenticated webpages or datasheets/MSDs from unknown manufacturers” and should not be entitled to weight. RRB at 15.

In Staff’s view, “the evidence shows that the sensor in the analyzed products is in fact a controller.” SIB at 14.

Upon review of the submissions and evidence of the current record, the undersigned finds that Reynolds has met its burden to show that it is likely to establish that the Accused Products include the claimed “controller.” As discussed above, *supra* Part III.E.3, the undersigned is not convinced that claim differentiation requires a “controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article” to be a separate structure from a “sensor” or a “puff-actuated controller.” There is no dispute that the “pressure sensor” structure in the Accused Products is “configured to activate current flow through the electrical resistance heater in response to a draw.” Tr. (Wensley) at 258:18-22; Tr. (McAlexander) at 460:10-13 (“[Q]: So the pressure sensor in each of the accused products, it controls the flow of current to the heater, right? [A]: It does.”). The conclusion that the “pressure sensor” in the Accused Products is a “controller” is confirmed by product documentation produced by Respondents, which [REDACTED]

[REDACTED] See, e.g., CX-1151C.3²⁶ [REDACTED]

²⁶ Although Respondents state that these documents are “unauthenticated” and from “unknown manufacturers,” RRB at 15, they were produced by Respondents Breeze and Bidi, *see* Tr. (McAlexander) at 472:2-473:22, and admitted into evidence without objection from Respondents.

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The expert testimony and evidence presented by Reynolds is sufficient to show that the Accused Products likely include the claimed controller. *See* Tr. (Wensley) at 257:20-260:23; CDX-0009.67-75; CX-1052.10-11 (SMOD 6000); CX-1051.7-10-11 (ONEE Stick 5200); CX-1072.10-11 (ONEE Stick); CX-1048.14-16 (Posh Max 2.0); CX-1050.12-14 (Esco Bars Kilo); CX-1047.12-13, 15 (Hyppe Max Flow); CX-1067.12-14 (BIDI Stick); CX-1070.9-10 (Loon Maxx); CX-1065.17-18 (Loon Air); CX-1074.11-12 (MORF Bar Touch 20K Kit); CX-1046.11-13 (NOVO Bar AL9000); CX-1045.14, 16 (NOVO Bar AL6000); CX-1037.10-11 (Lost Mary MO5000); CX-1057.9-10 (Lost Mary MT15000 Turbo); CX-1028.11, 13 (EBCREATE BC5000); CX-1042.13, 15 (RAZ DC25000); CX-1062.11-13 (Geek Bar Pulse); CX-1066.13, 15 (Breeze Plus); CX-1025.12-13 (Breeze Prime); CX-1024.11-12 (Breeze Pro); CX-1071.9-10 (ONEE Max).

Accordingly, Reynolds met its burden to show that it is likely to establish that the Accused Products meet the additional limitations of Limitation [1g].²⁸

* * *

Accordingly, for the reasons discussed above, Reynolds has failed to show a likelihood of success on the merits as to infringement of claim 1 of the '202 patent by the Accused Products.

²⁷ Moreover, even if a “sensor” and a “controller” had to be separate components, Reynolds has introduced evidence that the “pressure sensors” in the Accused Products include both sensor components and control circuitry. Tr. (Wensley) at 258:11-17 (“[Q]: Does it make any difference to your analysis whether or not that construction is adopted? [A]: No, it doesn’t. [Q]: Why not? [A]: In either adoption, there is a controller that routes current to the heater element in response to a draw, and whether the sensor is separate or not is immaterial.”).

²⁸ For the same reasons as discussed above, *supra* Part V.B.1, however, Reynolds has failed to meet its burden to show that the Accused Products are a “smoking article.”

C. Claim 4

Claim 4 depends from claim 1, and requires in addition that “the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece.” The parties do not dispute that this added limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3; Tr. (Wensley) at 261:2-262:16; CDX-0009.76-84. However, as held *supra*, Reynolds has not carried its burden to show a likelihood of infringement of claim 1 by the Accused Products. Therefore, Reynolds cannot show a likelihood of success as to claim 4. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989) (“One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.”).

D. Claim 9

Claim 9 depends from claim 1, and requires in addition that “the electrical resistance heater is arranged in contact with the storage compartment.” The parties do not dispute that this added limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3; Tr. (Wensley) at 262:17-264:4; CDX-0009.85-93. However, as held *supra*, Reynolds has not carried its burden to show a likelihood of infringement of claim 1 by the Accused Products. Therefore, Reynolds cannot show a likelihood of success as to claim 9. *See Wahpeton*, 870 F.2d at 1552 n.9.

E. Claim 12

Claim 12 depends from claim 1, and requires in addition that “the electrical resistance heater is configured to allow airflow therethrough.” Reynolds accuses only a subset of the Accused Products of infringing claim 12. CDX-0009.10; Tr. (Wensley) at 237:8-15; Part I.C.1. The parties do not dispute that this added limitation is met. *See* RIB at 34-39; RRB at 11-15; SIB at 10-15; SRB at 2-3; Tr. (Wensley) at 264:5-266:4; CDX-0009.85-93. However, as held *supra*,

Reynolds has not carried its burden to show a likelihood of infringement of claim 1 by the Accused Products. Therefore, Reynolds cannot show a likelihood of success as to claim 12. *See Wahpeton*, 870 F.2d at 1552 n.9.

VI. DOMESTIC INDUSTRY – TECHNICAL PRONG

As discussed *supra*, in the context of Reynolds’ motion for temporary relief, Reynolds must show that it is reasonably likely to establish the existence of a domestic industry. *See Sulfentrazone*, EDIS Doc. ID 541146, at 97.

Reynolds contends that claims 1, 5, 9, and 14 of the ’202 patent are practiced by the DI Products. CIB at 110. Reynolds relies upon the witness statement of Mr. Wensley, along with corresponding claim chart demonstratives. CIB at 110 (citing CX-0006C (Wensley WS); CDX-0006C (Wensley WS Demonstratives)). Mr. Wensley’s technical domestic industry opinions were not addressed on cross-examination, and Respondents’ expert, Mr. McAlexander did not offer any opinions as to technical domestic industry. Tr. (McAlexander) at 454:15-18; *see generally* Tr. (Wensley) 266:16-294:15.

For the reasons discussed below—including because Respondents did not preserve a challenge to Reynolds’ evidence that the DI Products practice claims 1, 5, 9 and 14 of the ’202 patent—the undersigned finds that, for purposes of the temporary enforcement phase of this investigation, Reynolds has satisfied its burden to show a likelihood of success as to the technical prong of domestic industry.

A. Respondents’ Disputes as to the Technical Prong

During discovery in this matter, the parties agreed that Respondents’ TEO Opposition Memorandum, in conjunction with the parties’ interrogatory responses—would serve as the contentions for the temporary relief phase of this investigation. *See* EDIS Doc. ID 829388 (Aug.

13, 2024 Resps. Ground Rule 3.4.1 Ltr.) (“Respondents’ TEO Opposition provides Respondents’ initial contentions on noninfringement, invalidity, *failure to satisfy domestic industry*, irreparable harm, appropriate remedies, and bond.”) (emphasis added); EDIS Doc. ID 829587 (Aug. 15, 2024 Case Mgmt. Conf. Tr.) at 10:16-18 (“We have spoken to Respondents that they will be limited to the contentions for the TEO phase that they have provided to date.”). Respondents did not dispute—or in any way suggest that they disputed—that Reynolds would establish a likelihood of success as to the technical prong of domestic industry in their “contentions.” *See generally* EDIS Doc. ID 829336 (Resps. TEO Opposition Mem.).

In a joint filing on August 29, 2024, moreover, Respondents identified that “infringement and DI technical prong” “are contested” but only because “direct testimony [on these issues] is expected to conflict with testimony regarding whether the asserted patent is valid.” EDIS Doc. ID 831027 (Joint Submission on Use of Witness Statements) at 8. On the basis of Respondents’ representations as to the lack of dispute, the undersigned permitted direct testimony on technical domestic industry to be presented via witness statement, identifying cross-examination as the proper place to explore any potentially contradictory testimony. *See, e.g.*, Order No. 12 at 3 (“Respondents did not, in their opposition to Complainants’ temporary enforcement proceedings, contest technical domestic industry. Any purported ‘conflict with testimony regarding whether the asserted patent is valid,’ may be explored on cross-examination.”) (internal citations omitted)).

In their pre-hearing brief—filed nine days *after* witness statements on technical prong, *see* Order No. 7—Respondents first disputed the technical prong of domestic industry, raising arguments as to whether the DI Products practiced the claims under Respondents’ proposed claim constructions of “storage compartment” and “smoking article.” RPHB at 162-165; *see also*

CX-0006C (Wensley WS) at Q30 (“It is my understanding that for the TEO phase of the Investigation, Respondents have not challenged whether the VUSE Solo, Vibe, Ciro, and Alto practice claims 1, 5, 9, and 14 of the ’202 Patent.”). Those arguments are repeated in Respondents’ post-hearing briefing. *See* RIB at 116-118; RRB at 52.

New substantive contentions, however, are untimely and therefore waived for purposes of this TEO proceeding. *See* CRB at 42.²⁹ Although there was not a date in the temporary enforcement proceeding procedural schedule for the exchange of contentions, the parties identified such a date *by agreement*. EDIS Doc. ID 829587 (Aug. 15, 2024 Case Mgmt. Conf. Tr.) at 10:16-18. Moreover, *by agreement*, Respondents were limited—in the temporary relief phase—to the contentions identified in Respondents’ TEO Opposition Memorandum and in interrogatory responses as of August 12, 2024. *Id.*; *see also* EDIS Doc. ID 829388 (Aug. 13, 2024 Resps. Ground Rule 3.4.1 Ltr.). Respondents do not identify anywhere where these arguments were timely identified. Nor did Respondents—by leave of the undersigned or by agreement of the parties—supplement its contentions to raise the technical domestic industry disputes it now raises. This is not an instance where Respondents merely elaborated on a theory; rather, there is *no* timely disclosure of Respondents’ intention to challenge the technical prong of domestic industry in the temporary enforcement proceeding, or even the suggestion of such an intention.

Moreover, Respondents’ untimely challenge to the technical prong of domestic industry is particularly problematic because the challenge was only raised after Reynolds had concluded its presentation of direct testimony (via Mr. Wensley’s witness statement) as to whether the DI

²⁹ While Respondents’ arguments merely asserting failure of proof are not necessarily waived, they carry little weight given the timing of their disclosure, and the fact that, at this stage of the proceedings, Reynolds must only show a likelihood of success on the merits.

Products satisfied the technical domestic industry. This is highly prejudicial to Reynolds. *See, e.g.,* Ground Rule 4.4.2 (“Supplemental contentions may be stricken if there is a lack of good cause or where there is significant prejudice to opposing parties.”). The untimely challenge also disrupted the orderly procedure of the investigation, as the undersigned permitted the presentation of direct testimony on technical domestic industry on the basis that Respondents had not raised a specific challenge to Reynolds’ likelihood of success of establishing the technical prong of domestic industry. *See, e.g., Certain Electrical Connectors and Cages, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-1241, Order No. 42, EDIS Doc. ID 756212, at 7 (Nov. 9, 2021) (“untimely disclosures violate Ground Rule 4.4.2 and disrupt the orderly procedure of the investigation”); *see also Certain Residential Premises Security Monitoring & Automation Control Panels, & Components Thereof*, Inv. No. 337-TA-1273, Order No. 17, EDIS Doc. ID 769028, at 11 (Apr. 13, 2022) (“Mr. Bakewell’s alarm signal apportionment is a new theory on how ADT’s monitoring investments can be apportioned. The alarm signal apportionment was not disclosed by ADT in its final contentions and ADT does not offer any explanation as to why it was not.”); *Certain Silicon-On-Insulator Wafers*, Inv. No. 337-TA-966, Order No. 15, EDIS Doc. ID 594088, at 18-19 (May 9, 2016) (precluding complainant from relying on new information, new allocations, and documents not disclosed during fact discovery).

Accordingly, solely for purposes of the TEO phase of this investigation, Respondents did not preserve substantive challenges to Reynolds’ showing that the DI Products practice claims 1, 5, 9, and 14 of the ’202 patent.

B. Claim 1**1. Limitation [1pre]: An electrically-powered, aerosol-generating smoking article comprising:**

There is no timely dispute as to whether the DI Products meet this limitation. *See supra* Part VI.A; SIB at 45. The undersigned finds that Reynolds is likely to show that the DI Products practice Limitation [1pre]. *See* CX-0006C (Wensley WS) at Q34-Q41, Q89-Q94, Q142-Q146, Q194-Q199; CDX-0006C.8-10, 32-33, 51-52, 69-70 (and exhibits cited therein).

2. Limitation [1a]: an outer housing having two ends;

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1a]. *See* CX-0006C (Wensley WS) at Q42-Q46, Q95-Q99, Q147-Q151, Q200-Q204; CDX-0006C.11-12, 34-35, 53-54, 71-72 (and exhibits cited therein).

3. Limitation [1b]: a mouthpiece defined at one of the two ends

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1b]. *See* CX-0006C (Wensley WS) at Q47-Q51, Q100-Q104, Q152-Q156, Q205-Q209; CDX-0006C.13-14, 36, 55, 73 (and exhibits cited therein).

4. Limitation [1c]: an electrical power source arranged within the outer housing;

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1c]. *See* CX-0006C (Wensley WS) at Q52-Q55, Q105-Q108, Q157-Q160, Q210-Q213; CDX-0006C.15, 37, 56, 74 (and exhibits cited therein).

5. Limitation [1d]: an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1d]. *See* CX-0006C (Wensley WS) at Q56-Q60, Q109-Q113, Q161-Q165, Q214-Q218; CDX-0006C.16-18, 38-39, 57-58, 75-76 (and exhibits cited therein).

6. Limitation [1e]: a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material;

There is no timely dispute as to whether the DI Products meet this limitation.³⁰ *See supra* Part VI.A; SIB at 45. Moreover, as discussed above, *supra* Part III.E.2, the undersigned tentatively construes “storage compartment” as according to its plain and ordinary meaning to one of skill in the art, which is not limited to “containers” that are “configured to permit replenishment of the liquid in the smoking article.” Reynolds has shown it is likely that the DI Products practice Limitation [1e]. *See* CX-0006C (Wensley WS) at Q61-Q66, Q114-Q119, Q166-Q171, Q219-Q224; CDX-0006C.19-21, 40-41, 59-60, 77-78 (and exhibits cited therein).

³⁰ Moreover, as explained above with respect to infringement, *supra* Part V.B.6, the undersigned rejects Respondents’ argument that Limitation [1e] is not met because both the wick and the reservoir are identified as part of the “storage compartment,” as unsupported by persuasive evidence and contradicted by the testimony of both parties’ experts. *See, e.g.,* Tr. (Dean) at 527:2-6; Tr. (Wensley) at 252:8-13.

7. **Limitation [1f]: an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece; and**

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1f]. *See* CX-0006C (Wensley WS) at Q67-Q70, Q120-Q123, Q172-Q175, Q225-Q228; CDX-0006C.22-23, 42-43, 61-62, 79-80 (and exhibits cited therein).

8. **Limitation [1g]: a controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.**

Neither Respondents nor Staff dispute that that this limitation is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice Limitation [1f]. *See* CX-0006C (Wensley WS) at Q71-Q75, Q124-Q128, Q176-Q180, Q229-Q233; CDX-0006C.24-25, 44-46, 63-64, 81-82 (and exhibits cited therein).

* * *

Accordingly, for the reasons discussed above, Reynolds has shown a likelihood of success on the merits as to the practice of claim 1 of the '202 patent by the DI Products.

C. Claim 5

Claim 5 depends from claim 1, and requires in addition that “the storage compartment is configured as a cartridge.” Neither Respondents nor Staff dispute that that the additional limitation of claim 5 is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice the additional limitation of claim 5. *See* CX-0006C (Wensley WS) at Q76-Q78, Q129-Q131, Q181-Q183, Q234-Q236; CDX-0006C.26-27, 47, 65, 83 (and exhibits cited therein).

D. Claim 9

Claim 9 depends from claim 1, and requires in addition that “the electrical resistance heater is arranged in contact with the storage compartment.” Neither Respondents nor Staff dispute that the additional limitation of claim 9 is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice the additional limitation of claim 9. *See* CX-0006C (Wensley WS) at Q79-Q81, Q132-Q134, Q184-Q186, Q237-Q239; CDX-0006C.28-29, 48, 66, 84 (and exhibits cited therein).

E. Claim 14

Claim 14 depends from claim 1, and requires in addition that “the controller is configured to regulate the current flow through the electrical resistance heater during the draw on the electrically-powered, aerosol-generating smoking article.” Neither Respondents nor Staff dispute that the additional limitation of claim 14 is met. *See* RIB at 116-118; SIB at 45. Reynolds has shown it is likely that the DI Products practice the additional limitation of claim 14. *See* CX-0006C (Wensley WS) at Q82-Q85, Q135-Q138, Q187-Q190, Q240-Q243; CDX-0006C.30, 49, 67, 85 (and exhibits cited therein).

VII. DOMESTIC INDUSTRY – ECONOMIC PRONG

To meet the economic prong of the domestic industry requirement, Reynolds relies on certain alleged domestic investments, including investments in manufacturing and production activity at the Reynolds Operations Center (“ROC”) in Tobaccoville, NC, research and development activities—including related to support of its PMTAs—operating out of the Bowman Gray Technical Center in Winston-Salem, NC, and quality control activities coordinated at the ROC in Tobaccoville, NC. CIB at 98. Reynolds also relies on investments made by Reynolds’ third-party contract manufacturer, [REDACTED], a domestic company that

manufactures the VUSE Alto e-liquid “under the direction of” Reynolds [REDACTED] CIB at 106-07; CX-0922C (Feist Decl.). Reynolds relies upon expenditures from January 2013 through September 2023, CX-0004C (Mooney WS) at Q17, and states that these expenditures and activities are ongoing. *See* CIB at 101.³¹

The Reynolds DI Products are the VUSE Solo, the VUSE Vibe, the VUSE Ciro, and the VUSE Alto. CIB at 111-112; CX-0004C (Mooney WS) at Q11.

The evidence shows that, relevant here, Reynolds has two facilities in the United States; these are the Reynolds Operations Center in Tobaccoville, NC and the Bowman Gray Technical Center in Winston-Salem, NC. CIB at 95; CX-0004C (Mooney WS) at Q14. The evidence also shows that all of the e-liquids for the DI Products are manufactured in the United States—the e-liquid for the VUSE Solo, VUSE Vibe, and VUSE Ciro by Reynolds and the e-liquid for the VUSE Alto by [REDACTED] CX-0004C (Mooney WS) at Q14-Q15; CIB at 99, 101, 104, 106; CX-0922C (Feist Decl.). The cartridges for the VUSE Solo are manufactured in the United States by Reynolds, and the device is assembled in the United States by Reynolds. *See, e.g.,* CX-0004C (Mooney WS) at Q14. The cartridges for the VUSE Vibe, VUSE Alto, and VUSE Ciro and the “bodies” of the DI Products are manufactured in Indonesia or China. Tr. (Ferris) at 130:9-131:11.

For the reasons set forth below, Reynolds has shown that it is likely to establish the existence of a domestic industry based on Reynolds’ labor investments and plant and equipment investments.

³¹ Reynolds asserts the existence of a domestic industry under 19 U.S.C. § 1337(a)(2)(A) and (B) and does not provide specific arguments under 19 U.S.C. § 1337(a)(2)(C). *See* CIB at 94-109; RIB at 113 n.13.

A. Respondents' Disputes as to the Economic Prong

As discussed with respect to Respondents' disputes as to the technical prong of domestic industry, Respondents largely failed to preserve substantive challenges to Reynolds' showing of the economic prong of the domestic industry requirement. Respondents did not specifically dispute that Reynolds would establish a likelihood of success as to the economic prong of domestic industry in their "contentions." *See generally* EDIS Doc. ID 829336 (Resps. TEO Opposition Memo.).³² Respondents, moreover, did not oppose Reynolds' proposal to introduce economic domestic industry testimony—from Mr. Ferris as a fact witness and from Mr. Mooney as an expert witness—via witness statements. *See* Order No. 12 at 2 ("Respondents state that they do not intend to submit any witness statements, and do not oppose Complainants' proposal to introduce expert testimony as to public interest and economic domestic industry. Submission at 8. Respondents also do not oppose the introduction of fact witness direct testimony (which would implicate only Mr. Ferris) so long as 'the witness is made available for deposition prior to the hearing and for cross-examination at the hearing.'"). On the basis of the parties' representations as to the lack of dispute, the undersigned permitted direct testimony on economic domestic industry to be presented via witness statement. *Id.*

Again, it was not until Respondents' pre-hearing brief—filed nine days *after* witness statements on economic prong, *see* Order No. 7—that Respondents first disputed the economic prong of domestic industry, raising arguments as to whether investments pre-dating the patent issuance were cognizable, whether the investments of third-parties were cognizable, and

³² Respondents did reference the fact that one of the DI Products—the VUSE Ciro—had been removed from the market in the context of public interest, *id.* at 185, and disputed the applicability of findings in the 1199 investigation as to claim construction, infringement, and validity. *See id.* at 4-5, 48-49.

challenging Reynolds' showing of significance. RPHB at 157-161. Those arguments are repeated in Respondents' post-hearing briefing. *See* RIB at 113-16; RRB at 50-51.

New substantive contentions, however, are untimely and therefore waived for purposes of this TEO proceeding. *See* CRB at 39.³³ As discussed above regarding the technical prong, although there was not a date in the temporary enforcement proceeding procedural schedule for the exchange of contentions, the parties identified such a date *by agreement*. EDIS Doc. ID 829587 (Aug. 15, 2024 Case Mgmt. Conf. Tr.) at 10:16-18; *see* Part VI.A *supra*. Moreover, Respondents' untimely challenge to the economic prong of domestic industry is particularly problematic because the challenge was only raised after Reynolds had concluded its presentation of direct testimony (via Mr. Ferris and Mr. Mooney's witness statements) as to satisfaction of the economic prong of the domestic industry. This is highly prejudicial to Reynolds. *See* Part VI.A *supra*.

Accordingly, solely for purposes of the TEO phase of this investigation, Respondents did not preserve substantive challenges to Reynolds' showing on the economic prong of the domestic industry requirement.

B. Domestic Investments

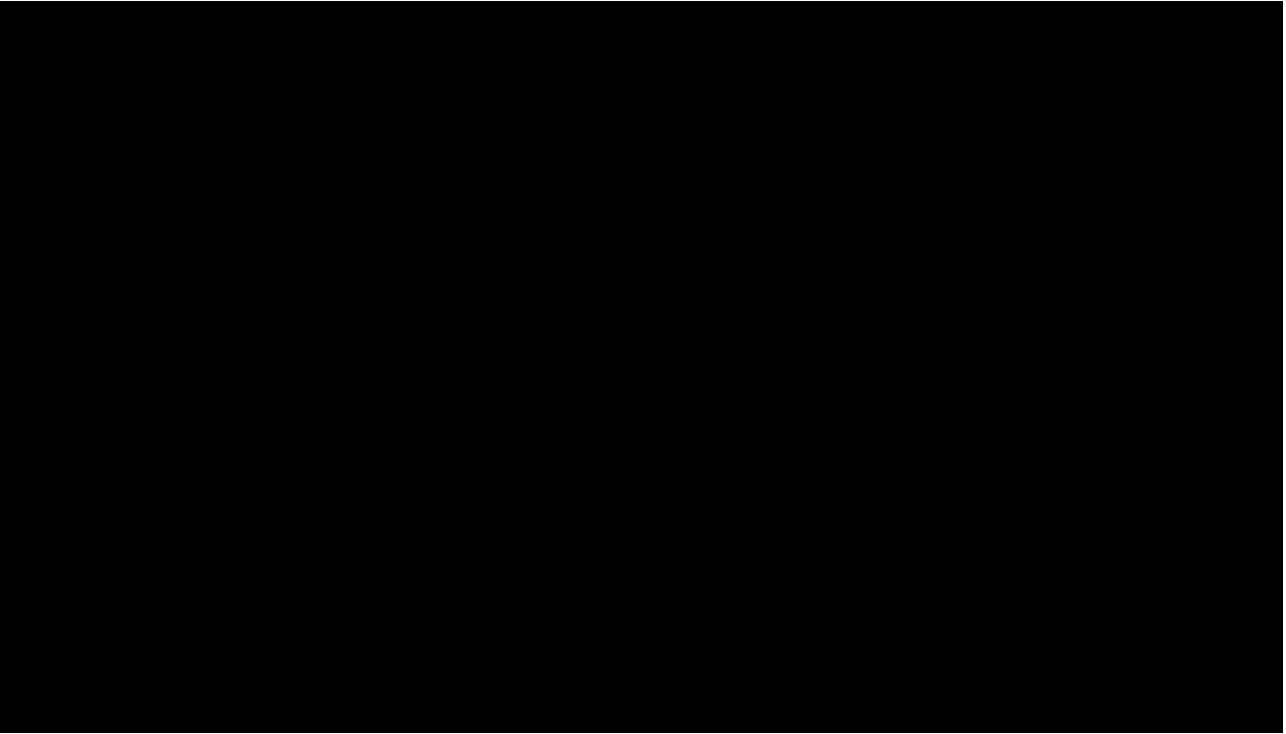
1. Plant and Equipment

Reynolds has provided calculations showing its investments in manufacturing equipment and facilities related to its manufacturing of the VUSE Solo cartridges and assembly of the VUSE Solo devices. *See* CIB at 98-99; CX-0004C (Mooney WS) at Q81, 82-84. Reynolds also identified manufacturing and equipment costs related to its manufacturing of the e-liquid used in

³³ While Respondents' arguments merely asserting failure of proof are not necessarily waived, they carry little weight given the timing of their disclosure, and the fact that, at this stage of the proceedings, Reynolds must only show a likelihood of success on the merits.

the VUSE Solo, Ciro, and Vibe DI Products. *See* CIB at 99; CX-0004C (Mooney WS) at Q81, Q85-87.

Mr. Mooney provided analysis that between January 2013 and July 2018, Reynolds invested approximately [REDACTED] in manufacturing equipment to produce the VUSE Solo. CX-0004C (Mooney WS) at Q82; CDX-0004C.2; CX-304C; CX-1101C. This equipment includes “cartridge manufacturing machines, cartridge assembly machines, and e-liquid filling machines, among others.” CX-0004C (Mooney WS) at Q83. Mr. Mooney also testified that between July 2013 and August 2017, Reynolds invested approximately [REDACTED] in building a [REDACTED] manufacturing space within its ROC facility in Tobaccoville, NC to perform manufacturing, assembly, and packaging activities. CX-0004C (Mooney WS) at Q84; CDX-0004C.2; CX-0294C. As to e-liquid manufacturing and production activities, Mr. Mooney testified that in 2019, Reynolds invested approximately [REDACTED] in equipment to manufacture e-liquid for the VUSE Vibe, Ciro, and Vibe DI products. Finally, Mr. Mooney identified [REDACTED] in facilities expenses between January 2019 and September 2023 related to operating, maintaining, and supporting manufacturing and production facilities related to the VUSE DI Products. CX-0004C (Mooney WS) at Q87; CX-1011C; CX-0289C. As shown in the table below, he calculated a total of approximately [REDACTED] in plant and equipment investments related to the VUSE DI Products:



CX-0004C (Mooney WS) at Q88; CDX-0004C.2.

Respondents and Staff do not dispute the calculations regarding investments. Respondents, as discussed above, waived any substantive challenge to Reynolds’ economic prong allegations. Even considering Respondents’ argument—that because the identified investments pre-date the March 12, 2024 issuance of the ’202 patent, they may not be relied upon to show domestic industry in “articles protected by the patent” under subprong (A), RIB at 113-14—the undersigned finds that for purposes of the temporary enforcement phase of this proceeding, Reynolds’ past investments in plant and equipment, combined with unrebutted testimony from Reynolds’ witnesses that investments in the VUSE Vibe, Solo, and Alto are ongoing,³⁴ are sufficient to show that Reynolds is likely to identify cognizable investments in

³⁴ The record indicates that as of the hearing, the VUSE Ciro was no longer sold. *See* Tr. (Mras) at 59:9-11. There is no evidence about when the Ciro ceased to be sold as compared to the March 12, 2024 issuance of the ’202 patent, but to the extent the Ciro was not sold after issuance of the ’202 patent, investments related to the VUSE Ciro may not be cognizable under subprongs (A) and (B).

plant and equipment. *See, e.g.*, Tr. (Mooney) at 373:13-16 (“So the data we have goes through the fall of 2023. So I quantify the investments through that. I also talk about that there are ongoing investments and the evidence of that.”), 373:22-23 (“I don’t have a specific number from post-March 2024. But the investments are ongoing.”); Tr. (Mras) at 59:9-11 (testifying that the VUSE Solo, Vibe, and Alto are still sold).

2. Labor or Capital

With respect to labor and capital, Reynolds has provided calculations showing its investments in labor and capital in three categories: (1) research and development; (2) manufacturing, assembly, and production; and (3) quality control and customer service. CIB at 100-105; CX-0004C (Mooney WS) at Q89.

a. Research & Development

As to research and development, Mr. Mooney identified investments in labor and capital related to “product discovery, design, and development related to the VUSE DI Products; external labor and capital related to product stewardship, integrity, and regulatory compliance in connection with the VUSE DI Products; and internal labor and capital investments related to product stewardship, integrity, regulatory compliance, and other R&D in connection with the VUSE DI Products.” CX-0004C (Mooney WS) at Q90. The evidence shows that as of May 2024, there are [REDACTED] employees in Reynolds’ Scientific and Regulatory Affairs and the United States Product Deploy departments, located in the Bowman Gray Technical Center in Winston-Salem. *See* CX-0007C (Ferris) at Q56-58; CX-0380.

With respect to product discovery, design, and development, the evidence shows that these activities include “product exploration, evaluation of existing products, identification of new and desirable features, design and development of prototypes implementing those new and

desirable features, performance studies, and product testing.” CX-0007C (Ferris WS) at Q61.

Mr. Ferris explained that this work is ongoing, including, for example, [REDACTED]

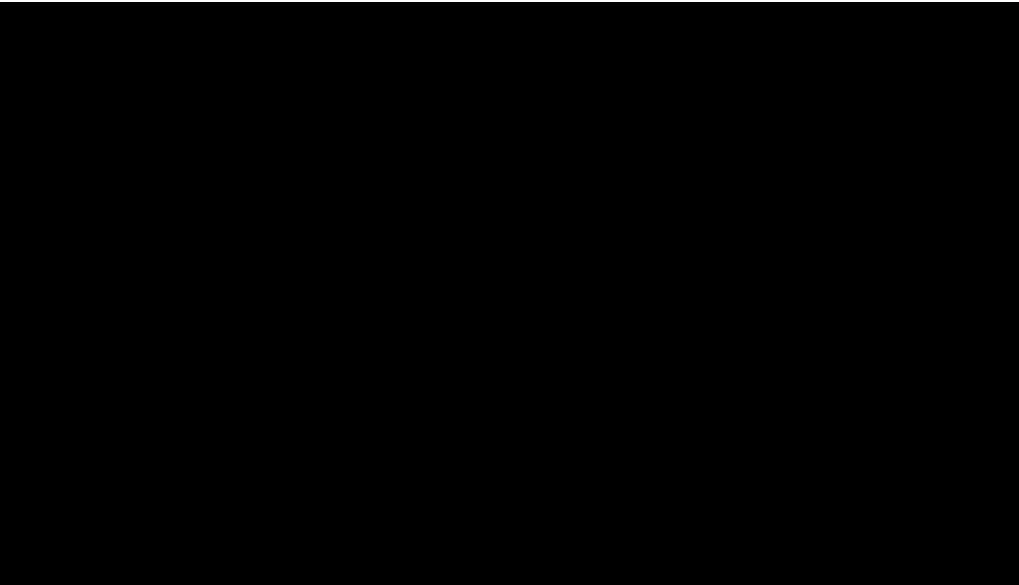
[REDACTED]. CX-0007C (Ferris WS) at Q65-Q75; *see also* CX-0004C (Mooney WS) at Q30 (noting that Reynolds “engages in sustaining R&D on the VUSE DI Products”). Mr. Mooney calculated that between January 2019 and September 2023, Reynolds invested approximately [REDACTED] in labor and fringe benefits for Reynolds’ employees related to product discovery, design, and development related to the VUSE DI Products. CX-0004C (Mooney WS) at Q91; CX-1012C; CDX-0004.3.

As to labor and capital related to product stewardship, integrity, and regulatory compliance in connection with the VUSE DI Products, Mr. Mooney identified both internal and external expenses related to the “evaluation of health risks, toxicological studies, chemical stability studies, behavioral studies, clinical studies, non-clinical studies, and more,” including activities related to the PMTA regulatory compliance process.³⁵ CX-0004C (Mooney WS) at Q32. Mr. Mooney identified approximately [REDACTED] employees at Reynolds focused on product

³⁵ The undersigned finds that these investments are likely cognizable under the circumstances here. *See Certain Strontium-Rubidium Radioisotope Infusion Sys.*, Inv. No. 337-TA-1110, Initial Determination, EDIS Doc. ID 684056, at 142-143 (Aug. 1, 2019) (finding investments in labor and capital to obtain FDA approval significant under Section 337(a)(3)(B)). Although “efforts to obtain regulatory approval may not on their own distinguish” a complainant’s activities from that of a mere importer, *Certain Strontium-Rubidium Radioisotope Infusion Systems, Including Generators*, Inv. No. 337-TA-1110, Comm’n Op., EDIS Doc. ID 696920, at 42 n.27, (Dec. 11, 2019), the undersigned finds that in the context of Reynolds’ manufacturing, production, and research and development activities, the PMTA investments are cognizable. Moreover, the evidence shows that the product stewardship research and development activities are collaborative with product design, development, and discovery activities. *See, e.g.*, CX-0004C (Mooney WS) at Q37 (“I understand that Reynolds’s employees perform product development activities as part of the PMTA process, including finalizing product specifications, manufacturing the product for testing purposes, working with outside vendors on study design, tracking execution of the study, and finalizing data sets and summary reports. I also understand that these employees collaborate with Reynolds’s Discovery, Design and Development R&D employees, which I mentioned earlier, to update products and implement cost savings initiatives.”).

stewardship, integrity, and regulatory compliance activities, as well as outside vendors who perform some of the required studies. CX-0004C (Mooney WS) at Q36-3Q8. The internal activities in this category of research and development include “numerous non-clinical and clinical studies to evaluate individual health risks among users of VUSE DI Products;” “an extensive behavioral-research program to assess tobacco-use patterns among purchasers;” and “population modeling and analysis demonstrating the net-population benefit of marketing each product over time.” CX-0004C (Mooney WS) at Q45 (quoting CX-0110C (Ferris Decl.); *see also* CX-0007C (Ferris WS) at Q84, Q78; Tr. (Mras) at 63:11-15 (“There are hundreds of scientific studies that go into a PMTA application, but some of the key studies would be toxicological analysis, behavioral studies, clinical studies, preclinical studies. It’s very much a robust science package that enters into the PMTA application.”). Reynolds also performs “routine analytical” studies, which are “chemistry testing to validate emissions and stability.” CX-0004C (Mooney WS) at Q56 (citing conversations with Dr. Christopher Junker, Vice President of Scientific and Regulatory Affairs at Reynolds). Also considered as part of the “product stewardship” category of research and development are “population effect” studies, which look at “consumers’ perceptions of risk and intention to purchase a product;” “testing that evaluates how consumers interact with products and can they do so safely;” and predictions of “human lives lost and/or saved after introduction of a new product to the market.” CX-0004C (Mooney WS) at Q57 (citing conversations with Dr. Junker). The evidence shows that these research expenses—which are primarily related to the filing of PMTAs—are ongoing, including because Reynolds has continuing reporting obligations to the FDA, because Reynolds conducts population risk, or post-market surveillance studies, and because Reynolds has recently filed new PMTAs on the VUSE DI Products. *See* CX-0004C (Mooney WS) at Q60-Q65; CX-0007C

(Ferris WS) at Q85-Q87. Moreover, the evidence shows that the PMTA process for the VUSE DI Products is ongoing. *See* CX-0007C (Ferris WS) at Q87 (“I mentioned earlier, but Reynolds has already submitted a PMTA for [REDACTED] VUSE DI Products. Reynolds also recently submitted PMTAs for the new versions of the VUSE Alto as I mentioned earlier.”), Q27 (“[Q]: Has Reynolds continued developing the VUSE line of products? [A]: Yes, after VUSE Solo, Reynolds launched VUSE Vibe, VUSE Ciro, and VUSE Alto. Reynolds continues to this day to develop and expand the VUSE line of products. In fact, [REDACTED] [REDACTED]). Mr. Mooney calculated the internal research and development spend in the product stewardship category at [REDACTED] between 2013 and September 2023 (which Mr. Ferris also broke out as over [REDACTED] between 2019 to September 2023, CX-0007C (Ferris WS) at Q94), and [REDACTED] in external spend from 2016 to September 2023:



CDX-0004C.3; CX-0004C (Mooney WS) at Q99; CX-1012C.

Respondents and Staff do not dispute the calculations regarding research and development investments. Respondents, as discussed above, waived any substantive challenge to Reynolds’ economic prong allegations. Even if Respondents’ arguments are considered, the

undersigned finds that Reynolds is likely to identify cognizable investments in labor and capital related to research and development that are sufficient to show a domestic industry. First, as discussed *supra*, the evidence of Reynolds' past investments, combined with unrebutted testimony from Reynolds' witnesses that research and development investments in the VUSE Vibe, Solo, and Alto are ongoing, are sufficient to show that Reynolds is likely to identify cognizable investments in labor and capital sufficient to show a domestic industry. Second, Respondents argue that the payments to external vendors are not justified by an explanation as to "the work actually performed or what portion of the alleged expenditure related to plant, equipment, labor, or capital." RIB at 115. The undersigned notes that even without considering the external vendor payments, Reynolds has identified evidence of approximately [REDACTED] ([REDACTED] in product design and discovery and [REDACTED] in product stewardship) in internal research and development expenses between 2019 and September 2023 related to the VUSE DI Products. *See* CX-1012C; CX-0007C (Ferris WS) at Q94. Further, the undersigned finds that Reynolds has introduced sufficient evidence that it is likely to substantiate the claimed third-party expenditures with sufficient detail, including because Reynolds introduced invoices, financial data, and sworn declarations from its third-party vendors providing details as to the work performed. CRB at 40; *see also* CX-0302C (financial data related to payments to [REDACTED] [REDACTED]); CX-0341C ([REDACTED] Invoices); CX-0922C (Declaration of [REDACTED] on behalf of [REDACTED]). For purposes of the temporary enforcement proceeding, this showing is sufficient to show a likelihood that Reynolds will be able to substantiate cognizable investments in labor and capital related to research and development.

b. Manufacture, Assembly, & Production

As to manufacture, assembly, and production, Mr. Mooney identified investments in labor and capital related to “internal and external domestic labor and capital related to the manufacture, assembly, and production of the VUSE DI Products.” CX-0004C (Mooney WS) at Q95. The evidence shows that these activities include “domestic production of the VUSE Solo cartridges, domestic assembly and packaging of the VUSE Solo devices, and domestic production of e-liquid used in the VUSE DI Products.” CX-0007C (Ferris WS) at Q97. Mr. Mooney calculated these investments as [REDACTED] between January 2014 and September 2023, including approximately [REDACTED] between 2020 and 2023. *See, e.g.*, CX-0004C (Mooney WS) at Q97; CDX-0004C.3; CX-1012C; CX-0295C; CX-0379C; CX-0007C (Ferris WS) at Q101 (“That is domestic internal labor expenses associated with the VUSE products at Reynolds’s ROC production facility. CX-0379C (Vapor Facility and Operations Maintenance Investments Summary) identifies these investments, which totaled over [REDACTED].”). The evidence also shows that these internal manufacturing investments are ongoing.³⁶ *See, e.g.*, Tr. (Mooney) at 373:13-16 (“So the data we have goes through the fall of 2023. So I quantify the investments through that. I also talk about that there are ongoing investments and the evidence of that.”), 373:22-23 (“I don’t have a specific number from post-March 2024. But the investments are ongoing.”); Tr. (Mras) at 59:9-11 (testifying that the VUSE Solo, Vibe, and Alto are still sold).

³⁶ Mr. Mooney also relied on evidence from the external manufacture of the VUSE Solo device in 2014 and 2015. *See* CX-0004C (Mooney WS) at Q96. There is no evidence that this investment is ongoing, as manufacture of the VUSE Solo moved to Reynolds’ ROC nearly a decade ago. *See* CX-0007C (Ferris WS) at Q35 (“Reynolds has manufactured the cartridges for the VUSE Solo in the United states [sic] for nearly a decade.”). Nor has Reynolds argued or explained how these are investments in an article protected by a patent, as required by subprong (B), nearly a decade before the patent issued. Accordingly, the undersigned does not consider these external labor and capital investments.

Respondents and Staff do not dispute the calculations regarding manufacture and production expenses. Respondents, as discussed above, waived any substantive challenge to Reynolds' economic prong allegations. Even if Respondents' arguments are considered, the undersigned finds that Reynolds is likely to identify cognizable investments in labor and capital related to manufacture and production that are sufficient to show a domestic industry. As discussed *supra*, the evidence of Reynolds' past investments, combined with unrebutted testimony from Reynolds' witnesses that manufacture and production investments in the VUSE DI Products are ongoing, are sufficient to show that Reynolds is likely to identify cognizable investments in labor and capital. For purposes of the temporary enforcement proceeding, this showing is sufficient to show a likelihood that Reynolds will be able to substantiate cognizable investments in labor and capital related to manufacture and production.

c. Quality Control

As to quality control, Mr. Mooney identified investments in labor and capital related to approximately [REDACTED] employees located at the ROC facility in Tobaccoville, NC who spend a portion of their time on Vapor products. CX-0004C (Mooney WS) at Q99; CX-0311C (Quality Control Employees and Allocation). The evidence shows that these employees perform "various functions, including but not limited to, performing incoming material inspection, quality sampling and testing, laboratory equipment calibration and validation, document control, and various types of reporting," assisting with "issues on the production floor," developing procedures, "field[ing] customer service calls relating to the VUSE DI Products," "testing products to address customer complaints," and "working with engineering to redesign products as needed to address those complaints." CX-0007C (Ferris WS) at Q107, Q109-Q110. Mr. Mooney calculated the labor expenses related to these quality control employees as [REDACTED]

between January 2019 and September 2023. CX-0004C (Mooney WS) at Q99. The evidence also shows that these internal quality control investments are ongoing. *See, e.g.*, Tr. (Mooney) at 373:13-16 (“So the data we have goes through the fall of 2023. So I quantify the investments through that. I also talk about that there are ongoing investments and the evidence of that.”), 373:22-23 (“I don’t have a specific number from post-March 2024. But the investments are ongoing.”); Tr. (Mras) at 59:9-11 (testifying that the VUSE Solo, Vibe, and Alto are still sold).

Respondents and Staff do not dispute the calculations regarding quality control expenses. Respondents, as discussed above, waived any substantive challenge to Reynolds’ economic prong allegations. Even if Respondents’ arguments are considered, the undersigned finds that Reynolds is likely to identify cognizable investments in labor and capital related to quality control that are sufficient to show a domestic industry. As discussed *supra*, the evidence of Reynolds’ past investments, combined with un rebutted testimony from Reynolds’ witnesses that quality control investments in the VUSE DI Products are ongoing, is sufficient to show that Reynolds is likely to identify cognizable investments in labor and capital. For purposes of the temporary enforcement proceeding, this showing is sufficient to show a likelihood that Reynolds will be able to substantiate cognizable investments in labor and capital related to quality control.

* * *

Based on the categories discussed above, Reynolds has shown evidence of approximately [REDACTED] in direct, internal investments in labor and capital related to research and development ([REDACTED] between 2019 and September 2023, CX-1012C), manufacture and production ([REDACTED] between 2020 and 2023, CX-0004C (Mooney WS) at Q97; CX-1012C), and quality control expenditures ([REDACTED] between 2019 and 2023, CX-0004C (Mooney WS) at Q99; CX-1012C) between approximately January 2019 and September 2023. In addition,

Reynolds has shown evidence of approximately [REDACTED] in external labor and capital expenditures related to research and development and product stewardship during the same time, for a total of approximately [REDACTED]. *See* CX-1012C. The un rebutted evidence also establishes that these investments are ongoing since issuance of the '202 patent on March 12, 2024. Accordingly, for the reasons discussed above, Reynolds is likely to identify cognizable investments in labor and capital as to the DI Products.

C. Significance

Reynolds contends that “Reynolds’s significant investments were necessary to bring the DI Products to market and to produce a legally saleable product in the U.S. These investments are integral to Reynolds’s future of alternatives to combustible cigarettes as well as to provide multiple choices for adult tobacco consumers in an effort to transition them away from traditional cigarettes.” CIB at 107 (citing CX-0004C (Mooney WS) at Q102-Q105). Reynolds argues that as also found in the 1199 investigation, the investments in product stewardship are qualitatively significant because “FDA PMTA submissions are important to the potential continued sale of VUSE as well as the overall integrity of the product,” Reynolds’ investments in e-liquid manufacturing are qualitatively significant because it “relates to a key component of the product,” and Reynolds’ “labor and capital investments in product development relating to VUSE are important to the development and oversight of a commercial product sold in the United States.” As to quantitative significance, Reynolds contends that its plant and equipment investments in the DI Products from 2013 through September 2023 [REDACTED] was [REDACTED] of the total COGS (which include substantially all relevant foreign investments) associated with the DI Products sold during that period [REDACTED] which is “well within the range accepted by the Commission as significant.” CIB at 108; CX-0004C (Mooney WS) at Q114. For labor and

capital, Reynolds contends that between 2018 and 2023, Reynolds' investments as a percentage of total cost of goods sold and research and development spend is [REDACTED] CIB at 108; CX-1012C; CDX-0004C (Mooney WS) at Q116-Q117. Reynolds also argues that its domestic PMTA research and development spend from January 2019 through September 2023 [REDACTED] represents [REDACTED] of Reynolds' total PMTA research and development spend. CIB at 108-09; CX-0004C (Mooney WS) at Q118-Q119; CDX-0004C.5.

As discussed above, Respondents have waived any substantive challenge to whether Reynolds' investments in the DI Products are significant.

Upon review of the evidence of record, the undersigned finds that Reynolds has met its burden to show that it is likely to establish significant investments in plant and equipment related to manufacture and assembly of the DI Products and labor and/or capital relating to research and development, manufacture and production, and quality control of the VUSE DI Products

First, the evidence shows that Reynolds' plant and equipment investments in manufacturing and production and labor investments in research and development, manufacturing and production, and quality control are likely qualitatively significant. Reynolds' employees credibly testified that the VUSE DI Products are a "core component" of Reynolds' strategic goals to build a portfolio of reduced-risk products, Tr. (Mras) at 54:1-13, and that the VUSE DI Products were "100 percent developed by Reynolds in the U.S." *Id.* at 58:11-13; *see also* CX-0007C (Ferris WS) at Q18-Q19. Ms. Mras also testified that the research and development that goes into the PMTA submission process is a "robust science package," which Mr. Ferris testified is necessary for Reynolds to sell the VUSE DI Products. CX-0007C (Ferris WS) at Q30 ("Reynolds could not legally sell any of the VUSE DI Products in the United States without its [REDACTED] of domestic industry investments."). Additionally, the

evidence shows that all of the e-liquids for the VUSE DI Products currently sold (i.e., the VUSE Vibe, VUSE Alto, and VUSE Solo) are manufactured domestically. *See* CX-0007C (Ferris) at Q44, Q35. Mr. Ferris also testified that the identified investments “relate to critical aspects of the VUSE DI Products, including the manufacture of cartridges and e-liquid, as well as the safety, integrity, research and development, and quality control of the entire systems. Reynolds could not produce or legally sell any of the VUSE DI Products without these crucial domestic investments.” CX-0007C (Ferris WS) at Q112.

In this context, the evidence further shows that Reynolds’ labor and plant and equipment investments are likely quantitatively significant. The evidence shows that [REDACTED] of Reynolds’ product development and design investments occur in the United States, *see* Tr. (Mras) at 58:11-13, and that [REDACTED] of Reynolds’ PMTA research and development investments occur in the United States. *See* CDX-0004C.5 (and exhibits cited therein). Moreover, all of the e-liquids used in the VUSE DI Products are manufactured domestically, with the VUSE Solo, Ciro, and Vibe product e-liquids manufactured by Reynolds in Tobaccoville, NC, and the VUSE Alto e-liquid manufactured by third-party [REDACTED]. *See* CX-0007C (Ferris WS) at Q26, Q28 (“In sum, the e-liquid for all of the VUSE line of products are produced in the United States). *Cf.* *Certain Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm’n Op., 2020 WL 2093834, at *41 (April 28, 2020) (finding quantitative significance where “all, i.e., 100 percent, of Kyocera’s R&D and engineering expenditures relating to complainant’s Fusion Nailers occurs in the United States”), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination, 2021 WL 5448436, at *41 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development

activities were based in the United States), *not reviewed in relevant part*, Commission Notice, EDIS Doc. ID 762554 (Feb. 4, 2022); *Certain Automated Teller Machines, ATM Modules, Components Thereof and Products Containing Same*, Inv. No. 337-TA-972, Final Initial Determination, EDIS Doc. ID 602395, at 197, (Feb. 1, 2017) (finding significance where development of product “was almost entirely domestic”), *not reviewed in relevant part by* Comm’n Notice, EDIS Doc. ID 602178 at 3, (Jan. 30, 2017); *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276, Comm’n Op., 2023 WL 8109999, at *42 (Nov. 14, 2023); *Certain Ground Fault Circuit Interrupters*, Inv. No 337-TA-739, Comm’n Op., 2012 WL 2394435, at *51 (finding economic prong satisfied where evidence that “virtually all research and development of the Leviton GFCIs occurs in the United States”).

Moreover, as compared to the total cost of goods for the VUSE DI Products—which Mr. Mooney credibly testified would capture foreign investment, Tr. (Mooney) at 372:10-17³⁷—the evidence shows that the domestic investments in plant and equipment between 2013 and September 2023 are █████ of total cost of goods. *See* CX-0004C (Mooney WS) at Q112; CDX-0004C.4 (and exhibits cited therein). Mr. Mooney also provided an analysis of labor and capital investments between 2018³⁸ and September of 2023 indicating that Reynolds’ domestic investments in the VUSE DI Products represented █████ of total COGS and R&D spend. *See* CX-0004C (Mooney WS) at Q116-117; CDX-0004C.4.

Based on the evidence of record, the undersigned finds that Reynolds has shown a likelihood of success that it will satisfy the economic prong of the domestic industry requirement

³⁷ Respondents, as discussed above, waived any substantive challenge to Reynolds’ economic prong showing. However, even if considered, the undersigned credits Mr. Mooney’s testimony that his COGS analysis accounts for foreign manufacturing costs. *Contra* RIB at 116.

³⁸ This percentage is likely understated, as the labor expenses for quality control were not available for 2018. *See* CX-0004C (Mooney WS) at Q99.

with respect to the '202 patent at least because the evidence shows past evidence of significant investment and unrebutted testimony that such investments are ongoing.

VIII. INVALIDITY

As discussed *supra*, in the context of Reynolds' motion for temporary relief, a likelihood of success on the merits cannot be met "if the alleged infringer raises a 'substantial question' regarding invalidity, i.e., asserts an invalidity defense that the patentee cannot prove 'lacks substantial merit.'" *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007).

Here, Respondents contend that claims 1, 4, 5, 9, 12 and 14 of the '202 patent are invalid as anticipated by and/or obvious over U.S. Patent No. 6,155,268 ("Takeuchi"; RX-0010) and that claims 1, 4, 5, 9, 12 and 14 are obvious over the combination of U.S. Patent App. Pub. 2006/0016453 ("Kim"; RX-0013) in view of Int'l Pat. Pub. WO 00/28843 ("Pinemann"; RX-0014). Respondents further contend that the Asserted Claims are invalid for lack of written description under 35 U.S.C. § 112.

For the reasons discussed below, the evidence of record shows that Respondents have raised a substantial question of invalidity based on both the Takeuchi reference as well as based on Kim in view of Pinemann. As the claims are tentatively construed, the evidence fails to show a substantial question of invalidity based on lack of written description.

A. Anticipation and/or Obviousness by Takeuchi³⁹

Takeuchi is titled “Flavor Generating Device,” and issued on December 5, 2000. RX-0010, cover. There is no dispute that Takeuchi constitutes prior art to the ’202 patent.⁴⁰ See SIB at 18; RIB at 44; CIB at 59. Takeuchi discloses two devices: (1) flavor-generating device 10 depicted in Figure 1; and (2) flavor-generating device 100 depicted in Figure 8. RX-0010 at Figs. 1, 8. Respondents contend that both devices separately and independently anticipate and/or render obvious the asserted claims. RIB at 44.

“A claim is anticipated when ‘the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.’” *Spanston, Inc. v. U.S. Int’l Trade Comm’n.*, 629 F.3d 1331, 1356 (Fed. Cir. 2010). Anticipation requires

³⁹ Respondents reference both anticipation and obviousness as to Takeuchi, but identified no missing limitations. See, e.g., RIB at 44; but see RDX-0201.30, 40 (identifying each limitation of the claims at issue as “present in Takeuchi”); Tr. (Alarcon) at 155:24-156:4 (asserting that Dr. Dean alleged obviousness over Takeuchi only with respect to claim 14); Tr. (Dean) at 484:3-9 (“principal conclusion” is that “claims in ’202 have been anticipated by a patent identified as Takeuchi”). Because the undersigned finds—with the exception of claims 5 and 12, for which no obviousness analysis was provided—that there is a substantial question of invalidity as to anticipation by Takeuchi, the undersigned does not reach obviousness. In this regard, however, the undersigned notes that no evidence of secondary considerations of non-obviousness was presented by the parties. See, e.g., Tr. (Alarcon) at 221:24-223:15 (agreeing that he did provide an opinion as to objective evidence of secondary considerations).

⁴⁰ Reynolds contends that the prior consideration of Takeuchi (and Kim and Pinemann) by the PTO during examination imposes “an enhanced burden” to establish invalidity. CIB at 59 (citing *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011)). Shortly after *Tokai*, however, the Supreme Court clarified that the burden to show invalidity—at trial, by clear and convincing evidence—is the same regardless of whether a reference was previously considered during examination. See *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 99 (2011); see also *Homeland Housewares, LLC v. Rsch.*, No. CV 11-3720-GW(JEMX), 2013 WL 12134266, at *10 (C.D. Cal. Feb. 28, 2013) (noting that it is unclear “whether *Tokai* survives *i4i*”); *Pfizer Inc., v. Teva Pharms. USA, Inc.*, 803 F. Supp. 2d. 409, 440 n.69 (E.D. Va. 2011) (same). Moreover, even before *i4i*, the fact that a reference had been considered during examination was not sufficient to show that an invalidity defense lacked substantial merit. See *Novo Nordisk v. Bio-Technology General Corp.*, 52 Fed. Appx. 142, 147–48 (Fed. Cir. 2002) (overturning grant of preliminary injunction on grounds of substantial question of anticipation even though PTO considered references).

evidence that a single prior-art reference discloses “all of the limitations of the claims arranged or combined in the same way as recited in the claims.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369-70 (Fed. Cir. 2008).

1. Claim 1

The parties do not dispute that Takeuchi discloses Limitations [1pre], [1c], [1e], and [1f]. CIB at 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. For the reasons discussed above and below, Reynolds has not shown that the Takeuchi invalidity defense raised by Respondents “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377.

a. Limitation [1pre]: An electrically-powered, aerosol-generating smoking article comprising:

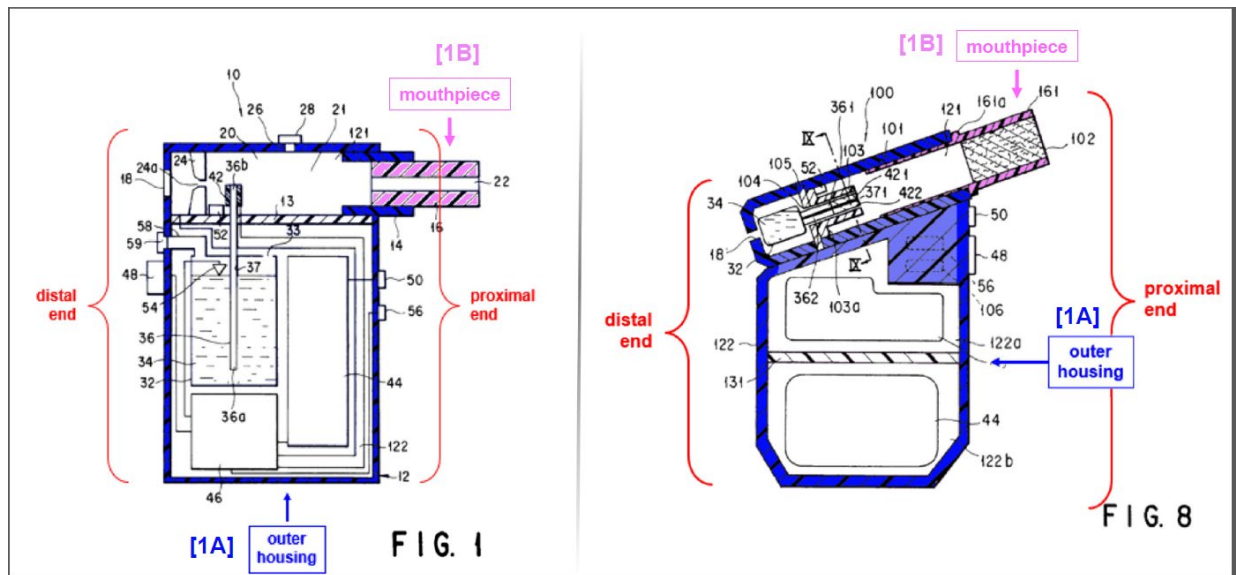
Neither Reynolds nor Staff dispute that that this limitation is disclosed in Takeuchi. *See* 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses an electrically-powered, aerosol-generating smoking article. *See* RX-0010 at 5:43-46 (when “used as a simulated smoking article, it is possible for the liquid flavor source 34 to contain tobacco components such as tobacco extracts and a tobacco smoke condensate”); *id.* at 6:12-14 (“electric power is supplied from a power source 44 detachably mounted within the lower chamber 122 of the casing 12 to the electric heater 42”); *id.* at 5:33-39 (“in order to add smoke to the flavor, it is possible for the liquid flavor source 34 to contain a substance forming aerosol when heated,” including, for example, “glycerin, propylene glycol, and a mixture thereof”); Tr. (Dean) at 510:4-7; RDX-0201.32.

Accordingly, Respondents have raised a substantial question of patentability with respect to this limitation that Reynolds has not shown lacks substantial merit.

b. Limitation [1a]: an outer housing having two ends;

The parties dispute that this limitation is disclosed in Takeuchi. The parties do not dispute that Takeuchi discloses “an outer housing,” but dispute whether the outer housing includes “ends” as claimed. *See* CIB at 61 (“Takeuchi does not disclose that the outer housing for either of the figures has ‘ends.’”); RIB at 46-49; SIB at 19-21.

Respondents identify “casing 12” as the outer housing for the two Takeuchi embodiments (devices 10 and 100) relied upon. RIB at 46. In device 10, the inner space created by casing 12 is “partitioned into upper chamber 121 and lower chamber 122.” RX-0010, 4:31-33. In device 100, the upper chamber 121 is “provided on the lower chamber 122 along the included upper wall of the lower chamber.” RX-0010, 8:63-67. In the below annotated figures, Dr. Dean identified a “distal” and “proximal” “end” of each of the devices in Takeuchi, identified from the perspective of the user, with the “outer housing” annotated in bright blue:



RDX-0201.33 (annotating RX-0010 at Figs. 1, 8); Tr. (Dean) at 510:8-24; RIB at 46. In device 10, above left, inhalation port holder 14 “is mounted at one side end portion of the upper chamber 121 of the casing 12,” and mouthpiece 16 (annotated in pink) is “detachably inserted

therein.” RX-0010, 4:39-43. In device 100, mouthpiece 161 “is detachably inserted directly, i.e., without through a holder, into the open end portion (upper end portion) of the upper chamber 121.” *Id.* at 9:9-12. In both devices, air intake port 18 is provided “at the closed end” of the upper chamber. *Id.* at 9:8-9. Accordingly, Respondents argue that Takeuchi discloses an “outer housing” with two “ends” as claimed. RIB at 46-48. Respondents also argue that in an *inter partes* review, Reynolds contended that Takeuchi included an “end of the housing” identifying what Dr. Dean identified as the “proximal end” of device 10 as an “end.” RIB at 49 (citing RX-0112.0028; RX-0111.0042). Respondents submit that the identified “ends” in Takeuchi are consistent with the usage of “ends” in the ’202 patent, as in both the Takeuchi devices and the ’202 patent, “air passes longitudinally from the distal end to the proximal end when a user takes a draw.” RIB at 49 (citing ’202 patent, 5:62-6:3 (“an outer housing having a mouth-end and an end distal to the mouth-end, wherein the mouth-end comprises an opening adapted for egress of an aerosol generated within the smoking article and the distal end comprises an opening adapted for intake of air into the smoking article”).

In opposition, Reynolds contends that Takeuchi does not disclose that the outer housing has “ends,” but rather identifies “a side end portion of the upper chamber,” not an end of the “outer housing.” CIB at 60; CRB at 20. Reynolds submits that Takeuchi describes the portions identified by Dr. Dean as “ends” as “side wall[s] of the casing 12.” CIB at 61 (citing RX-0010, 7:31-33). Reynolds also argues that “ends” in the ’202 patent refers to “longitudinal ends,” “extremes of the longitudinal length of the device,” and “positioned lengthwise.” CIB at 61-62 (citing Tr. (Alarcon) at 157:1-4); CRB at 20 (citing Tr. (Wensley) at 295:10-16 (“ends” defined “as when you have an object that is narrower than it is long, the two ends that are on the long ends are the ends”). Takeuchi, Reynolds submits, uses “ends” in the same manner. CIB at 61

(citing RX-0010, Abstract). Respondents' contention that "ends" should be judged from the perspective of the user, Reynolds argues, contradicts "a POSA's plain and ordinary meaning of the term." CRB at 19. As to the positions taken in the *inter partes* review, Reynolds argues that the position was taken by "a different expert, in a different matter, and presented in the context of a different patent." CIB at 62; *see also* CRB at 20-21. Reynolds also argues that the identification of an "end" in Takeuchi was in the context of the broadest reasonable interpretation standard of claim construction, not the *Phillips* standard. CIB at 62. Finally, Reynolds contests Respondents' assertion that the form factors between the Accused Products and the Takeuchi devices are similar, arguing that the Takeuchi figures "do not depict the actual form factor" and are "therefore irrelevant." CRB at 21.

In response, Respondents argue that Reynolds' assertion that the '202 patent uses "ends" to refer to solely to refer to longitudinal extremes is not supported by evidence and is contradicted by Dr. Dean's testimony. RRB at 24 (citing Tr. (Dean) at 510:19-24 ("[Q]: What do you mean by proximal and distal? [A]: That's a fairly standard term used medically and when there is a device whose orientation is important with respect to the user. 'Proximal' means the end that is closest to the user, and 'distal' means the end that is furthest away.")). Respondents also submit that the "side end portion of the upper chamber" is part of the casing 12, and thus there is no distinction between the "end" of the outer housing or casing and an "end" of the upper chamber. RRB at 24-25 (citing RX-0010, 4:39-41). Respondents also argue that Mr. Alarcon recognized that Takeuchi's outer housing "has a physical end to the – or a physical limit to that side wall." RRB at 25 (citing Tr. (Alarcon) at 196:1-16). As to the *inter partes* review, Respondents submit that the broadest reasonable interpretation standard and the *Phillips* standard both look to the "ordinary usage as they would be understood by one of ordinary skill in the art,"

and that the position taken by Reynolds in the *inter partes* review is relevant. RRB at 25 (quoting 37 C.F.R. § 42.100 (2018)).

In Staff's view, Reynolds' position that Takeuchi does not disclose "ends" "relies on a litigation-inspired definition of the term 'end.'" SIB at 21. Staff contends that "applying the plain and ordinary meaning of the claim terms, the evidence shows that Takeuchi discloses 'an outer housing having two ends.'" SIB at 21. Staff argues that Reynolds' position is "contrary to the plain and ordinary meaning of the term 'end,' contradicts [Reynolds'] own descriptions of Takeuchi to the Patent Office, and conflicts with [Reynold's] infringement theory in this case, where [Reynolds'] expert recognizes that the boundary of the device closest to the user is an 'end.'" SRB at 5-6 (citing CDX-0009.20; RX-0111.0042). Staff additionally argues that the "longitudinal extremes" definition of "ends" is at odds with the '202 patent, as "[n]either the claims nor the specification of the '202 Patent require the 'outer housing' to have a particular shape," but rather disclose that the shape and dimensions "may vary." SRB at 7 (citing '202 patent, 19:59-60).

The parties' dispute is essentially a question of the meaning of the term "ends," as applied to the Takeuchi reference. Reynolds contends that "ends" refers to the "longitudinal ends" or "longitudinal extremes" of a device, while Respondents contend that the "ends" correspond to the outer extent of the housing, judged from the perspective of the user. *See* CIB at 61 ("the '202 patent consistently uses the term 'end' to refer to longitudinal ends, and repeatedly describes the 'ends' as being positioned lengthwise"); CRB at 20 (citing to Mr. Wensley's testimony that he would "define ends as when you have an object that is narrower than it is long, the two ends that are on the long ends are the ends"); RRB at 26 ("the 'ends' are proximal and distal ends with respect to the user").

For purposes of the temporary relief phase of the investigation and based on the current evidence of record, the term “ends” in the ’202 patent is construed according to its plain and ordinary meaning to one of skill in the art, which is not limited to the “longitudinal ends” or the extremes of a device in a lengthwise configuration. In light of this construction, and upon review of the submissions and evidence of the current record, the undersigned finds that Respondents have raised a substantial question of patentability with respect to this limitation which Reynolds has not shown lacks substantial merit.

The specification of the ’202 patent repeatedly refers to the device’s “ends” from the perspective of the user, referring to one end as the “mouth-end” that “is used *by the smoker* to inhale” and a second end that is “distal to the mouth-end.” *See, e.g.*, ’202 patent, Abstract, 5:65-66 (emphasis added); *see also id.* at 5:65- 5:24-26 (similar); 5:46-47 (similar); 20:4-9 (similar); 24:30-21 (“During use, the mouth-end 15 of the smoking article 10 is placed in the lips of the smoker.”). The specification further indicates that these “ends” correspond to openings in the device’s housing relating to movement of gas. *See id.* at 5:65-6:3 (referencing “an outer housing having a mouth-end and an end distal to the mouth-end, wherein the mouth-end comprises an opening adapted for egress of an aerosol generated within the smoking article and the distal end comprises an opening adapted for intake of air into the smoking article”); *id.* at 6:65-7:3 (similar); *id.* at 7:46-51 (similar); *id.* at 20:4-10 (similar). Dr. Dean’s testimony is consistent with the usage in the ’202 patent, as he explained that “distal” is a “fairly standard term used medically and when there is a device whose orientation is important with respect to the user . . . ‘distal’ means the end that is furthest away [from the user].” Tr. (Dean) at 510:19-24. Dr. Dean’s definition of “distal” is consistent with the ’202 patent’s identification of a “distal end” as the end opposite the “mouth-end” “used by the smoker.” ’202 patent, Abstract, 5:65-66.

Further, the specification of the '202 patent makes clear that the device and/or outer housing need not conform to any particular shape or dimension: in particular, “the dimensions and shape of the outer container 20 can vary.” ’202 patent, 19:59-60. Although the example embodiments are described as “generally tubular” or “rod-shaped,”⁴¹ the intrinsic record indicates that the invention is not so limited. In addition to the specification’s statement that the shape “can vary,” dependent claim 17—which depends from claim 1—adds the additional limitation “wherein the electrically-powered, aerosol-generating smoking article is generally rod-shaped.” *Id.* at cl. 17; *see Cioffi v. Google, Inc.*, 632 F. App’x 1013, 1019 (Fed. Cir. 2015) (appearance of a limitation in a dependent claim gives rise to a presumption that the claim from which it depends lacks such a limitation).⁴² Reynolds’ argument that the ’202 patent uses “ends” to refer to “longitudinal ends” is thus a function of the particular shape of the embodiments depicted in the ’202 patent, not a limit on the meaning of the term “ends” when applied to a device that varies from one that is rod-shaped or generally tubular. *See* CIB at 61 (citing ’202 patent, 8:47-49 (referencing the “embodiments” in Figs. 1-3); Tr. (Alarcon) at 157:5-9 (testifying regarding the same embodiments). Reynolds’ asserted construction—that the claimed “ends” must be “longitudinal ends”—would have the practical effect of imposing a particular shape on the outer housing, *e.g.*, an object that is narrower than it is long, which is at odds with the specification’s statement that the “dimensions and shape . . . can vary.” ’202 patent, 19:59-60; Tr. (Wensley) at 295:10-16 (he would “define ends as when you have an object that is narrower

⁴¹ *See* ’202 patent, 19:53-55 (describing the embodiment of Figure 1 as “generally rod-like or tubular in nature, generally akin to a cigarette-type smoking article”); *id.* at 19:59-62 (“Although the dimensions and shape of the outer container 20 can vary, a representative outer housing is generally tubular in shape (*e.g.*, having an overall length of about 11 cm and an outer diameter of about 1.5 cm).”).

⁴² Moreover, a requirement that the outer housing be tubular or rod-shaped would be at odds with Reynolds’ infringement contentions, which are directed at products that are not necessarily tubular or rod-shaped. *See, e.g.*, CDX-0009.13 (depicting the ONEE Max Accused Product).

than it is long, the two ends that are on the long ends are the ends”). Moreover, as noted above, the specification repeatedly refers to “ends” of the housing in terms of certain openings; in none of these passages is any reference made to a “longitudinal” requirement.⁴³

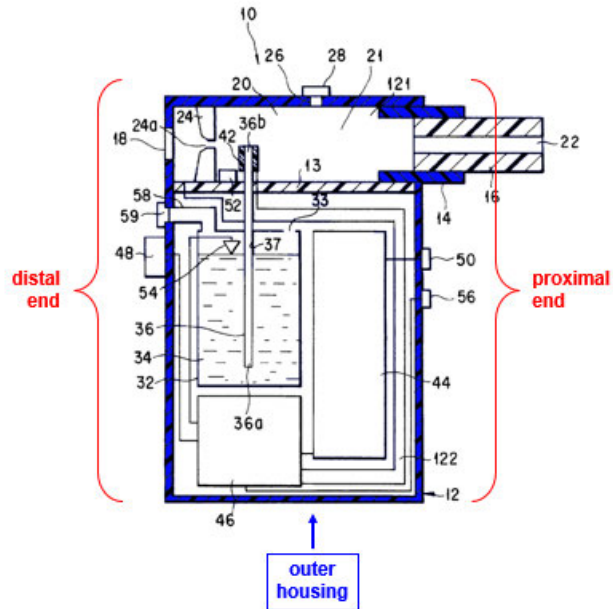
Based on the evidence and arguments currently of record, the undersigned thus finds that the meaning of “ends” in the ’202 patent is not limited to “longitudinal ends” or the longitudinal extremes of the claimed housing, as argued by Reynolds.

Other than the challenge to the meaning of “ends,” Reynolds argues that Dr. Dean’s identification in Takeuchi of the “proximal” and “distal” ends does not disclose the claimed “outer housing having two ends” because Takeuchi describes the “side end portions” as part of the upper chamber 121, not the casing 12. *See* CRB at 20 (“Takeuchi describes these as the side ends of the upper chamber 121, not the outer housing as Respondents allege.”); CIB at 60. The undersigned finds this argument to be unpersuasive, as the full quote from Takeuchi makes clear that the “side end portion of the upper chamber 121” is part of the casing: “inhalation port holder 14 defining a cylindrical opening is mounted at one side end portion of the upper chamber 121 *of the casing 12.*” *Compare* ’202 patent, 4:39-41 (emphasis added) *with* CIB at 60 (citing portion of ’202 patent, 4:39-41). There is no dispute that casing 12 is an outer housing; the “side end portion[s] of upper chamber 121” are, accordingly part of the outer housing. *See* Tr. (Alarcon) at 196:9-10 (“[Q]: So you agree that the casing is an outer housing? [A]: Yeah, I think it’s a housing.”).

Additionally, the determination that Takeuchi discloses “ends” is consistent with arguments made by Reynolds as a petitioner—and ultimately adopted by the PTAB—regarding

⁴³ For the same reason, Mr. Wensley’s testimony about the meaning of “ends” in the context of a pencil—a rod-shaped or generally tubular object—is also unavailing. CRB at 20 (citing Tr. (Wensley) at 295:10-16, 296:14-22).

Takeuchi's disclosures in an *inter partes* review. There, Reynolds argued—and the PTAB ultimately agreed—that LED 56 in Takeuchi (see below) was “located at one end of the housing (casing 12),” where LED 56 was not at a longitudinal extreme. RX-0112.28 (“[T]he preponderance of the evidence in this record establishes that Takeuchi's LED 56 is located at one end of the housing (casing 12) and on an outer extent of the casing. . . . Takeuchi discloses a device having ‘an LED at a first end of the housing’ as recited in claims 1 and 2.”); RX-112.23 (summarizing Petitioner Reynolds' argument).⁴⁴



Accordingly, for all the reasons discussed above and based on the arguments and evidence introduced in the temporary relief proceedings,⁴⁵ Respondents have raised a substantial

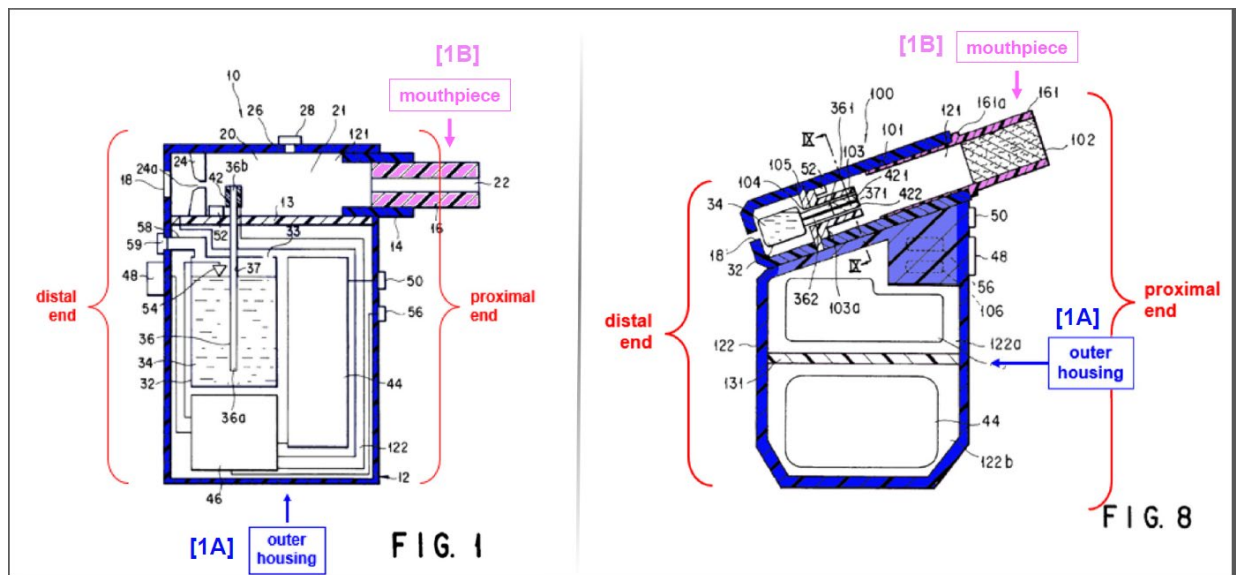
⁴⁴ The undersigned recognizes that the *inter partes* review involved different patents and a broadest reasonable interpretation claim construction standard, but the technology at issue, many of the terms, and the Takeuchi reference are the same. Compare, e.g., RX-0112.5 (“The ’331 patent relates to an electronic atomization cigarette that functions as a cigarette substitute.”), RX-0112.6 (Patent Owner challenging construction and disclosure of term “an LED at a first end of the housing”), RX-00012.7 (“Takeuchi, U.S. 6,155,268”) with CIB at 7 (The ’202 Patent is directed to devices and components thereof that provide adult tobacco consumers with a smoking alternative to traditional cigarettes.”), CIB at 60 (“Takeuchi does not disclose [1A] ‘an outer housing have two ends.’”). Moreover, Reynolds purports to rely on “plain and ordinary” meaning here, which is also the standard that the PTAB stated it was relying upon. See CRB at 20-21 (relying on plain and ordinary meaning, e.g., “what are the two ends of a car?”); RX-0112.0009 (under broadest reasonable construction standard, “absent any special definitions, we give claim terms their ordinary and customary meaning”); *PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC*, 815 F.3d 734, 744 (Fed. Cir. 2016) (noting that a construction may be the same under both broadest reasonable interpretation standard and the *Phillips* framework).

⁴⁵ The undersigned notes that the construction relating to “ends” is tentative and made based on the arguments and evidence presented in connection with the temporary relief phase of this investigation. Additional or different arguments or evidence may alter the construction. See *Natera, Inc. v.*

question of invalidity with respect to this limitation that Reynolds has not shown lacks substantial merit.

c. Limitation [1b]: a mouthpiece defined at one of the two ends

The parties dispute this limitation. Respondents contend that devices 10 and 100 in Takeuchi include the claimed “mouthpiece defined at one of the two ends,” as identified in the annotated figures below:



RDX-0201.33 (annotating RX-0010, Figs. 1, 3); Tr. (Dean) at 511:14-22; RIB at 49-50.

Respondents also point to Takeuchi’s disclosures that device 10 includes a “mouthpiece 16 having an inhalation port 22 . . . detachably inserted into the holder 14,” and device 100 includes a “mouthpiece 161 [that] may be detachably inserted directly . . . into the open end portion (upper end portion) of the upper chamber 121.” RX-0010, 4:41-42, 9:10-12.

Reynolds does not dispute that the devices in Takeuchi disclose a mouthpiece, but rather disputes that the mouthpiece is “defined at ‘one of the two ends’ as required by the claims, at

NeoGenomics Lab ’ys, Inc., 106 F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”).

least for the reasons explained with respect to limitation [1A].” CIB at 63; *see also* CRB at 19-21 (raising arguments directed only to whether Takeuchi discloses “ends” as claimed); Tr. (Alarcon) at 158:2-4 (“For the reason I mentioned, that Takeuchi does not disclose ends; therefore, it does not disclose a mouthpiece at one of two ends.”), 196:14-16 (“[Q]: You also agree that Takeuchi discloses a mouthpiece, right, highlighted at [element] 16 [in Fig. 1 of Takeuchi]?” [A]: Yes, Takeuchi has a mouthpiece.”).

In Staff’s view, “the evidence shows that Takeuchi discloses . . . ‘a mouthpiece defined at one of the two ends’ as recited by claim 1 of the ’202 patent.” SIB at 21; SRB at 6.

For the reasons discussed above with respect to Limitation [1a], and based on the arguments and evidence introduced in the temporary relief proceedings, Respondents have raised a substantial question of invalidity with respect to this limitation that Reynolds has not shown lacks substantial merit. *See, e.g.*, RX-0010, 4:41-42, 9:10-12; Tr. (Dean) at 511:14-22.

d. Limitation [1c]: an electrical power source arranged within the outer housing;

Neither Reynolds nor Staff dispute that that this limitation is disclosed in Takeuchi. *See* 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses “an electrical power source arranged within the outer housing.” *See* RX-0010, 6:12-14 (in devices 10 and 100, “electric power is supplied from a power source 44 detachably mounted within the lower chamber 122 of the casing 12 to the electric heater 42”); *id.* at 6:15-17 (power source 44 can be “a DC power source available on the market such as a primary battery (dry battery), or a secondary battery (rechargeable battery)”); Tr. (Dean) at 511:23-512:5; RDX-0201.34 (identifying electrical power source in Takeuchi’s Figs. 1 and 3 in green).

Accordingly, Respondents have raised a substantial question of patentability with respect to this limitation that Reynolds has not shown lacks substantial merit.

- e. **Limitation [1d]: an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source**

The parties dispute that this limitation is disclosed in Takeuchi. The parties do not dispute that Takeuchi discloses a “heater,” “positioned within the outer housing” and “configured for electrical connection with the electrical power source”; rather, the parties’ dispute is limited to whether the disclosed heater is the claimed “electrical resistance heater,” as opposed to a dielectric or inductive heater. *See* CIB at 64 (“Takeuchi is silent as to the type of heater it uses.”); RIB at 51; SIB at 19-21.

Respondents contend that although Takeuchi does not disclose the “heater” as an “electrical resistance heater,” *ipsissimis verbis*, Dr. Dean testified that descriptions of the heater’s operation and schematics make clear that the heater is an electrical resistance heater. RIB at 51-52 (citing Tr. (Dean) at 512:25-514:11). Specifically, Respondents point to the schematics in Figs. 2A-2C, which depict “connections to opposite sides of tubular heater 42 (shown in cross-section) and a switch placed between the negative terminal of power source 44 (illustrated as a battery) and one side of tubular heater 42.” RIB at 53. Relying on Dr. Dean’s explanation of these schematics, Respondents contend that “Figures 2A-2C indicate an electrical resistance heater based on the presence of connections on opposite sides of tubular heater 42 with one side connected to a positive battery terminal and a second side connected to a negative battery terminal.” RIB at 53-54 (citing Tr. (Dean) at 513:4-22; RDX-0201.35 (annotating RX-0010, Figs. 2A-2C)). Respondents also contend that Takeuchi discloses various modifications to the heater, which are “simple substitutions.” RIB at 55-57. Respondents criticize Mr. Alarcon’s

testimony that the heater in Takeuchi could be an inductive or dielectric heater as unsupported by evidence. RIB at 57-58.

In opposition, Reynolds argues that Takeuchi does not describe the heater as an “electrical resistance heater” and does not include “any description of the electrical characteristics that suggest or necessitate a resistance heating element,” as opposed to an inductive or dielectric heater. CIB at 64 (citing Tr. (Alarcon) at 159:12-16, 159:21-160:19). Reynolds contends that Dr. Dean’s “conclusory assertions are insufficient to establish invalidity as a matter of law.” CIB at 66 (citing *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (“Broad conclusory statements offered by . . . experts are not evidence”). Reynolds contends that Dr. Dean’s testimony “suggested at best a possibility—and certainly not an inevitability—that the heaters in Takeuchi could be resistance heaters,” which is “legally insufficient to support a finding of anticipation.” CRB at 22-23 (citing *PersonalWeb Techs., LLC v. Apple, Inc.*, 917 F.3d 1376, 1382-83 (Fed. Cir. 2019) (“Inherency . . . may not be established by probabilities or possibilities”)). Reynolds contends that the schematics in Figs. 2A-2C show the “control circuit,” rather than showing that the heater is an electrical resistance heater. CRB at 23. Reynolds contends that Takeuchi’s heater 42 is “a heating mechanism that is likely based on dielectric heating.” CIB at 65.

In response, Respondents argue that Reynolds’ argument that Takeuchi’s heater 42 is “likely dielectric” is inconsistent with the disclosure in Takeuchi that the heater 42 is a “tubular body” rather than “two plates” and Mr. Alarcon’s testimony that a dielectric heater requires two portions or plates to operate. RRB at 29 (citing Tr. (Alarcon) at 159:21-25, 218:16-219:2; RX-0010, 6:7-10).

In Staff's view, Takeuchi discloses the claimed "electrical resistance heater." SIB at 24. Staff points to Dr. Dean's testimony that he is "100 percent certain" that the heaters in Takeuchi are "electrical resistance heaters," including because of the schematic diagrams in Figs. 2A-2C and the various types of electrical resistance heaters in Figs. 3-7, 10, and 11. SIB at 22-24 (quoting Tr. (Dean) at 513:3). Staff contends that contrary to Reynolds' argument that Takeuchi does not disclose a current flow of the heater, Figs. 2A-2C disclose the current flow of the heater. SRB at 8-9.

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents' arguments and evidence that Takeuchi discloses the claimed "electrical resistance heater" lack substantial merit.

Dr. Dean identified disclosures and schematics in Takeuchi that he testified describe, to one of skill in the art, the claimed "electrical resistance heater." Specifically, he testified that the schematic diagrams in Figs. 2A-2C show the operation of an electrical resistance heater. Tr. (Dean) at 513:4-22; RDX-0201.35 (annotating RX-0010, Figs. 2A-2C). Dr. Dean also testified that the various heater configurations disclosed in Takeuchi were all consistent with electrical resistance heaters, and that Takeuchi did not disclose configurations or schematics consistent with inductive or dielectric heaters. Tr. (Dean) at 513:23-514:22. Mr. Alarcon, on the other hand, testified that Takeuchi was "silent" as to the type of heater it describes, and that it could be a dielectric or inductive heater. Tr. (Alarcon) at 158:24-159:8.⁴⁶ Mr. Alarcon testified, directly contrary to Dr. Dean, that the schematics at Figs. 2A-2C do not necessarily mean that current is flowing through the heater. Tr. (Alarcon) at 160:9-161:3. The parties, then, have presented

⁴⁶ Mr. Alarcon acknowledged that electrical resistance heaters were known in the art at the time of the invention. See Tr. (Alarcon) at 221:14-23.

conflicting expert testimony on the technical details of Takeuchi's disclosure with respect to the disclosed "heater." Such a conflict is "best decided on the basis of a more developed record." *See, e.g., Baxalta Inc. v. Genentech, Inc.*, No. 17-509-TBD, 2018 WL 3742610, at *8 (D. Del. Aug. 7, 2018) (Dyk, J., sitting by designation) ("With respect to both of the merits issues, the parties have presented challenging questions of law and sharply conflicting expert testimony. Both issues are best decided on the basis of a more developed record. But Genentech has at the very least established that there are difficult questions with respect to infringement and invalidity. These difficult merits questions weigh in favor of denying injunctive relief at this stage.").

Moreover, that Takeuchi does not, *ipsissimis verbis*, describe its heater as an "electrical resistance heater" or use the word "resistance," CIB at 64, does not prevent a finding of anticipation. *See, e.g., In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (anticipation requires the elements "'arranged or combined in the same way as in the claim,' [but] the reference need not satisfy an *ipsissimis verbis* test.") (internal citations omitted); *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 913 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 2561 (2023) ("[T]he district court erred in interpreting these linguistic differences as fatal to a finding of anticipation . . . [A] prior art inventor need not 'conceive of its invention using the same words as the patentee would later use to claim it.'"); *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1351 (Fed. Cir. 2000) ("The [reference] does not expressly disclose in words elements (8)-(10) of claim 1 of the '801 patent. The [reference] might nevertheless be anticipating if a person of ordinary skill in the art would understand the brochure as disclosing elements (8)-(10) and if such a person could have combined the brochure's description of the invention with his own knowledge to make the claimed invention.").

The Federal Circuit’s decision in *Helifix* (and the description of the same decision in *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001)) is instructive. In *Helifix*, the Federal Circuit overturned a grant of summary judgment of invalidity, but upheld a denial of a preliminary injunction on the basis that a “substantial question” of invalidity was raised. 208 F.3d at 1352. There, the Federal Circuit:

expressly held that the quantum of evidence put forth—while falling short of demonstrating invalidity itself—was sufficient to prevent issuance of the preliminary injunction. Particularly instructive for purposes of this case is the treatment of the anticipation issue in *Helifix*. A particular reference which did not on its face disclose all the limitations of the claim in suit was argued to be anticipatory, even though there was a conflict in the testimony as to whether the reference would have taught one of ordinary skill in the art the claim limitations not expressly stated on the face of the reference. Although insufficient to demonstrate invalidity for the purposes of the summary judgment motion, the reference was enough to prevent issuance of the preliminary injunction.

Amazon.com, 239 F.3d at 1359 (describing and applying *Helifix*). Here, as in *Helifix*, Reynolds argues that Takeuchi does not “on its face disclose” an electrical resistance heater, and here, as in *Helifix*, there is “a conflict in the testimony as to whether the reference would have taught one of ordinary skill in the art the claim limitations not expressly stated on the face of the patent.” *Id.*

Based on the evidence of record, including Dr. Dean’s testimony and his description of the Takeuchi schematics, the undersigned finds that Respondents have raised a substantial question as to whether Takeuchi discloses the claimed “electrical resistance heater” and Limitation [1d] of the ’202 patent and that Reynolds has not shown that Respondents’ argument lacks substantial merit.

- f. **Limitation [1e]: a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material;**

Neither Reynolds nor Staff dispute that that this limitation is disclosed in Takeuchi. *See* 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses “a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material.” *See* Tr. (Dean) at 514:23-516:1; RDX-0201.37.

Specifically, in device 10 of Takeuchi, Respondents identify “liquid container 32 housing a liquid flavor source 34,” which is within the lower chamber 122 of the outer housing (*i.e.*, casing 12). RIB at 59 (citing RX-0010, 5:28-30, 2:6-7, 4:36-37). A capillary tube 36 is inserted within the liquid container, RX-0010, 5:47-49, and before heating, “the liquid flavor source 34 is already transported to the outlet port 36a [36b] of the capillary tube 36 by the capillary force of the capillary tube 36.” *See* RX-0010, 7:57-59, Figs. 2A-2C. “Upon gasification of the liquid flavor source 34 within the outlet port 36a [36b] by the heating with the heater 42, the liquid flavor source 34 is newly supplied from the liquid container 32 into the outlet port 36a [36b] of the capillary tube 36 by the capillary [action] of the capillary tube 36.” RX-0010, 7:64-8:1, Figs 2A-2C; Tr. (Dean) at 516:24-517:1.

In device 100, the process is similar. “[S]mall exchangeable liquid container 32 containing the liquid flavor source . . . is arranged in the upper chamber 121” of the outer housing. RX-0010, 9:23-26. “[L]iquid passageway 371” is defined between two parallel plates

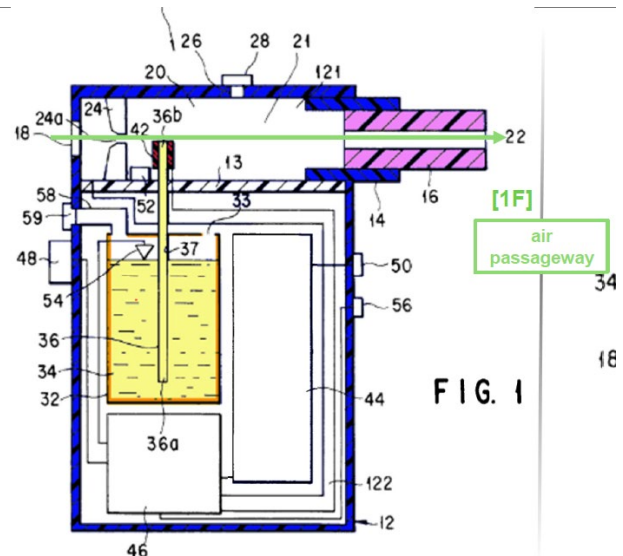
and is “in fluid communication with the liquid flavor source 34 in the container 32,” RX-0010, 9:35-38, 9:45-50, 9:24-31. Upon heating, the “gasification” (volatization) and supply of new liquid (wicking) process occurs substantially the same way as in device 10. *See* RIB at 63; RX-0010, Fig. 10.

Accordingly, Respondents have raised a substantial question of invalidity with respect to this limitation that Reynolds has not shown lacks substantial merit.

- g. Limitation [1f]: an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece; and**

Neither Reynolds nor Staff dispute that that this limitation is disclosed in Takeuchi. *See* 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses “an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece.” *See* Tr. (Dean) at 516:2-517:1; RDX-0201.38.

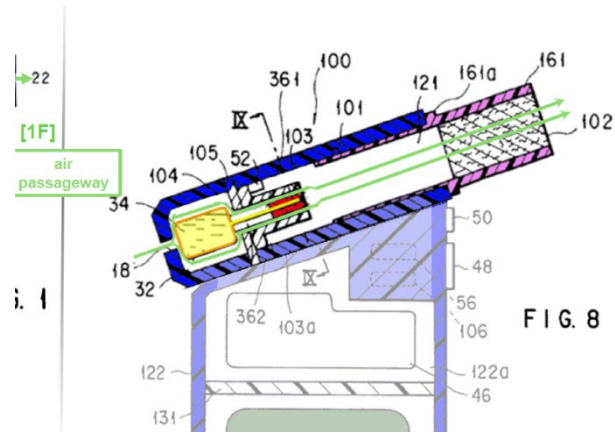
Specifically, in device 10 of Takeuchi, annotated at right, “an air intake port 18 for introducing the air into the upper chamber 121 is formed on the other side portion of the upper chamber.” RIB at 63 (citing RX-0010, 4:48-50). A “gas passageway 20 is defined within the upper chamber 121 of the casing 12, between the air intake port 18 and the inhalation port 22.”



“Squeeze hole 24a” is “arranged with the gas passageway 20 and positioned close to the air intake port 18 . . . to regulate or direct the air . . . selectively toward a outlet portion” of capillary tube 36 (which, as discussed *supra*, is the “wick” that transports the liquid aerosol-forming material to the heater). The heater 42 then volatilizes the liquid aerosol-forming material as described *supra*, in connection with Limitation [1e]. *See* RIB at 64-65 (citing RX-0010, 4:61-67, Figs. 2A-2C). The “gasified flavor source is mixed with the main air introduced through the air intake port 18 and the squeeze hole 24a into a region around the outlet port 36a [36b] of the capillary tube 36 in accordance with the inhaling action of the user and, then, the mixture is transferred into the inhalation port 22.” RX-0010, 8:5-10, Abstract.

In device 100, annotated at right, the process is similar. “Cylindrical body 103” defines “an air passageway 104” between the air intake port 18 and the inhalation port. RX-0010, 9:51-57, 9:8-9. “The air passageway (air guiding path) 104 guides, along it, the air introduced by the inhalation action of the user from the air intake port 18.” RX-0010, 9:62-66.

Upon heating, “[t]he introduced air embraces or surrounds the gasified liquid



flavor source at the outlet portion of the liquid passageway 371, and is directed toward the inhalation port by the air passageway 104.” See RX-0010, Fig. 10, 9:62-66, 10:5-12; RIB at 64.

Accordingly, Respondents have raised a substantial question of invalidity with respect to this limitation that Reynolds has not shown lacks substantial merit.

h. Limitation [1g]: a controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.

The parties dispute this limitation. Reynolds does not dispute that Takeuchi discloses a controller or that the controller operates in response to a draw on the device. See RIB at 65; CIB at 66-67; CRB at 23 (“[T]he private parties agree that a control circuit drives the heaters in Takeuchi.”). For the disclosure of this element, Respondents point to Takeuchi’s disclosure that the heater and power source are “driven under the control of the control circuit 46,” and that the heaters are “controlled on the basis of a signal from a sensor for detecting the inhaling action of the user.” RX-0010, 7:48-49, 7:50-53, 7:45-56, 8:55-58, Figs. 1, 8; Tr. (Dean) at 516:11-16; RDX-0201.39.

Reynolds contends that, for the same reasons as discussed with respect to Limitation [1d], Takeuchi does not disclose an “electrical resistance heater.”⁴⁷

In Staff’s view, “the Staff is of the view that Takeuchi discloses [an] ‘electrical resistance heater’ and as such Takeuchi discloses the ‘controller’ limitation as well.” SIB at 26.

Reynolds does not rely on new arguments for Limitation [1g] (as opposed to arguments as to whether Takeuchi discloses the claimed “electrical resistance heater”). *See* CIB at 66-67; *see also* CRB at 21-24. For the reasons discussed above with respect to Limitation [1d], and based on the arguments and evidence introduced in the temporary relief proceedings, Respondents have raised a substantial question of invalidity with respect to this limitation that Reynolds has not shown lacks substantial merit.

* * *

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claim 1 of the ’202 patent based on alleged anticipation by Takeuchi, and Reynolds has not shown that the Takeuchi invalidity defense “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377. Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits. *Helifix*, 208 F.3d at 1352 (“In the face of Blok–Lok’s challenge to the validity of the ’801 patent, Helifix could not establish a likelihood of success on the merits.”).

⁴⁷ Reynolds also argues that “whether the heater can turn on does not disclose current flow through the heater, as there are types of heaters that do not operate based on current flowing through them,” which is an argument related to whether Takeuchi discloses an electrical resistance heater or a dielectric heater. CIB at 66-67 (citing Tr. (Alarcon) at 162:10-15 (“For example, the example I mentioned of dielectric heating, turning on the heater would not – would not have -- you would not have current flowing through that type of heater.”)). There does not appear to be a dispute that if the heater in Takeuchi is an electrical resistance heater, current will flow through it. *See, e.g.*, Tr. (Dean) at 513:14-16 (“When that switch is closed, current is able to flow, entering the resistive element and causing it to heat up.”).

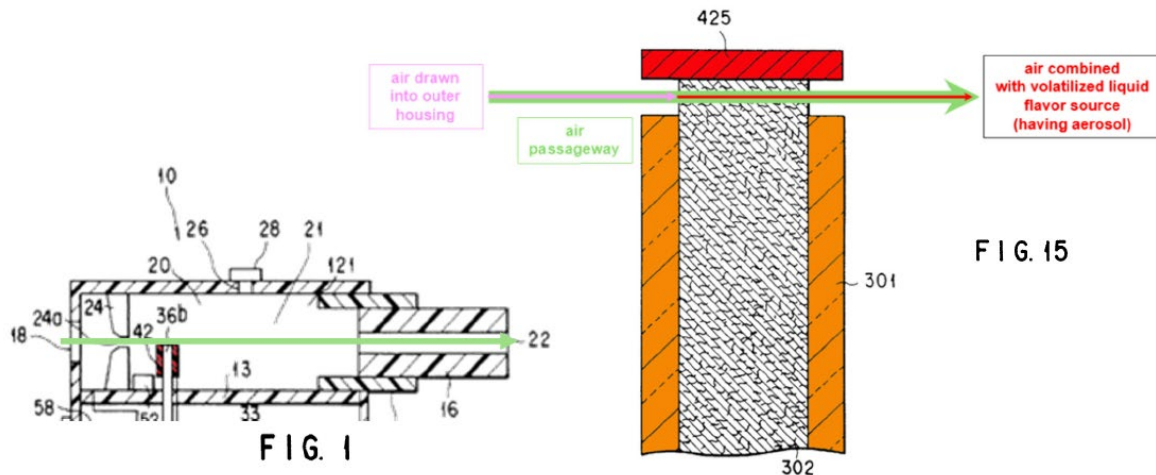
2. Claim 4

Claim 4 depends from claim 1, and requires in addition that “the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece.”

The parties dispute the disclosure of the additional limitation of claim 4 in Takeuchi. Respondents point *inter alia* to Figure 15, annotated by Dr. Dean below, in Takeuchi as disclosing the additional limitation of claim 4, which Respondents identify as an embodiment of the liquid passageway (*e.g.*, storage compartment) that “is applicable to both devices 10 and 100.” RIB at 68; RX-0010, 10:64-67 (describing Fig. 15 as “another embodiment of the liquid passageway for a liquid flavor source used in a flavor-generating device according to the invention”); RRB at 30. Respondents argue that, “[u]nder the interpretation of ‘storage compartment’ as including both the primary storage and liquid transport storage, both enclosure 301 and intercommunicating pore structure 302 are part of the ‘storage compartment.’” RIB at 69.⁴⁸ The liquid passageway of Figure 15 is filled with an “intercommunicating pore structure” which is in “fluid communication with the liquid flavor source contained in the liquid container.” RX-0010, 3:42-46, 10:53-62. Heater 425 is provided “on the protruded end of the intercommunicating pore structure 302.” RX-0010, 10:61-63. Relying on Dr. Dean, Respondents

⁴⁸ Respondents argued for purposes of infringement and the technical prong of the domestic industry requirement that the wick and the bulk fibrous material are separate components that would not be considered together as the claimed storage compartment. *See supra* Part V.B.6, Part VI.B.6. As discussed *supra*, the undersigned rejected that position as contradicted by the testimony of both parties’ experts and unsupported by persuasive evidence, including because Dr. Dean testified with respect to Takeuchi that both the “intercommunicating pore structure” and the liquid container “enclosure” would be considered to be the claimed “storage compartment.” *See* Tr. (Dean) at 527:2-6; RDX-0201.037 (testifying that the plain and ordinary meaning of “storage compartment” is “something that is capable of holding consumable material that can be used by the device”); *id.* at 514:25-515:12 and RDX-0201.037 (opining that the “storage compartment” in Takeuchi includes the “narrow space coming off” the “larger receptacle”); Tr. (Wensley) at 252:8-13 (“[Q]: And why did you include both the bulk fibrous material and the wick as being part of the claimed storage compartment? [A]: Because those two components, combined, hold the liquid. They store the liquid, so that is the storage compartment.”).

contend that the user's draw "creates a pressure gradient within device 10 and device 100 causing air to flow from air intake port 18, through intercommunicating pore structure 302, through the mouthpiece, and ultimately into the user's mouth." RIB at 69 (citing Tr. (Dean) at 519:3-520:1).



RDX-0201.41 (annotating RX-0010, Figs. 1, 15). Respondents contend that air flows through the intercommunicating pore structure and mixes with volatilized liquid. RIB at 70-71 (citing Tr. (Dean) at 519:3-520:1). Respondents also contend that Figures 4 and 5 of Takeuchi also teach the additional limitation of claim 4, as Dr. Dean testified that aerosol is produced at the end of capillary tube 36 and air intake port 61 and 362d plates 3. RIB at 71 ("That is, the aerosol passes at least partially through the capillary tube 36 and mixes with the air drawn through air intake port 18, eventually being transported through inhalation port 22 to the user's mouth."); Tr. (Dean) at 521:2-522:11; RDX-0201.41-42.

Reynolds, in opposition, argues that Figure 15 is a separate embodiment that cannot be "mixed" with the embodiments of devices 10 or 100 to establish anticipation. CIB at 67 (citing *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008)); CRB at 24-25.

Relying on Mr. Alarcon, Reynolds also argues that the aerosol is not produced in the identified storage compartment, but outside of it, and thus does not pass through the storage compartment. CIB at 68 (citing Tr. (Alarcon) at 163:1-7, 168:8-23); CRB at 25-26.

In response, Respondents argue that it is not “mixing” embodiments because Takeuchi “on its face explains that Figure 15 merely provides ‘another embodiment of the liquid passageway’ which may be ‘used in a flavor-generating device according to the invention.’” RRB at 30 (citing RX-0010, 10:64-67). Respondents also contend that Mr. Alarcon did not support his contention that the gasified liquid flavor source is only combined with air to form an aerosol after exiting the identified “storage compartment.” RRB at 32. Respondents contend that Dr. Dean explained the fluid dynamics of the pressure gradient that creates airflow through the liquid passageway, undermining Mr. Alarcon’s testimony. RRB at 32 (citing Tr. (Dean) at 519:7-17, 516:20-22).

In Staff’s view, Takeuchi discloses the additional limitation of claim 4. SIB at 29. Staff points to Fig. 2B, which Staff contends depicts “that an aerosol begins to form at the lower portion of Takeuchi’s heater plates (e.g., 42 in the Figure 1 above), and then passes through the remainder of the outlet portion of the liquid storage container before moving through the device to the mouthpiece.” SIB at 28 (citing RX-0010, Fig. 2B, 7:5708:4). Staff also credits Dr. Dean’s testimony as to Figs. 1 and 4. SIB at 29 (citing Tr. (Dean) at 522:8-11).

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents’ assertion that Takeuchi discloses that “the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece” lacks substantial merit.

As an initial matter, the undersigned does not agree that Figure 15 and device 10 or 100 violate the axiom that different embodiments may not be combined in an anticipation analysis. *See* CRB at 24-25 (citing *Net MoneyIN*, 545 F.3d at 1369). As the Federal Circuit has repeatedly recognized, where a reference explicitly contemplates the combination of the disclosed functionalities, a “combination” may still anticipate. *See, e.g., Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir. 2016) (“This case is distinguishable from *Net MoneyIN* because, in contrast to the reference in that case, Paul explicitly contemplates the combination of the disclosed functionalities.”); *Victaulic Co. v. Iancu*, 753 F. App’x 895, 900 (Fed. Cir. 2018) (“This case is distinguishable from *Net MoneyIN* because, as mentioned above, Lewis expressly contemplates the use of multiple segments, nuts and bolts, and axial insertion as required by claim 1.”). Here, Takeuchi explicitly contemplates using the liquid passageway of Figure 15 with any of the disclosed devices. *See* RX-0010, 10:64-67 (describing Fig. 15 as “another embodiment of the liquid passageway for a liquid flavor source used in a flavor-generating device according to the invention”); *see also id.* at 11:4-9 (“these features can be combined appropriately depending on the object of the flavor-generating device”).

As to where the aerosol actually forms—i.e., outside the identified “storage compartments,” as Mr. Alarcon contends, or within, as Dr. Dean contends—the undersigned finds that Reynolds has not shown that Respondents’ position lacks substantial merit. The parties have presented credible but conflicting expert testimony on the technical details of Takeuchi’s disclosure, including where precisely an aerosol is formed, and where air first mixes with the volatilized liquid, and such a conflict is “best decided on the basis of a more developed record,” and creates a “substantial question” as to invalidity. *See, e.g., Baxalta*, 2018 WL 3742610, at *8; *Amazon.com*, 239 F.3d at 1359 (“a conflict in the testimony as to whether the reference would

have taught one of ordinary skill in the art” is sufficient to raise a “substantial question” as to invalidity).

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claim 4 of the ’202 patent based on alleged anticipation by Takeuchi, and Reynolds has not shown that the Takeuchi invalidity defense “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377. Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits as to claim 4. *Helifix*, 208 F.3d at 1352.

3. Claim 5

Claim 5 depends from claim 1, and requires in addition that “the storage compartment is configured as a cartridge.”

The parties dispute the disclosure of the additional limitation of claim 5 in Takeuchi. Respondents point to the description of device 100 in Takeuchi, which includes “a small exchangeable liquid container 32 containing the liquid flavor source.” RIB at 74 (quoting RX-0010, 9:23-24. As used in the ’202 patent, Respondents argue that a “cartridge” is “a removable liquid storage container,” RIB at 74 (citing ’202 patent, 5:57-61, 8:17-23), and the “exchangeable liquid container 32” is “a cartridge integrated into the ‘storage compartment.’” RIB at 74.

Reynolds argues that because Respondents identified both the liquid container and the capillary structure of Takeuchi as the “storage compartment,” Respondents had to show that both the liquid container and the capillary tube 36 are “removable” (and thus, “configured as a cartridge”). CIB at 68-69 (citing Tr. (Alarcon) at 164:13-16); CRB at 26-27.

Respondents, in response, contend that “Complainants have provided no explanation why a multicomponent ‘storage compartment’—such as Takeuchi’s liquid container 32 and the

substantially parallel plates forming the liquid passageway 371—would not satisfy claim 5 when one of those components (e.g., the liquid container) is ‘configured as a cartridge.’” RRB at 33.

In Staff’s view, “Takeuchi discloses the additional limitation of claim 5.” SIB at 30.

Upon review of the submissions, arguments, and evidence of record in the temporary enforcement phase of this investigation, the undersigned finds that, based on the current arguments and contentions, Reynolds has shown that Respondents’ assertion that Takeuchi discloses that “the storage compartment is configured as a cartridge” lacks substantial merit and thus Respondents have not raised a substantial question of invalidity as to this limitation.

The parties agree that “a cartridge” must be “removable” or “exchangeable.” *See* CIB at 68 (“Dr. Dean did not even suggest that the entirety of what he says is a storage compartment is removable, and thus a ‘cartridge’ under his interpretation of the term.”); RIB at 74 (“Because the ‘liquid container 32’ is ‘exchangeable,’ it is a removable liquid storage container and thus a ‘cartridge’”). This is consistent with the ’202 specification, which describes a “cartridge” as removable. *See* ’202 patent, 5:57-61 (“During use, a cartridge containing some form of tobacco is positioned within the smoking article, and after use, the used cartridge is removed from the outer housing of the device.”); Tr. (Dean) at 506:12-18, 522:12-21, 537:13-15 (“A cartridge is -- the definition of a cartridge is something that can, in this context, contain aerosol-forming material and that it can be exchanged.”).

The parties dispute whether, to be “configured as a cartridge,” all pieces of a multi-part “storage compartment” need to be removable. Based on the plain language of the claims, it is the “storage compartment” itself—not components or pieces thereof—that must be “configured as a cartridge”—not “substantially” or “partially” “configured as a cartridge” or “integrated into” the storage compartment. ’202 patent, cl. 5. Respondents have not presented persuasive or sufficient

evidence in support of their theory that a single removable component “integrated into” the storage compartment renders the storage compartment, considered as a whole, to be “a cartridge.”⁴⁹ Nor have Respondents presented evidence that the capillary structure (which Respondents contend is part of the “storage compartment”) is removable.

Accordingly, for the reasons discussed above, Reynolds has shown that Respondents’ current contentions and evidence do not raise a substantial question of invalidity as to the added limitation of claim 5. *See Titan Tire*, 566 F.3d at 1377; *Helifix*, 208 F.3d at 1352.⁵⁰

4. Claim 9

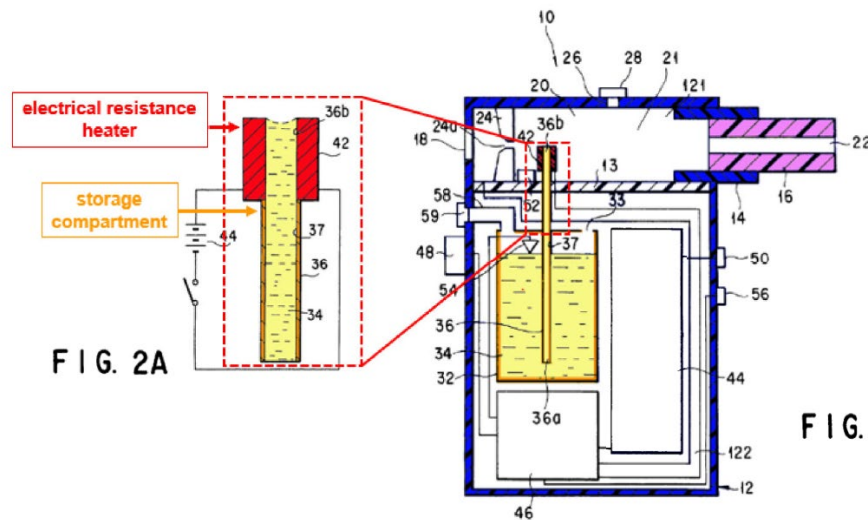
Claim 9 depends from claim 1, and requires in addition that “the electrical resistance heater is arranged in contact with the storage compartment.”

Other than arguments regarding the disclosure in Takeuchi of an “electrical resistance heater,” Reynolds does not dispute the disclosure of this additional limitation in Takeuchi. *See* CIB at 69; CRB at 24-27. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses the additional limitation of claim 9. Specifically, in device 10, heater 42 “consists of a tubular body mounted to the capillary tube 36.” RX-0010, 6:7-9. Similarly for device 100, using the storage compartment and heater design of Figure 11, “plate heaters 423 and 424 [are] ... provided in the opposing regions of the plates 361 and 362 defining the liquid passageway there between.” *Id.* at 10:22-27. As

⁴⁹ The undersigned notes that the construction of “wherein the storage compartment is configured as a cartridge” as requiring the entirety of the identified “storage compartment” to be removable is tentative and made based on the arguments and evidence presented in connection with the temporary relief phase of this investigation. Additional or different arguments or evidence may alter the construction. *See Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”).

⁵⁰ Claim 5 is at issue only with respect to technical domestic industry; Reynolds does not contend that the Accused Products practice claim 5. *See* CIB at 30, 119.

shown in the annotated figure below, and as explained by Dr. Dean, below, the heater “is arranged in contact with” capillary tube 36 (device 10) or with plates 361 and 362 (device 100), which, as discussed *supra*, are part of the “storage compartment.” Tr. (Dean) at 523:9-21 (“[A]: In Figure 2A, the enlargement to the left, what we see is the orange walls of the storage compartment are juxtaposed with the lower portion of the electrical resistance heater surface. [Q]: And is that juxtaposition in contact? [A]: Definitely, yes.”); RIB at 74-75.



RDX-0201C.45 (annotating RX-0010, Figs. 1, 2A).

For the reasons discussed above with respect to Limitation [1d], and based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds has not shown that Respondents’ contention that Takeuchi discloses the claimed “electrical resistance heater” lacks substantial merit. The undisputed evidence currently of record further demonstrates that Respondents have raised a substantial question of invalidity with respect to this limitation as a whole and Reynolds has not shown that these arguments lack substantial merit.

5. Claim 12

Claim 12 depends from claim 1, and requires in addition that “the electrical resistance heater is configured to allow airflow therethrough.”

Relying on Dr. Dean, Respondents contend that “airflow” is “movement of a gas within a specific area or system.” RIB at 76 (citing Tr. (Dean) at 524:21-25). Respondents contend that Figs. 2B and Fig. 11, as annotated and explained by Dr. Dean, show that gas and liquid droplets are formed when the heaters are turned on, which flows past the internal walls of the heater. RIB at 76 (citing Tr. (Dean) at 523:22-524:8, 524:21-25). This flow, Respondents contend, discloses the claimed “airflow.”

Reynolds disputes the disclosure of the additional limitations of claim 12 because Reynolds contends (1) Takeuchi does not disclose the claimed “electrical resistance heater”;⁵¹ (2) airflow and “aerosol” only occurs outside the storage compartment and heater components; and (3) the “heater frame” 92 in Fig. 7 is not the same as a heater.⁵² CIB at 69-70. Reynolds contends that “a POSA would understand that airflow refers specifically to the movement of air, not the flow of aerosol or volatilized liquid.” CRB at 26.

In Staff’s view, “Takeuchi discloses the additional limitation of claim 12.” SIB at 31. Staff argues that “there is no reason why the term ‘air flow’ definitionally would not include the movement of evaporated liquid through and out of the top of Takeuchi’s heater as Dr. Dean testified.” SIB at 31.

Upon review of the submissions and current evidence of record, the undersigned finds that, based on the current record, Reynolds has shown that Respondents’ Takeuchi-based argument for this claim lacks substantial merit. Takeuchi describes a system in which volatilized liquid combines with air. Claim 12 requires airflow “through” the electrical resistance heater. *See*

⁵¹ As discussed above with regard to claim 1, the evidence shows a substantial question of invalidity with respect to this issue.

⁵² Dr. Dean did not rely on Figure 7 of Takeuchi, *see* RDX-0201.46. Accordingly, this argument appears to be irrelevant to the evidence presented at the hearing.

'202 patent, cl. 12. Respondents' description of Fig. 11 of the Takeuchi device acknowledges that the gas flowing "through" the heater is gas that has not yet mixed with air. *See* RIB at 76 (stating that in the Figure 11 embodiment, the volatilized liquid forms a gas that "will flow past the internal walls of the heater, out of the open top of the heater, and into the surrounding upper chamber *where the gas and droplets will mix with air* that has been drawn into the device") (emphasis added); *see also* CIB at 70 ("when the heater is activated, the e-liquid is instantly vaporized and pushed into the upper chamber, where it then mixes with the airflow"). Dr. Dean testified that the Figure 2B embodiment works in a similar manner to that of Figure 11. *See* Tr. (Dean) at 524:11-13.⁵³ Respondents' position that there is a "heater" configured "to allow airflow therethrough" ('202 patent, cl. 12) thus relies on the proposition that the flow of volatilized liquid through the heater constitutes "airflow" even before it has mixed with "air." *See* RIB at 76 (contending that "airflow" can "generally refer to movement of a gas"). This position appears inconsistent with the plain meaning of "*air*flow."⁵⁴ And while Respondents rely on Dr. Dean's testimony to suggest that airflow can include any flow of gas (regardless of whether it includes "air"), that testimony was conclusory and, at least on this record, unpersuasive. *See* Tr. (Dean) at 524:21-25 ("[Q]: Are you aware of any reason why the term 'air flow' definitionally would not include the movement of evaporated liquid through and out of the top of Takeuchi's heater? [A]: No.").⁵⁵

⁵³ As discussed above regarding claim 4, there is a substantial question regarding whether an aerosol including air passes "through the storage compartment" based on the Figure 15 liquid passageway. However, Respondents do not rely on Figure 15 for purposes of claim 12.

⁵⁴ A requirement that "airflow" include air is also consistent with Respondents' discussion of claim 12 in connection with the Kim reference, where Respondents argue that there is "airflow" based on the flow of "air" (not simply a gas). *See* RRB at 41 ("air flowing through the hole . . . flows through the coil itself").

⁵⁵ To the extent the parties present additional evidence or arguments at a later point in the investigation, those will be considered and may affect the analysis. *See Natera, Inc. v. NeoGenomics Lab'ys, Inc.*, 106

Accordingly, for the reasons discussed above, Reynolds has shown that Respondents' current contentions and evidence do not raise a substantial question of invalidity at this time as to the added limitation of claim 12. *See Titan Tire*, 566 F.3d at 1377; *Helifix*, 208 F.3d at 1352.

6. Claim 14

Claim 14 depends from claim 1, and requires in addition that “the controller is configured to regulate the current flow through the electrical resistance heater during the draw on the electrically-powered, aerosol-generating smoking article.”

Other than arguments regarding the disclosure in Takeuchi of an “electrical resistance heater,” Reynolds does not dispute the disclosure of this additional limitation in Takeuchi. *See* CIB at 70-71; CRB at 24-27. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Takeuchi discloses the additional limitation of claim 14. Respondents contend—without challenge from Reynolds or Staff—that activation and deactivation of the current is sufficient to satisfy the requirement that the controller “regulate” the current flow. RIB at 78-79. For the same reasons as discussed with respect to Limitation [1g], Respondents contend that the control circuit 46 satisfies the additional limitation of claim 14. RIB at 79. Additionally, even if something more were required, Respondents contend that Takeuchi discloses that the control circuit 46 permits the heater to “be controlled on the basis of a signal from a sensor for detecting the inhaling action of the user, with the result that the flavor can be supplied to the user with high stability” and that control circuit 46 performs “processing and control . . . in accordance with, for example, a known analog control, a

F.4th 1369, 1375 (Fed. Cir. 2024) (the trial court “has no obligation to definitively construe claims at the preliminary injunction stage”).

two-position control or a combination thereof.” RIB at 79 (quoting RX-0010, 2:29-34, 6:59-62); Tr. (Dean) at 525:3-14.

For the reasons discussed above with respect to Limitation [1d], and based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds has not shown that Respondents’ assertion that Takeuchi discloses the claimed “electrical resistance heater” lacks substantial merit. The undisputed evidence currently of record further demonstrates that Respondents have raised a substantial question of invalidity with respect to this limitation as a whole and Reynolds has not shown that these arguments lack substantial merit.

* * *

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claims 1, 4, 9, and 14 of the ’202 patent based on alleged anticipation by Takeuchi, and Reynolds has not shown that such contentions “lack substantial merit.” *Titan Tire*, 566 F.3d at 1377. As to claims 5 and 12, Reynolds has shown that Respondents’ contentions that Takeuchi anticipates lack “substantial merit” based on the submissions, arguments, and evidence of record in the temporary enforcement phase of the investigation.

Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits as to claims 1, 4, 9, and 14. *Helifix*, 208 F.3d at 1352 (“In the face of Blok-Lok’s challenge to the validity of the ’801 patent, Helifix could not establish a likelihood of success on the merits.”).

B. Obviousness over Kim & Pienemann

Kim, U.S. Patent App. Pub. No. 2006.0016453 (RX-0013), is titled “Cigarette Substitute Device,” and was published on January 26, 2006. RX-0013, cover. There is no dispute that Kim constitutes prior art to the ’202 patent. *See* SIB at 33; RIB at 80; CIB at 71. Pienemann, Int’l Pat.

Pub. WO 00/28843 (RX-0014), is titled “System for Supplying an Inhalable Aerosol,” and was published on May 25, 2000. RX-0014, cover. There is no dispute that Kim constitutes prior art to the ’202 patent.⁵⁶ See SIB at 33; RIB at 82; CIB at 71.

Respondents contend that claims 1, 4, 5, 9, 12, and 14 are invalid as obvious over the combination of Kim and Pienemann. Specifically, Respondents contend that one of skill in the art would modify Kim in view of Pienemann to “(1) regulate Kim’s electrical resistance heater (*i.e.*, the coil) to prevent overheating or inadvertent activation; and (2) add accessibility to the housing to allow insertion and removal of Kim’s replaceable porous chip.” RIB at 84. The proposed combination, then, modifies Kim to “(1) use Pienemann’s control system to regulate Kim’s heater, and (2) use Pienemann’s pivoting housing flap to provide access for the insertion and removal of Kim’s porous chip.” RIB at 84 (citing Tr. (Dean) at 497:20-498:9; 507:2-15; 529:4-530:1).

Pursuant to 35 U.S.C. § 102, a patent claim is invalid as obvious if: “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.” 35 U.S.C. § 103(a). “Obviousness is a question of law based on underlying questions of fact.” *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1379 (Fed. Cir. 2008). The underlying factual determinations include: “(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-

⁵⁶ As discussed above, *supra*, the prior consideration of Kim and Pienemann during examination does not alter the burden by which Respondents must show invalidity.

obviousness.” *Id.* at 1380 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are often referred to as the “*Graham* factors.”

A critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit’s rigid application of a “teaching-suggestion-motivation” test—while the Court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does,” it described a more flexible analysis:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id. at 418.

1. Claim 1

Respondents contend that Kim discloses each limitation of claim 1 with the exception of Limitation 1[g], a “controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.” Respondents contend that one of ordinary skill in the art would modify Kim to “(1) use Pienemann’s control system to regulate Kim’s heater” in order to obtain the invention of claim 1 of the ’202 patent. Reynolds disputes the disclosure of Limitations [1d] and [1g] in the

combination of Kim and Pienemann, and further contends that one of ordinary skill would not have been motivated to modify Kim as claimed and that Kim would be “non-functional.”

The parties do not dispute that Kim discloses Limitations [1pre]⁵⁷, [1a], [1b], and [1f]. CIB at 59-71; CRB at 19-27; SIB at 17-31; SRB at 5-9. For the reasons discussed above and below, Reynolds has not shown that the combination of Kim and Pienemann alleged to invalidate claim 1 “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377.

a. Limitation [1pre]: An electrically-powered, aerosol-generating smoking article comprising:

Neither Reynolds nor Staff separately dispute that that this limitation is disclosed in the combination of Kim and Pienemann. *See* CIB 71-83; CRB at 27-33; SIB at 32-41.⁵⁸ In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that the combination of Kim and Pienemann discloses an electrically-powered, aerosol-generating smoking article. *See* RX-0013, [0001] (“a device adapted to deliver to a user nicotine and volatile palatability enhancing agent[s] mixture having a cigarette-like taste and aroma”); *id.* at Abstract (“in response to an electric power supplies and suction by a user, [the device] evaporates nicotine mixture and delivers them to the user”); Tr. (Dean) at 489:18-20; RDX-0201.12 (annotating RX-0013, Fig. 1); *see also* RX-0014, 5:21-23 (“The aerosol-forming material 2 may consist of, for example, cut leaf tobacco, cut tobacco stems, reconstituted tobacco, or a carrier material treated with aromatic substances.”).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

⁵⁷ Reynolds’ arguments as to [1pre] repeat the motivation to combine, reasonable expectation of success, and operability arguments addressed with respect to other disputed limitations. CIB at 77. Those arguments are addressed in detail below.

⁵⁸ Staff’s response brief does not address Kim and Pienemann. *See generally* SRB.

b. Limitation [1a]: an outer housing having two ends;

Neither Reynolds nor Staff separately dispute that that this limitation is disclosed in Kim. *See* CIB 71-83; CRB at 27-33; SIB at 32-41. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses an “outer housing having two ends.” *See* RX-0013, Fig. 1, [0012] (“The cigarette substitute device (1) of the present invention is comprised of a housing (2) in the form of an elongated tube, a mouth tip (3), an LED (Light Emitting Diode) (4), a porous chip (5), three 3 Volt mini-battiest [sic] (6) with 7 mm diameter, two electric wires (7-U) and (7-L), an electric shorting connector (8), an on/off electric connector (9), and a sliding knob (10). The housing (2) is preferably manufactured of a stiff plastic sheet with a diameter, length and weight which approximate the size of a conventional combustible cigarette.”); Tr. (Dean) at 489:21-490:3; RDX-0201.12 (annotating RX-0013, Fig. 1).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

c. Limitation [1b]: a mouthpiece defined at one of the two ends

Neither Reynolds nor Staff separately dispute that that this limitation is disclosed in Kim. *See* CIB 71-83; CRB at 27-33; SIB at 32-41. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses an “a mouthpiece defined at one of the two ends.” *See* RX-0013, Figs. 1, 6, [0012] (“The cigarette substitute device (1) of the present invention is comprised of a housing (2) ***in the form of an elongated tube, a mouth tip*** (3), an LED (Light Emitting Diode) (4), a porous chip (5), three 3 Volt mini-battiest [sic] (6) with 7 mm diameter, two electric wires (7-U) and (7-L), an electric

shorting connector (8), an on/off electric connector (9), and a sliding knob (10).”) (emphasis added); Tr. (Dean) at 490:4-11; RDX-0201.12 (annotating RX-0013, Fig. 1).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

d. Limitation [1c]: an electrical power source arranged within the outer housing;

Neither Reynolds nor Staff separately dispute that that this limitation is disclosed in Kim. *See* CIB 71-83; CRB at 27-33; SIB at 32-41. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses an “an electrical power source arranged within the outer housing.” *See* RX-0013, Fig. 1, [0012] (“The cigarette substitute device (1) of the present invention is comprised of a housing (2) in the form of an elongated tube, a mouth tip (3), an LED (Light Emitting Diode) (4), a porous chip (5), *three 3 Volt mini-battiest [sic]* (6) with 7 mm diameter, two electric wires (7-U) and (7-L), an electric shorting connector (8), an on/off electric connector (9), and a sliding knob (10).”) (emphasis added); Tr. (Dean) at 490:12-19; RDX-0201.12 (annotating RX-0013, Fig. 1).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

e. Limitation [1d]: an electrical resistance heater positioned within the outer housing, the electrical resistance heater being configured for electrical connection with the electrical power source

The parties dispute that this limitation is disclosed in Kim. Respondents contend that Kim discloses two possibilities for a “heater”: (1) an “electric shorting connector”; and (2) “an electric heating coil.” RIB at 93 (citing RX-0013, [0015] (“FIG. 5 is an enlarged cross-sectional view of the portion ‘C’ in FIG. 1, showing the electric shortening connector (8) embedded in the porous

chip (5). An electric heating coil (8-3) may be installed instead of the shorting connector.”), [0018]). Respondents, relying on Dr. Dean, submit that the “electric heating coil” is an electrical resistance heater. RIB at 92-93 (citing Tr. (Dean) at 490:20-492:22).

Reynolds argues that the shorting connector in Kim is not a resistance heater, and that one of ordinary skill would not substitute the electric heating coil. CIB at 77-78. Relying on Mr. Alarcon, Reynolds contends

The extremely small space requirement for the coil would pose practical challenges in the device’s design, including the fact that the Kim batteries could not provide sufficient current to heat such a coil. Additionally, the tiny structure could interfere with the movement of the chip and, being suspended on a wire, could easily pull apart, presenting further technical difficulties.

CIB at 78 (citing Tr. (Alarcon) at 175:8-18). Mr. Alarcon testified that the size of any coil in Kim’s device would be roughly the size of a grain of rice, which would require low resistance and a very high current draw that the disclosed batteries in Kim could not support. CIB at 75-76 (citing Tr. (Alarcon) at 173:18-174:9). Reynolds argues that Kim does not disclose “any explanation of how the coil would be connected or function in the device.” CRB at 30. Because “Respondents fail to address the technical and practical difficulties of using a coil in Kim’s device,” Reynolds contends that the arguments should be rejected. CRB at 31.

Respondents, in response, argue that the flaws of Kim’s disclosed coil heater do not undermine the obviousness analysis, as “an inoperative device . . . is prior art for all that it teaches.” RRB at 38 (quoting *Symbol Tech., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991)). Moreover, Respondents submit that Dr. Dean addressed the size limitation of the proposed coil, noting that incandescent coils of a very small size are known, for example, in the incandescent coils in Christmas tree lightbulbs. RRB at 35 (citing Tr. (Dean) 492:2-10).

Staff, relying on Dr. Dean, agrees that “Kim discloses all the limitations of Claim 1 of the ’202 Patent.” SIB at 35 (citing RDX-0201.12).

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents’ assertion that Kim discloses the claimed “electrical resistance heater” lacks substantial merit.

Reynolds apparently does not dispute that the disclosed “electric heating coil” described in Kim is an “electrical resistance heater.” *See* CRB at 29-31; Tr. (Dean) at 491:9-16 (“[Q]: Is Kim’s coil heater an electrical resistance heater? [A]: Yes, it is. [Q]: How do you know that? [A]: Because it is configured to an electrical circuit, which when closed, causes current to flow through the coil, which causes it to heat due to a resistive phenomenon. And that’s an electrical resistance heater.”).

As an initial matter, that the expressly disclosed “electric heating coil,” which Kim teaches “may be installed instead of the shorting connector,” RX-0013, [0015], is alleged to be inoperable does not necessarily end the obviousness inquiry. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (“Even if a reference discloses an inoperative device, it is prior art for all that it teaches.”); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) (“Under § 103, however, a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein”); *I/P Engine, Inc. v. AOL Inc.*, 576 F. App’x 982, 989 (Fed. Cir. 2014) (“[E]ven assuming arguendo that the Culliss filtering system was not fully functional, this does not mean that it does not qualify as prior art for purposes of the obviousness analysis.”). Moreover, to the extent Reynolds is asserting a non-enablement argument, it is Reynolds who bears the burden of showing that Kim is not enabled. *Cameron Int’l Corp. v. Nitro Fluids, L.L.C.*, No. 2021-1183, 2022 WL 636099, at *6 (Fed. Cir.

Mar. 4, 2022) (“prior art published patent applications are presumed enabling”). A finding of non-enablement requires a showing that one of ordinary skill in the art could not make and use the disclosed invention. *Id.* Despite the allegation that the batteries identified in the disclosed embodiment in Kim were inoperative, Mr. Alarcon was able to calculate with specificity the voltage—and thus the batteries—that he contended would be required to “make and use” the electrical shorting connector. Tr. (Alarcon) at 173:10-13 (“And what I did is I looked at that, and understanding the dielectric strength of the media, calculated that it would require at least 30 volts to operate this.”). And although Mr. Alarcon testified that the “electric heating coil” may be understood as inoperable or impractical, Tr. (Alarcon) at 173:20-174:6, 175:8-18, Dr. Dean identified coils on a similar scale, and testified that the “electric heating coil” embodiment disclosed in Kim would be operable. Tr. (Dean) at 491:20-492:14. Under the circumstances here, the parties’ conflicting expert testimony is “best decided on the basis of a more developed record.” *See, e.g., Baxalta*, 2018 WL 3742610, at *8; *see also Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010 (Fed. Cir. 2009) (conflicting expert testimony, *inter alia*, on obviousness “supports the district court’s overriding decision that the defendants had made out a sufficient case of obviousness to defer the matter for trial on the merits, as opposed to granting the preliminary relief sought by the plaintiffs”).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

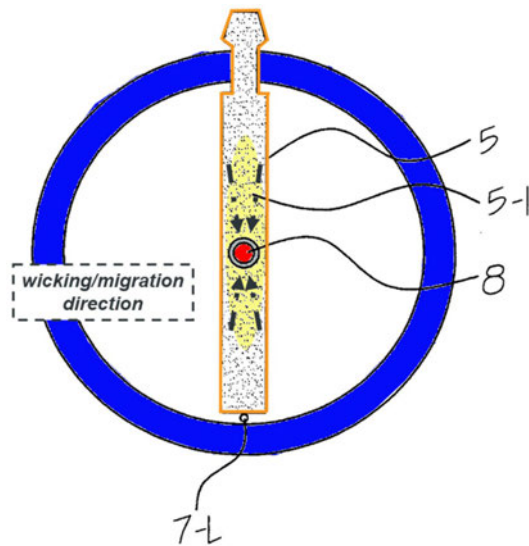
- f. **Limitation [1e]: a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material;**

Neither Reynolds nor Staff dispute that that this limitation is disclosed in Kim. *See* CIB 71-83⁵⁹; CRB at 27-33; SIB at 32-41. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses “a storage compartment defined within the outer housing, the storage compartment being configured for storage of a liquid aerosol-forming material and being arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater to volatilize the liquid aerosol-forming material.” *See* Tr. (Dean) at 494:20-495:10; RDX-0201.14 (annotating RX-0013, Fig. 4).⁶⁰

⁵⁹ Reynolds does state that “the combination of Kim and Pienemann does not disclose at least elements [1P], [1D], [1E], and [1G],” CIB at 77, but no additional explanation, evidence, or argument is presented specific to Limitation [1e]. *See generally* CRB; CIB.

⁶⁰ As discussed above, *supra*, the undersigned tentatively rejects Respondents’ construction of “storage compartment” as requiring that the storage compartment “permit replenishment.” The disclosure of Kim is evaluated under the plain and ordinary meaning of “storage compartment,” which is not limited to “containers” that are “configured to permit replenishment of the liquid in the smoking article.” *Supra* Part III.E.2.

Specifically, Kim teaches a “porous chip 5” that is composed of “porous polymeric material” that has “absorbed therein the volatile liquid composition of mixture of nicotine and



volatile palatability enhancing agents.” RX-0013, [0015]; Tr. (Dean) at 493:13-494:4. Porous chip 5 is within housing 2 of Kim. RX-0013, Fig. 1. As Dr. Dean explained, with reference to the annotated version of Figure 4, left, the liquid aerosol-forming material is “wicked into contact” with the heater, as replacement liquid “migrates” through the porous chip as the liquid closest to the heater is gasified. Tr.

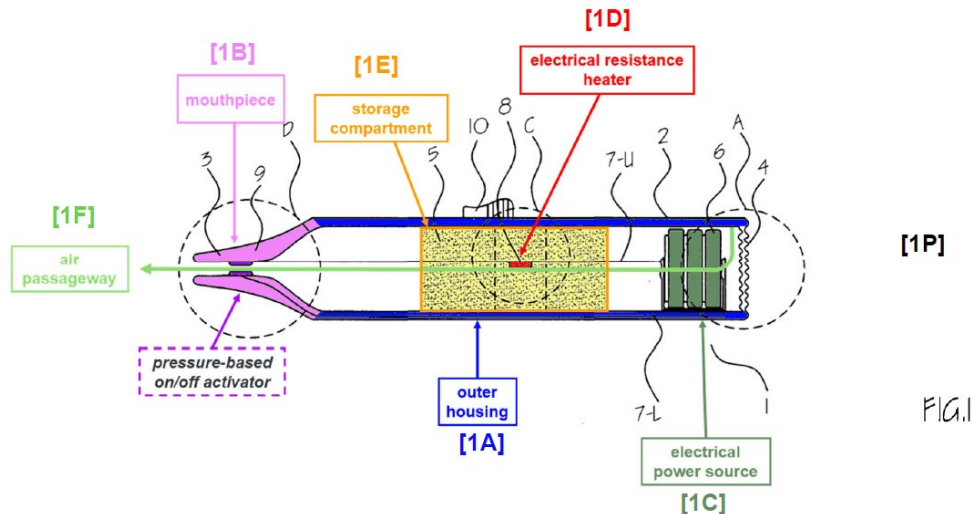
(Dean) 494:20-495:10; RDX-0201.14 (annotating RX-0013, Fig. 4).

Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

- g. Limitation [1f]: an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article through the mouthpiece; and**

Neither Reynolds nor Staff dispute that that this limitation is disclosed in Kim. *See* CIB 71-83; CRB at 27-33; SIB at 32-41. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses “an air passageway through at least a portion of the outer housing, the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered,

aerosol-generating smoking article through the mouthpiece.” See Tr. (Dean) at 495:14-496:4; RDX-0201.12 (below, annotating RX-0013, Fig. 1).



Specifically, Kim teaches a “porous hemi-circle (11) for air inlet” that is disposed “just behind the LED 4.” RX-0013, [0013]. “As the smoker puffs, the evaporated mixture is delivered to the smoker[’]s mouth by *the air stream which comes from the outside through the porous hemi circle (11).*” RX-0013, [0019] (emphasis added); Tr. (Dean) at 495:14-496:4.

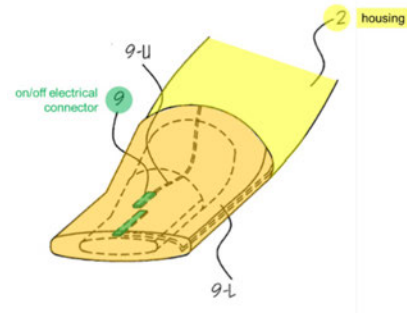
Accordingly, Respondents have raised a substantial question of patentability with respect to this claim limitation that Reynolds has not shown lacks substantial merit.

- h. Limitation [1g]: a controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.**

The parties dispute the disclosure of this limitation in the combination of Kim and Pienemann.

Respondents rely on a modification of Kim, in view of Pienemann, as disclosing this limitation. Respondents contend that in Kim, the “cigarette substitute operates when a user’s lips

are placed on a mouthpiece,” rather than being “puff” or “draw” activated. RIB at 97 (citing RX-0013, [0016], [0018]-[0019], Fig. 6). As shown at right, the pressure of a user’s lips presses metal plates 9-U and 9-L together, activating the heating element. RX-0013, [0018], Fig. 6



(annotated at right). Respondents contend that one of skill in the art would recognize that inadvertent activation by something other than the user’s lips was a “readily apparent shortcoming” of Kim that one of skill would have reason to improve. RIB at 84-85 (citing Tr. (Dean) at 497:5-498:9). Respondents contend that Pienemann’s control system provides such an improvement, as Pienemann teaches a “cascade-activated” controller whereby (1) an on/off switch on the external housing activates the device; and then (2) a puff detector delivers current to the electrical heater only when the user is inhaling on the device. RIB at 85 (citing Tr. (Dean) at 496:24-497:14, 497:20-498:9; RX-0014,⁶¹ 9:9-11, 9:19-24, 10:28-30, 11:10-16, 17:6-11); *see also* RIB at 97. Relying on Dr. Dean, Respondents submit that the “cascade activation” in Pienemann would avoid accidental heater activation. RIB at 85 (citing Tr. (Dean) at 497:5-11). In addition, Pienemann’s control system would “help manage the generated heat and avoid overheating Kim’s porous chip.” RIB at 85-86 (citing Tr. (Dean) at 497:15-19). Respondents argue that one of ordinary skill would have been able to modify Kim to include Pienemann’s control system by replacing Kim’s pressure switch with Pienemann’s controller, switching device, and puff detector. RIB at 86 (citing Tr. (Dean) at 529:8-16, 530:11-22, 499:4-12).

⁶¹ Respondents’ opening brief inconsistently cites to RX-0013 and RX-0014 as Pienemann, but Pienemann is RX-0014. *See, e.g.*, RIB at 85.

In opposition, Reynolds argues that Respondents have not sufficiently shown that one of ordinary skill would have reason to modify Kim to incorporate Pienemann’s control system or a reasonable expectation of success in doing so. Reynolds argues that the design goals of Kim and Pienemann differ, with Kim directed to providing a small, simple, cigarette-mimicking device, and Pienemann directed to a cigar-shaped, more sophisticated device with a separate controller placed in a user’s pocket, rather than internal to the housing. CIB at 73 (citing RX-0013, [0001], [0012]); CRB at 33. Reynolds also argues, relying on Mr. Alarcon’s testimony, that Pienemann’s control system does not solve the “accidental activation” issue of Kim, as it includes an activation switch, 60, positioned on the outside of the device. CIB at 74 (citing Tr. (Alarcon) at 169:9-170:1). Reynolds also faults Respondents for failing to offer “any details on how such a modification would be implemented” or “any specific design aspects necessary for the modification,” CIB at 74, and contends, based on Mr. Alarcon’s testimony, that the engineering required would not be “simple and routine.” CRB at 32-33; CIB at 75 (citing Tr. (Alarcon) at 172:1-173:3). Reynolds also highlights Mr. Alarcon’s testimony that Kim—as a function of its electrical heater—would be non-functional, and thus “there would be no rationale for [one of ordinary skill] to consider integrating Kim with another reference.” CIB at 76 (citing Tr. (Alarcon) at 174:11-15); CRB at 28. Reynolds also contends that the “button press” activation of Pienemann’s controller is not “a controller that activates current flow through the heater in response to a draw, or an inhalation.” CIB at 79 (citing Tr. (Alarcon) at 176:6-18). Reynolds also contends that, for the same reasons as discussed with respect to Limitation [1d], Kim does not disclose an “electrical resistance heater.”⁶²

⁶² For the same reasons as discussed above with respect to Limitation [1d], *supra*, the undersigned finds that Reynolds has not shown that Respondents’ arguments that Kim discloses an “electrical resistance heater” lack substantial merit.

In response, Respondents argue that Pienemann explicitly discloses that the device, like in Kim, may be “cigarette-shaped” and that the control circuitry may be “housed inside the housing of the inhaler device,” RX-0014, cl. 21, 3:13-14, and thus Reynolds’ arguments about the differing design goals of Kim and Pienemann are contrary to the express teachings of Pienemann. RRB at 36. Respondents also submit that the “feasibility of bodily incorporation” of Kim and Pienemann is “legally irrelevant,” as the test for obviousness is directed to whether one of skill in the art would have been motivated to combine the claimed teachings. RRB at 36; RIB at 100-01 (quoting *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016)). Respondents also submit that potential challenges associated with the modification are “entirely speculative” and do not indicate a lack of a reason to combine the references. RRB at 37. Finally, Respondents argue that Reynolds’ arguments regarding the button-press activation in Pienemann ignore the two-step “cascaded system,” which uses both a button-press and a puff detector. RRB at 36.

In Staff’s view, “the Staff believes the evidence shows that a POSITA would have been motivated to combine Kim and Pienemann.” SIB at 39. Staff characterized Mr. Alarcon’s challenges to the combination as “conclusory.” SIB at 38 (citing Tr. (Alarcon) at 168:16-18).

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents’ assertion that the combination of Kim and Pienemann discloses the claimed “controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article” lacks substantial merit.

As an initial matter, there does not appear to be a dispute that Pienemann’s control system discloses a “controller configured to activate current flow through the electrical resistance

heater in response to a draw on the electrically-powered, aerosol-generating smoking article.”⁶³

The evidence of record indicates that the “puff detector” in Pienemann, which “which reacts to the pressure change when the user announces [inhales] air and causes the power supply to one of the zones 13 or 15 via a switching device,” is a “controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article.” *See* RX-0014, 11:10-13; Tr. (Dean) at 498:4-9 (“Pienemann has a cascaded system of one on/off switch that is on the external housing of the device that can be used to turn on and activate the entire device. And then he has a puff-activated control system which delivers current to the electrical heater only when the user is taking a puff on the device or inhaling on the device.”).

As to whether one of ordinary skill in the art would have had reason to combine Kim and Pienemann as urged by Respondents, and a reasonable expectation of success in doing so, the undersigned finds that Reynolds has not shown that Respondents’ arguments lack substantial merit. Dr. Dean testified that one of ordinary skill would have reason to use Pienemann’s control system in place of Kim’s lip-activated pressure switch to address the issue of accidental activation. Tr. (Dean) at 497:20-498:9, 497:5-14. Dr. Dean testified that making that modification to Kim would have been “a standard and normal engineering activity.” Tr. (Dean) at 498:22-24. Although Reynolds and Mr. Alarcon contend that one of ordinary skill would not be motivated to combine Kim and Pienemann because Kim is alleged to be “inoperable,” as

⁶³ Although Reynolds asserted in its opening brief that Pienemann’s controller is “activat[ed] on the press of a button,” CIB at 79, Reynolds did not renew that contention in its reply brief, and the testimony cited by Reynolds only references Kim. *See* Tr. (Alarcon) at 176:6-18 (“[Q]: Does Kim disclose activating current flow in response to a draw? [A]: No. Kim discloses when you press with your lips on the tip, that it would activate. That’s different than an inhalation.”); *see generally* CRB. Reynolds has not argued or presented evidence that the “puff detector” in Pienemann—which is part of the “cascaded” activation system—is not the claimed “controller” responsive to a “draw.”

discussed above with respect to Limitation [1d], *supra*, the operability of Kim is the subject of directly contradictory expert testimony, and further, Kim is presumed to be enabled. *Cameron Int'l*, 2022 WL 636099, at *6. As to the alleged differences in designs and goals between Pienemann and Kim, Respondents have pointed to disclosures in Pienemann that the device may be cigarette-shaped (as in Kim) and that the control circuit may be located within the housing (as in Kim). *See* RX-0014, cl. 21, 3:13-14. Finally, although the undersigned agrees that Respondents' evidence did not specifically show how the proposed modification would be accomplished, in view of the Federal Circuit's direction that "bodily integration" is not required for an obviousness combination, the evidence fails to show that Respondents' identification of a reasonable expectation of success—supported by Dr. Dean's testimony—lacks substantial merit.

Accordingly, based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds has not shown that Respondents' assertion that the combination of Kim and Pienemann discloses the claimed "controller configured to activate current flow through the electrical resistance heater in response to a draw on the electrically-powered, aerosol-generating smoking article" lacks substantial merit.

* * *

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claim 1 of the '202 patent based on alleged obviousness over the combination of Kim in view of Pienemann,⁶⁴ and Reynolds has not shown that the Kim and Pienemann invalidity defense "lacks substantial merit." *Titan Tire*, 566 F.3d at 1377.

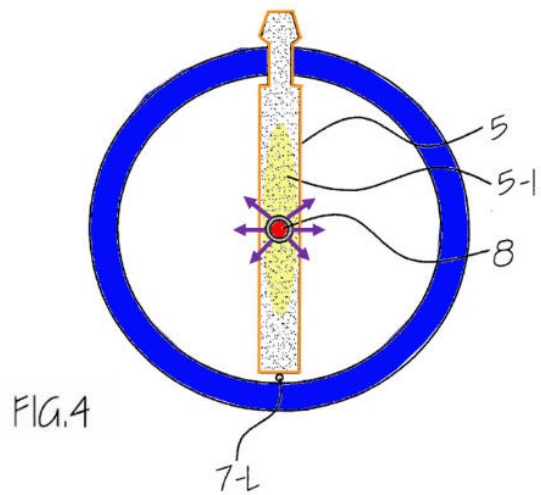
⁶⁴ No evidence of secondary considerations of non-obviousness was presented by the parties. *See, e.g.*, Tr. (Alarcon) at 221:24-223:15 (agreeing that he did provide an opinion as to objective evidence of secondary considerations).

Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits. *Helifix*, 208 F.3d at 1352 (“In the face of Blok–Lok’s challenge to the validity of the ’801 patent, *Helifix* could not establish a likelihood of success on the merits.”).

2. Claim 4

Claim 4 depends from claim 1, and requires in addition that “the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece.”

The parties dispute the disclosure of the additional limitation of claim 4 in the combination of Kim and Pienemann. Respondents, relying on Dr. Dean, contend that one of ordinary skill “would have understood that, during use, air flowing through the device enters the [porous chip 5] having the evaporated vapors of nicotine and volatile palatability enhancing agents absorbed therein, and mixes with the vapors to create an



aerosol.” RIB at 98 (citing Tr. (Dean) at 500:21-501:3). Figure 4, annotated by Dr. Dean right, shows the “generated aerosol” passing through “at least a portion of porous chip 5 as the aerosol is driven outward.” RIB at 99 (citing Tr. (Dean) 501:4-19; RDX-0201.20 (annotating RX-0013, Fig. 4)).

Reynolds, in opposition, repeats their argument that one of ordinary skill would not have had a reason to combine Kim and Pienemann, or have been reasonably successful in doing so. CIB at 79. Additionally, relying on Mr. Alarcon, Reynolds asserts that the evaporated mixture in Kim “exits from the side of the chip” and only then combines with air to form an aerosol. CIB at

80 (citing Tr. (Alarcon) at 177:1-17). Reynolds also contends that Respondents' arguments conflate "aerosol" and "airflow" in claims 4 and 12. CRB at 31.

In response, Respondents state that "Kim's device directs the airflow primarily around the sides of the chip," but, relying on Dr. Dean, contend that "at least some of the air flowing through the device enters the pores of the chip." RRB at 39-40 (citing Tr. (Dean) at 500:21-501:3).

In Staff's view, Reynolds' argument "ignores that the vaporized nicotine mixture is first generated within the chip and then driven outwards, as Mr. Alarcon admits." SIB at 99 (citing Tr. (Alarcon) at 177:7-9).

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents' assertion that Kim discloses that "the aerosol that is produced passes at least partially through the storage compartment before exiting through the mouthpiece" lacks substantial merit.

As to where aerosol actually forms—*i.e.*, outside the identified "storage compartment," as Mr. Alarcon contends, or also within, as Dr. Dean contends—the undersigned finds that Reynolds has not shown that Respondents' position lacks substantial merit. The parties have presented conflicting expert testimony on the technical details of Kim's disclosure, including credible testimony from Dr. Dean, and such a conflict is "best decided on the basis of a more developed record," and creates a "substantial question" as to invalidity. *See, e.g., Baxalta*, 2018 WL 3742610, at *8; *Amazon.com*, 239 F.3d at 1359 ("a conflict in the testimony as to whether the reference would have taught one of ordinary skill in the art" is sufficient to raise a "substantial question" as to invalidity); Tr. (Dean) at 495:14-23; RDX-0201.12; Tr. (Dean) at 500:25-501:19; RDX-0201.20.

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claim 4 the '202 patent based on obviousness over the combination of Kim and Pienemann, and Reynolds has not shown that the Kim and Pienemann invalidity defense “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377. Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits as to claim 4. *Helifix*, 208 F.3d at 1352.

3. Claim 5

Claim 5 depends from claim 1, and requires in addition that “the storage compartment is configured as a cartridge.”

The parties dispute the disclosure of the additional limitation of claim 5 in Kim and Pienemann. Respondents identify porous chip 5 as the “storage compartment,” and state that Kim “contemplates that porous chip 5 can be replaceable” because Kim discloses a holding case for “spare porous chips.” RIB at 99-100 (citing RX-0013, [0019]; Tr. (Dean) at 506:12-507:1). Kim is silent as to how the porous chip 5 is replaced, but Respondents contend that one of ordinary skill would use Pienemann’s “pivoting flap” in the housing to insert and remove the porous chip 5. RIB at 100 (citing RX-0014, Fig. 5; RDX-0201.26 (annotating RX-0014, Fig. 5); Tr. (Dean) at 507:3-508:5). Respondents, relying on Dr. Dean, argue that such a modification would be “obvious, routine, predictable, and successful.” RIB at 100 (citing Tr. (Dean) at 533:16-21, 507:16-20).

Reynolds raises similar arguments as to the combination of the “hinged flap” from Pienemann into Kim as addressed above with respect to Limitation [1g]. Specific to the additional limitation of claim 5, Reynolds argues that Respondents and Dr. Dean provided “no explanations regarding how a POSA would utilize the pivoting flap if implemented in Kim’s

device, nor did Dr. Dean identify how such an integration could occur without disrupting the slider mechanism of the device, crucial for the chip's mobility." CIB at 74-75; CRB at 32-33. Reynolds also argues that the size of Kim makes adding a hinged flap, as taught in Pienemann, difficult. CIB at 74 (citing Tr. (Alarcon) at 170:4-16). Reynolds also argues that "Dr. Dean further failed to provide adequate testimony regarding this limitation, as his entire analysis relies on citing language from the '202 patent, and fails to indicate any disclosure in Kim or Pienemann that he suggests discloses this limitation." CIB at 80.

Respondents, in response, again point out that "bodily integration" is not the test for obviousness, RRB at 36, and point to disclosures in Pienemann that the device may be shaped—like Kim—like a "cigarette," such that the size does not teach away from combining Pienemann and Kim.

In Staff's view, "the adduced evidence during the Hearing shows that the combination of Kim and Pienemann discloses the additional limitation of this claim." SIB at 40.

Upon review of the submissions, arguments, and evidence of record in the temporary enforcement phase of this investigation, the undersigned finds that Reynolds has not shown that Respondents' assertion that the combination of Kim and Pienemann discloses that "the storage compartment is configured as a cartridge" lacks substantial merit.

As discussed above with respect to Takeuchi, the parties agree that "a cartridge" must be "removable" or "exchangeable." *See* CIB at 68; RIB at 74; '202 patent, 5:57-61; Tr. (Dean) at 537:13-15.

As to whether one of ordinary skill in the art would have had reason to combine Kim and Pienemann as urged by Respondents, and a reasonable expectation of success in doing so, the undersigned finds that Reynolds has not shown that Respondents' arguments lack substantial

merit. Kim itself discloses that the porous chips are—in some way—exchangeable, as it discloses spare porous chips. RX-0013, [0019]; Tr. (Dean) at 507:10-15 (“Kim describes that the chip can be replaced, and he talks about a compartment that holds the replacement chips, but he doesn't actually give the details of how that would be done. If we combine the hinge flap-style axis that’s described in Pinemann, then we would have the ability to replace Kim’s porous chip.”). Dr. Dean testified that this modification would have been “a matter of accepted engineering practice and not difficult.” Tr. (Dean) at 507:16-20. Although Reynolds and Mr. Alarcon contend that one of ordinary skill would not be motivated to combine Kim and Pienemann because Kim is alleged to be “inoperable,” as discussed above with respect to Limitation [1d], *supra*, the operability of Kim is the subject of contradictory expert testimony, and further, Kim is presumed to be enabled. *Cameron Int’l*, 2022 WL 636099, at *6. As to the alleged differences in designs and goals between Pienemann and Kim, CIB at 74, Respondents have pointed to disclosures in Pienemann that the device may be similarly shaped (e.g., also cigarette-shaped as in Kim). *See* RX-0014, 3:13-14. Finally, although Respondents’ evidence did not specifically show how the proposed modification would be accomplished, in view of the Federal Circuit’s direction that “bodily integration” is not required for an obviousness combination, the evidence fails to show that Respondents’ identification of a reasonable expectation of success—supported by Dr. Dean’s testimony—lacks substantial merit.

Accordingly, for the reasons discussed above, Reynolds has not shown that Respondents’ contention that the combination of Kim and Pienemann renders obvious the additional limitation of claim “lacks substantial merit.” *Titan Tire*, 566 F.3d at 1377. *Helifix*, 208 F.3d at 1352.

4. Claim 9

Claim 9 depends from claim 1, and requires in addition that “the electrical resistance heater is arranged in contact with the storage compartment.”

Reynolds does not separately dispute the disclosure of this additional limitation in Kim. 71-83; CRB at 27-33. In addition, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that Kim discloses the additional limitation of claim 9. Specifically, Kim teaches that the heating element—electric shortening connector or coil—is “embedded” or “disposed” in the porous chip 5, which Respondents have identified as corresponding to the claimed “storage compartment.” RIB at 101-02 (citing RDX-0201.21 (annotating RX-0013, Fig.5); RX-0013, [0015]; Tr. (Dean) at 505:6-17).

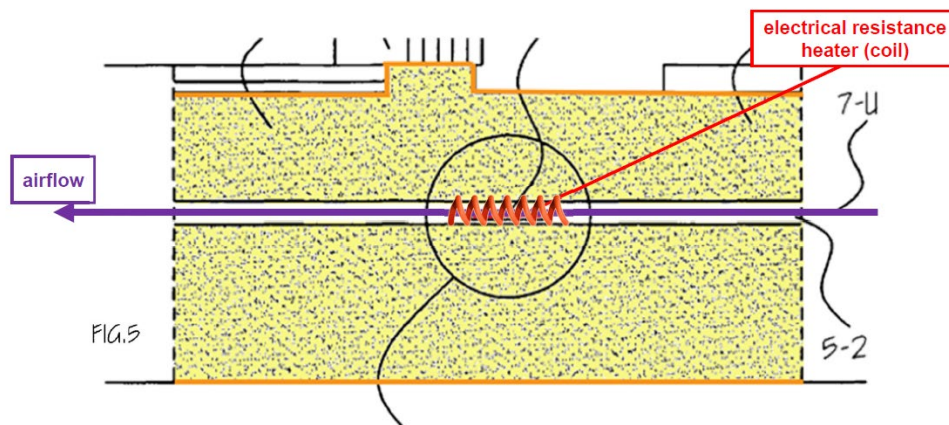
For the reasons discussed above with respect to Limitation [1d], and based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds has not shown that Respondents’ assertion that Kim discloses the claimed “electrical resistance heater” lacks substantial merit. Additionally, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that the additional limitation of claim 9 is rendered obvious by the combination of Kim and Pienemann.

5. Claim 12

Claim 12 depends from claim 1, and requires in addition that “the electrical resistance heater is configured to allow airflow therethrough.”

As discussed above with respect to the additional limitation of claim 9, *supra*, the alleged electrical resistance heater in Kim is “embedded” within the porous chip 5, which Respondents have identified as the claimed “storage compartment.”

Dr. Dean testified that in Kim, there is “a vacant space or void at the center of the axis upon which the coil is oriented, and that’s an airflow channel.” Tr. (Dean) at 506:2-5. Based on this testimony, Respondents contend that “airflow would pass through any empty interior spaces or voids defined by the coil.” RIB at 103. Dr. Dean annotated Figure 5 of Kim (below) to show the asserted airflow and heating coil.



RDX-0201.22 (annotating RX-0013, Fig. 5).

Reynolds’ disputes the disclosure of the additional limitations of claim 12 because Reynolds contends (1) Kim does not disclose the claimed “electrical resistance heater”; and (2) airflow only occurs around the chip and heater. CIB at 81-82. Reynolds also references its arguments as to Takeuchi, CRB at 31, and contends that “[t]he movement of air through the device is not synonymous with the generation or passage of aerosol, and these claims are not met for the reasons Reynolds previously explained.”

In Staff’s view, “the adduced evidence during the Hearing shows that the combination of Kim and Pienemann discloses the additional limitation of this claim.” SIB at 41.

Upon review of the submissions and current evidence of record, the undersigned finds that Reynolds has not shown that Respondents’ assertion that Kim discloses that “the electrical resistance heater is configured to allow airflow therethrough” lacks substantial merit. Dr. Dean

testified that there is an “airflow channel” through the chip in Kim, which is consistent with Figure 5 of the Kim reference. *See* Tr. (Dean) at 506:2-5 (testifying, with respect to Figure 5 of Kim, that there is an “airflow channel”); RDX-0201.22; RX-0013, Fig. 5; *id.* at [0015] (describing “cylindrical hole (5-2)”). The parties have presented conflicting expert testimony on whether there is airflow through the coil heater in this channel, and such a conflict is “best decided on the basis of a more developed record,” and creates a “substantial question” as to invalidity. *See, e.g., Baxalta*, 2018 WL 3742610, at *8; *Amazon.com*, 239 F.3d at 1359 (“a conflict in the testimony as to whether the reference would have taught one of ordinary skill in the art” sufficient to raise a “substantial question” as to invalidity).

For the reasons discussed above with respect to Limitation [1d], and based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds also has not shown that Respondents’ assertion that Kim discloses the claimed “electrical resistance heater” lacks substantial merit. Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits as to claim 12. *Helifix*, 208 F.3d at 1352.

6. Claim 14

Claim 14 depends from claim 1, and requires in addition that “the controller is configured to regulate the current flow through the electrical resistance heater during the draw on the electrically-powered, aerosol-generating smoking article.”

Other than arguments regarding whether “[one of ordinary skill in the art] would be motivated or successful in combining the references,” and the disclosure of an electrical resistance heater and a controller, Reynolds does not dispute the disclosure of this additional limitation in the combination of Kim and Pienemann. *See* CIB at 82; CRB at 27-30. In addition, the undisputed evidence establishes that the control system in Pienemann—upon which

Respondents rely—including a puff detector “which reacts to the pressure change when the user announces [inhales] air and causes the power supply to one of the zones 13 or 15 via a switching device” and, in combination with the controller 32, may “control the voltage or current for the thermal resistor (3) of the substrate portion (1; 1’; 1”) in such a way that the heating power is set to a higher value on the first puff than on the following puffs, as well as to interrupt the power supply after a defined puff time to avoid overheating.” RX-0014, cl. 19, 11:10-13.

For the reasons discussed above with respect to Limitations [1d] and [1g], and based on the arguments and evidence introduced in the temporary relief proceedings, Reynolds has not shown that Respondents’ assertions that Kim and Pienemann disclose the claimed “electrical resistance heater” and “controller . . . configured to activate current flow” lack substantial merit. Additionally, the undisputed evidence currently of record demonstrates that Respondents will likely be able to establish that the additional limitation of claim 14 is disclosed by Kim and Pienemann.

* * *

Accordingly, for the reasons discussed above, Respondents have raised a substantial question as to invalidity of claims 1, 4, 5, 9, 12, and 14 of the ’202 patent based on alleged obviousness over Kim and Pienemann, and Reynolds has not shown that such contentions “lack substantial merit.” *Titan Tire*, 566 F.3d at 1377.

Accordingly, Reynolds has failed to meet its burden to establish a likelihood of success on the merits as to claims 1, 4, 5, 9, 12, and 14. *Helifix*, 208 F.3d at 1352 (“In the face of Blok–Lok’s challenge to the validity of the ’801 patent, Helifix could not establish a likelihood of success on the merits.”).

C. Written Description

Respondents contend that, to the extent the claims are not limited to smoking articles that contain tobacco (or solid tobacco), and/or to the extent they encompass articles with “no tobacco at all,” the claims are not supported by adequate written description. RIB at 105-08; *see also* RRB at 45-8.

To satisfy the written description requirement of Section 112, a patent must “reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (explaining the “hallmark” of an adequate written description is “disclosure”). An applicant establishes it was in possession of the invention “by describing the invention[] with all its claimed limitations.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis omitted). This description can be made using “words, structures, figures, diagrams, formulas, etc.” *Id.* A patentee can also “rely on information that is ‘well-known in the art’ to satisfy written description.” *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (citation omitted). Whether a specification complies with the written description requirement is a question of fact judged from the perspective of a person of ordinary skill. *See Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014).

Respondents argue that there are more than 500 references to “tobacco”—including in the Title, Abstract, and Summary of Invention—in the ’202 patent, and that such references restricting the invention to devices containing tobacco “permeate” the entire patent. RIB at 107. Relying on Dr. Dean, Respondents contend that “a person of ordinary skill would understand that the inventors were in possession only of a device that included solid tobacco.” RIB at 106 (citing

Tr. (Dean) 484:3-486:2. Citing to *Gentry Galley*, Respondents argue that the “claims may be no broader than the supporting disclosure.” RIB at 105-06 (citing *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998)). Respondents contend that Mr. Alarcon’s testimony that the ’202 patent discloses non-tobacco smoking articles is “a cherry-picking exercise in which he removes select passages of the specification from their context.” RIB at 106-07.

In opposition, Reynolds contends that the ’202 patent discloses embodiments with liquid tobacco—*e.g.*, liquid tobacco extracts—and embodiments with no tobacco at all. CIB at 83 (citing Tr. (Alarcon) at 152:9-16). Reynolds argues that the ’202 patent does not contain any language limiting the claims or invention to only those with solid tobacco, or only those with tobacco. CIB at 83. As to solid tobacco, Reynolds cites to the embodiments in the patents addressing the use of tobacco extracts and components “derived-from” tobacco. CIB at 85 (citing ’202 patent, 12:31-33, 23:35-56, 13:23-21, 12:15, 4:51-53; Tr. (Alarcon) at 152:25-153:13). Reynolds asserts that tobacco extract may be the only form of tobacco in the device, as the ’202 patent discloses an embodiment in which “tobacco extract can be carried by a substrate or positioned within the cartridge,” and that the “substrate for the tobacco extract can be provided by generally solid substances, such as alumina beads . . . synthetic fibers, or the like.” CIB at 85-86 (quoting ’202 patent, 23:35-56, 13:23-31). Reynolds also argues that the specification discloses embodiments where liquid tobacco extracts are incorporated into the cartridge with the liquid aerosol-forming material. CIB at 86 (citing ’202 patent, 23:15-23; Tr. (Alarcon) at 154:4-9). Reynolds also submits that although the patent indicates that “high nicotine content” tobacco extracts are identified as “not preferred,” that is not a disavowal or disclaimer. CIB at 87. Moreover, Reynolds argues that related patents expressly claim smoking articles with

“essentially pure nicotine, extracts composed predominantly of nicotine, or formulations composed predominantly of nicotine,” further “confirm[ing] that the inventors of the ’202 patent possessed an invention that did not include solid tobacco.” CIB at 87. Reynolds also argues that the portions of *Gentry Gallery* upon which Respondent rely has been described as “disfavored” in subsequent cases. CIB at 88 (citing *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, No. SA CV 04–00689, 2007 WL 8081360, at *20 (C.D. Cal. Jan. 22, 2007)).

As to whether the ’202 patent provides adequate written description support for the claims if not limited to solid or liquid tobacco, Reynolds argues that the position is not supported by expert testimony, as Dr. Dean focused solely on “solid tobacco.” CIB at 89; CRB at 34. Reynolds also contends, relying on Mr. Alarcon, that the ’202 patent “includes multiple disclosures that support claims that do not include any tobacco at all.” CIB at 89 (citing Tr. (Alarcon) at 154:16-19); CRB at 34. Reynolds argues that there is no disavowal of non-tobacco products and that the ’202 patent describes an embodiment with solely “non-tobacco aerosol components” and incorporates by reference a reference that describes “fractionated plant extracts that are non-tobacco.” CIB at 89-90 (citing ’202 patent, 26:6-12, 13:16).

In response, Respondents submit that the alleged “non-tobacco aerosol component” embodiment identified by Reynolds discloses only a non-tobacco cartridge, but explicitly includes tobacco provided “in another region of the smoking article 10.” RRB at 42-43 (quoting ’202 patent, 26:15-19). As to the reference incorporated by reference in the ’202 patent, Respondents contend that the incorporation by reference is expressly limited to the teachings of “tobacco extracts” in that reference. RRB at 43 (citing ’202 patent, 13:1-4). In a fair reading of the patent, Respondents argue, “a POSA would not have found an embodiment of the invention

disclosed that only contained liquid tobacco extracts” or only non-tobacco components. RRB at 46.

In Staff’s view, “if ‘smoking article’ is given its plain and ordinary meaning such that the claims are construed broad enough to cover tobacco free devices, there is a substantial question regarding validity 35 U.S.C. § 112.” SIB at 42. Staff contends that the title, abstract, field of invention, background of invention, summary of the invention, and “every disclosed embodiment” includes tobacco. SIB at 42-43.

The undersigned tentatively construed the claims as limited to smoking articles incorporating tobacco or tobacco-derived components. *See supra* Part III.E.1. Even under that construction, Respondents argue that the claims are invalid for lack of written description, as “a person of ordinary skill would understand that the inventors were in possession only of a device that included ***solid*** tobacco.” RIB at 106 (emphasis added). Based on the evidence and arguments of record, the undersigned finds that Reynolds has shown that Respondents’ arguments that the claims are limited to “solid tobacco” to lack substantial merit.

The specification, while disavowing smoking articles that do not contain tobacco in some form, *see supra* Part III.E.1, does not limit the incorporated tobacco to solid tobacco. 4:65-67 (“Thus, the present invention relates to smoking articles, and in particular, to smoking articles that incorporates tobacco ***in some form.***”) (emphasis added)), 9:28-43 (“The tobacco that is incorporated within the smoking article can be employed in various forms; and combinations of various forms of tobacco can be employed, or different forms of tobacco can be employed at different locations within the smoking article. For example, the tobacco can be employed in the form of . . . a tobacco extract.”). The specification also describes the use of “components derived from, or provided by, tobacco.” ’202 patent, 4:51-53. As Mr. Alarcon explained, the

specification describes liquid tobacco extracts, and teaches that “at least a portion”—which implies a possibility for more than just “a portion”—of the device’s tobacco may be provided as a liquid tobacco extract. *See, e.g.*, ’202 patent, 12:31-33 (“At least a portion of the tobacco incorporated with the smoking article can be provided in the form of a tobacco extract.”); Tr. (Alarcon) at 153:11-13 (“In column 12 of the patent, it says ‘at least a portion.’ And a POSA would understand that can also mean all can be the liquid or non-solid tobacco.”). Mr. Alarcon also pointed to embodiments in the specification that he testified could include only liquid tobacco extracts. *See, e.g.*, Tr. (Alarcon) at 153:15-154:15. On the current record, Mr. Alarcon’s testimony is consistent with the specification, which describes tobacco extracts as being carried by a substrate, or mixed with “generally liquid or fluid substances” in a cartridge. ’202 patent, 13:22-38, 23:15-23 (“In a further embodiment, tobacco can be incorporated within a cartridge 85 having the ability to act as a type of liquid storage container of the smoking article. For example, powdered spray dried tobacco extract can be incorporated within the liquid storage container 85, or *liquid tobacco extracts or essences* can be combined within components contained within the liquid storage container (e.g., aerosol-forming materials) so as to be intimately combined with those components.”). The specification also describes—albeit as not preferred—tobacco-incorporating products including “essentially pure nicotine, extracts composed predominantly of nicotine, or formulations composed predominantly of nicotine.” ’202 patent, 23:28-34; Tr. (Alarcon) at 154:10-15.

Dr. Dean’s contrary testimony that the ’202 patent specification does not indicate that the inventor possessed an ENDS device without a source of solid tobacco is largely conclusory and unsupported by explanation or citation to the specification. *See* Tr. (Dean) at 487:4-488:3. In view of the intrinsic evidence, Dr. Dean’s testimony is insufficient on this record to support a

claim scope limited to “solid tobacco.” *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (“conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court”).

Accordingly, based on the evidence of record—including Mr. Alarcon’s testimony and the ’202 patent—the undersigned finds that Reynolds has shown that Respondents’ argument that “a person of ordinary skill would understand that the inventors were in possession only of a device that included solid tobacco” lacks substantial merit. *See* RIB at 106. As tentatively construed (*i.e.*, limited to smoking articles incorporating tobacco, including tobacco-derived components), the undersigned finds that Reynolds has carried its burden to show that Respondents’ written description arguments lack substantial merit.⁶⁵

⁶⁵ To the extent, however, that the claims were alternatively construed to cover non-tobacco smoking articles—that is, devices that do not incorporate tobacco or tobacco-derived components—the undersigned agrees that Respondents have raised a substantial question as to whether the ’202 patent contains adequate written description, and that Reynolds has not shown that Respondents’ written description arguments lack substantial merit. “[A] broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.” *See Cooper Cameron Corp. v. Kvaerner Oilfield Prod., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002); *Toro Co. v. Ariens Co.*, 232 F.3d 915 (Fed. Cir. 2000) (finding claims invalid for lack of written description where patentee “has broadened the claims beyond what the original claims claim and the written description discloses”). The written description analysis is not limited to expert testimony. *See, e.g., University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004) (“[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met.”). As discussed above, *supra* Part III.E.1, the ’202 patent exclusively, in unambiguous and definitional language, describes an invention that incorporates tobacco “in some form.” Reynolds—relying on Mr. Alarcon—has identified two places in the specification that allegedly describe “non-tobacco” embodiments. Mr. Alarcon identifies an embodiment described in column 26 that describes “non-tobacco aerosol components” and the incorporation of the Raymond reference in column 13, which he states describes non-tobacco plant extracts. Tr. (Alarcon) at 154:24-155:10. Mr. Alarcon’s testimony as to these embodiments, however, is contradicted by the specification. As to the column 26 embodiment, although “non-tobacco aerosol components” are disclosed as part of the cartridge, the embodiment includes “tobacco 89 located in another region of the smoking article 10 rather than from nicotine incorporation within the cartridge 85.” ’202 patent, 26:6-19. That is, the embodiment in column 26 expressly still includes tobacco. As to the Raymond reference, Raymond is incorporated by reference as disclosing “[e]xemplary types of tobacco extracts, tobacco essences, solvents, tobacco extraction processing conditions and techniques, and tobacco extract collection and isolation procedures.” ’202 patent, 13:1-21.

IX. UNENFORCEABILITY

Respondents raise a further defense based on prosecution laches. *See* RIB at 108-112; RRB at 47-50. Respondents argue that “RJR waited an extraordinary 17-years from the time it filed priority application 11/550,634 in October 2006 until it presented claims for examination in March 2023, when it filed the application that eventually issued as the ’202 patent.” RIB at 110. Respondents further argue that “RJR waited 17 years to present the claims of the ’202 patent for examination that purported to cover non-tobacco products, and only several years after such products were publicly sold by many of the Respondents.” *Id.* Respondents argue that they have been prejudiced because the accused products were sold or invested in “during the period of delay.” *Id.* Respondents rely heavily on analogy to the district court opinion in *Sonos, Inc. v. Google LLC*, No. C-20-06754 WHA, 2023 WL 6542320 (N.D. Cal. 2023). Respondents argue that the facts presented here raise a substantial question of enforceability of the ’202 patent that precludes issuance of preliminary relief.

Reynolds argues, in opposition, that Respondents’ argument “is based solely on a single factor—the passage of time,” and that this reasoning is flawed. CIB at 91. Reynolds argues that “there are multiple justifications for filing continuing applications” and that Respondents’ arguments show that the ’202 patent “was neither unduly successive nor repetitive in comparison to its related patents.” *Id.* at 92. Reynolds argues that Respondents have “failed to present a convincing argument regarding intervening rights” and “rely solely on web captures purported to show sales of the Accused Products,” which Reynolds argues “does not constitute proof of

Neither of these disclosures provide support for a claim scope that encompasses non-tobacco smoking articles. Accordingly, even if the undersigned construed “smoking article” as not limited to smoking articles incorporating tobacco, Reynolds has not shown a likelihood of success on the merits, as Respondents have raised a substantial question that the ’202 patent contains inadequate written description.

intervening rights.” *Id.* at 93. Reynolds argues that “the claims of the ’202 patent have undergone public prosecution since the priority date, and the disclosure was made publicly accessible with the publication of U.S. Ser. No. 11/550,634 on April 24, 2008, and through every publication within the patent family since that date.” *Id.* Reynolds further notes that “Respondents did not elicit any testimony on this defense.” *Id.* at 94; *see also* CRB at 36-38.

Staff argues that, with respect to prosecution laches, “[t]here was no evidence presented at the Hearing concerning this issue, including any evidence of the subjective intent underlying Reynolds’ patent prosecution strategy. SIB at 43 (citing *Personalized Media Commc’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023)). Staff contends that Respondents “failed to provide any proof of their contentions [of] unenforceability at the TEO phase.” *Id.* at 44.

In consideration of the parties’ arguments, the undersigned finds that on the current record, Respondents have not raised a substantial question regarding unenforceability due to prosecution laches. Prosecution laches “may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.” *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010) (internal quotation omitted). Prosecution laches requires showing that: “(1) the patentee’s delay in prosecution [is] unreasonable and inexcusable under the totality of circumstances and (2) the accused infringer must have suffered prejudice attributable to the delay.” *Personalized Media Commn’s, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023); *see also* *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (“Two elements underlie the defense of laches: (a) the patentee’s delay in bringing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered material prejudice attributable to the delay.”). The Federal Circuit has held that

“an examination of the totality of the circumstances[] include[s] the prosecution history of all of a series of related patents.” *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1386 (Fed. Cir. 2005); *see also id.* at 1385 (“[t]he doctrine should be applied only in egregious cases of misuse of the statutory patent system”).

Here, Respondents did not present substantial evidence of an unreasonable and inexcusable delay under the “totality of circumstances.” Respondents reference a 17-year gap between the priority application and the application that ultimately issued as to the ’202 patent. *See* RIB at 110-11; RRB at 48-49. However, Respondents presented no argument showing that the circumstances of any delay were unreasonable or inexcusable. Respondents did not, for example, identify actions by Reynolds that resemble the type of conduct recognized by the Federal Circuit as unjustifiable prosecution delay, such as refiling applications containing previously-allowed claims, repetitive filing of applications that were merely placeholders, or a “consistent pattern of receiving a rejection on an application, filing a continuation application without any amendments, and abandoning the original application.” *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1361-62, 1366-69 (Fed. Cir. 2021); *Symbol Tech.*, 422 F.3d at 1385 (“there are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions”); *Finjan, Inc. v. Juniper Network, Inc.*, 2018 WL 4181905, at *3 (N.D. Cal. Aug. 31, 2018) (finding that “mere recitation of the number of years that lapsed between the time Finjan filed its application for the parent patent and the applications for the patents here, rounded out with the conclusory statement that ‘Finjan unreasonably and unduly delayed in prosecution each of’ the four patents and that ‘[d]uring the delay, Juniper was prejudiced because it spent considerable resources marketing, selling, and importing updated versions of the accused products’” was insufficient to state a

claim for prosecution laches). Moreover, as Reynolds notes (and Respondents do not contest), the '202 patent expires 20 years from its priority date in 2006 and the underlying disclosure was published in 2008. See CIB at 92-93. There is thus no issue regarding any extension of patent term caused by the asserted delay, or any concealed specification. *Cf. Cancer Rsch.*, 625 F.3d at 732 (“the facts of this case are not likely to be frequently repeated, as patent terms are now measured from effective filing date”).

Further, as held *supra*, the claims of the '202 patent as construed herein do not extend beyond smoking articles that include tobacco or tobacco-derived products. Thus, Respondents' argument that “RJR waited 17 years” to claim non-tobacco products (RIB at 110) is not supported by the claim construction adopted here.⁶⁶

For at least these reasons, on the current record, Respondents have not raised a substantial question regarding the enforceability of the '202 patent based on their prosecution laches claim.⁶⁷

X. IRREPARABLE HARM

As discussed above, Reynolds, as the party seeking a preliminary injunction, must show it is likely to suffer irreparable harm if the injunction is not granted and establish a causal nexus between the alleged infringement and the alleged harm. *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016). The Federal Circuit has found “[p]rice erosion,

⁶⁶ Moreover, ordinarily “there is nothing improper, illegal, or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market.” *BlephEx, LLC v. Myco Indus.*, 24 F. 4th 1391, 1404 (Fed. Cir. 2022) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988)).

⁶⁷ Respondents rely heavily on the district court’s holding in *Sonos, Inc. v. Google, LLC*, 2023 WL 6542320 (N.D. Cal. Oct. 6, 2023). That decision is currently on appeal before the Federal Circuit. Moreover, in that case there was evidence that the patentee submitted superfluous disclosures, *id.* at *26 n.11, and added new matter while representing otherwise, *id.* at *24-25.

loss of goodwill, damage to reputation, and loss of business opportunities” as “examples of possible grounds for finding irreparable harm.” *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, No. 2023-1058, 2024 WL 358136, at *3 (Fed. Cir. Jan. 31, 2024).

Reynolds contends that it has suffered irreparable harm in the following categories:

(1) reputational harm; (2) harm caused by lost sales and market share; (3) harm caused by price and value erosion; (4) harm caused by FDA delays. CIB at 122. Each of these categories is addressed in detail below.

A. Reputational Harm

Reynolds contends that it has “spent decades” and “invested ‘billions trying to build a portfolio of potentially reduced-risk products.’” CIB at 124 (citing Tr. (Mras) at 54:17). Key to the realization of this goal, Reynolds submits, are the VUSE DI Products. CIB at 124-25.

Reynolds also points to investments in quality control and Reynolds’ investments in filing and receiving regulatory approvals to market and sell their products. CIB at 125 (citing Tr. (Mras) at 61:25-62:8, 63:8-15). Reynolds describes their “unrivalled track record” in obtaining PMTA (“Premarket Tobacco Product Application”) approvals from the FDA, and their commitment to “responsibly marketing and delivering its innovative products to adult tobacco consumers,” including investments and efforts in keeping products away from youth. CIB at 126-27 (citing Tr. (Mras) at 59:21-60:6 (describing age-gated technology); CX-0005C (Murrelle WS) at Q50 (describing drop in use of Reynolds products among youth)). Reynolds argues that in contrast, “Respondents are not preventing underage access to their products—that market segment is the core of their business model.” CIB at 128. Reynolds argues that “are reaching American youth by stealing Reynolds’s patented technology, importing it, and using it to offer flavors that they cannot legally sell; improperly and unethically targeting American youth with candy- and

dessert-flavored versions of Reynolds's patented technology; and selling these infringing products into the U.S. markets without investing the tens of millions of dollars necessary to obtain FDA authorization to do so legitimately." CIB at 128. Reynolds argues that Reynolds' technology has been incorporated into Respondents' products that target youth, into products with "offensive" or "criminal associations that tarnish others in the industry," and into products that are sold without approval from the FDA. CIB at 129-133. These bad acts, Reynolds argues are being attributed to Reynolds. CIB at 133-134. As evidence, Reynolds points to comments by Senator Durbin at a hearing before the Senate Judiciary Committee that "group[ed] 'Big Tobacco'"—which Reynolds alleges "plainly includes Reynolds"—with "companies selling illicit disposable vaping products." CIB at 134 (citing CX-0377.3-4; Tr. (Mooney) at 314:2-16); *see also* CIB at 135 (citing CX-1159.72 (comments at a House Energy & Commerce Subcommittee Hearing)). Reynolds also points to media coverage which "lumped Reynolds in with companies like Respondents who are selling illegal vaping products." CIB at 135-36 (citing CX-0389). Reynolds argues that the negative public perception "has placed significant pressure on regulatory agencies that are painting with a broad brush when taking restrictive regulatory action, including a blanket policy of rejecting all PMTAs involving flavors other than tobacco or, more recently, menthol." CIB at 137 (citing Tr. (Mras) at 66:8-19; CX-0895C.94). Reynolds also contends that enforcement action by the FDA and Customs against illicit vaping products has held up shipments of its approved vaping products at ports. CIB at 138 (citing Tr. (Mras) at 68:23-25; Tr. (Ferris) at 125:13-126:1). Reynolds also argues that the lower quality of Respondents products is harming their reputation. CIB at 138-40.

Respondents contend that Reynolds' reputational harm claims do not have an adequate nexus to the alleged patent infringement. RIB at 137. Respondents argue that in the patent

context, redressable reputational harm is found where there is harm to the “patent owner’s ‘reputation as an innovator’” or there is “customer ‘confusion between an inferior accused product and a patentee’s superior product.’” RIB at 137-38 (citing *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013) and *Reebok Int’l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1558 (Fed. Cir. 1994)); RRB at 55-56. Respondents argue that testimony from Reynolds’ witnesses was “purely conclusory” and did not provide evidence of customer confusion or evidence that anyone credited Respondents for Reynolds’ “putative invention.” RIB at 138. As to Reynolds’ claims related to “guilt by association,” Respondents argue that these arguments are speculative, novel, and usurp the FDA’s authority to enforce and apply the Federal Food, Drug, and Cosmetic Act (“FDCA”). RIB at 139-41 (citing *Certain Disposable Vaporizer Devices*, Inv. No. 337-TA-1381, Determination on Institution, EDIS Doc. ID 810442, at 2-3 (Dec. 15, 2023) (declining to institute on FDCA-related claims)); RRB at 52-55. Respondents also contend that Reynolds “fails to account for the degree to which its own history and business practices have damaged its reputation, for reasons that have nothing to do with Respondents,” including “its checkered history of enticing youths to buy cigarettes.” RIB at 142; RRB at 58. Respondents also argue that there is zero evidence that the FDA or Customs has conflated Reynolds’ products with the Accused Products, and that such “unsubstantiated assertions” are insufficient to justify a temporary exclusion order. RRB at 57 (citing *Well Cell Global LLC v. Calvit*, No. 2023-1229, 2023 WL 6156082, at *3 (Fed. Cir. Sept. 21, 2023)).

In response, Reynolds contends that the reputational harm is not limited to “reputation as an innovator,” but can encompass instances where an “infringer is using the patentee’s technology to manufacture cheap, knock-off goods.” CRB at 44 (citing *Cancer Rsch. Ctr. v. BioPet Vet Lab, Inc.*, No. 2:10CV616, 2011 WL 1119565, at *1 (E.D. Va. Mar. 1, 2011) (finding

likelihood of irreparable harm when infringing products were of lesser quality and had been ill-received by customers)). Reynolds renewed its arguments that Respondents' bad acts—which Reynolds characterizes as selling illicit products targeted at youth, CRB at 45—are being attributed to Reynolds and/or causing regulatory enforcement issues. CRB at 45-48. As to the Respondents' arguments regarding FDA enforcement, Reynolds argues that “[i]f Respondents were importing infringing, but otherwise benign, widgets, the result here would be the same. But the fact that these widgets are not actually widgets at all, but vaping devices that Respondents have no right to sell in the U.S., and which are a public scourge, the equitable TEO factors—which are the equitable preliminary-injunction factors like the balance of equities and the public interest—are even more compelling and one-sided than if Respondents were just selling anodyne infringing devices.” CRB at 50. Reynolds, relying on Dr. Murrelle, also contend that Reynolds “has moved well past any reputational problems that were caused during the days of Joe Camel.” CRB at 53 (citing Tr. (Murrelle) at 433:21-434:1).

In Staff's view, the record does not establish a connection between the alleged reputational harm and the alleged infringement. SIB at 53; SIB at 49-51. Staff asserts that there is insufficient evidence of customer confusion or “guilt-by-association,” and that to the extent the DI Products are being grouped with other vaping products, Reynolds has some share of the blame, as neither the Accused Products or the DI Products are “safe,” and that Reynolds' DI Products are also used by youth. SIB at 53-54 (citing Tr. (Mras) at 101:14-103:9, 88:3-6; RX-0052; CX-0371); SRB at 12 (“[T]he picture that Complainants try to paint of this Investigation as a battle between good and evil is as unavailing as it is irrelevant.”). Staff also asserts that “[a]ny grievance about violations of FDA regulations, such as use of allegedly adulterated or misbranded products, is better suited for adjudication before the FDA.” SRB at 10.

Reputational harm has previously been found to weigh in favor of injunctive relief where a patentee was itself practicing the patented invention and where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that patentee's status as an innovator. *See, e.g., Douglas*, 717 F.3d at 1344-45. On the current record, the undersigned finds that Reynolds has not sufficiently substantiated a likelihood of these harms.

Reynolds has not argued or identified persuasive evidence of customer confusion; indeed, the evidence of record indicates that the DI Products and the Accused Products are sold primarily in different sales channels and are categorized as different types of ENDS devices. *See, e.g., Tr. (Ferris)* at 110:19-111:8 (“[Q]: Are the RCS products and the disposable products sold through the same channels? [A]: Somewhat. There’s a very limited overlap, but there is some. Most of RCS channels, we estimate 90 percent of that volume flows through what we would consider to track channels. . . whereas we think disposables sell only less than 5 percent of their volume through these so-called tracked channels.”), 110:2-11 (“So in the vapor space, we categorize it into three subcategories. We have the rechargeable closed system space, also known as RCS. That’s where VUSE products or the type of system VUSE products are. We have disposables, which are single-use, sometimes rechargeable units that, after use, are thrown away and consumer will purchase a new one.”); *Tr. (Mooney)* at 307:8-11 (“So what this is showing is, on the left side, RCS products are largely sold in the measured retail channel. Disposables are largely sold in the untracked channel, the non-measured retail channel.”). This evidence is consistent with Dr. McDuff’s testimony that “these are differentiated products” with “different attributes,” and that he had not seen “evidence of customer confusion.” *Tr. (McDuff)* at 656:16-19; *see also Tr. (Mras)* at 69:16-20 (identifying “gimmicky features, higher fill, lower price point” in Accused Products as compared to DI Products), 84:4-7 (“[Q]: You’ve successfully

positioned VUSE as a premium-style product within the vaping market, correct? [A] Within the competitive set of rechargeable closed systems, I would say yes.”).

Similarly, Reynolds has not argued or identified persuasive evidence of a loss of product distinctiveness; again, and for the same reasons as discussed above, the evidence introduced at the hearing suggests that the DI Products and the Accused Products are differentiated in the market.

As to the risk to Reynolds’ “status as an innovator,” the undersigned finds that the record does not support the alleged harm to Reynolds’ status as an innovator. Reynolds has not provided persuasive evidence of harm to its “perception in the *marketplace* by customers, dealers, and distributors,” including for the reasons discussed above, *i.e.*, that the products are different categories of ENDS products and are sold in different sales channels. *See Douglas*, 717 F.3d at 1344 (emphasis added); *Tinnus Enterprises, LLC v. Telebrands Corp.*, 846 F.3d 1190, 1208 (Fed. Cir. 2017) (citing a customer review as evidence of harm “to Tinnus’s reputation and . . . its status as the innovator in this market”) (emphasis added); *Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 731 F. App’x 962, 975 (Fed. Cir. 2018), *vacated in non-relevant part*, 729 F. App’x 936 (Fed. Cir. 2018) (considering evidence of alleged “damage [to patentee’s] reputation in the market segment”); *SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, No. 2023-1058, 2024 WL 358136, at *5 (Fed. Cir. Jan. 31, 2024) (citing evidence of continuing to secure “investments and customers” as rebutting alleged reputational harm).

Moreover, the evidence establishes that Reynolds [REDACTED], which weighs against its assertions of harm to innovator status. *Contrast with Douglas*, 717 F.3d at 1345 (“Lastly, the evidence shows that Douglas had never licensed the infringed patents, and intentionally chose

not to, so that it could maintain market exclusivity. Exclusivity is closely related to the fundamental nature of patents as property rights. It is an intangible asset that is part of a company's reputation, and here, Douglas's exclusive right to make, use, and sell the patented inventions is under attack by Buyers's infringement."); *see also Apple Inc. v. Samsung Elecs. Co.*, 801 F.3d 1352, 1373 (Fed. Cir.) (Reyna, J. concurring), *majority opinion modified and superseded on reh'g*, 809 F.3d 633 (Fed. Cir. 2015) ("In the context of reputational injury, if patented features appear in products other than the infringer's products, the marginal impact of the infringer's use of those features may be minimized.").⁶⁸

Regarding Reynolds' additional alleged reputational harms, the undersigned finds that those harms are not sufficiently substantiated. First, much of the alleged harm—including alleged harm resulting from the FDA's "de facto flavor ban" in 2020 and the denial of Reynolds' PMTA for menthol-flavored products in October 2023 (*see* CIB at 137)—predates the issuance of the '202 patent on March 12, 2024. *See* Tr. (Mras) at 79:22-24 ("[Q]: In October 2023, the FDA issued a marketing denial order for menthol-flavored VUSE, correct? [A] That is correct."); Tr. (Ferris) at 117:12-13 ("In 2020 was the de facto flavor ban from the FDA."); CIB at 137.⁶⁹ Additionally, Reynolds has not shown that the FDA or Customs has confused Reynolds' products with the Accused Products. Indeed, the FDA, at the congressional hearing cited by Reynolds, distinguished between domestic and foreign ENDS products. *See, e.g.*, CX-0377.54

⁶⁸ The cases cited by Reynolds are not on point. *See* CIB at 140. In *Douglas Dynamics*, [REDACTED], there was *inter alia* no license to the patents at issue. In *Fred Hutchinson Cancer Research Center*, 2011 WL 1119565 (E.D. Va. Mar. 1, 2011), the defendant did not "refute any of the evidence Plaintiffs presented to establish irreparable harm." *Id.* at *5.

⁶⁹ Ms. Mras stated that Reynolds' "foundational patent is really what unlocked the market," and referenced "decades working on innovation within the R&D functions," and referenced the VUSE products as a "core component of that." Tr. (Mras) at 54:1-13. Ms. Mras testified that the VUSE Solo, Ciro, Vibe, and Alto products were launched in 2013, 2016, 2017, and 2018. *See* Tr. (Mras) at 58:2-59:4; CDX-0002C.8 (and documents cited therein).

(“[Director King]: We do want to make it clear though, when we follow the science that the top two brands used among kids are Chinese manufacturers. But number three and four are domestic.”).⁷⁰

Moreover, while Reynolds relies heavily on Senator Durbin’s comment regarding “Big Tobacco” at that hearing (*see* CIB at 134), the full context of the hearing does not show persuasive support for Reynold’s position. As an initial matter, a single statement by a senator at a hearing is not persuasive evidence of irreparable reputational harm. Further, Senator Durbin immediately followed that statement with a description of activities by JUUL—[REDACTED] [REDACTED]. *See* CX-0377.3 (“[i]t started with Juul, backed by a \$13 billion from tobacco giant Altria”). [REDACTED] weighs against Reynolds’ claim of reputational harm based on Senator Durbin’s comments. *See* RIB at 67-69. In addition, at that hearing, the Director of the Center for Tobacco Products at the FDA testified that “there are several big tobacco entities that are manufacturing e-cigarettes with flavors that have been documented to appeal to kids.” CX-0377.30. This testimony, which is consistent with data showing the use of menthol flavors by youth (*see* RX-0052.2⁷¹, RX-0178, CX-1142)—as well as evidence concerning the availability of menthol flavors from Reynolds, JUUL, and Njoy—also weighs against Reynolds’ reputational harm arguments.⁷² The same

⁷⁰ Other statements at the hearing similarly differentiate among ENDS products. *See* CX-0377.22 (“[Sen. Tillis]: “[I]t seems to me that a lot of these products that were up there, are not being dumped on the market by Big Tobacco.”); *id.* at 45 (“[Sen. Lee]: My concern here is that the federal government has said that it wants to be tough on tobacco. And in saying that it’s issued a bunch of regulations for legal approval, only then to sit on those applications for legal products in the US, produced by US companies, while turning a blind eye to illegal Chinese imports.”).

⁷¹ 28.2% of high school e-cigarette users and 16.2% of middle school e-cigarette users in this survey reported using menthol flavored e-cigarettes in the past 30 days.

⁷² Ms. Mras testified that menthol flavors are available from JUUL and Njoy, as well as through the VUSE product. *See* Tr. (Mras) at 75:20-25; *see also* Tr. (Mooney) at 368:12-14; *id.* at 363:18-21.

record reveals that Reynolds itself was invited to participate in the hearing but declined to participate. *Id.* at 56 (“[Sen. Durbin]: I’d also like to note for the record that we invited e-cigarette manufacturers, Altria, R.J. Reynolds, Japan Tobacco International and Miracle Shenzhen Technology to send representatives to testify at the hearing. None of them agreed to do so.”).

Finally, Reynolds’ arguments and evidence rely repeatedly on Reynolds’ distinction between the alleged illegal and improper acts by Respondents and Reynolds’ asserted lawful activities. *See* CIB at 124-133. However, in expressing FDA’s view that the Commission should not initiate an investigation into certain Reynolds’ Lanham Act claims based on false representations of FDA authorization, the FDA stated that “nearly every ENDS product now on the market (including at least one of Complainant’s own) lacks FDA authorization, and thus is not lawful.” *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID 807175 (FDA Letter) (Oct. 27, 2023). The FDA further opposed the institution of claims before the Commission “where the claims seek to enforce the FDCA.” *Id.* The Commission agreed, finding that would be improper for the Commission to “resolve whether the accused products are not ‘allowed’ and should be excluded from the market.” EDIS Doc. ID 810442. To the extent Reynolds attempts to have the issue of legality and illegality of Reynolds’ and Respondents’ ENDS products addressed by the Commission here, this similarly seeks action by the

Testimony at the hearing showed that VUSE products have been among the top brands used by youth. *See* RIB at 142-43; RRB at 58; Tr. (Mras) at 86:10-17, 87:19-23, 88:3-6. Reynolds continues to sell menthol-flavored VUSE under an administrative stay after the FDA issued a marketing denial order for menthol-flavored VUSE. *See* Tr. (Mras) at 79:22-80:17; *see also* CX-0895C.94 (relied upon by Reynolds, CIB at 137) (“According to FDA, such data is needed to overcome the ‘known risk’ that flavors, including menthol, pose to youth.”).

Commission that improperly overlaps with the FDA’s authority to determine which vaping products are “allowed.” *See generally* RRB at 52-55.⁷³

Accordingly, Reynolds has not shown persuasive evidence of irreparable reputational harm.

B. Lost Sales and Market Share

Reynolds contends that “it has lost billions in lost sales and market share” as the disposables portion of the vapor market has grown. CIB at 140 (quoting Tr. (Mras) at 55:18-21). Reynolds, relying on data presented by Mr. Ferris and Mr. Mooney, contends that the RCS market was growing at double-digit rates from 2016 to 2019, until “2020 when the market suffered a jolt because Reynolds removed flavors from the market in compliance with FDA’s guidance.” CIB at 141 (citing Tr. (Ferris) at 114:2-13; CX-0393C; CDX-0005C.9; Tr. (Mooney) at 305:5-25). Reynolds also contends that “real world data” from Louisiana’s enforcement of a registry that removed Respondents’ Accused Products from the market shows [REDACTED] [REDACTED] CIB at 142 (citing Tr. (Mooney) at 310:2-15; CDX-0005C.18). Reynolds contends that internal Reynolds’ analysis estimates that [REDACTED] [REDACTED] CIB at 142-43 (citing Tr. (Mooney) at 308:20-309:5; CDX-0005C.14-15 (and exhibits cited therein)). Reynolds contends

⁷³ Reynolds argues that the FDA did not ask the Commission to decline institution here. *See* CRB at 51. However, Reynolds’ patent infringement claim (unlike the Authorization Claims in 1381) implicates multiple issues besides whether Respondents’ products are authorized or allowed for sale, including the substantive issues of patent infringement. There is no impediment to the Commission’s consideration of those issues. Reynolds also argues that the FDA “issued an MGO for tobacco-flavored VUSE Alto on July 18, 2024.” *Id.* at 51. This does not obviate testimony provided in September 2024 that there is a marketing denial order, which has been administratively stayed, for menthol-flavored VUSE. *See* Tr. (Mras) at 79:22-80:17.

that it would capture [REDACTED] of these sales. Tr. (Ferris) at 114:14-20. Reynolds also identifies the reallocation of [REDACTED] in marketing to enforcement efforts, and asserts that “Reynolds will never be able to quantify the loss of sales growth and market share that it suffered because [REDACTED] [REDACTED] CIB at 143 (citing Tr. (Ferris) at 124:17-125:8).

Respondents, in opposition, contend that Reynolds has not substantiated its claims of lost market share. RIB at 120. Respondents argue that the Accused Products and DI Products are not “close competitors,” as they operate in different categories of the ENDS market. RIB at 121 (citing Tr. (Ferris) at 110:2-11). Respondents also argues that consumer vape preferences depend on a number of factors, and Reynolds has not shown that it would capture sales of the Accused Products. Respondents identify flavor, convenience, higher e-liquid volumes, price, and sales channels as differentiating factors between the Accused Products and DI Products that drive consumer preference. RIB at 121-122 (citing Tr. (McDuff) at 546:5-19; Tr. (Mooney) at 362:21-24, 362:25-363:3; RDX-0401X.9 (citing to RX-0038.36); Tr. (Mooney) at 365:11-12); RRB at 60. Respondents argue that, [REDACTED]

[REDACTED]

RIB at 123 (citing Tr. (Mooney) at 383:9-10; CDX-0005C.17; CX-0325C); RRB at 61.

Respondents also point out that only a subset of products in the ENDS market are at issue in the investigation, but Reynolds’ evidence is directed to total bans on disposable ENDS productss.

RIB at 124. Respondents additionally argue that the same demand drivers—flavor, convenience, e-liquid volume, price, and sales channel—are unclaimed in the ’202 patent, such that Reynolds has failed to establish a causal nexus for its alleged injury. RIB at 135-137 (citing *Ethicon Endo-*

Surgery, Inc. v. Covidien LP, 2017 WL 4392877, at *7 (D. Mass. Oct. 2, 2017) (existence of “various factors besides the patented [technology that] are responsible” for competitive harm demonstrates that irreparable harm did not “result[] from the alleged infringement” and that the nexus required for injunctive relief was not present)); RRB at 70. Respondents also contend that any damage as a result of lost sales is quantifiable, RIB at 120-21, including because Reynolds quantified similar harms in a co-pending investigation and because [REDACTED] [REDACTED]. RIB at 130-32, 127-30.

In response, Reynolds contends that despite being in different device categories, the DI Products and Accused Products directly compete. CRB at 57-58 (citing Tr. (Ferris) at 110:12-14; Tr. (Mooney) at 361:4-12). Reynolds also contends that the “existence of other competitors” in the marketplace does not undermine its claims of irreparable harm. CRB at 59 (citing *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011)).

In Staff’s view, “the evidence shows that the alleged lost market share/sales or price erosion harm from patent infringement, if any, does not justify a TEO. Complainants’ evidence, in the form of testimony from fact and expert witnesses, is simply too conclusory, unsubstantiated, fails to take into consideration market realities including market segments, drivers for consumer demand, lack of a nexus between the alleged harm and the alleged unfair trade practice, and Reynolds’ own behavior [REDACTED].” SIB at 47. Staff argues that Reynolds’ claims of lost sales and lost market share ignore the difference in format between the Accused Products and the DI Products and the existence of competing rechargeable closed system ENDS devices. Moreover, Staff submits that “the evidence simply does not support the conclusion that the popularity or growth of the Accused Products in the market has come about at the expense of the DI Products.” SIB at 48. Staff also contends that disposable

ENDS devices will remain on the market even if the Accused Products are subject to a temporary exclusion order. SIB at 48 n.11.

“Lost sales (without more) are presumed to be compensable through damages, so they do not require injunctive relief.” *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App’x 297, 301 (Fed. Cir. 2009); *see also id.* (“Thus, we find that, no matter how much evidence of lost revenue AMS presented, this evidence by itself could not support a finding of irreparable injury.”). The Federal Circuit has also explained that:

Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature.” *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). For example, a battery does not necessarily drive demand for a laptop merely because its removal would render the laptop ineffective as a portable computer. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1376 (Fed. Cir. 2012). If a particular patented battery, however, lasted significantly longer than other batteries and its removal would decrease demand for the laptop, it may be reasonable to conclude the patented battery drives consumer demand for the laptop. *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364–65 (Fed. Cir. 2013).

Natera, 106 F. 4th 1369, 1379-80 (Fed. Cir. 2024). On the other hand, evidence of a two-supplier market and unwillingness to license the asserted patent support a finding of irreparable economic harm. *Id.* at 1378-79. On the current record, the undersigned finds that Reynolds has not sufficiently substantiated a likelihood of the asserted economic harms.

As discussed *supra* Part I.C, there are only 51 Accused Products at issue in this temporary enforcement proceeding for which Reynolds has provided substantive infringement evidence. This does not represent the entirety of the market of non-Reynolds ENDS devices, the entirety of the market for disposable ENDS devices,⁷⁴ or even all of Respondents’ allegedly

⁷⁴ The parties presented conflicting expert testimony as to Respondents’ market share. *See, e.g.*, Tr. (Mooney) at 319:20-320:3 (Respondents’ market share is “over 88 percent in some ways when you measure it”); Tr. (McDuff) at 644:18-645:5 (testifying that he believed Respondents’ market share was

infringing products. *See supra* Part I.C.2 (identifying Additional Accused Products for which Reynolds presented no evidence of infringement); Tr. (Mras) at 93:2-20 (identifying Blu and Njoy disposable products as not accused of infringement); Tr. (Mras) at 77:8-12 (identifying [REDACTED]); Tr. (McDuff) at 553:15-554:10; RX-0066C.18. Reynolds has not identified persuasive evidence that consumers would choose a DI Product if a temporary enforcement order is issued, as opposed to a disposable ENDS product not at issue in this proceeding, or a non-infringing (e.g., because it is licensed) or unaccused rechargeable closed system ENDS product offered by another provider, e.g., Njoy or Blu. *See SmartSky Networks*, 2024 WL 358136, at *4 (upholding finding of no irreparable harm because no evidence that “any consumers who chose [an Accused Product] would have chosen [the DI Product] rather than, for example, [an] unaccused [] product or a non-infringing product offered by another provider”).

Moreover, evidence in the record shows that features other than those claimed in the ’202 patent drive consumer demand, including the ENDS device category, sales channel, flavor, price, and volume of e-liquid. *See, e.g.*, Tr. (Mooney) at 362:21-363:6; Tr. (McDuff) at 12-14 (“I saw evidence of flavor, convenience and volume, sales channel, and pricing as being important.”), 547:6-4 (citing internal Reynolds documents identifying “flavor as the top purchase decision factor for all vapor products, followed by price”). Mr. Ferris, testifying on behalf of Reynolds, explicitly identified price and flavor as “why Reynolds is losing market share to disposables.”⁷⁵

“in the ballpark of 60 percent” and that he hasn’t “seen data to support a figure [as] high” as 88 percent”); RIB at 124.

⁷⁵ Additionally, as with Reynolds’ alleged reputational harm, much of the alleged harm—including loss of market share—predates the issuance of the ’202 patent on March 12, 2024. *See* Tr. (Ferris) at 117:12-18 (“In 2020 was the de facto flavor ban from the FDA. So VUSE pulled non-tobacco, non-menthol flavors out of the market, and the RCS system as a whole saw a significant decline that year. At the same time as

Tr. (Ferris) at 122:19-14. This evidence weighs against Reynolds' claim that lost market share and lost sales are tied to infringement of the '202 patent. Tr. (McDuff) at 549:14-19 (testifying that these are "differentiated products where demand does not switch completely fluidly between the two products").⁷⁶

Reynolds' evidence, moreover, is largely focused on the impact of removing all flavored products or all disposable ENDS devices from the market. *See, e.g.*, CX-0325C (examining impact of a "total flavor ban"); CDX-0005C.18 (examining impact of taking all disposables off the market). That is not the same as excluding the subset of Respondents' allegedly infringing products from the market (as requested by Reynolds, *see* CIB at 169-70). *See generally* RIB at 124 (citing evidence that "some flavored disposable ENDS products would remain on the market regardless of whether a TEO is entered"); SIB at 48 n.11.⁷⁷ Moreover, even in the scenario of a total ban of flavors, the evidence suggests that [REDACTED]

the first year, there was a spike in the disposables volumes as they continued to offer flavors in the market post the de facto flavor ban from the FDA.").

⁷⁶ Reynolds has not presented evidence of particular advantages resulting from the claimed invention of the '202 patent that drive demand for the Accused Products. *See Apple Inc. v. Samsung Electronics Co., Ltd.*, 735 F.3d 1352, 1366 (Fed. Cir. 2013) ("the importance of a general feature of the type covered by a patent is typically insufficient to establish a causal nexus"). For example, Reynolds did not present any evidence of secondary considerations of non-obviousness that could be relevant to this issue. *See, e.g.*, Tr. (Alarcon) at 221:24-223:15 (agreeing that he did provide an opinion as to objective evidence of secondary considerations). The evidence of record—including from an expert retained by Reynolds in an *inter partes* review also involving the Takeuchi references—shows that ENDS devices were well-known prior to the '202 patent. *See, e.g.*, RX-0111 (Decl. of Robert Sturges) at ¶ 31 ("Electronic Cigarettes ('e-cigarettes') were well-known before April 2004. In fact, they have been well-known since at least the mid-1990s, as demonstrated by, for example, the Voges and Takeuchi references . . ."), ¶ 32 ("By April 14, 2004, a great deal was known about e-cigarettes and the variety of ways they could be designed."); Tr. (Alarcon) at 206:4-9 ("[Q]: My question is the first sentence. 'By April 14, 5 2004, a great deal was known about e-cigarettes and the variety of ways they could be designed.' Yes or no? Do you agree with that? [A.]: I don't -- I don't disagree with it. I take it on its face."); Tr. (Mooney) at 316:4-10 (equating ENDS products and e-cigarettes); Tr. (Dean) at 481:11-14 (testifying that he began working with ENDS devices in 2003). Accordingly, Reynolds' nexus argument that "[t]he primary basis of demand is consumers want a vaping product" (CIB at 150) is unpersuasive.

⁷⁷ Moreover, Reynolds has presented no evidence of infringement for many Respondents' products accused in the Complaint. *See* Part I.C.2 *supra*.

[REDACTED]. See, e.g., CX-0325C.12 [REDACTED]
 [REDACTED])⁷⁸; CDX-0005C.19 (same);
 Tr. (Mooney) at 382:10-383:12 [REDACTED]
 [REDACTED]). At best, the evidence suggests only that “some
 portion” of sales of the DI Products may be lost to disposable ENDS devices. Tr. (Mooney) at
 383:4-6. The evidence provides too attenuated of a connection between the alleged lost sales of
 the DI Products and Respondents’ products and is too speculative to support a finding of
 irreparable harm on this record. See *SmartSky Networks*, 2024 WL 358136, at *4; *Abbott Labs v.*
Andrx Pharm., Inc., 452 F.3d 1331, 1347-48 (“potential lost sales” alone does not establish
 irreparable harm).⁷⁹

Further, the undersigned agrees that Reynolds has not shown that asserted harms related
 to lost market share and lost sales are not compensable with monetary damages. *Automated*
Merch. Sys., 357 F. App’x at 301 (“The burden is now on the patentee to demonstrate that its
 potential losses cannot be compensated by monetary damages.”). Evidence from internal
 Reynolds analyses and an analysis submitted in a co-pending investigation involving many of the
 same DI Products and Accused Products indicate that the economic harms are quantifiable. See

⁷⁸ Reynolds’ attempt to cast this evidence as “four-year old data that does not reflect current market
 share,” CRB at 59, is unpersuasive, as Mr. Mooney relied upon this same data. Tr. (Mooney) at 309:9-
 310:1.

⁷⁹ Reynolds also referenced [REDACTED] and [REDACTED] internal analyses that [REDACTED]
 [REDACTED] See CDX-00005C.15. The analysis
 is as to [REDACTED] and not specific to Reynolds products or
 specific to removal of Respondents’ disposable ENDS devices. As discussed, the evidence does not
 persuasively show that consumers would choose the VUSE DI Products as opposed to non-infringing
 products, non-accused products, or Respondents’ accused products for which Reynolds did not present an
 infringement analysis, and there is too attenuated of a connection between the alleged lost sales of the DI
 Products and Respondents’ products. See *supra*. Respondents also point out that the analysis are for 2027,
 RIB at 124-25, and Reynolds has not explained how a 2027 market analysis should apply to an analysis of
 irreparable harm in 2024 and 2025.

RX-0164C.144 (Herrington Report submitted in 1381 Investigation [REDACTED])

[REDACTED]),⁸⁰ 37 (identifying the VUSE Alto, VUSE Ciro, VUSE Solo, and VUSE Vibe as the “VUSE DI Products”); Tr. (Mooney) at 354:21-24; Tr. (Mooney) at 350:20-351:6.

Nor has Reynolds substantiated its argument that Respondents would be unable to satisfy a monetary judgment. Reynolds contends that “if Respondents stop selling their illegal products—because a TEO issues or FDA successfully enforces an import ban—Respondents may go out of business and be unable to pay damages for past infringement.” CIB at 153. Reynolds’ argument is circular (*e.g.*, that a temporary exclusion order may drive Respondents out of business is not evidence that Respondents could not satisfy a monetary judgment in the absence of a temporary enforcement order), speculative, and unsupported by citation to any evidence. Respondents have retained counsel and experts, and are full participants in the present investigation. There is no persuasive evidence of Respondents’ current inability to satisfy a money judgment.⁸¹

Additionally, [REDACTED] weighs against a finding that the alleged damages are not compensable. *See, e.g., Nichia Corp. v.*

⁸⁰ Reynolds did not seek a TEO in the 1381 Investigation. *See* Tr. (Mooney) at 357:15-17.

⁸¹ This distinguishes the present investigation from the cases cited by Reynolds. *See, e.g., Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1154 (Fed. Cir. 2011) (finding likely inability to satisfy a judgment based on analysis that the alleged infringer “posed a ‘[m]oderate risk of severe financial stress, such a bankruptcy, over the next 12 months’ and fell within the 49th percentile nationally in the category of ‘Financial Stress,’” and public filings indicating that the infringers’ parent company had recently taken out a substantial loan); *In re Est. of Ferdinand Marcos, Hum. Rts. Litig.*, 25 F.3d 1467, 1480 (9th Cir. 1994) (upholding preliminary injunction, in part, because evidence that the current assets of the subject estate were less than a likely judgment and evidence that the executors of the estate had twice been enjoined from transferring or secreting assets).

Everlight Americas, Inc., 855 F.3d 1328, 1343 (Fed. Cir. 2017) (holding that evidence of licenses to “significant competitors” supported a finding that patentee had failed to establish that it would suffer irreparable harm in the absence of an injunction). Here, Reynolds [REDACTED] [REDACTED] RX-0070C. The [REDACTED] [REDACTED].⁸² Tr. (McDuff) at 560:14-19; Tr. (Mras) at 77:8-12 (“[Q]: Ms. Mras, RJR, in fact, [REDACTED] [REDACTED] Isn’t that right? [A]: Yes, for the most part.”); Tr. (Mras) at 75:16-22 (confirming that JUUL and Njoy are the two largest pod-based rechargeable closed system vape brands and competitors to VUSE in the vapor category); Tr. (Ferris) at 127:21-25. Reynolds has also [REDACTED] [REDACTED]. See, e.g., CIB at 164 (identifying [REDACTED] [REDACTED]);⁸³ Tr. (McDuff) at 561:3-; JX-0008C.180; RDX-0401C.29.⁸⁴

Accordingly, Reynolds has not shown persuasive evidence of irreparable harm as a result of lost sales or lost market share.

⁸² Reynolds’ [REDACTED] CRB at 72, is unpersuasive and not supported by the record.

[REDACTED] Testimony by Reynolds’ employees establishes that [REDACTED] Tr. (Mras) at 75:16-22.; Tr. (Ferris) at 141:1-13.

⁸³ Reynolds attempts to distinguish the [REDACTED] CRB at 73; however, Reynolds also identifies [REDACTED] CIB at 164.

⁸⁴ The [REDACTED] differentiate the present case from *Robert Bosch*, cited by Reynolds, CRB at 59. Compare Tr. (Mras) at 93:16-20 (“Q. You haven’t accused [REDACTED] right? [A]: We have not, [REDACTED] with *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011) (finding that lack of two-player market did not weigh against a finding of irreparable harm where patentee “sought to enforce its rights against other infringers in the market” and “diligently pursued infringers”).

C. Price Erosion

Reynolds argues that the Accused Products are “underpricing the VUSE products by an average of [REDACTED] per milliliter.” CIB at 144 (citing Tr. (Mooney) at 310:19-311:4; CDX-0005C.19 (and exhibits cited therein). Reynolds contends that Respondents are able to underprice because they have not had to invest in research and development and because they have not invested in the PMTA process at the same “magnitude” as Reynolds. CIB at 144. Relying on Mr. Ferris’ testimony, Reynolds contends that [REDACTED]

[REDACTED]

[REDACTED] CIB at 144 (citing Tr. (Ferris) at 126:12-127:20). Reynolds submits, again relying on Mr. Ferris, that:

[REDACTED]

CIB at 145 (citing Tr. (Ferris) at 128:3-13). Reynolds argues that Dr. McDuff’s evidence showing [REDACTED] for VUSE products “have no basis in fact and should be disregarded.” CIB at 145.

Respondents argue that Reynolds [REDACTED] for the VUSE products, including after the Accused Products were on the market, and that Ms. Mras testified that [REDACTED]. RIB at 125-26. Respondents also argue that [REDACTED] is not “genuine price erosion.” RIB at 126. Respondents also contend that because many competing products would remain on the market in the event of a temporary exclusion order, there is no evidence that maintaining the status quo would have any permanent impact on Reynolds’ pricing power. RIB at 127. Respondents also argue, as they did with respect to lost

sales and lost market share, that any price erosion damages are readily quantifiable and that Reynolds' [REDACTED] undermine claims that economic damages are irreparable. RIB at 126-32.

In response, Reynolds contends that price erosion is not limited to scenarios in which a patentee is forced to lower prices, but may also be found when a patentee can no longer “maintain its premium pricing.” CRB at 62 (citing *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012)). Reynolds also contests Respondents’ arguments regarding whether the alleged economic harms are irreparable for the same reasons as discussed with respect to lost sales and lost market share.

In Staff’s view, “despite Reynolds’ claims of price erosion, Ms. Mras admitted that Reynolds has [REDACTED]

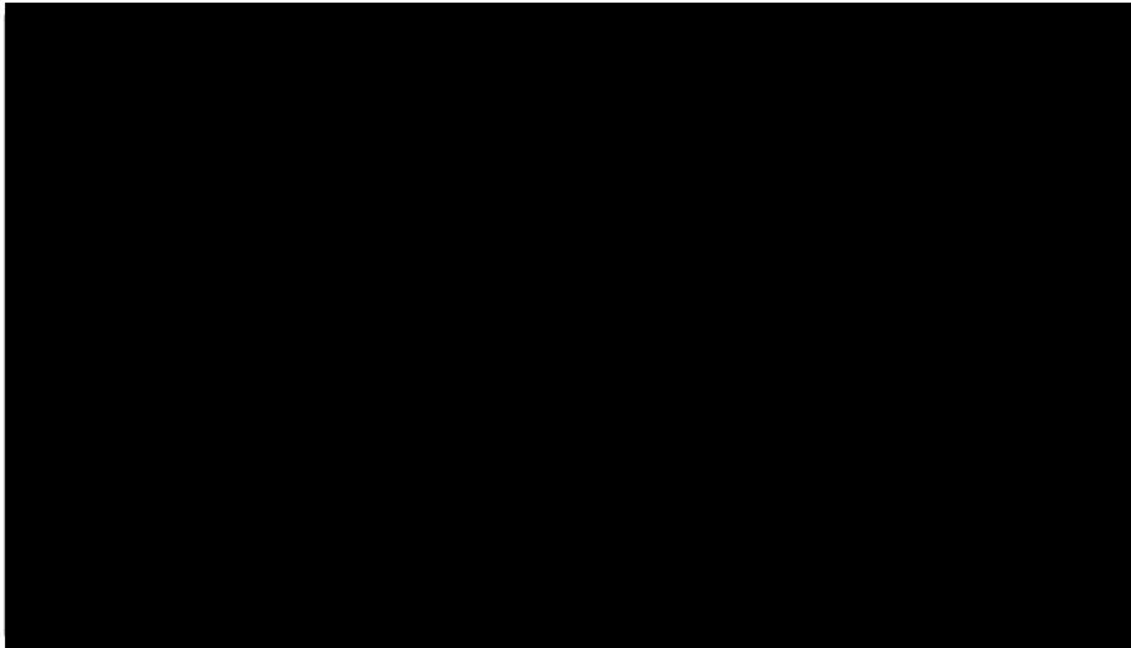
[REDACTED]

[REDACTED] SIB at 49 (citing Tr. (Mras) at 81:24-84:7).

In view of the evidence of record and arguments of record, the undersigned finds that Reynolds has not substantiated its allegations of irreparable harm as a result of price erosion.

The parties presented contradictory evidence on price erosion. Reynolds presented testimony from Mr. Ferris that [REDACTED] and testimony from Mr. Mooney that Respondents’ Accused Products were less expensive than the DI Products. *See, e.g.*, Tr. (Ferris) at 126:21-23; Tr. (Mooney) at 310:16-311:6. Respondents’ expert, Dr. McDuff, however, presented evidence that the retail price of the DI Products [REDACTED]

[REDACTED]



RDX-0401C.25, 26 (similar, on a per-milliliter basis); Tr. (McDuff) at 557:1-558:18; RX-0028C (identifying a price per milliliter of VUSE DI Products of [REDACTED] in first half of 2023 and a price per milliliter of [REDACTED] in the first half of 2024). Although Reynolds contends that Dr. McDuff's analysis "has no basis in fact," CIB at 145, that argument is unpersuasive, as the source of Dr. McDuff's data is a Reynolds document. *See* RX-0028C (citing to RJRDISP_002395800 at tab "National," which is JX-0007C). On this record—and without persuasive explanation from Reynolds as to the discrepancies between Mr. Ferris' testimony and its pricing data⁸⁵—Reynolds has not shown that Dr. McDuff's testimony should be discounted.

Additionally, many of the same issues as discussed with respect to alleged reputational harm and lost sales apply equally to Reynolds' price erosion allegations. The alleged harm—[REDACTED]
[REDACTED]—predates the issuance of the '202 patent. *See, e.g.*, Tr. (Ferris) at

⁸⁵ Ms. Mras' testimony regarding promotional spend as to "certain SKUs within the portfolio" did not identify the products to which she referred, when such spend occurred, the extent of the price decrease, or explain how such promotional spending is consistent with the retail pricing data presented by Dr. McDuff. Tr. (Mras) at 82:24-83:11. On this record, her testimony is insufficient to carry Reynolds' burden to show price erosion.

126:21-23 [REDACTED]; Tr. (Ferris) at 128:3-13 (referencing need to [REDACTED] Reynolds has also failed to establish that the alleged price erosion is related to sales of Respondents' Accused Products, and not to non-infringing products, non-accused products, licensed products, or even Respondents' accused products for which Reynolds failed to present evidence of infringement. *See supra* Part I.C.; Part X.B. Mr. Ferris, for example, identified that [REDACTED] CDX-0003C.24 [REDACTED] Tr. (Ferris) at 141:3-13 (agreeing that Reynolds is [REDACTED] .

Moreover, as discussed above, the undersigned finds that Reynolds has failed to meet its burden to show that—even if taken as true—its claims of lost sales and lost market share are not compensable with monetary damages. Substantially the same analysis applies to Reynolds' alleged harms from price erosion, including because Reynolds' [REDACTED] . *See, e.g., Nichia*, 855 F.3d at 1343 (holding that evidence of licenses to “significant competitors” supported a finding that patentee had failed to establish that it would suffer irreparable harm in the absence of an injunction).

D. Regulatory Delays

Reynolds' final category of alleged irreparable harm is distraction of the FDA; Reynolds argues that Respondents' “sales of illegal youth-oriented products and filing of faux placeholder PMTAs has and continues to require the FDA to divert significant time and resources to enforcement and screening of deficient PMTAs.” CIB at 145-46. Reynolds contends that it has

been irreparably harmed in its “efforts to get its cutting-edge technology into the hands of the adult consumers who would benefit from access to these products.” CIB at 146; CRB at 63.

Reynolds also argues that “as a result of Respondents’ illegal youth-directed products, FDA has issued blanket denials of all flavored products, even meritorious applications for adult-oriented flavors, such as the Mixed Berry Alto pod.” CIB at 147; CRB at 65. Reynolds also contends that “[t]he grant of a TEO and CDOs would allow these resources to shift back to reviewing meritorious PMTAs and to focus on policies that would selectively permit marketing of responsible flavors rather than the de facto ban it imposed because it was spread too thin to dig into the science more carefully.” CIB at 147-48.

Respondents contend that attempts to blame Respondents for delays and backlog at the FDA is unsupported, speculative, and “completely divorced from [Reynolds’] claim of infringement of the ’202 patent.” RIB at 143. Respondents argue that Reynolds has no evidence that Respondents’ PMTAs were facially defective or submitted in bad faith, and that the fact that the FDA rejected PMTAs is not evidence of bad faith, as Reynolds has also had PMTAs rejected. RIB at 144; RRB at 72. Respondents also contend that there is no evidence tying an alleged PMTA backlog to Respondents or to alleged infringement of the ’202 patent, including because “the overwhelming surge in PMTA applications” occurred in 2020 and 2021, well before the ’202 patent issued. RIB at 145; RRB at 71. Respondents also argue that a temporary exclusion order would have no effect on the PMTA process or the FDA, as a temporary exclusion order would not prohibit FDA regulatory filings. RIB at 145 (citing *Murthy v. Missouri*, 144 S. Ct. 1972, 1995-96 (2024) (denying injunctive relief where injunction would not redress the alleged injury)); RRB at 73. Respondents further argue that there is no evidentiary support for Reynolds’ theory that Respondents “have somehow influenced the substance of FDA review decisions in a

manner that harms [Reynolds].” RIB at 146-47. Respondents argue that the theory of a “biased and irrational FDA” depends on a theory that “rather than properly apply the statutory criteria and its expertise, the agency has been biased by the Accused Products against all non-tobacco flavored ENDS products.” RIB at 147. Respondents argue that it was rechargeable closed system ENDS devices like the DI Products and JUUL—rather than disposables—that drove the initial “flavor ban” in 2020. RIB at 147. Regardless, Respondents argue, “the FDA’s years-old position on flavor in ENDS products cannot possibly be attributed to Respondents’ alleged infringement of a patent that issued in March 2024.” RIB at 147-48; RRB at 73.

In response, Reynolds argues that the alleged harm is redressable because “[t]his harm can be stopped by excluding the infringing products so that FDA can devote its resources to individualized review of serious PMTAs.” CRB at 65.

In Staff’s view, “the alleged harm through delays related to FDA marketing authorization approval process for the Reynolds products is not tied, through credible evidence, to the alleged patent infringement for which Reynolds is seeking a remedy under Section 337.” SIB at 54. Staff submits that the data relied upon by Dr. Murrelle is not specific to disposable ENDS devices or to Respondents. SIB at 54. Staff also argues that “the evidence shows that the PMTA filings at the FDA have been on a downward trend in recent years” and are “substantially declining.” SIB at 54 (citing Tr. (Murrelle) at 426:21-427:21).

In view of the evidence and arguments of record, the undersigned finds that Reynolds has not carried its burden to substantiate these harms.

As discussed above in connection with Reynolds’ claims of reputational harm, Reynolds’ arguments and evidence rely on Reynolds’ distinctions between alleged illegal and improper acts and filings by Respondents and Reynolds’ asserted lawful or “meritorious” activities and filings.

See, e.g., CIB at 147 (“[A]s a result of Respondents’ illegal youth-directed products, FDA has issued blanket denials of all flavored products, even meritorious applications for adult-oriented flavors, such as the Mixed Berry Alto pod.”). The FDA, however, has previously stated that “nearly every ENDS product now on the market (including at least one of Complainant’s own) lacks FDA authorization, and thus is not lawful.” *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID 807175 (FDA Letter) (Oct. 27, 2023); *see also* EDIS Doc. ID 810442 (finding that would be improper for the Commission to “resolve whether the accused products are not ‘allowed’ and should be excluded from the market”). To the extent Reynolds attempts to have the issue of legality and illegality of Reynolds’ and Respondents’ ENDS products or the merits of Reynolds’ and Respondents’ PMTA filings addressed by the Commission here, this similarly seeks action by the Commission that improperly overlaps with the FDA’s authority to determine which vaping products are “allowed,” or which PMTAs are “meritorious,” or which flavors are “adult-oriented.” *See generally* RRB at 52-55.

Moreover, Reynolds has failed to tie the alleged harms to infringement of the ’202 patent. Delays from PMTA backlogs substantially predate the issuance of the ’202 patent, and the evidence suggests the backlogs have substantially decreased since the issuance of the ’202 patent. *See, e.g.*, Tr. (Murrelle) at 426:14-427:21 (testifying that of the 26 million PMTAs filed, 8 million were filed in 2020 and 17 million were filed in 2021); CX-0628 (same); CX-0005C (Murrelle WS) at Q36; CX-0377.18 (Director of the Center for Tobacco Products representing that the FDA is “99 percent through” the PMTA backlog as of June 12, 2024). Reynolds has also failed to establish that the alleged delays at the FDA are related to Respondents’ Accused Products, and not to non-infringing products (such as licensed products or open system ENDS devices), non-accused products, or even Respondents’ accused products for which Reynolds

failed to present evidence of infringement. *See supra* Part I.C.; Part X.B. Dr. Murrelle, for example, conceded that the PMTA data upon which he relied did not break out filed PMTAs by ENDS device categories, by company, or by products. Tr. (Murrelle) at 424:6-426:10. Similarly, the evidence regarding the FDA’s refusal to approve flavored ENDS devices—including testimony from Reynolds’ own expert—fails to show that it is related to Respondents’ alleged infringement of the ’202 patent. For example, Dr. Murrelle testified that there was “an exponential rise in sales” which raised public health concerns among “youth and young adults” “just after the JUUL e-cigarettes entered the market” and that experts attributed JUUL’s popularity to its flavored pods and youth-targeted marketing. CX-0005C (Murrelle WS) at Q42-Q44. The record contains other evidence suggesting that the FDA’s increased enforcement efforts predate any alleged infringement by Respondents, and are in part traceable to JUUL, [REDACTED]. *See, e.g.*, CX-0377.3 (“[Senator Durbin]: It started with Juul, backed by a \$13 billion from tobacco giant Altria in a partnership which the American Heart Association has characterized as a match made in tobacco heaven. I would say tobacco hell. The company introduced flashy devices, kid friendly flavors and advertisements featuring young, attractive people. That unleashed a wave of nicotine addiction that then FDA Commissioner, Scott Gottlieb described in 2018 as an epidemic with more than 5 million teens reported that they were using e-cigarettes.”); JX-0377.63 ([Executive Director of the Vapor Technology Association]: “youth vaping in the United States has dramatically resolved from the peak of the JUUL epidemic in 2019”).⁸⁶

* * *

⁸⁶ Moreover, because Reynolds has not shown that the alleged harms relating to regulatory enforcement are tied to alleged infringement of the ’202 patent, the remedy sought—a temporary enforcement order excluding infringing products—would have questionable remedial effect on these alleged harms.

Reynolds has, accordingly, failed to establish that it is likely to suffer irreparable harm if a temporary exclusion order is not granted, including because it has failed to establish a causal nexus between alleged infringement of the '202 patent and the alleged harms. Defects in Reynolds' claims of alleged irreparable harm include: (1) Reynolds' failure to sufficiently tie the alleged harm to Respondents or Respondents' Accused Products—as opposed to non-infringing products, non-accused products, licensed products, or Respondents' accused products for which Reynolds failed to introduce substantive evidence of infringement; (2) Reynolds' reliance on alleged harms that pre-date the issuance of the '202 patent on March 12, 2024;⁸⁷ (3) Reynolds' reliance on arguments as to which vaping products are “allowed,” or which PMTAs are “meritorious,” or which flavors are “adult-oriented”—all issues that improperly overlap with determinations within FDA purview; and (4) Reynolds' failure to substantiate claims that the economic harm is irreparable in view of [REDACTED] and calculation of damages in the same categories in a co-pending investigation.

XI. BALANCE OF EQUITIES AND THE PUBLIC INTEREST⁸⁸

In view of the above, a temporary exclusion order should not issue because Reynolds has not shown a likelihood of success on the merits and because Reynolds has failed to establish irreparable harm. In light of those conclusions, the remaining two factors are not material. *See Certain Composite Wear Components and Welding Products*, Inv. No. 337-TA-644, Comm'n Op., EDIS Doc. ID 444172, at 10 (Feb. 10, 2011) (“A preliminary injunction cannot be granted unless the movant establishes both of the first two factors, *i.e.*, likelihood of success on the

⁸⁷ Reynolds did not address the issue of timing of its allegations of harm vis a vis the issuance of the '202 patent. *See generally* CRB at 43-73.

⁸⁸ Pursuant to 19 C.F.R. § 210.66(a), this Initial Determination does not address the separate issue of public interest under 19 U.S.C. § 1337(e)(1).

merits and irreparable harm.”); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (same). However, to the extent Reynolds showed a likelihood of success on the merits, the current evidence of record indicates that the balance of the equities would be neutral and the public interest would weigh in favor of a temporary exclusion order.

As discussed above, a party seeking a preliminary injunction must also establish that “the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1369 (Fed. Cir. 2017). The district court must weigh the harm to the moving party if the injunction is not granted against the harm to the non-moving party if the injunction is granted. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). As to public interest, “although there exists a public interest in protecting rights secured by valid patents, the focus of the district court’s public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.” *Sulfentrazone*, EDIS Doc. ID 541146 at 121 (quoting *Hybritech*, 849 F.2d at 1458).

Reynolds claims that Respondents would “suffer no cognizable harm because they have no right to market and sell these products in the U.S.” CIB at 156. Reynolds argues that “[e]xcluding illegal products from the market that Respondents have no right to sell in the first place harms no one and benefits many by protecting both responsible competitors like Reynolds, and the public at large.” CIB at 157. Reynolds claims that it faces substantial hardship in being “forced to compete against products that incorporate and infringe its own patented invention” and that Reynolds is unlikely to be able to collect monetary damages. CIB at 158. Reynolds also argues that given the ’202 patent’s imminent expiration in October of 2026—only a few months after an exclusionary remedy would be expected to issue in the violation phase of the

investigation—tips the balance of hardships or supports a finding of irreparable harm. CIB at 159 (citing *Read Corp. v. Viper Int’l Ltd.*, 78 F.3d 605 (Fed. Cir. 1996)). As to public interest, Reynolds asserts that public policy favors the enforcement of patent rights, and that in addition, an “exclusion order that will not only vindicate Reynolds’s patent rights and protect the U.S. marketplace against unfair trade practices, but it will also serve the public interest by removing Respondents’ youth-targeted products. An exclusion order will support FDA’s and DOJ’s enforcement efforts to remove the illicit products from the market, and will free up resources for FDA to clear the PMTA backlog and bring new products to market that may be even more helpful in aiding smokers to quit.” CIB at 160-61.

Respondents, in opposition, argue that any purported harm to Reynolds from maintaining the status quo during the pendency of the investigation can be compensated through monetary damages, and that a temporary enforcement order would likely shut down Respondents’ businesses, including because they have small market share. RIB at 148; RIB at 150 (alleging that just two Respondent Accused Product brands have a market share over 3%); RRB at 74. Moreover, Respondents contend that the limited time remaining on the ’202 patent term is “a direct result of [Reynolds’] patent prosecution strategy.” RIB at 149. As to public interest, Respondents argue that public health benefits associated with a competitive e-cigarette market—as related to smoking cessation and harm reduction—outweigh the general interest in enforcing patent rights. RIB at 152-55.

Staff asserts that it is “presently of the view that the balance of equities tips in favor of Respondents,” including because of the size disparity of the parties and because Reynolds has not shown irreparable harm. SIB at 55-56. As to public interest, Staff submits that no evidence

was presented at the hearing as to a critical public interest, and thus this factor favors a temporary enforcement order.

In view of the evidence and arguments of record, the undersigned finds that the balance of equities (if Reynolds were to show likelihood of success on the merits) does not strongly favor either Reynolds or Respondents. Both Reynolds and Respondents presented evidence and arguments⁸⁹ as to equitable considerations. Reynolds contends that it will—because of the approaching expiration date—essentially lose its intellectual property enforcement rights in the ’202 patent without a temporary exclusion order, while Respondents contend that they may lose their businesses.⁹⁰ As discussed above, Reynolds has not shown that the Accused Products likely infringe the ’202 patent and thus this factor does not favor Reynolds. If Reynolds had made that showing, however, this factor would be neutral. *Cf. M-I LLC v. FPUSA, LLC*, 626 F. App’x 995, 999 (Fed. Cir. 2015) (concluding that “the district court did not err in finding that the balance of equities is neutral” where it “weighed M-I’s patent rights against FPUSA’s business concerns”).

As to the public interest, the evidence does not show a “critical public interest that would be injured by the grant of preliminary relief.” *Sulfentrazone*, EDIS Doc. ID 541146 at 121 (quoting *Hybritech*, 849 F.2d at 1458). Respondents have pointed to a public health need for e-cigarette availability to meet smoking cessation and harm reduction needs. RIB at 152-55. As discussed above, however, any temporary exclusion order would not cover non-accused products (e.g., Njoy or Blu products), non-infringing products (e.g., licensed products or open system

⁸⁹ Again, to the extent Reynolds attempts to have the issue of legality and illegality of Reynolds’ and Respondents’ ENDS products addressed by the Commission here, this seeks action by the Commission that improperly overlaps with the FDA’s authority.

⁹⁰ As discussed above, however, not all of Respondents’ products would necessarily be subject to a temporary exclusion order. *See supra* Part I.C.2. The lack of evidence as to the harm from a more limited temporary exclusion order weighs against a finding that the balance of equities favors Respondents.

ENDS devices), and Respondents' accused products for which Reynolds failed to introduce substantive evidence of infringement. Moreover, Reynolds introduced evidence of multiple other harm reduction options, including: Reynolds's DI Products; over a dozen ENDS manufactured by other companies that FDA has determined are appropriate for the protection of the public health; JUUL ENDS products, including [REDACTED]; heat-not-burn burn products like IQOS; smokeless tobacco (such as Red Man chewing tobacco, Grizzly or Kodiak); snus (such as Camel); oral tobacco and nicotine products (such as Velo, ZYN, and on!); and nicotine replacement therapies (such as Commit, Nicorette, and NicoDerm). CX-0005C (Murrelle WS) at Q67-Q70. Accordingly, to the extent Reynolds could show a likelihood of success on the merits, the undersigned finds that in the absence of a "critical public interest that would be injured by the grant of preliminary relief," the general public interest in the enforceability of patent rights would favor the grant of preliminary relief. *Sulfentrazone*, EDIS Doc. ID 541146 at 121 (quoting *Hybritech*, 849 F.2d at 1458).

XII. BONDING⁹¹

Section 337 provides that "[t]he Commission may require the complainant to post a bond as a prerequisite to the issuance of [a temporary relief] order under this subsection." 19 U.S.C. § 1337(e)(2). "In determining whether to require a bond as a prerequisite to the issuance of temporary relief, the Commission will be guided by practice under Rule 65 of the Federal Rules of Civil Procedure."⁹² 19 C.F.R. § 210.52(c); *see also* 19 C.F.R. § 210.68(a) ("In every

⁹¹ Pursuant to 19 C.F.R. § 210.66(a), this Initial Determination does not address the separate issues of "remedy, the public interest, and bonding by the respondents pursuant under sections 337(e)(1), (f)(1), and (j)(3) of the Tariff Act of 1930."

⁹² The parties cite to the Commission Opinion in *Certain Crystalline Cefadroxil Monohydrate* and discuss certain factors related to determining the appropriate rate for a complainant's bond. *See* CIB at 175; RRB at 80; SRB at 18; *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Op., 1991

investigation under this part involving a motion for temporary relief, the question of whether the complainant shall be required to post a bond as a prerequisite to the issuance of such relief shall be addressed by the parties, the presiding administrative law judge, and the Commission in the manner described in §§ 210.52, 210.59, 210.61, 210.62, and 210.66.”).

Federal Rule of Civil Procedure 65 states:

The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.

Fed. R. Civ. P. 65(c). “The amount of a bond is a determination that rests within the sound discretion of a trial court.” *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1385 (Fed. Cir. 2006) (internal citation omitted). “The party against whom a preliminary injunction is sought has the burden of establishing the amount of a bond necessary to secure against the wrongful issuance of the injunction.” *LEGO A/S v. ZURU Inc.*, 799 Fed. Appx. 823, 837-38 (Fed. Cir.

WL 790062, at *16 (Jan. 10, 1990). That opinion, however, cites to Commission Rule 210.24(e)(1)(iii) in place at the time, which stated that “[t]he factors the Commission will consider in determining whether to require a bond include the following: (A) The strength of the complainant's case; (B) Whether posting a bond would impose an undue hardship on the complainant; (C) Whether the respondent has responded to the motion for temporary relief (in the time and manner specified by paragraph (e)(9) of this section or by order of the Commission or the presiding administrative law judge); (D) Whether the respondent will be harmed by issuance of the temporary exclusion order sought by the complainant; and (E) Any other legal, equitable, or public interest consideration that is relevant to whether complainant should be required to post a bond as a condition precedent to obtaining temporary relief (including the question of whether the complainant is using the temporary relief proceedings, or is likely to use a temporary exclusion order, to harass the respondents or for some other improper purpose).” 19 C.F.R. § 210.24(e)(1)(iii), 53 Fed. Reg. 49130 (1988). However, as discussed above, current Commission Rule 210.52(c) states that “[i]n determining whether to require a bond as a prerequisite to the issuance of temporary relief, the Commission will be guided by practice under Rule 65 of the Federal Rules of Civil Procedure” 19 C.F.R. § 210.52(c); see also *Certain Sulfentrazone, Sulfentrazone Compositions & Processes for Making Sulfentrazone*, Inv. No. 337-TA-914, Initial Determination on Complainant’s Motion for Temporary Relief, EDIS Doc. ID 541146, at 123 (Aug. 12, 2014); *Certain Muzzle-Loading Firearms and Components Thereof*, Inv. No. 337-TA-777, Initial Determination on Complainant’s Motion for Temporary Relief, EDIS Doc. ID, at 60 (Aug. 31, 2011); *Certain Silicon Microphone Packages & Prods. Containing the Same*, Inv. No. 337-TA-695, Initial Determination on Complainant’s Motion for Temporary Relief, EDIS Doc. ID 422312, at 107 (Mar. 24, 2010).

2020) (internal citations omitted); *see also Int'l Equity Invs., Inc. v. Opportunity Equity Partners Ltd.*, 441 F.Supp.2d 552, 566 (S.D.N.Y. 2006) (“[T]he burden is on the party seeking security to establish a rational basis for the amount of the proposed bond.”). In addition, “a court is not required to order security in respect of claimed economic damages that are no more than speculative.” *Int'l Equity Invs.*, 441 F.Supp.2d at 566.

Respondents argue that issuing a TEO with no bond requirement would carry a high risk of wrongfully enjoining Respondents during this investigation, which they assert would have devastating consequences for their business. RRB at 80. Respondents contend that the evidence has shown that Reynolds should be required to post a bond in the amount that would likely be earned by Respondents over the time period they would be kept off the market during this investigation if a temporary exclusion order is granted from December 19, 2024 to November 24, 2024 (about 11 months). *Id.* at 81. Respondents submit that their expert, Dr. McDuff, estimated the bond amount using financial information provided by Respondents combined with market share data from Reynolds for the first half of 2024 to calibrate expected revenue and gross profits that Respondents are expected to earn during this time. *Id.* Respondents state that “Dr. McDuff applied a margin of [REDACTED] as a reasonable middle-ground baseline approximation based on the available data, with the understanding that there may be differing margins for different Respondents within the supply chain, and the overall profit across the supply chain may be even greater.” *Id.* Respondents assert that the available financial data show that they are expected to earn [REDACTED] in revenue from December 2024 to November 2025. *Id.* at 82. Thus, Respondents contend that applying estimated profit margins of [REDACTED] results in projected losses from being off the market, and a bond estimate, of [REDACTED], or [REDACTED] per day. *Id.*

In addition, Dr. McDuff performed a market-based approach for the bond value. *Id.* Respondents submit that using the total disposable vape market (\$5.16 billion per year in 2024), the 2024 market size, and projected growth rate of 11.2%, Dr. McDuff estimated the market size in 2025 as \$5.74 billion. *Id.* Respondents contend that subtracting brick and mortar retailer profits ([REDACTED] retailer share x [REDACTED] retailer margins = [REDACTED]) results in [REDACTED] in 2024 and [REDACTED] in 2025. *Id.* Respondents also submit that multiplying these values by Respondents' share of disposable sales ([REDACTED]) approximates Respondents' sales as [REDACTED] in 2024 and [REDACTED] in 2025. *Id.* In addition, Respondents contend that multiplying these values by Respondents' estimated gross margin ([REDACTED]) shows Respondents' profit as [REDACTED] in 2024 and [REDACTED] in 2025. *Id.* Respondents claim that multiplying these values by the estimated duration of the TEO in each year results in a bond of [REDACTED] in 2024 and in [REDACTED] in 2025. *Id.* Respondents therefore assert that these values yield approximately the same result as Dr. McDuff's first calculation. *Id.* Thus, Respondents argue that, in the event that temporary relief is granted, Reynolds should be required to post a bond of [REDACTED], or [REDACTED] per day during the TEO period.

Respondents also argue that Reynolds' proposed bond of zero (or \$1 million to \$2.5 million in the alternative) lacks merit and should be rejected because Reynolds is not likely to succeed on the merits, Reynolds can afford to post a bond, and the harm caused by any temporary relief would significantly hurt Respondents. *Id.* at 80. In addition, Respondents argue that Reynolds' assertion of the costs to litigate the remainder of this investigation is not based on reliable or credible evidence and fails to consider any damage to Respondents if temporary relief is wrongfully issued. *Id.* at 81.

Reynolds argues that it should not be required to pay any bond, or should at most, be required to post a minimal bond. CIB at 174. Reynolds contends that while the policy behind the bonding requirement is to deter complainants from filing frivolous motions for temporary relief or using temporary relief proceedings as a means of harassing respondents, “[t]his case is anything but frivolous.” *Id.* at 174-75. According to Reynolds, Respondents have failed to meet their burden to establish that a bond of [REDACTED] should be required. CRB at 88. Reynolds argues “[t]hat amount is entirely speculative, unreliable, grossly overstated, and contradicted by the record.” *Id.* Reynolds argues that Dr. McDuff admitted there was a lack of financial information across all Respondents and that he was never asked to talk to any Respondents other than Breeze about their financial information or to obtain their projected sales over the TEO period. *Id.* at 88-89. Reynolds contends that while Dr. McDuff identified three brands of Accused Products that could be removed from his calculations, he did not provide ways to account for defaulting Respondents who sell or manufacture an Accused Product but are not the only Respondent involved in the sale of that Accused Product. *Id.* at 89-90.

In addition, Reynolds asserts that Dr. McDuff only used financial data from Breeze – one of the 20 appearing Respondents. *Id.* at 90. Reynolds argues that Dr. McDuff’s analysis does not account for the fact that “(1) not all sales for the listed brands are made by the named Respondents, (2) his sales include sales that would be made by various defaulting Respondents; (3) many named Respondents have disclaimed sales of the Accused Products; (4) there are complex distribution chains and Respondents are not all at the same level of Breeze; and (5) not all brands are sold at the same price as Breeze.” *Id.* Moreover, Reynolds contends that record evidence shows that Respondents do not anticipate losing profits that Dr. McDuff calculates. *Id.*

at 92. Reynolds also submits that Dr. McDuff's analysis assumes that all brands are sold at the same price, when the evidence shows they are not. *Id.* at 93.

If a bond were required, Reynolds argues that it should be no more than \$1.2 million to \$2.5 million. *Id.* at 94. Reynolds asserts that its expert, Mr. Mooney, testified that a conservative measure of Respondents' incremental cost to litigate the temporary enforcement issues would be \$1.2 million to \$2.5 million, which is the average cost to litigate at the ITC for six months. *Id.*

Staff states that it does not believe that the filing of the instant motion for a TEO is frivolous as the totality of the circumstances may warrant some measure of a bond. SRB at 18. Staff, however, submits that Reynolds should not be required to post a bond because neither of the private parties have offered reliable bond calculations. *Id.* at 19. For example, Staff contends that several issues with Dr. McDuff's methodology render his bond calculation too speculative. *Id.* Staff asserts that the only actual revenue data that Dr. McDuff used came from Breeze. *Id.* Staff also notes that each of the Respondents fall on different points along the supply chain and have different profit margins, which Dr. McDuff acknowledged. *Id.* In addition, Staff contends that Dr. McDuff's calculations for "market share data is based on milliliter volume which means those shares of the market can in fact be different in terms of dollars of sales." *Id.* at 20. Staff also asserts that the evidence shows that different products are sold at different prices. *Id.* Lastly, Staff contends that Dr. McDuff used projected revenues by brand and not by respondent. *Id.* With respect to Mr. Mooney's methodology, Staff asserts that it is too speculative to be useful as a measure for a bond. *Id.* at 21.

Based on the submissions of the parties and review of the record evidence, the undersigned finds that Respondents have not met their burden to establish a reliable basis for the amount of their proposed bond in the event the Commission determines that Reynolds is entitled

to temporary relief. Under the circumstances presented, Dr. McDuff's bond calculation is speculative for several reasons. First, Dr. McDuff's calculation for Reynolds' bond is only based on financial data from Respondent Breeze.⁹³ *See* Tr. (McDuff) at 693:6-13, 707:10-14, 708:24-709:22 (acknowledging the lack of financial information across all Respondents), 710:23-711:21; RX-0035C; Tr. (Mooney) at 743:6-8. Because Dr. McDuff did not have financial data for most of the Respondents, he used market share data and Breeze financial data to "get an estimate of revenues for all of the brands" and "project that forward using growth rates." *See* Tr. (McDuff) at 695:5-19. The record evidence demonstrates, however, that while Dr. McDuff used market share data that was based on milliliter volume, brands could have different market shares depending on whether the shares were measured in volume or whether they were measured in dollars. *See* Tr. (McDuff) at 713:20-714:24. Further highlighting the issue with Dr. McDuff's sole reliance on Breeze's financial data, the record evidence shows that not all brands sell at the same price.⁹⁴ *See* Tr. (McDuff) at 716:11-25 (discussing, for example, [REDACTED] [REDACTED]); RX-28C; Tr. (Mooney) at 743:6-12. In addition, as Dr. McDuff acknowledged, Respondents in this investigation are on different points along the supply chain and "[t]here is different pricing along the supply chain." *See* Tr. (McDuff) at 709:23-710:22 (agreeing that generally, revenue generated for the sale of an accused product will be higher for a distributor than for a manufacturer); *see also* Tr. (Mooney) at 746:1-24; CDX-0014C.15.

⁹³ While Dr. McDuff's asserted [REDACTED] profit margin may have been a "middle ground" based on Respondents Breeze, Element Vape, and SV3, he acknowledged that he only had actual revenue data for Breeze. *See* Tr. (McDuff) at 696:11-18, 707:10-708:14, 708:24-709:22, 710:23-711:21.

⁹⁴ For example, Dr. McDuff acknowledged that Geek Bar is sold for less than Breeze and thus, he did not know for sure whether the estimate of lost profits for Geek Bar could be too high. *See* Tr. (McDuff) at 716:18-717:12.

Moreover, the market share data Dr. McDuff cites is not sufficiently reliable as it encompasses more than the TEO-Analyzed Accused Products.⁹⁵ *See supra* at Part I.C; RDX-0501C.3; Tr. (McDuff) at 728:11-13 (agreeing that his market share data included sales by defaulting Respondents), 722:19-21 (projected revenues are by brand, not by Accused Product or by Respondent). Dr. McDuff's bond calculation is based on projected revenues by brand, rather than by Respondent. *See* Tr. (McDuff) at 722:11-724:23; RDX-0501C.8. The record evidence, however, shows that there is not a one-to-one Respondent-to-brand correspondence in this investigation and thus, Dr. McDuff's calculation is too speculative to account for, *inter alia*, defaulting respondents or brands that are sold or manufactured by more than one respondent.⁹⁶ *See supra* at Part I.C.; RIB at 41 (identifying Additional Accused Products sold by "other or multiple respondents").

Despite substantial issues relating to Respondents' estimates, the evidence of record indicates that Respondents would likely suffer some harm in the event temporary relief were granted. *See supra* at Section XI. Therefore, in the event the Commission determines that Reynolds is entitled to temporary relief, the undersigned recommends a bond in the amount of \$2.5 million, which Reynolds does not dispute would be an appropriate bond under the circumstances. Mr. Mooney's alternative calculation determines Respondents' incremental cost

⁹⁵ That is, because Dr. McDuff calculated lost revenues for the entirety of a brand, it is overinclusive at least because it encompasses the Additional Accused Products for which Reynolds did not present substantive evidence of infringement. The Additional Accused Products—which would not be subject to a temporary exclusion order, *supra* Part I.C.2—for example, include fourteen Geek Bar brand products. *See* RIB at 41. But Dr. McDuff's calculations are based on sales of the entirety of the Geek Bar brand, or all Geek Bar products. *See* RDX-0501C.3.

⁹⁶ While Dr. McDuff testified that his calculation allowed flexibility because any brands could be removed, he did not testify that any Respondents could be removed. *See* Tr. (McDuff) at 697:14-698:17. Nor is Dr. McDuff's calculation flexible to permit removal of products, as opposed to brands.

to litigate at the ITC for six months, *i.e.*, the length of the TEO proceedings.⁹⁷ *See* Tr. (Mooney) at 750:22-751:18; CX-1192.8; CDX-0014C.20.

Accordingly, the undersigned recommends a bond in the amount of \$2.5 million be imposed on Reynolds in the event the Commission determines that Reynolds is entitled to temporary relief.

XIII. CONCLUSION

Based on the foregoing, and the record, it is the undersigned's initial determination that Complainants' Motion for Temporary Relief is DENIED. Complainants have not shown likelihood of success on the merits with respect to infringement of asserted claims 1, 4, 9, and 12 of the '202 patent; or with respect to invalidity of the asserted claims. In addition, Complainants have not persuasively shown irreparable harm in the event a temporary exclusion order is not issued.

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's initial determination. The pleadings of the parties filed with the Secretary, and the transcript of the pre-hearing conference and the hearing, as well as other exhibits, are not certified, since they are already in the Commission's possession in accordance with Commission rules.

Pursuant to Commission Rule 210.66, this initial determination shall become the determination of the Commission 30 calendar days after the 120-day deadline imposed by Commission Rule 210.66(a), unless the Commission modifies, reverses, or sets aside the Initial Determination in whole or part within that period.

⁹⁷ Under the circumstances, the undersigned finds Mr. Mooney's reliance on publicly available information regarding the cost of litigating at the ITC to be sufficient. Neither Respondents nor Staff provide any evidence challenging the reliability of that information. *See* RRB at 81; SRB at 21.

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.⁹⁸ The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

⁹⁸ Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).