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June 11, 2024

VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street S.W.
Washington, DC 20436

Re: Certain Disposable Vaporizer Devices and Components Thereof

Dear Secretary Barton:

In accordance with the Commission's Temporary Change to Filing Procedures dated March 16, 2020, Complainants, RAI Strategic Holdings, Inc. ("RAI"), R.J. Reynolds Vapor Company ("RJR"), R.J. Reynolds Tobacco Company ("RJRT"), and RAI Services Company ("RAISC") (collectively, "Reynolds") are e-filing the following documents in support of Complainants' request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as Amended:

1. A verified non-confidential Complaint with non-confidential exhibits and public versions of the confidential exhibits, pursuant to Commission Rule 210.8(a)(1)(i);
2. Copies of the Confidential Exhibits 3C, 105C, 123C, and 224C-227C pursuant to Commission Rule 210.8(a)(1)(ii) and 201.6(c);
3. A non-confidential Statement of Public Interest, pursuant to Commission Rule 210.8(b);
4. Certified copy of the asserted United States Patent Nos. 11,925,202 ("the '202 patent") listed as Exhibit 1 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(i);
5. Certified copy of the assignment for the '202 patent listed as Exhibit 2 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(ii);
6. Certified copy of the prosecution history for the '202 patent listed as Appendix A in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(c)(1);

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U.S. Patent No. 11,925,202

June 11, 2024

Page 2

7. Reference documents identified in the prosecution history of the '202 patent listed as Appendix B in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(c)(2);

8. Reynolds's Motion for Temporary Exclusion Order, Memorandum in Support, and with non-confidential exhibits, pursuant to Commission Rule 210.52; and

9. A letter of certification, pursuant to Commission Rules 201.6(b) and 210.5(d), requesting confidential treatment of information appearing in Confidential Exhibits 3C, 105C, 123C, and 224C-227C to the verified non-confidential Complaint and certain proprietary commercial and financial information in Reynolds's Motion for Temporary Exclusion Order evidencing its significant investments in the domestic industry and showing irreparable harm suffered from the infringing acts.

In addition, Reynolds has mailed the physical exhibits identified in the Complaint to the Commission, Attention Dockets.

Please contact me if you have any questions about this request. Thank you for your attention to this matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'DMM', is positioned above the printed name.

David M. Maiorana

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VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street S.W.
Washington, DC 20436

Re: Certain Disposable Vaporizer Devices and Components Thereof

Dear Secretary Barton:

Jones Day represents Complainants, RAI Strategic Holdings, Inc. (“RAI”), R.J. Reynolds Vapor Company (“RJRV”), R.J. Reynolds Tobacco Company (“RJRT”), and RAI Services Company (“RAISC”) (collectively, “Reynolds”) in its action pursuant to Section 337 of the Tariff Act of 1930, as Amended.

Pursuant to Commission Rules 201.6(b) and 210.5(d), Reynolds respectfully requests confidential treatment of Confidential Exhibits 3C, 105C, 123C, and 224C-227C to the Complaint.

The information for which confidential treatment is sought is propriety and not otherwise publicly available. Specifically, Confidential Exhibits 3C, 105C, 123C, and 224C-227C contain proprietary commercial information regarding the tobacco heating articles at issue, Reynolds’s patented technology and its infringement by the proposed Respondents, as well as Reynolds’s investments and employment activities made in furtherance of its domestic industry under 19 U.S.C. § 1337(a)(3).

Reynolds also requests confidential treatment of certain information in its Memorandum in Support of Motion for Temporary Relief Under 19 U.S.C. § 1337(e), which has been redacted from the public version of the Memorandum.

The information for which confidential treatment is sought is propriety and not otherwise publicly available. Specifically, the confidential information contains proprietary commercial and financial information regarding the tobacco heating articles at issue, Reynolds’s patented technology and its infringement by the proposed Respondents, as well as Reynolds’s investments and employment activities made in furtherance of its domestic industry under 19 U.S.C. §

June 11, 2024

Page 2

1337(a)(3) and other sensitive financial information regarding sales and market share disclosed in connection with Reynolds's showing of irreparable harm in support of its request for temporary relief.

The Commission has routinely held that this type of information qualifies as confidential business information pursuant to Rule 201.6(a) because:

- 1) It is not publicly available;
- 2) Unauthorized disclosure of such information could cause substantial harm to the competitive position of Reynolds; and
- 3) The disclosure of such information could impair the Commission's ability to obtain information necessary to perform its statutory function.

Please contact me if you have any questions about this request. Thank you for your attention to this matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. Maiorana', written in a cursive style.

David M. Maiorana

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June 11, 2024

Dear Proposed Respondent:

Re: *Certain Disposable Vaporizer Devices and Components Thereof*

19 C.F.R. 210.56 NOTICE

Notice is hereby given that the attached complaint and motion for temporary relief (non-confidential copies are on the enclosed flash drive) was filed with the U.S. International Trade Commission in Washington, D.C. on June 11, 2024. The filing of the complaint and motion will not institute an investigation on that date, however, nor will it begin the period for filing responses to the complaint and motion pursuant to 19 C.F.R. 210.13 and 210.59.

Upon receipt of the complaint, the Commission will examine the complaint for sufficiency and compliance with 19 C.F.R. 210.4, 210.5, 210.8, and 210.12. The Commission's Office of Unfair Import Investigations will conduct informal investigatory activity pursuant to 19 C.F.R. 210.9 to identify sources of relevant information and to assure itself of the availability thereof. The motion for temporary relief will be examined for sufficiency and compliance with 19 C.F.R. 201.8, 210.4, 210.5, 210.52, 210.53(a) (if applicable), 210.54, 210.55, and 210.56, and will be subject to the same type of preliminary investigative activity as the complaint.

The Commission generally will determine whether to institute an investigation on the basis of the complaint and whether to provisionally accept the motion for temporary relief within 35 days after the complaint and motion are filed or, if the motion is filed after the complaint, within 35 days after the motion is filed—unless the 35-day deadline is extended pursuant to 19 C.F.R. 210.53, 210.54, 210.55(b), 210.57, or 210.58. If the Commission determines to institute an investigation and provisionally accept the motion, the motion will be assigned to a Commission administrative law judge for issuance of an initial determination in accordance with 19 C.F.R. 210.66. See 19 C.F.R. 210.10 and 210.58.

If the Commission determines to conduct an investigation of the complaint and motion for temporary relief, the investigation will be formally instituted on the date the Commission publishes a notice of investigation in the FEDERAL REGISTER pursuant to 19 C.F.R. 210.10(b). If an investigation is instituted, copies of the complaint, the notice of investigation, and the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210) will be served on each respondent by the Commission pursuant to 19 C.F.R. 210.11(a). Responses to the complaint, the notice of investigation, and the motion for temporary relief must be filed within 10 days after Commission service thereof, and must comply with 19 CFR 201.8, 210.4, 210.5,

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June 11, 2024

Page 2

210.13, and 210.59. See also 19 C.F.R. 201.14 and 210.6 regarding computation of the 10-day response period.

If, after reviewing the complaint and motion for temporary relief, the Commission determines not to institute an investigation, the complaint and motion will be dismissed and the Commission will provide written notice of that decision and the reasons therefor to the complainant and all proposed respondents pursuant to 19 C.F.R. 210.10.

For information concerning the filing and processing of the complaint and its treatment, and to ask general questions concerning section 337 practice and procedure, contact the Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Room 401, Washington, DC 20436, telephone 202-205-2560. Such inquiries will be referred to the Commission investigative attorney assigned to the complaint. (*See also* the Commission's Rules of Practice and Procedure set forth in 19 C.F.R. Part 210.)

To learn the date that the Commission will vote on whether to institute an investigation and the publication date of the notice of investigation (if the Commission decides to institute an investigation), contact the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., room 112, Washington, DC 20436, telephone 202-205-2000.

This notice is being provided pursuant to 19 C.F.R. 210.56.

Very truly yours,

A handwritten signature in black ink, appearing to read 'DMM', is positioned above the printed name.

David M. Maiorana

PUBLIC VERSION
UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN DISPOSABLE VAPORIZER
DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-_____

**COMPLAINANTS' MOTION FOR TEMPORARY RELIEF
UNDER 19 U.S.C. § 1337(E) AND MEMORANDUM IN SUPPORT**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND	6
A. Overview of the '202 Patent	6
B. Proposed Respondents	6
1. Breeze Respondents	6
(a) Capital Sales Company	7
(b) KMT Services LLC d/b/a KMT Distribution and Dank Shop	7
(c) Dongguan (Shenzhen) Shikai Technology Co., Ltd.	8
2. iMiracle Proposed Respondents.....	8
(a) Vapeonly Technology Co. Ltd.....	8
(b) iMiracle (Shenzhen) Technology Co., Ltd.	9
(c) Guangdong Qisitech Co., Ltd.	10
(d) Fewo Intelligent Manufacturing Limited.....	11
(e) Nevera (HK) Ltd.	11
(f) Guangdong Cellular Workshop Electronics Technology Co., Ltd.	12
(g) Wonder Ladies Ltd.	12
(h) Sailing South Ltd.	12
(i) Marea Morada Ltd.	12
(j) Social Brands, LLC.....	13
(k) Zhuhai Qisitech Co., Ltd.....	13
(l) Shenzhen Han Technology Co., Ltd.	13
(m) Palma Terra Ltd.	14
(n) Shenzhen IVPS Technology Co., Ltd.	14
(o) Heaven Gifts International Ltd.	15
3. Loon Proposed Respondent	15
(a) Maduro Distributors Inc. d/b/a The Loon	15
4. Bidi Proposed Respondents	16

TABLE OF CONTENTS
(continued)

	Page
(a) Bidi Vapor, LLC	16
(b) Kaival Brands Innovations Group Inc.	16
5. Hyppe Proposed Respondents.....	17
(a) Kimsun Technology (HuiZhou) Co., Ltd.	17
(b) Shenzhen Yanyang Technology (HuiZhou) Co., Ltd.	17
6. Esco Bars Proposed Respondents	18
(a) Pastel Cartel, LLC.....	18
(b) American Vape Company, LLC	18
(c) Affiliated Imports, LLC	19
(d) Shenzhen Innokin Technology Co., Ltd.	19
(e) Shenzhen Funyin Electronic Technology Co., Ltd.	20
7. Mr. Fog Proposed Respondents	20
(a) Shenzhen LC Technology Co., Ltd.....	20
(b) LCF Labs, Inc.	20
8. Kangvape Proposed Respondent.....	21
(a) Shenzhen Kangvape Technology Co., Ltd.	21
9. Flum Proposed Respondent	21
(a) Flumgio Technology Ltd.	21
10. Posh Proposed Respondent.....	21
(a) Shenzhen Pingray Technology	21
C. Proposed Distributor Proposed Respondents.....	22
1. SV3 LLC d/b/a Mi-One Brands.....	22
2. Price Point Distributors Inc. d/b/a Price Point NY	23
3. Flawless Vape Shop Inc.....	23
4. Flawless Vape Wholesale & Distribution Inc.....	23
5. Thesy, LLC d/b/a Element Vape	24
6. VICA Trading Inc. d/b/a/ Vapesourcing.....	24
7. Ecto World, LLC d/b/a Demand Vape	24
8. Midwest Goods Inc. d/b/a Midwest Distribution.....	25

TABLE OF CONTENTS
(continued)

	Page
III. LEGAL STANDARDS	25
IV. THE TRADITIONAL EQUITABLE INJUNCTION FACTORS WEIGH HEAVILY IN FAVOR OF GRANTING REYNOLDS’S REQUESTED TEMPORARY EXCLUSION ORDER.....	26
A. Reynolds Will Succeed on the Merits.....	26
1. Reynolds Is Likely To Prove Infringement By The Proposed Respondents	27
(a) Claim Construction Considerations	27
(b) Infringement By Proposed Respondents.....	28
2. Reynolds Is Likely To Prevail Against Any Invalidity Or Unenforceability Defense	48
(a) Legal Standards.....	49
(i) Presumption of Validity	49
(ii) Anticipation.....	50
(iii) Obviousness	50
(b) Factual Background	51
(c) The Previous ITC Investigation.....	53
(d) The Previous IPR	55
(e) The Federal Circuit’s Affirmance.....	56
(f) Conclusion	57
3. Reynolds Will Prove Importation Of The Accused Products.....	57
(a) Breeze Proposed Respondents	58
(b) iMiracle Proposed Respondents.....	59
(c) Loon Proposed Respondent	63
(d) Bidi Proposed Respondents	63
(e) Hyppe Proposed Respondents.....	63
(f) Esco Bars Proposed Respondents	64
(g) Mr. Fog Proposed Respondents	65
(h) Kangvape Proposed Respondent.....	65
(i) Flum Proposed Respondent	66

TABLE OF CONTENTS
(continued)

	Page
(j) Posh Proposed Respondent	66
(k) Distributor Proposed Respondents.....	66
4. Reynolds Will Demonstrate A Domestic Industry	69
(a) Reynolds Will Again Prove An Economic Domestic Industry (“DI”).....	69
(i) Reynolds Has Been Investing In The U.S. Economy For Nearly 150 Years.....	69
(ii) Reynolds Has Always Been A Pioneer In The Discovery And Development Alternatives To Combustible Cigarettes, Including E-Cigarettes.....	70
(iii) Reynolds Will Show That It Meets The Economic DI Requirements Of 19 U.S.C. § 1337(a)(3)(A)-(C).....	71
(1) Reynolds’s Significant Investments In Plant & Equipment.....	72
(2) Reynolds’s Significant Investments In Labor & Capital.....	74
(3) Reynolds’s Substantial Investments In Exploitation Of The ’202 Patent	83
(iv) Reynolds Will Again Succeed in Showing That Its Investments In The DI Products Are Qualitatively and Quantitatively Significant	84
(b) Reynolds Satisfies The Technical Prong	86
B. Reynolds Will Be Irreparably Harmed Absent The Requested Temporary Relief.....	109
1. FDA’s Regulation Of The Domestic Industry and Accused Products.....	113
2. Reynolds Has Suffered Irreparable Harms	117
(a) All Harm Being Suffered By Reynolds is Irreparable, Even That Which is Quantifiable.....	117
(b) Reynolds is Being Irreparably Harmed By Proposed Respondents’ Direct Competition Using Reynolds’s Patented Technology.....	118
(c) Reynolds Is Losing Sales and Market Share Because Of The Infringing Accused Products	121

TABLE OF CONTENTS
(continued)

	Page
(d) Reynolds is Being Irreparably Harmed by Erosion of Market Value As A Result Of The Infringement.....	126
(e) Reynolds Is Suffering Irreparable Harm To Its Reputation.....	127
(f) Reynolds Is Being Irreparably Harmed Because Delays At FDA Caused By Proposed Respondents Are Causing Lost Business Opportunities	131
3. Reynolds’s Only Meaningful Remedy Is a Temporary Exclusion Order; Without It, Reynolds Will Not Likely Recover For Any Of The Harm It Has Suffered.....	132
C. The Balance Of The Equities Weighs Strongly In Favor Of Temporary Relief.....	134
D. The Public Interest Weighs Strongly In Favor Of Temporary Relief.....	136
V. THE REQUESTED EXCLUSIONARY ORDERS WOULD NOT HAVE ANY ADVERSE EFFECT ON THE STATUTORY PUBLIC-INTEREST FACTORS.....	138
A. Factor No. 1: Public Health, Safety, Or Welfare In The U.S.	139
B. Factor No. 2: Competitive Conditions In The U.S. Economy	140
C. Factor No. 3: Production Of Like Or Directly Competitive Articles In The U.S.	141
D. Factor No. 4: U.S. Consumers	142
VI. REQUESTED EXCLUSIONARY ORDERS	143
A. Temporary Limited Exclusion Order.....	144
B. Cease-And-Desist Orders.....	144
VII. BOND REQUIREMENTS	146
A. Reynolds Should Not Be Required To Post A Bond	146
B. No Amount Of Bond Would Be Sufficient To Compensate Reynolds For Irreparable Harm Caused By Continued Importation.....	147
VIII. CONCLUSION.....	148

TABLE OF AUTHORITIES

	Page
CASES	
<i>Abbott Labs. v. Andrx Pharm., Inc.</i> , 452 F.3d 1331 (Fed. Cir. 2006)	133, 142
<i>Aevoe Corp. v. Shenzhen Membrane Precise Electron Ltd.</i> , No. 2:12-CV-00054-GMN, 2012 WL 1532308 (D. Nev. May 1, 2012).....	132
<i>Am. Academy of Pediatrics v. Food & Drug Admin.</i> , 379 F. Supp.3d 461 (D. Md. 2019)	112, 113
<i>Am. Academy of Pediatrics v. Food & Drug Admin.</i> , Case No. 8:18-cv-00883-PWG, ECF No. 179 (D. Md. Apr. 3, 2020).....	113
<i>Am. Academy of Pediatrics v. Food & Drug Admin.</i> , Civil Action No. 8:18-cv-883-DLB, Dkt. No. 220 (D. Md. Apr. 19, 2024)	114
<i>AstraZeneca LP v. Apotex, Inc.</i> , 633 F.3d 1042 (Fed. Cir. 2010)	127
<i>Baker Hughes Inc. v. Nalco Co.</i> , 676 F. Supp. 2d 547 (S.D. Tex. 2009), <i>aff'd per curiam</i> , 374 F. App'x 979 (Fed. Cir. 2010)	126
<i>BlephEx, LLC v. Myco Indus., Inc.</i> , 24 F.4th 1391 (Fed. Cir. 2022)	49
<i>Broadcom Corp. v. Qualcomm Inc.</i> , 543 F.3d 683 (Fed. Cir. 2008)	134
<i>Bushnell, Inc. v. Brunton Co.</i> , 673 F. Supp.2d 1241 (D. Kan. 2009)	132
<i>Canon, Inc. v. GCC Int'l Ltd.</i> , 263 F. App'x 57 (Fed. Cir. 2008)	132
<i>Celsis In Vitro, Inc. v. CellzDirect, Inc.</i> , 664 F.3d 922 (Fed. Cir. 2012)	26, 116, 126, 130, 134
<i>Certain Arrowheads with Deploying Blades & Components Thereof & Packaging Therefor</i> , Inv. No. 337-TA-977, Comm'n Op., 2017 WL 11261373 (U.S.I.T.C. Apr. 28, 2017)	143

TABLE OF AUTHORITIES

	Page
<i>Certain Batteries & Electrochemical Devices Containing Composite Separators, Components Thereof, & Prods. Containing Same,</i> Inv. No. 337-TA-1087, EDIS Doc. ID No. 652457, Order No. 32 (U.S.I.T.C. Aug. 8, 2018), <i>aff'd as modified</i> , EDIS Doc. ID No. 655141, Notice of Comm'n (U.S.I.T.C. Sept. 7, 2018)	71
<i>Certain Carburetors & Prods. Containing Such Carburetors,</i> Inv. No. 337-TA-1123, EDIS Doc. ID No. 692517, Comm'n Op. (U.S.I.T.C. Oct. 28, 2019)	70-71
<i>Certain Cartridges for Elec. Nicotine Delivery Sys. & Components Thereof,</i> Inv. No. 337-TA-1141, EDIS Doc. ID No. 685251, Order No. 38 (U.S.I.T.C. Aug. 14, 2019)	79
<i>Certain Cartridges for Elec. Nicotine Delivery Sys. & Components Thereof,</i> Inv. No. 337-TA-1141, EDIS Doc. ID No. 707185, Comm'n Notice (U.S.I.T.C. Apr. 7, 2020)	138
<i>Certain Crystalline Cefadroxil Monohydrate,</i> Inv. No. 337-TA-293, USITC Pub. 2373, Comm'n Op. (U.S.I.T.C. Jan. 10, 1990)	145
<i>Certain Dental Implants,</i> Inv. 337-TA-934, Comm'n Op., 2016 WL 11603664 (U.S.I.T.C. May 11, 2016)	143
<i>Certain Dielectric Miniature Microwave Filters and Multiplexers Containing Same,</i> Inv. No. 337-TA-359, Initial Determination (Mar. 17, 1994) and Comm'n Order (Apr. 18, 1994)	26
<i>Certain Doxorubicin & Preparations Containing Same,</i> Inv. No. 337-TA-300, 1990 WL 710463 (U.S.I.T.C. May 21, 1990)	79
<i>Certain Electronic Nicotine Delivery Sys. & Components Thereof,</i> Inv. No. 337-TA-1139, EDIS Doc. ID No. 697216, Final Initial Determination (U.S.I.T.C. Dec. 13, 2019), EDIS Doc. ID No. 709572, Comm'n Opinion (U.S.I.T.C. May 5, 2020)	79, 138
<i>Certain Flooring Prods.,</i> Inv. No. 337-TA-443, USITC Pub. 3508, 2001 WL 1693827 (U.S.I.T.C. Nov. 2, 2001)	147
<i>Certain Hardware Logic Emulation Sys.,</i> Initial Determination at 148-50	146

TABLE OF AUTHORITIES

	Page
<i>Certain Integrated Repeaters, Switches, Transceivers & Prods. Containing Same,</i> Inv. No. 337-TA-435, USITC Pub. 3547, 2001 WL 1769747 (U.S.I.T.C. July 19, 2001)	147
<i>Certain Integrated Repeaters, Switches, Transceivers and Products Containing Same,</i> Inv. No. 337-TA-435, EDIS Doc . ID No. 146901, Comm’n Op. (U.S.I.T.C. Oct. 8, 2002).....	145
<i>Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (III),</i> Inv. No. 337-TA-1076, EDIS Doc. ID No. 679042, Comm’n Op. (U.S.I.T.C. June 20, 2019)	137
<i>Certain Minoxidil Powder Salts & Compositions for Use in Hair Treatment,</i> Inv. No. 337-TA-267, Initial Determination, 1988 WL 582867 (U.S.I.T.C. Feb. 16, 1988)	79
<i>Certain Printing & Imaging Devices & Components Thereof,</i> Inv. No. 337-TA-690, EDIS Doc. ID No. 444708, Comm’n Op. (U.S.I.T.C. Feb. 17, 2011)	70
<i>Certain Robotic Vacuum,</i> Inv. No. 337-TA-1057, Comm’n Op., 2019 WL 1292948 (U.S.I.T.C. Feb. 1, 2019)	143
<i>Certain Strontium-Rubidium Radioisotope Infusion Sys.,</i> Inv. No. 337-TA-1110, EDIS Doc. ID 684056, Initial Determination (U.S.I.T.C. Aug. 1, 2019)	79
<i>Certain Sys. For Detecting & Removing Viruses or Worms, Components Thereof, & Prods. Containing Same,</i> Inv. No. 337-TA-510, Comm’n Op., 2005 WL 8153587 (U.S.I.T.C. Aug. 23, 2005)	143
<i>Certain Tobacco Heating Articles & Components Thereof,</i> Inv. No. 337-TA-1199, EDIS Doc. ID No. 754503, Comm’n Op. (Oct. 19, 2021), <i>aff’d sub nom.</i> , 63 F.4th 1328 (Fed. Cir. 2023).....	<i>passim.</i>
<i>Certain Tobacco Heating Articles and Components Thereof,</i> Inv. No. 337-TA-1199, EDIS Doc. ID No. 742491, Initial Determination (U.S.I.T.C. May 14, 2021)	<i>passim.</i>
<i>Certain Tobacco Heating Articles,</i> EDIS Doc. ID No. 722975, Order No. 19.....	51
<i>Certain Tobacco Heating Articles,</i> EDIS Doc. ID No. 731117, Order No. 35	68, 72, 74, 79

TABLE OF AUTHORITIES

	Page
<i>Certain Vaporizer Cartridges & Components Thereof</i> , Inv. No. 337-TA-1211, EDIS Doc. ID No. 764256, Comm’n Op. (U.S.I.T.C. Mar. 1, 2022).....	138
<i>Douglas Dynamics, LLC v. Buyers Prods. Co.</i> , 717 F.3d 1336 (Fed. Cir. 2013)	116, 118, 134
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	25
<i>ePlus, Inc. v. Lawson Software, Inc.</i> , No. 09-cv-620, 2011 WL 2119410 (E.D. Va. May 23, 2011)	135, 136
<i>Ez-XBRL Sols., Inc. v. Chapke</i> , No. 17-cv-LMB-TCB, 2018 WL 5808724 (E.D. Va. Sept. 25, 2018), <i>report and recommendation adopted</i> , 2018 WL 5809406 (E.D. Va. Oct. 22, 2018).....	135
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	50
<i>H.H. Robertson, Co. v. United Steel Deck, Inc.</i> , 820 F.2d 384 (Fed. Cir. 1987)	131, 133
<i>In re Est. of Ferdinand Marcos, Hum. Rts. Litig.</i> , 25 F.3d 1467 (9th Cir. 1994).....	132
<i>Kinetic Concepts, Inc. v. Smith & Nephew, Inc.</i> , 688 F.3d 1342 (Fed. Cir. 2012)	50
<i>Kolcraft Enter., Inc. v. Chicco USA, Inc.</i> , No. 09-cv-3339, 2019 WL 4242482 (N.D. Ill. 2019)	135
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	49
<i>LEGO v. ZURU Inc.</i> , 799 F. App’x 823 (Fed. Cir. 2020)	145
<i>Metalcraft of Mayville, Inc. v. The Toro Co.</i> , 848 F.3d 1358 (Fed. Cir. 2017)	133
<i>Microsoft Corp. v. i4i P’ship</i> , 564 U.S. 91 (2011).....	48

TABLE OF AUTHORITIES

	Page
<i>Monsanto Co. v. Scruggs</i> , 249 F. Supp.2d 746 (N.D. Miss. 2001)	135
<i>Mylan Institutional LLC v. Aurobindo Pharma Ltd.</i> , 857 F.3d 858 (Fed. Cir. 2017)	26
<i>Net MoneyIN Inc. v. VeriSign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008)	49
<i>Philip Morris Products S.A. v. RAI Strategic Holdings, Inc.</i> , No. 22-1846, 2023 WL 5970786 (Fed. Cir. Sept. 14, 2023)	52, 55
<i>Philip Morris Products SA v. RAI Strategic Holdings, Inc.</i> , IPR2020-01602, Paper 32 (Mar. 30, 2022)	54
<i>Polymer Techs., Inc. v. Bridwell</i> , 103 F.3d 970 (Fed. Cir. 1996)	130
<i>Precision Dynamics Corp. v. Typenex Med., L.L.C.</i> , No. 13-CV-860, 2014 WL 4851542 (E.D. Wis. Aug. 25, 2014)	133, 142
<i>Presidio Components, Inc. v. Am. Tech. Ceramics Corp.</i> , 702 F.3d 1351 (Fed. Cir. 2012)	117
<i>Procter & Gamble Co. v. Teva Pharm. USA, Inc.</i> , 566 F.3d 989 (Fed. Cir. 2009)	50
<i>Purdue Pharma L.P. v. Boehringer Ingelheim GmbH</i> , 237 F.3d 1359 (Fed. Cir. 2001)	125
<i>QBAS Co., Ltd. v. C Walters Intercoastal Corp.</i> , No. SACV 10-406 AG (MLGx), 2010 WL 7785955 (C.D. Cal. Dec. 16, 2010).	116
<i>R.J. Reynolds Vapor Company v. Food & Drug Administration</i> , 65 F.4th 182 (5th Cir. 2023)	77
<i>RMH Tech LLC v. PMC Indus., Inc.</i> , 352 F. Supp.3d 164 (D. Conn. 2018)	126
<i>Robert Bosch, LLC v. Pylon Mfg. Corp.</i> , 659 F.3d 1142 (Fed. Cir. 2011)	117, 120, 132
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 470 F.3d 1368 (Fed. Cir. 2006)	49, 145

TABLE OF AUTHORITIES

	Page
<i>Spansion, Inc. v. Int’l Trade Comm’n</i> , 629 F.3d 1331 (Fed. Cir. 2010)	49, 137, 138, 142
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985)	50
<i>Titan Tire Corp. v. Case New Holland, Inc.</i> , 566 F.3d 1372 (Fed. Cir. 2009)	49
<i>Titanium Metals Corp. of Am. v. Banner</i> , 778 F.2d 775 (Fed. Cir. 1985)	49
<i>Trebro Mfg, Inc. v. Firefly Equip, LLC</i> , 748 F.3d 1159 (Fed. Cir. 2014)	117
STATUTES	
19 U.S.C. § 1337	<i>passim</i> .
35 U.S.C. § 103	49
35 U.S.C. § 282	47, 48
REGULATIONS	
19 C.F.R. § 210.52	1, 25, 145
19 C.F.R. § 210.68	145
81 Fed. Reg. 28,973 (May 10, 2016)	112
89 Fed. Reg. 18,668 (Mar. 14, 2024)	139
H.R. Rep. No. 100-576 at 635-36 (1988) (Conf. Rep)	146

TABLE OF EXHIBITS FILED WITH COMPLAINT

Exhibit No.	Description
1	Certified Copy of U.S. Patent No. 11,925,202
2	Certified Copy of Recorded Assignments for U.S. Patent No. 11,925,202
3C	Licensing Agreements relating to U.S. Patent No. 11,925,202 (CONFIDENTIAL)
4	Declaration of Kenneth S. Luchesi
4-1	Product Purchase Chart - Accused Products
4-2	Product Purchase Chart - Other Products
4-3	Product Purchase Receipt of 4/14/2024 - Fli High Smoke Shop
4-4	Product Purchase Receipt of 4/14/2024 - Olmsted Smoke Shop
4-5	Product Purchase Receipt of 4/14/2024 - Vitrum Vape Shop
4-6	Product Purchase Receipt of 4/15/2024 - Gavidae Express
4-7	Product Purchase Receipt of 4/15/2024 - Mi-pod
4-8	Product Purchase Receipt of 4/15/2024 - Ohm City Vapes
4-9	Product Purchase Receipt of 4/15/2024 - Smokerz Station
4-10	Product Purchase Receipt of 4/18/2024 - Circle K
4-11	Product Purchase Receipt of 4/18/2024 - Ohm City Vapes
4-12	Product Purchase Receipt of 4/18/2024 - Price Point NY
4-13	Product Purchase Receipt of 4/20/2024 - Awesome Sauce Vapor
4-14	Product Purchase Receipt of 4/20/2024 - Planet of the Vapes
4-15	Product Purchase Receipt of 4/20/2024 - Smoke Ohio LLC
4-16	Product Purchase Receipt of 4/23/2024 - Cloud 9 Smoke & Vape Co.
4-17	Product Purchase Receipt of 4/23/2024 - USA Smoke Shop
4-18	Product Purchase Receipt of 4/23/2024 - Olmsted Smoke Shop
4-19	Product Purchase Receipt of 4/24/2024 - Price Point NY
4-20	Product Purchase Receipt of 4/24/2024 - Ohm City Vapes
4-21	Product Purchase Receipt of 4/28/2024 - Wild Bills Tobacco
4-22	Product Purchase Receipt of 4/24/2024 - Cloud 9 Smoke & Vape
4-23	Product Purchase Receipt of 5/01/2024 - Ohm City Vapes
4-24	Product Purchase Receipt of 5/01/2024 - Price Point NY
4-25	Product Purchase Receipt of 5/02/2024 - Puff Ignite
4-26	Product Purchase Receipt of 5/02/2024 - Mi-pod
4-27	Product Purchase Receipt of 5/02/2024 - Ohm City Vapes
4-28	Product Purchase Receipt of 5/02/2024 - Price Point NY
4-29	Product Purchase Receipt of 5/02/2024 - Ziip Stick
4-30	Product Purchase Receipt of 5/13/2024 - Price Point NY

Exhibit No.	Description
4-31	Product Purchase Receipt of 5/15/2024 - Smoke Shop 216
4-32	Product Purchase Receipt of 5/20/2024 - Smoke Ohio LLC
5	Teardown Report - Breeze Smoke Plus
6	Teardown Report - Breeze Smoke Prime
7	Teardown Report - Breeze Smoke Pro Edition
8	Teardown Report - EBCreate BC5000
9	Teardown Report - EBCreate BC5000 Thermal Edition
10	Teardown Report - EBDesign BC5000
11	Teardown Report - EBDesign TE6000
12	Teardown Report - Elf Bar BC5000 Malibu
13	Teardown Report - Pod King XC5000
14	Teardown Report - Elf Bar TE5000
15	Teardown Report - Elf Bar TE6000
16	Teardown Report - Funky Lands Ti7000
17	Teardown Report - Funky Republic Fi3000
18	Teardown Report - Funky Republic Ti7000
19	Teardown Report - Geek Bar B5000
20	Teardown Report - Geek Bar Pulse
21	Teardown Report - Lost Mary BM5000
22	Teardown Report - Lost Mary MO5000
23	Teardown Report - Lost Mary MT15000 Turbo
24	Teardown Report - Lost Mary Off-Stamp SW9000
25	Teardown Report - Lost Mary OS5000
26	Teardown Report - Raz CA6000
27	Teardown Report - RAZ DC25000
28	Teardown Report - RAZ TN9000
29	Teardown Report - Rabbeaats RC10000
30	Teardown Report - Rabbeaats RC10000 Touch
31	Teardown Report - Space Mary SM8000
32	Teardown Report - Novo bar AL 6000
33	Teardown Report - Novo Bar AL 9000
34	Teardown Report - Priv bar turbo
35	Teardown Report - Loon Air +
36	Teardown Report - Loon Maxx
37	Teardown Report - Bidi Stick
38	Teardown Report - Hype Max 1600



Exhibit No.	Description
39	Teardown Report - Hype Max Air 5000
40	Teardown Report - Hype Max Air Flow Mesh
41	Teardown Report - Posh Max 2.0
42	Teardown Report - Esco Bars 2500 Mesh
43	Teardown Report - Esco Bars Kilo
44	Teardown Report - Mr. Fog Max
45	Teardown Report - Mr. Fog Switch
46	Teardown Report - Kang Vape ONEE- Max 5000
47	Teardown Report - Kangvape Onee Stick 1800
48	Teardown Report - Kang Vape ONEE Stick 5200
49	Teardown Report - Kang Vape SMOD Max 6000
50	Teardown Report - Flum Float
51	Teardown Report - Flum Gio
52	Teardown Report - Flum Mi
53	Teardown Report - Flum Pebble
54	Teardown Report - Flum UT Bar
55	Infringement Chart - Breeze Smoke Plus
56	Infringement Chart - Breeze Smoke Prime
57	Infringement Chart - Breeze Smoke Pro Edition
58	Infringement Chart - EBCreate BC5000
59	Infringement Chart - EBCreate BC5000 Thermal Edition
60	Infringement Chart - EBDesign BC5000
61	Infringement Chart - EBDesign TE6000
62	Infringement Chart - Elf Bar BC5000 Malibu
63	Infringement Chart - Pod King XC5000
64	Infringement Chart - Elf Bar TE5000
65	Infringement Chart - Elf Bar TE6000
66	Infringement Chart - Funky Lands Ti7000
67	Infringement Chart - Funky Republic Fi3000
68	Infringement Chart - Funky Republic Ti7000
69	Infringement Chart - Geek Bar B5000
70	Infringement Chart - Geek Bar Pulse
71	Infringement Chart - Lost Mary BM5000
72	Infringement Chart - Lost Mary MO5000
73	Infringement Chart - Lost Mary MT15000 Turbo
74	Infringement Chart - Lost Mary Off-Stamp SW9000

Exhibit No.	Description
75	Infringement Chart - Lost Mary OS5000
76	Infringement Chart - Raz CA6000
77	Infringement Chart - RAZ DC25000
78	Infringement Chart - RAZ TN9000
79	Infringement Chart - Rabbeaats RC10000
80	Infringement Chart - Rabbeaats RC10000 Touch
81	Infringement Chart - Space Mary SM8000
82	Infringement Chart - Novo bar AL 6000
83	Infringement Chart - Novo Bar AL 9000
84	Infringement Chart - Priv bar turbo
85	Infringement Chart - Loon Air +
86	Infringement Chart - Loon Maxx
87	Infringement Chart - Bidi Stick
88	Infringement Chart - Hype Max 1600
89	Infringement Chart - Hype Max Air 5000
90	Infringement Chart - Hype Max Air Flow Mesh
91	Infringement Chart - Posh Max 2.0
92	Infringement Chart - Esco Bars 2500 Mesh
93	Infringement Chart - Esco Bars Kilo
94	Infringement Chart - Mr. Fog Max
95	Infringement Chart - Mr. Fog Switch
96	Infringement Chart - Kang Vape ONEE- Max 5000
97	Infringement Chart - Kangvape Onee Stick 1800
98	Infringement Chart - Kang Vape ONEE Stick 5200
99	Infringement Chart - Kang Vape SMOD Max 6000
100	Infringement Chart - Flum Float
101	Infringement Chart - Flum Gio
102	Infringement Chart - Flum Mi
103	Infringement Chart - Flum Pebble
104	Infringement Chart - Flum UT Bar
105C	Confidential Ferris Declaration
106	State of Michigan, Department of Licensing and Regulatory Affairs Business Entity Search - Breeze Smoke LLC
107	FDA Center for Tobacco Products Warning Letter to Breeze Smoke, LLC (May 25, 2023)
108	Trademark Application Serial No. 97839842 for BREEZE PRIME
109	Profile of Capital Sales Company on Better Business Bureau website

Exhibit No.	Description
110	State of Michigan, Department of Licensing and Regulatory Affairs Business Entity Search - Capital Sales Company
111	Capital Sales Company Contact Information
112	Capital Sales Company Page on CDAWeb.net
113	Breeze Smoke (Distributed by Capital Sales Company) Booth Location Search NACS Show 2022
114	State of Michigan, Department of Licensing and Regulatory Affairs Business Entity Search - KMT Services LLC
115	KMT Services LLC Listing of Assumed Names
116	OpenCorporates Company Search - KMT Services LLC
117	Letter from American Academy of Pediatrics, et al. to FDA regarding MDO enforcement
118	Dank Shop Webpage
119	China Business Registration Search Result for Dongguan (Shenzhen) Shikai Technology Co., Ltd.
120	Vapeonly Technology Company Limited LinkedIn Profile
121	ELFBAR Flowers and Bubbles Trademark Application (US Serial Number: 97580609)
122	Heaven Gifts Trademark Record (US Registration Number: 6111314)
123C	Confidential Business Intelligence Report Regarding Heaven Gifts
124	CNBC Article "China e-cigarette titan behind 'Elf Bar' floods the U.S. with illegal vapes" (Dec. 6, 2023) (avail. at https://www.cnbc.com/amp/2023/12/06/china-e-cigarette-titan-behind-elf-bar-floods-the-us-with-illegal-vapes.html)
125	China Business Registration Search Result for Guangdong Qisitech Co. Ltd.
126	China Business Registration Search Result for Fewo Intelligent Manufacturing Limited
127	Rabbeaats RC10000 Product Packaging
128	State of Texas, Franchise Business Entity Search - Social Brands LLC
129	Social Brands Website
130	Palma Terra Limited UK Company Registration
131	One Stop Report for Palma Terra Limited
132	IVPS Trademark (US Registration Number: 5640028)
133	SMOK Trademark (US Registration Number: 6072213)
134	SMOK Logo Trademark (US Registration Number: 4545449)
135	Smok Website Contact Us Page
136	SMOK VAPOR Trademark Application (US Serial Number: 86341836)
137	Smok Tech Website Product Page
138	Heaven Gifts Contact Us Website Page

Exhibit No.	Description
139	Heaven Gifts Contact Us Website Page (Chinese Version)
140	Heaven Gifts Contact Us Website Page (Translated)
141	Heaven Gifts Brand Introduction Website Page
142	AP News Article "Elf Bar and other e-cigarette makers dodged US customs and taxes after China's ban on vaping flavors" (Dec. 19, 2023) (avail. at https://apnews.com/article/vaping-elf-bar-ecigarettes-china-teens-77033584983ad47fc5795baa46b4705e)
143	State of Minnesota, Secretary of State Business Entity Search - Maduro Distributors Inc.
144	Maduro Distributors v. Loonvape.net, No. 1:23-cv-01646, Complaint (E.D. Mich. Dec. 4, 2023)
145	FDA Center for Tobacco Products Warning Letter to Maduro Distributors (August 20, 2021)
146	Loon Website Loon Maxx Product Page
147	Loon Website Loon Air and Air+ Order Form Page
148	Loon Website Product Order Form
149	Bidi Vapor LLC Florida Limited Liability Registration
150	Bidi Vapor LLC 2024 Annual Report
151	BIDI Trademark (US Registration Number: 6208498)
152	State of Delaware, Department of State Business Entity Search - Kaival Brands Innovations Group, Inc.
153	State of Delaware, Department of State Business Entity Search - Kaival Brands Innovations Group, Inc. (Second Company)
154	Kaival Brands Innovations Group, Inc. 10-Q March 2024
155	Kaival Brands Fiscal Report Q1 2024
156	Hyppe Max Air 5000 Product Packaging
157	State of Texas, Franchise Tax Account Status Business Entity Search - Pastel Cartel LLC
158	Esco Bars Kilo Product Packaging
159	FDA Import Alert 98-06 (April 1, 2024)
160	State of Texas, Franchise Tax Account Status Business Entity Search - Pastel Cartel Vape, LLC
161	State of Texas, Franchise Tax Account Status Business Entity Search - American Vape Company LLC
162	ESCO BARS Trademark (US Registration Number: 6859518)
163	State of Texas, Franchise Tax Account Status Business Entity Search - Affiliated Imports, LLC
164	FDA Center for Tobacco Products Warning Letter to Shenzhen Innokin (May 25, 2023)
165	SIDEPIECE Trademark Application (US Serial Number: 90280397)

Exhibit No.	Description
166	State of California, Secretary of State Business Entity Search - LCF Labs Inc.
167	LCF Labs Inc. California Statement of Information
168	Shenzhen Pingray Technology Co. Ltd Website Contact Us Page
169	State of Arizona, Corporations Commission Business Entity Search - SV3, LLC
170	MI-POD Trademark (US Registration Number: 6533037)
171	Mi-Pod Website Product Page
172	State of New York, Department of State Business Entity Search - Price Point Distributions Inc.
173	Price Point NY Website Product Page
174	Flawless Vape Shop Inc. California Statement of Information
175	Flawless Vape Shop Website Contact Page
176	Flawless Vape Website Product Page
177	Flawless Vape Wholesale & Distribution Inc. California Statement of Information
178	Thesy, LLC California Statement of Information
179	Element Vape Website Product Page
180	Vica Trading Inc. California Statement of Information
181	Vape Sourcing Website Product Page
182	State of New York, Department of State Business Entity Search - Ecto World LLC
183	City of New York v. Magellan Tech., Inc., et al., Amended Complaint (S.D.N.Y. August 17, 2023)
184	Demand Vape Website Contact Us Page
185	Demand Vape Website Product Page
186	State of Illinois, Secretary of State Business Entity Search - Midwest Goods Inc.
187	Midwest Goods Website Home Page
188	Midwest Distribution Wholesale Website
189	Midwest Goods Website Product Page
190	Breeze Smoke Breeze Pro Instructional Guide: "How to Spot Unauthorized Breeze" (Compilation)
191	Mi-One Brands (Mi-Pod) Website Product Page - EB Disposable Vapes
192	Lost Mary Website Product Page
193	Geek Bar Website Product Page
194	Podking Website Product Page
195	FDA Marketing Denial Orders List (Published June 6, 2024)
196	Bidi Vapor Website Product Page
197	Wholesale Bidi Vapor Website Home Page
198	Wholesale Bidi Vapor Website Product Page

Exhibit No.	Description
199	Hyppe Catalogue Advertising
200	Esco Bars Direct Website Product Page
201	Ohm City Vapes Website Product Page
202	Price Point NY Website Product Page - Mr. Fog Products
203	Kang Vape Cig Website Product Page
204	Flumgio Website Product Page
205	Element Vape Website Product Page
206	Price Point NY Website Product Page - Flum Products
207	Now Posh Website Product Page
208	Mi-One Brands (Mi-Pod) Website Product Page - Multiple Brands
209	Flawless Vape Shop Product Page
210	FDA Tobacco Products Marketing Orders
211	Bidi Vapor Website Article "BIDI Vapor receives US FDA nod for PMTA moves to next phase" (available at https://wholesale.bidivapor.com/bidi-vapor-receives-us-fda-nod-for-pmta-moves-to-next-phase/)
212	FDA Center for Tobacco Products Warning Letter to Maduro Distributors d/b/a The Loon (Aug. 20, 2021)
213	Loon Webpage - PMTA Notice
214	Geek Bar Webpage - PMTA
215	Geek Vape Webpage - What is PMTA?
216	FDA Center for Tobacco Products Warning Letter to Shenzhen Kanger Technology Co. Ltd. d/b/a Kangertech (Sept. 14, 2023)
217	Smok Tech Webpage - Innovation Keeps Changing the Vaping Experience
218	Breeze Smoke, LLC v. FDA, Docket No. 21-03902, Petition For Review (6th Cir. Oct. 04, 2021)
219	Pastel Cartel LLC v. FDA, No. 1:23-CV-1010-DAE, Order Denying Without Prejudice Plaintiff's Motion For Preliminary Injunction (W.D. Tex. Dec. 14, 2023)
220	Kang Vape Cig Webpage - PMTA
221	Mi-Pod Wholesale Webpage - Mi-Pod PMTA
222	FDA Article "FDA Denies Marketing of Bidi E-Cigarette" (Jan. 22, 2024) (available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-bidi-e-cigarette)
223	FDA Article "FDA Denies Marketing of SMOK E-Cigarette Products" (Jan. 16, 2024) (available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-smok-e-cigarette-products)
224C	Claim Chart - RJR Vuse Vibe
225C	Claim Chart - RJR Vuse Alto
226C	Claim Chart - RJR Vuse Ciro

Exhibit No.	Description
227C	Claim Chart - RJR Vuse Solo
228	Foreign Counterparts of '202 patent
229	Kaival Brands Reports Fiscal 2024 First Quarter Financial Results and Provides Business Update (Mar. 27, 2024) (available at https://ir.kaivalbrands.com/news/news-details/2024/Kaival-Brands-Reports-Fiscal-2024-First-Quarter-Financial-Results-and-Provides-Business-Update/default.aspx)
230	Midwest Goods Inc., dba Midwest Distribution Illinois v. Breeze Smoke LLC, No. 1:23-CV-05406, Declaration of Mudassir Yasin (N.D. Ill. Feb. 2, 2024)
231	Infringement Chart - Air Bar 7500 with appended Air Bar 7500 Teardown Report
232	Infringement Chart - Air Bar Box with appended Air Bar Box Teardown Report
233	Infringement Chart - Air Bar Diamond with appended Air Bar Diamond Teardown Report
234	Infringement Chart - Air Bar Lux with appended Air Bar Lux Teardown Report
235	Infringement Chart - Air Bar Mini with appended Air Bar Mini Teardown Report
236	Infringement Chart - Air Bar Nex with appended Air Bar Nex Teardown Report
237	Infringement Chart - Cali Boxx with appended Cali Boxx Teardown Report
238	Infringement Chart - Cali UL with appended Cali UL Teardown Report
239	Infringement Chart - Fume Eternity 20000 with appended Fume Eternity 20000 Teardown Report
240	Infringement Chart - Fume Infinity with appended Fume Infinity Teardown Report
241	Infringement Chart - Fume Mini with appended Fume Mini Teardown Report
242	Infringement Chart - Fume x Nicky Jams with appended Fume x Nicky Jams Teardown Report
243	Infringement Chart - Fume Ultra 2500 with appended Fume Ultra 2500 Teardown Report
244	Infringement Chart - Fume X Fruitia with appended Fume X Fruitia Teardown Report
245	Infringement Chart - HQD Cuvie Glaze 15000 with appended HQD Cuvie Glaze 15000 Teardown Report
246	Infringement Chart - HQD Cuvie Plus with appended HQD Cuvie Plus Teardown Report
247	Infringement Chart - Hyde Edge Micro with appended Hyde Edge Micro Teardown Report
248	Infringement Chart - Hyde Rave Edge with appended Hyde Rave Edge Teardown Report
249	Infringement Chart - Hyde ID with appended Hyde ID Teardown Report
250	Infringement Chart - Hyde IQ with appended Hyde IQ Teardown Report
251	Infringement Chart - Hyde Mag with appended Hyde Mag Teardown Report
252	Infringement Chart - N Bar with appended N Bar Teardown Report

Exhibit No.	Description
253	Infringement Chart - Hyde Rebel with appended Hyde Rebel Teardown Report
254	Infringement Chart - Hyde Rebel Pro with appended Hyde Rebel Pro Teardown Report
255	Infringement Chart - Ignite V25 with appended Ignite V25 Teardown Report
256	Infringement Chart - Ignite V35 with appended Ignite V35 Teardown Report
257	Infringement Chart - Ignite V50 with appended Ignite V50 Teardown Report
258	Infringement Chart - Juicehead 5K with appended Juicehead 5K Teardown Report
259	Infringement Chart - Juicy Bar JB5000 with appended Juicy Bar JB5000 Teardown Report
260	Infringement Chart - Juicy Model Q with appended Juicy Model Q Teardown Report
261	Infringement Chart - Juicy Model QS with appended Juicy Model QS Teardown Report
262	Infringement Chart - Juicy Model X with appended Juicy Model X Teardown Report
263	Infringement Chart - Juicy Model X3 with appended Juicy Model X3 Teardown Report
264	Infringement Chart - Tyson Iron Mike with appended Tyson Iron Mike Teardown Report
265	Infringement Chart - Tyson Heavyweight with appended Tyson Heavyweight Teardown Report
266	Infringement Chart - Tyson 2.0 Round 2 with appended Tyson 2.0 Round 2 Teardown Report
267	Infringement Chart - Kado Bar BR5000 with appended Kado Bar BR5000 Teardown Report
268	Infringement Chart - Lava Plus 2600 with appended Lava Plus 2600 Teardown Report
269	Infringement Chart - Mr. Vapor Elite with appended Mr. Vapor Elite Teardown Report
270	Infringement Chart - Mr. Vapor Flex with appended Mr. Vapor Flex Teardown Report
271	Infringement Chart - Mr Vapor Lux with appended Mr Vapor Lux Teardown Report
272	Infringement Chart - Mr. Vapor Maxx with appended Mr. Vapor Maxx Teardown Report
273	Infringement Chart - North FT12000 with appended North FT12000 Teardown Report
274	Infringement Chart - Lightrise TB 18K with appended Lightrise TB 18K Teardown Report
275	Infringement Chart - Orion bar 10000 with appended Orion bar 10000 Teardown Report

Exhibit No.	Description
276	Infringement Chart - Orion Bar 7500 with appended Orion Bar 7500 Teardown Report
277	Infringement Chart - Puff Bar Plus with appended Puff Bar Plus Teardown Report
278	Infringement Chart - Puff Bar XXL with appended Puff Bar XXL Teardown Report
279	Infringement Chart - Puff Air Mesh with appended Puff Air Mesh Teardown Report
280	Infringement Chart - Zbold Pro with appended Zbold Pro Teardown Report
281	Infringement Chart - Zstick with appended Zstick Teardown Report

**TABLE OF EXHIBITS FILED WITH MOTION
FOR TEMPORARY EXCLUSION ORDER**

Exhibit No.	Description
282	Tobacco Product Use Among U.S. Middle and High School Students – National Youth Tobacco Survey, 2023
283	Results from the Annual National Youth Tobacco Survey
284	Philip Morris International’s Heated Tobacco Product IQOS Replaces Marlboro As Its Leading Brand
285	<i>Philip Morris Products SA v. RAI Strategic Holdings, Inc.</i> , IPR2020-01602, Paper 32 (Mar. 30, 2022)
286	How Reynolds American Builds a Better Tomorrow
287	AP News, “Elf Bar Finds An Easy Way Around US Vape Import Ban: A Name Change”
288	Convenience Store New, “FDA Levels Penalties Against Retailers for Elf Bar Sales”
289	Premarket Tobacco Product Applications
290	Tobacco Product Applications: Metrics & Reporting
291	FDA Makes Determinations on More Than 99% of the 26 Million Tobacco Products for Which Applications Were Submitted
292	E-Cigarettes Authorized by the FDA
293	Premarket Tobacco Product Marketing Granted Orders
294	Tobacco Products Search Results
295	Altria: California’s Flavour Ban Leads to Large Illicit Market
296	NY Post, “NYC Flooded With Illegal Flavored Vapes From China Despite Ban To Protect Kids: Study”
297	VAPE Directory & Information – The Louisiana Office of Alcohol and Tobacco Control
298	How Much Does A Vape Cost? (2024 Price Chart)



Exhibit No.	Description
299	Perception Of The Relative Harm Of Electronic Cigarettes Compared To Cigarettes Amongst US Adults from 2013 to 2016: Analysis Of The Population Assessment of Tobacco and Health (PATH) Study Data
300	Vuse Vibe and Vuse Ciro Receive US FDA Marketing Authorization
301	Our Commitment To Underage Access Prevention
302	Improving Enforcement Against Illicit Market
303	FDA Pledges To Ramp Up Fight Against Unauthorized Vapes
304	FDA Files Complaints Seeking Maximum Fines Against 20 More Retailers For Selling Unauthorized Elf Bar E-Cigarettes
305	FDA Warns 61 Brick and Mortar Retailers for the Sale of Unauthorized E-Cigarettes Popular Among Youth
306	FDA Seeks Approximately \$20,000 Each From 22 Retailers Selling Elf Bar And Other Unauthorized E-Cigarettes
307	Attorney General Bonta Joins Multistate Coalition in Letter to FDA on Flavored Disposable E-Cigarettes
308	Thousands Of Unauthorized Vapes Are Pouring Into The US Despite The FDA Crackdown On Fruity Flavors
309	FDA Issues Warning Letters to 14 Online Retailers For Selling Unauthorized E-Cigarettes
310	Philip Morris International Submits Applications To Commercialize IQOS ILUMA Tobacco Heating System to U.S. Food And Drug Administration
311	Law360, “GOP Reps. Want IP Enforcers To Get Tougher On Infringers”
312	Courthouse News, “Durbin Demands FDA Testimony On Unauthorized Vape Sales”
313	New York Times, “Top Senators Urge Stores to Stop Selling Illicit Vapes”



I. INTRODUCTION

Complainants RAI Strategic Holdings Inc., R.J. Reynolds Vapor Company, RAI Services Company, and R.J. Reynolds Tobacco Company (collectively, “Complainants” or “Reynolds”) bring this motion under 19 U.S.C. § 1337(e) and (f) and 19 C.F.R. § 210.52, requesting a temporary limited exclusion order and cease-and-desist orders directed to each Proposed Respondent in this action regarding certain disposable vaporizer devices, and components thereof, that infringe one or more claims of United States Patent No. 11,925,202 (“the ’202 Patent”).

The illicit and unlawful acts of Proposed Respondents are precisely what preliminary relief in the form of a temporary exclusion order (“TEO”) is designed to address and protect against. Indeed, it is hard to imagine a set of facts where a TEO is more warranted than on the facts of this case.

Reynolds has spent more than a decade investing hundreds of millions of dollars developing new technologies designed to offer alternatives to combustible cigarettes that help transition smokers away from traditional cigarettes. Reynolds’s investments reflect its commitment to maintaining its reputation as a responsible industry participant and creating “a better tomorrow” where we live in a smokeless world. Through their infringement, Proposed Respondents are threatening to destroy and are irreparably harming Reynolds’s decade of development work, hundreds of millions of dollars in investments, and years of maintaining the reputation it has worked so hard to rebuild. The manner in which Respondents are causing this irreparable harm is not just unlawful, but reprehensible.

Proposed Respondents are stealing Reynolds’s patented technology and placing it in disposable e-cigarettes that they are marketing to youth through the use of dessert and candy-flavors. Making matters worse, they are doing this illegally in violation of flavor bans and the

Food and Drug Administration’s (“FDA”) admonishments that such products should not be on the market. FDA’s enforcement actions against at least certain Proposed Respondents have thus far been unsuccessful because of Proposed Respondents’ shady business practices, causing FDA to engage in a game of “whack-a-mole,” whereby another bad actor pops up every time one is spotted and tamped down. Proposed Respondents’ use of Reynolds’s patented technology while targeting youth is disgraceful and has had a rippling effect on the reputation of the entire industry, including reputable companies like Reynolds who are playing by the rules.

The Centers for Disease Control (“CDC”) recently published findings from the 2023 National Youth Tobacco Survey (“NYTS”) concerning the use of e-cigarettes by middle school and high school students. CDC reported that, “[a]mong students reporting current e-cigarette use, 89.4% reported using a flavored product during the past 30 days, excluding those who only used tobacco-flavored or unflavored e-cigarettes,” and that candy-flavored categories accounted for more than a third of the most commonly used types. Exhibit 282 at 1.¹ CDC further observed that “[a]mong students who reported current e-cigarette use, disposables were the most commonly used device type.” *Id.* at 3; *see also* Exhibit 283 at 4 (noting that nearly 90% of e-cigarette-using youth use flavored products and over 60% use flavored disposable vapes). The 2023 NYTS results confirm earlier reports of rapidly accelerating flavored disposable vape use among minors. *See generally* Exhibits 282 and 283. The harm to youth—and to Reynolds’s reputation from use of its patented technology in this manner—is severe.

All of Proposed Respondents’ illicit and unlawful infringement should be stopped, and it should be stopped immediately. Reynolds submits here a powerful showing on all of the

¹ The exhibits cited herein numbered from 1 through 281 refer to exhibits filed with Reynolds’s complaint; exhibits numbered 282 and higher are attached to this motion.

[REDACTED]

requisite factors for temporary relief to bring this to a stop, including likelihood of success on the merits, irreparable harm, the balance of equities, and public interest.

Reynolds is highly likely to succeed on the merits. Indeed, Reynolds has already succeeded on most (if not all) of the merits issues. Reynolds recently asserted the grandparent of the '202 Patent in an ITC investigation and succeeded on the issues of infringement, validity, domestic industry and public interest. *Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, EDIS Doc. ID No. 754503, Comm'n Op. (Oct. 19, 2021), *aff'd sub nom.*, 63 F.4th 1328 (Fed. Cir. 2023) ("the 1199 Investigation"). Reynolds is likely to succeed on those issues again here because they are either identical or substantially the same as those already resolved in Reynolds's favor in the 1199 Investigation.

With respect to infringement (both accused and domestic industry products), the asserted claims of the '202 Patent substantially overlap with those asserted in the 1199 Investigation. Any terms requiring construction have already been construed in Reynolds's favor. With these constructions already resolved in Reynolds's favor, infringement and the technical prong of domestic industry here are not even a close call.

With respect to validity, the key limitations of the '202 Patent have already survived vigorous challenges before the ITC, the PTAB and the Federal Circuit in connection with the challenges stemming from the 1199 Investigation.

With respect to economic prong of the domestic industry, Reynolds has already successfully proved the existence of one in the 1199 Investigation based on the exact same line of products on which Reynolds is relying here for domestic industry. The only difference between the 1199 Investigation and the facts here is that Reynolds now relies on *more* products

[REDACTED]

within the line of domestic industry products, which necessarily means the investments are more significant in this case.

With respect to importation, that is not an issue that will seriously be contested. All Proposed Respondents are Chinese manufacturers or domestic distributors working with the Chinese manufacturers who indisputably import the products into the United States.

Reynolds is suffering irreparable harm. The Proposed Respondents are undermining and irreparably harming Reynolds's decades of work, investment, and building of a legitimate reputation in the eyes of the public and before the FDA. They are stealing Reynolds's patented technology, having not invested a bit of research or development on their own, placing that patented technology in high-demand products that neither Reynolds nor any other company can legally sell, improperly and unethically targeting American youth with candy- and dessert-flavored versions of Reynolds's patented technology, and selling all of these products into the U.S. markets without any effort to invest the tens of millions of dollars necessary to obtain FDA authorization to do so legitimately. All of this is creating a tilted playing field in which Reynolds is competing against its own patented technology with both hands tied behind its back. The loss of investment, reputation, market share, distribution channels, pricing power, ability to introduce new products in a timely manner, and so much more is beyond irreparable harm.

The balance of equities weighs overwhelmingly in favor of temporary relief. As a result of Proposed Respondents' infringement, Reynolds is being forced to compete against its own patented inventions used in products Reynolds cannot legally sell and that are in highest demand; it is being completely cut out of distribution channels; it is losing more market share by the day; and as a result of these impermissible and illicit trade practices, Reynolds is losing over a [REDACTED] dollars a year, more than [REDACTED] a month, and [REDACTED] of

[REDACTED]

dollars a day. All the while, Proposed Respondents' practices are damaging Reynolds's reputation and causing severe erosion in the value of the market.

To be sure, granting temporary relief will result in lost revenue to Proposed Respondents. But that does not tip the balance of equities in their favor, because any revenue that Proposed Respondents will lose is clearly the product of their unlawful and illicit activities, and those activities, which are harming the public interest, are appropriately halted by a temporary exclusion order.

The public interest weighs in favor of temporary relief. The public interest factor has been addressed many times in ITC cases involving the proposed exclusion of e-cigarettes and related nicotine delivery devices. Not once has the ITC found that the public interest weighs against banning infringing e-cigarettes and related nicotine delivery devices from importation. The case for the same outcome here is especially strong because the continued importation of the Accused Products is actually *harming* the public interest. Proposed Respondents are causing substantial, ongoing, and ever-increasing harm to minors who obtain Proposed Respondents' products as well as the public's interest in preventing underage vapor use.

The only effective remedy against the irreparable harm being caused by Proposed Respondents is preliminary relief in the form of a TEO. Although the '202 Patent has just issued, because it is a continuation of prior patents in this area, it is set to expire in October 2026, so every day that Proposed Respondents are allowed to continue to import their infringing products is an affront to this Nation's trade laws. These unfair trade practices must be stopped, and stopped immediately.



II. BACKGROUND

A. Overview of the '202 Patent

U.S. Patent No. 11,925,202 issued on March 12, 2024 and claims priority through a series of continuation applications (including application number 15/286,087 which issued as U.S. Patent No. 9,901,123) to an application filed on October 18, 2006. It is currently assigned to Complainant RAI Strategic Holdings, Inc. The '202 Patent has 30 claims: 2 independent claims and 28 dependent claims. Exhibit 1 at 32:58-35:7.

The '202 Patent is directed to devices and components thereof that provide adult tobacco consumers with a smoking alternative to traditional cigarettes. The '202 Patent generally concerns a smoking article that includes an electrical power source that powers a heater to heat an aerosol-forming material in a storage compartment portion of the smoking article. The storage compartment is arranged such that the liquid aerosol-forming material can be wicked into contact with the heater to volatilize the liquid aerosol-forming material. The smoking article may additionally include a controller that is configured to activate current flow through the heater in response to a draw on the smoking article.

B. Proposed Respondents

In the Verified Complaint filed contemporaneously herewith, Reynolds identified the following Proposed Respondents that have violated Section 337 by importing, selling for importation, or selling after importation disposable vaping products that infringe the '202 Patent.

1. 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 and a registered agent at 4654 Lilly Court, West Bloomfield, Michigan 48323. *See* Exhibit 106 at 1. The addresses at 1471 E. Nine Mile Road, Unit 200, Hazel Park, Michigan 48030, at 450 W. Fourth

[REDACTED]

Street, Royal Oak, Michigan 48067, and at 26056 Van Dyke Ave. STE 3537, Centerline, MI 48015 are also associated with Breeze Smoke. *See* Exhibits 5 at 4; 107 at 4; 108 at 2. “Breeze Smoke, LLC” is listed as the distributor on the packaging for Breeze Smoke products. *See* Exhibits 6 at 4; 7 at 4; *see also* 5 at 5 (“Distributed by: Breeze Smoke”).

(a) Capital Sales Company

Capital Sales Company (“Capital Sales”) is a Michigan limited liability company with a registered address at 450 W. 4th Street, Royal Oak, Michigan 48067 and an address at 1471 E. Nine Mile Road, Unit 200, Hazel Park, Michigan 48030. *See* Exhibits 109 at 1; 110 at 1. Capital Sales imports, sells, and/or distributes for sale one or more of the Accused Products alone or in partnership with Breeze Smoke via the website capitalcsc.com. *See* Exhibits 111 (indicating contact information for “Breeze Smoke Inquiries – Breeze@capitalcsc.com”); 112 (stating that Capital Sales “is the exclusive distributor for Breeze Smoke.”); 113 (showing the booth location of “Breeze Smoke (distributed by Capital Sales Company)” at the National Association of Convenience Stores Show 2022).

(b) KMT Services LLC d/b/a KMT Distribution and Dank Shop

KMT Services LLC d/b/a KMT Distribution and Dank Shop (“KMT Services”) is a Michigan limited liability company with a registered address at 721 E. Eight Mile Road, Hazel Park, Michigan 48030 and a registered address at 23250 Sherwood Avenue, Warren, Michigan, 48091. *See* Exhibits 114 at 1; 116 at 1. KMT Services also conducts business under the assumed names KMT Distribution and Dank Shop. *See* Exhibit 115 at 1. KMT operates the website dankshop.com through which KMT Services markets Breeze Smoke products, offers Breeze Smoke products for distribution, and/or offers Breeze Smoke products for sale. *See* Exhibits 117 at 3, note 12; 118 at 8..

(c) Dongguan (Shenzhen) Shikai Technology Co., Ltd.

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 and at F/5, Building T2, South Coast of Convention and Exhibition Bay, Fuhai Street, Bao’an District, Shenzhen, Guangdong, China 518103. *See* Exhibits 6 at 4; 119. Shikai Technology manufactures Breeze-Smoke products. *See id.*; *Certain Disposable Vaporizer Devices and Components and Packaging Thereof*, Inv. No. 337-TA-1381 (Violation), EDIS Doc. ID No. 812691, Respondent Breeze Smoke, LLC and Dongguan (Shenzhen) Shikai Technology Co., Ltd.’s Response to Complainants’ Verified Complaint at ¶¶ 46–48 (U.S.I.T.C. Oct. 13, 2023) (“Certain Disposable Vaporizer Devices, Inv. No. 1381”). Shikai Technology also has an address at Room 501-510, Building 16, Nan’an Plaza, Exhibition Bay, Zhancheng Community, Fuhai Street, Bao’an District, Shenzhen, Guangdong, China. *See* Exhibit 119. “Dongguan Shikai Technology Co., Ltd” is listed on the packaging of Breeze Smoke products as the manufacturer of those products. *See* Exhibits 6 at 3–4; 7 at 4–5.

Breeze Smoke, Capital Sales, KMT Services and Shikai Technology, collectively, are referred to herein as the “Breeze Proposed Respondents.”

2. iMiracle Proposed Respondents

(a) Vapeonly Technology Co. Ltd.

Vapeonly Technology Co. Ltd. (“Vapeonly”) is a Chinese limited company with its principal place of business at 19H Maxgrand Plaza, No. 3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong and an address at Room 306-311, Tianshu Building, No. 6099, Bao’an Avenue, Bao’an District, Shenzhen, China 518000. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812394, Respondents Shenzhen Weiboli Technology Co. Ltd, Vapeonly Technology Co. Ltd., iMiracle (Shenzhen) Technology Co., Ltd., Guangdong Qisitech

Co., Ltd., and Shenzhen Han Technology Co., Ltd. Response to the Verified Complaint at ¶ 51; Exhibit 120. Vapeonly's LinkedIn profile states that "Vapeonly Technology Company Ltd. is a company based out of Baoan District, Shenzhen China," and that it "[focuses] on Elf Bar disposable pod brand." See Exhibit 120 at 1. Vapeonly's LinkedIn profile also displays a trademark, consisting of a flower with three bubbles, which appears on the packaging of Elf Bar, EB Create, EB Design, and PodKing products. This trademark is registered to an iMiracle company. See Exhibit 121.

(b) iMiracle (Shenzhen) Technology Co., Ltd.

iMiracle (Shenzhen) Technology Co., Ltd. ("iMiracle (Shenzhen)") is a Chinese limited company with an address at Room 1203, Block 1, Wanting Building, Xixiang Subdistrict, Bao'an District, Shenzhen, China 518126; an address at Room 1606, Office Building T5, Qianhai China Resources Financial Center, No. 5035 Menghai Avenue, Nanshan Street, Qianhai Hong Kong-Shenzhen Cooperation Zone, Shenzhen, Guangdong Province, China 518052; and an address at Unit 3510-37, Luohu Business Center, No. 2028 Shennan East Road, Chengdong Community, Dongmen Street, Luohu District, Shenzhen, Guangdong, China. See Exhibits 17 at 6; 14 at 5; 10 at 5; 11 at 6; 13 at 5; 12 at 5; 15 at 5; 18 at 4; 21 at 5; *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812394, Respondents Shenzhen Weiboli Technology Co. Ltd., Vapeonly Technology Co. Ltd., iMiracle (Shenzhen) Technology Co., Ltd., Guangdong Qisitech Co., Ltd., and Shenzhen Han Technology Co., Ltd. Response to the Verified Complaint at ¶ 52. The packaging of Elf Bar, EB Design, Funky Republic, Pod King, and Lost Mary products list "iMiracle (Shenzhen) Technology Co., Ltd." as a company associated with those brands. See Exhibits 17 at 6; 14 at 5; 10 at 5; 11 at 6; 13 at 5; 12 at 5; 15 at 5; 18 at 4; 21 at 5 iMiracle (Shenzhen)) owns the trademark "HEAVEN GIFTS" (stylized) (U.S. Reg. No. 88548375). See

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Exhibits 122. The “Heaven Gifts” trademark is used by Heaven Gifts International Ltd. *See* Section (II)(B)(2)(o), *infra*.

iMiracle (Shenzhen) is associated with at least the following brands: Pod King, Geek Bar, Vapejoy, Manba, Coolplay, Suorin Air Bar, Geek Vape, Vapeonly, Kanger Tech, iJoy, VooPoo, Digiflavor, HotCig, Joyetech, Wismec, Artery, ELeaf, Heaven Gifts, Smok, iPha, Vaporesso, Kizoku, AAA, DOVPO, Golisi, JustFog, Innokin, MechLyfe, DJV, OBS, Smoany, YoCan, VGOD, NiteCor, Tnkk Vape, Sense, AugVape, Ampking, Vapefly, Vladdin, Vaptio, and/or Quanins. *See* [REDACTED] Exhibit 123C (identifying entities related to Shenzhen iMiracle); Exhibit 1234 at 2; *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 818868, Complainants’ Motion to Amend the Complaint and Notice of Investigation at 11–14 (describing iMiracle (Shenzhen)’s relationship with Heaven Gifts). iMiracle Shenzhen holds equity in Shenzhen Youwo Network Technology Co., Ltd. (associated with vape brands YouMe (HNB), Suorin, Idols, Air Bar, and Coolplay (Vape)), Shenzhen Yikanger Electronic Technology Co., Ltd. (vape brands Desire, Mad Dog, Supreme (Vape)), Shenzhen Jinzhiyuan Technology Co., Ltd. (vape brands Manba, Suorin, Vapejoy), and Shenzhen Senkeweipu Technology Co., Ltd. (vape brand Thinkvape). *See* [REDACTED] Exhibit 123C at 2 (identifying entities related to Shenzhen iMiracle); *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 818868, Complainants’ Motion to Amend the Complaint and Notice of Investigation at 11–14 (regarding iMiracle (Shenzhen)’s relationship with Heaven Gifts).

(c) Guangdong Qisitech Co., Ltd.

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. *See* Exhibits 10 at 5; 125. The packaging of Elf Bar, EB Design, RAZ, and Geek Bar products list “Guangdong Qisitech Co., Ltd.” as the manufacturer of these

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products. *See* Exhibits 27 at 6; 10 at 5; 26 at 5; 12 at 5; 28 at 5. The packaging of the Geek Bar products lists “GUANGDONG QISITECH CO., LTD.” as a company associated with those products. *See* Exhibits 20 at 4; 19 at 4 (“MANUFACTURED FOR GUANGDONG QISITECH CO., LTD.”).

(d) Fewo Intelligent Manufacturing Limited

Fewo 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; an address at Room 301, Building 12, No.5, Xinxia Road, Humen Town, Dongguan, Guangdong Province, China 523900; and an address at Room 101, Building 9, No. 243 Huaide Road, Humen Town, Dongguan, Guangdong, China. *See* Exhibits 16 at 5; 17 at 6; 126. On information and belief, Fewo Intelligent is sometimes called “Fewo Intelligent Manufacturing Co., LTD” or “Guangdong Fuwo Intelligent Manufacturing Co., Ltd.” *See* Exhibits 16 at 5; 17 at 6. The packaging of EB Create, Funky Lands, and Rabbeats products list “FEWO INTELLIGENT MANUFACTURING LIMITED” as the manufacturer of those products. *See* Exhibits 8 at 5; 16 at 5; 29 at 6. The packaging of Lost Mary products list “FEWO INTELLIGENT MANUFACTURING LIMITED” and “GUANGDONG FUWO INTELLIGENT MANUFACTURING CO., LTD.” as the manufacturer of those products. *See* Exhibits 24 at 5; 25 at 4.

(e) Nevera (HK) Ltd.

Nevera (HK) Ltd. (“Nevera (HK)”) is a Hong Kong limited company with an address at 19H, Maxgrand Plaza, No.3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong. *See* Exhibits 9 at 4; 8 at 4. The packaging of EB Create products list “NEVERA (HK) LIMITED” as a company associated with those brands. *Id.*

(f) Guangdong Cellular Workshop Electronics Technology Co., Ltd.

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. *See* Exhibit 18 at 5. “GUANGDONG CELLULAR WORKSHOP ELECTRONICS TECHNOLOGY CO., LTD.” is listed on the packaging of Funky Republic products as the manufacturer of those products. *Id.*

(g) Wonder Ladies Ltd.

Wonder Ladies Ltd. (“Wonder Ladies”) is a British Virgin Islands limited company with an address at Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands and Wickhams Cay, P.O. Box 145, Road Town, Tortola, British Virgin Islands. *See* Exhibit 22 at 5. “WONDER LADIES LIMITED” appears on the packaging for Lost Mary products as a company associated with those products. *Id.*

(h) Sailing South Ltd.

Sailing South Ltd. (“Sailing South”) is a British Virgin Islands limited company with an address at Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands. *See* Exhibit 16 at 4. “SAILING SOUTH LIMITED” appears on the packaging for Funky Lands products as a company associated with those products.” *Id.*

(i) Marea Morada Ltd.

Marea Morada Ltd. (“Marea Morada”) is a British Virgin Islands limited company with an address at Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands and an address at OMC Chambers, Wickhams Cay 1, Road Town, Tortola, VG1110 British Virgin

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Islands. *See* Exhibit 29 at 6; 30 at 6; 127. “MAREA MORADA LIMITED” appears on the packaging for Rabbeats products as a company associated with those products. *Id.*

(j) Social Brands, LLC

Social Brands LLC (“Social Brands”) is a Texas limited company with an address at 9696 Skillman Street STE 385 Dallas, Texas 75243. *See* Exhibit 128. “Social Brands, TX 75243, USA” appears on the packaging for Space Mary products as a company associated with those products. *See* Exhibit 31 at 5. Social Brands is also involved in the importation, distribution, and/or sale of several Accused Products, including Space Mary, Pod King, EB Design, Elfbar, Lost Mary, Funky Republic, and Geekvape (RAZ) brand products, among others. *See* Exhibit 129 at 1.

(k) Zhuhai Qisitech Co., Ltd.

1. 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. *See* Exhibits 20 at 4; 19 at 4. “Zhuhai Qisitech Co., LTD.” is listed on the packaging of Geek Bar products as the manufacturer of those products. *Id.*

(l) Shenzhen Han Technology Co., Ltd.

2. 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. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812394, Respondents Shenzhen Weiboli Technology Co. Ltd, Vapeonly Technology Co. Ltd., Imiracle (Shenzhen) Technology Co., Ltd., Guangdong Qisitech Co., Ltd., and Shenzhen Han Technology Co., Ltd. Response to the Verified Complaint at ¶ 54. Shenzhen Han manufactures electronic nicotine delivery systems (“ENDS”), including Lost Mary disposable vapes. *Id.*

(m) Palma Terra Ltd.

Palma Terra Ltd. (“Palma Terra”) is a British limited company with an address at Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands and an address at Chase Business Centre 39-41, Chase Side, London, United Kingdom N14 5BP. *See* Exhibits 24 at 5; 130 at 2; 131 at 3. “PALMA TERRA LIMITED” appears on the packaging for Off Stamp products as a company associated with those products. *See* Exhibit 24 at 5.

(n) Shenzhen IVPS Technology Co., Ltd.

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. *See* Exhibit 34 at 6. Shenzhen IVPS is also associated with the addresses at 3/F TeAn Jiejing Nenguan Tech Building, Shenzhen, China and 13F Block B3, Building Unit 9, Zone 2, Shenzhen Bay Tech-Eco Park, Nanshan District, Shenzhen, China. *See* Exhibits 132 at 2; 133 at 3; 134 at 2; 135 at 2. “SHENZHEN IVPS TECHNOLOGY CO., LTD.” is listed on the packaging of Smok PRIV Bar and Smok NOVO Bar products as a company associated with those products. *See* Exhibits 34 at 6; 32 at 6.

On information and belief, Shenzhen IVPS also occasionally does business or has done business in the past as Shenzhen Smok Technology Co. (“Smok Tech”) with an address at 3rd Fl. TeAn Jiejing Nengyuan Tech Building, Langshan Erhao Rd., Nanshan District, Shenzhen, China. *See* Exhibit 136 at 2; 135 at 2 (the “Contact Us” page on smoktech.com mentioning the company “IVPS”). On information and belief, Shenzhen IVPS, under the name Smok Tech, operates the website smoktech.com which it uses to offer Smok brand products for sale or distribution in the United States. *See* Exhibit 137 at 1.

(o) Heaven Gifts International Ltd.

Heaven Gifts International Ltd. (“Heaven Gifts”) is a Chinese limited company with the following addresses: Room 2004B-2005, Floor 20, No. 22, Lane 118, Zhongjiang Road, Putuo District, Shanghai, China; 11th Floor, Building T4, Lane 1199, Zhennan Road, Putuo District, Shanghai, China; RM 1606, Building T5, No. 5035 Menghai Ave., Nanshan District, Qianhai Cooperation Zone, Shenzhen, China; 28th Floor, Building A, Huahai Financial Innovation Center, Nanshan District, Shenzhen, China, and 19H, Maxgrand Plaza, No. 3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong. *See* Exhibits 38 at 3; 139 at 3; 140 at 3. On information and belief, Heaven Gifts is iMiracle (Shenzhen)’s parent company. *See* Exhibit 142 at 5. Heaven Gifts is associated with the brands one or more of the Accused Products, including Lost Mary and Elf Bar. *See* Exhibits 141 at 2, 4; 142 at 4-5.

Heaven Gifts claims to be the largest English-language-dedicated electronic-cigarette e-commerce sales platform founded in China in 2007, and claims to stock 16,000 e-cigarette items. *See* [REDACTED] Exhibit 123C at 2.

Vapeonly, iMiracle (Shenzhen), Guangdong Qisitech, Fewo Intelligent, Nevera (HK), Guangdong Cellular, Wonder Ladies, Sailing South, Marea Morada, Social Brands, Zhuhai Qisitech, Shenzhen Han, Palma Terra, Shenzhen IVPS, and Heaven Gifts, collectively, are referred to herein as the “iMiracle Proposed Respondents.”

3. Loon Proposed Respondent

(a) Maduro Distributors Inc. d/b/a The Loon

Maduro Distributors Inc. d/b/a The Loon (“Maduro Distributors”) is a Minnesota corporation with a registered address at 3021 82nd Lane NE, Blaine, Minnesota 55449 and a principal executive office address of 2738 104th Ct. NE, Blaine, Minnesota 55449. *See* Exhibits 143 at 1; 144 at 1 (stating Maduro Distributors does business as “The Loon”). Maduro

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Distributors advertises on the website theloonmn.com that Loon products are available in stores across the country. *See* Exhibit 145. Loon Maxx is a product offered on the website theloonmn.com. *See* Exhibit 146 at 1. Loon Air is a product offered on the website loonwholesale.com. *See* Exhibits 147; 148. “The Loon” appears on the packaging for Loon products as the distributor. *See* Exhibit 35 at 3.

4. Bidi Proposed Respondents

(a) Bidi Vapor, LLC

Bidi Vapor, LLC (“Bidi Vapor”) is a Florida limited company with a registered address at 200 South Orange Avenue, STE 2300, Orlando, Florida 32801. *See* Exhibits 149 at 1; 150. The address at 4460 Old Dixie Highway, Grant-Valkaria, Florida 32949 is also associated with Bidi Vapor. *See* Exhibit 151 at 2. “Bidi Vapor, LLC” appears on the packaging for the Bidi Stick Regal as a company associated with the product. *See* Exhibit 37 at 6.

(b) Kaival Brands Innovations Group Inc.

Kaival Brands Innovations Group Inc. (“Kaival Brands Innovations”) is a Delaware corporation with a registered address at 16192 Coastal Highway, Lewes, Delaware 19958, and/or 1209 Orange Street, Wilmington, Delaware 19801, with a corporation headquarters at 4460 Old Dixie Highway, Grant-Valkaria, Florida 32949 and an address at 401 N. Wickham Road, Suite 130, Melbourne, Florida 32935. *See* Exhibits 152; 153; 154 at 1. Kaival Brands Innovations is the “exclusive U.S. distributor of all products manufactured by Bidi Vapor, LLC.” *See* Exhibit 155 at 1.

Bidi Vapor and Kaival Brands Innovations, collectively, are referred to herein as the “Bidi Proposed Respondents.”



5. Hyppe Proposed Respondents

(a) Kimsun Technology (HuiZhou) Co., Ltd.

Kimsun Technology (HuiZhou) Co., Ltd. (“Kimsun Technology (HuiZhou)”) is a Chinese limited company with an address at “No. 8 Taixiang Road, Hig-Tech [sic] Industrial Park, Huicheng Dist., Huizhou, Guandong, China 516025.” *See* Exhibit 38 at 6. “KIMSUN TECHNOLOGY (HUIZHOU) CO., LTD.” is listed on the packaging of the Hyppe Max 1600 puffs as the factory. *Id.* The packaging for the Hyppe Max Air 5000 and the Hyppe Max Air Flow Mesh lists “SHENZHEN TECHNOLOGY (HUIZHOU) CO., LTD.” as the name of the factory for this product. *See* Exhibits 39 at 6; 40 at 6. The address for Kimsun Technology (HuiZhou) on the Hyppe Max 1600 package is the same address listed for an entity called Shenzhen Technology (HuiZhou) on the Hyppe Max Air 5000 package, with the exception that “High-Tech Industrial Park” is spelled “Hig-Tech Industrial Park.” Based on this shared address, Kimsun Technology is the factory referred to on the packaging of Hyppe Max Air 5000 and the Hyppe Max Air Flow Mesh products.

(b) Shenzhen Yanyang Technology (HuiZhou) Co., Ltd.

Shenzhen Yanyang 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. *See* Exhibit 156 at 2. “SHENZHEN YANGYANG TECHNOLOGY CO.,LTD” is listed on the packaging of the Hyppe Max Air 5000 as the factory. *Id.*

Kimsun Technology (HuiZhou) Co., Ltd. and Shenzhen Yanyang, collectively, are referred to herein as the “Hyppe Proposed Respondents.”

6. Esco Bars Proposed Respondents

(a) Pastel Cartel, LLC

Pastel Cartel, LLC (“Pastel Cartel”) is a Texas limited liability company located at 5900 Balcones Drive, Suite 100, Austin, TX 78731-4298. *See* Exhibit 157. “Pastel Cartel LLC” is listed on the packaging as the designer of Esco Bars products. *See* 43 at 6. The location listed under Pastel Cartel on the Esco Bars KILO packaging is “Pflugerville, TX 78660.” Exhibit 158. The FDA Import Alert 98-06 identifies Pastel Cartel as a “firm [that] may be importing/manufacturing/shipping a new tobacco product (“Esco Bar”/“Escobar”) without marketing authorization.” *See* Exhibit 159 at 17. The FDA Import Alert 98-06 lists “13326 Immanuel Rd Ste 3, Pflugerville, TX 78660-8006 UNITED STATES” as the Pastel Cartel address. *Id.*; *see also* Exhibit 160. Pastel Cartel admitted that “in the past it sold for importation, imported and/or sold after importation certain accused Esco Bar products,” and “it has continued to sell previously imported inventory of accused Esco Bar products.” *See* Certain Disposable Vaporizer Devices, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents’ Response to the Amended Complaint at ¶ 358.

(b) American Vape Company, LLC

American Vape Company, LLC (“American Vape”) is a Texas limited liability company located at 13326 Immanuel Road, Pflugerville, Texas United States 78660. *See* Exhibit 161. American Vape is located at the same address associated with Pastel Cartel. *See* Exhibit 162 at 2. American Vape admitted that it “sold for importation, imported, and/or sold after importation Esco Bars Disposable Vapes.” *See* *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents’ Response to the Amended Complaint at ¶ 357.

(c) Affiliated Imports, LLC

Affiliated Imports, LLC (“Affiliated Imports”) is a Texas limited liability company located at 5900 Balcones Drive, Suite 100, Austin, TX 78731-4298. *See* Exhibit 163. Affiliated Imports is listed at the same address associated with Pastel Cartel. *See* Exhibit 157. The FDA Import Alert 98-06 lists “13326 Immanuel Rd, Pflugerville, TX 78660-8006 UNITED STATES” as the address associated with Affiliated Imports. *See* Exhibit 159 at 8. The FDA Import Alert 98-06 identifies Affiliated Imports as a firm that “may be importing/manufacturing/shipping a new tobacco product (“Esco Bar”/“Escobar”) without marketing authorization.” *Id.* Affiliated Imports admitted that it is registered to American Vape Company and acts as American Vape Company’s and Pastel Cartel’s consignee and importer of record for incoming shipments of Esco Bars Disposable Vapes to the United States. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents’ Response to the Amended Complaint at ¶ 59 (admitting to allegations in the Amended Complaint).

(d) Shenzhen Innokin Technology Co., Ltd.

Shenzhen Innokin Technology Co., Ltd. (“Shenzhen Innokin”) is a Chinese limited company with an address at Building 6, XinXinTian Industrial Park, Xinsha Road, Shajing, Bao’an District, Shenzhen, Guangdong Province, China 518104. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812376, Respondent Shenzhen Innokin Technology Co., Ltd.’s Response to Complaint at ¶ 60 (admitting to allegations in the Complaint). Shenzhen Innokin admitted that it manufactured certain Esco Bar products in a prior litigation. The FDA sent a warning letter to Shenzhen Innokin identifying Shenzhen Innokin as a distributor of Esco Bars products to U.S. retailers. *Id.* Pastel Cartel admitted that Shenzhen Innokin “has in the past manufactured some Esco Bars Disposable Vapes.” *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel



Respondents' Response to the Amended Complaint at ¶ 60 (admitting to allegations in the Amended Complaint).

(e) Shenzhen Funyin Electronic Technology Co., Ltd.

Shenzhen Funyin Electronic Technology Co., Ltd. ("Shenzhen Funyin") is a Chinese limited company located at 205 and 401, Building A3, Fuyuan Ind. Zone, Tangwei Community, Fuhai St., Bao'an District, Shenzhen, Guangdong China 518000. *See* Exhibit 165 at 2. Pastel Cartel admitted that Shenzhen Funyin "has in the past manufactured some Esco Bars Disposable Vapes." *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents' Response to the Amended Complaint at ¶ 61 (admitting to allegations in the Amended Complaint).

Pastel Cartel, American Vape, Affiliated Imports, Shenzhen Innokin, and Shenzhen Funyin, collectively, are referred to herein as the "Esco Bar Proposed Respondents."

7. Mr. Fog Proposed Respondents

(a) Shenzhen LC Technology Co., Ltd.

Shenzhen LC Technology Co., Ltd. ("Shenzhen LC") is a Chinese limited company with an address at Licheng Technology Park, Shajing Town, Bao'an District, Shenzhen, Guangdong Province, China. *See* Exhibit 44 at 5. "Shenzhen LC Technology Co., Ltd." is listed on the packaging of Mr. Fog brand products as the manufacturer of those products. *Id.*

(b) LCF Labs, Inc.

LCF Labs, Inc. ("LCF Labs") is a California company with a registered address at 895 S Rockefeller Avenue, Unit 103, Ontario, California 91761. *See* Exhibits 166 at 1; 167 at 1. "LCF Labs" appears on the packaging for Mr. Fog products as a company associated with those products. *See* Exhibit 45 at 4.

[REDACTED]

Shenzhen LC and LCF Labs, collectively, are referred to herein as the “Mr. Fog Proposed Respondents.”

8. Kangvape Proposed Respondent

(a) Shenzhen Kangvape Technology Co., Ltd.

Shenzhen Kangvape Technology Co., Ltd. (“Shenzhen Kangvape”) is a Chinese limited company with an address at Chuangxin Port, Hanyu Bay District, Fuhai Street, Bao’an District, Shenzhen, China. *See* Exhibit 48 at 4. “Shenzhen Kangvape Technology Co.,Ltd.” is listed on the packaging of Kangvape products as the manufacturer of those products. *Id.*

Shenzhen Kangvape is referred to herein as the “Kangvape Proposed Respondent.”

9. Flum Proposed Respondent

(a) Flumgio Technology Ltd.

Flumgio Technology Ltd. is a Chinese limited company with an address at Room 21, Unit A, 11F, Tin Wui Industrial Building, No. 3 Hing Wong Street, Tuen Mun, N.T. *See* Exhibit 53 at 5. “Flumgio Technology LTD” appears on the packaging of Flum products as a company associated with those products. *Id.*

Flumgio Technology Ltd.is referred to herein as the “Flume Proposed Respondent.”

10. Posh Proposed Respondent

(a) Shenzhen Pingray Technology

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. *See* Exhibit 41 at 6. Shenzhen Pingray is also associated with the address “B F 3, 28 Heyi Beifang; Shajing Town , Shenzhen, CHINA” and with the address Floors 2, 3 and 4, Building G, Wanfeng Western Entrepreneurship Park, Heyi Community, Shajing Street, Bao’an District, Shenzhen, Guangdong, China. *See* Exhibit 159 at 6; *see also* Exhibit 168.

[REDACTED]

“Shenzhen Pingray Technology Co., Ltd.” is listed on the packaging of Posh products as the manufacturer of those products. *See* Exhibit 41 at 6.

Shenzhen Pingray is referred to herein as the “Posh Proposed Respondent.”

C. Proposed Distributor Proposed Respondents

Numerous entities, including the below Proposed Respondents, sell after importation into the United States several of the Accused Products through websites and electronic marketplaces. These Proposed Respondents are collectively referred to herein as the “Distributor Proposed Respondents.”

1. SV3 LLC d/b/a Mi-One Brands

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. *See* Exhibit 169 at 2. SV3 is also associated with the address 4908 E. McDowell Rd., Phoenix, Arizona 85008. *See* Exhibit 170 at 2. SV3 LLC conducts business under the trade name Mi-One Brands and operates Mipod.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812708, Respondent SV3 LLC d/b/a Mi-One Brands' Response to the Complaint and Supplement to the Complaint at ¶ 90. The MI-POD website advertises one or more of the Accused Products. *See* Exhibit 171. Shenzhen Weiboli, Vapeonly, and iMiracle (Shenzhen) admitted that SV3 LLC d/b/a Mi-One Brands at one point sold some Elf Brand products. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812394, Respondents Shenzhen Weiboli Technology Co. Ltd, Vapeonly Technology Co. Ltd., iMiracle (Shenzhen) Technology Co., Ltd., Guangdong Qisitech Co., Ltd., and Shenzhen Han Technology Co., Ltd. Response to the Verified Complaint at ¶ 86.

2. Price Point Distributors Inc. d/b/a Price Point NY

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. *See* Exhibit 172 at 1. Price Point’s admitted to selling various nicotine-containing products on the website pricepointny.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812408, Respondent Price Point Distributors, Inc. d/b/a Price Point NY’s Response to the Notice of Investigation and Complaint at ¶ 89. This website advertises one or more of the Accused Products for sale. *See* Exhibit 173.

3. Flawless Vape Shop Inc.

Flawless Vape Shop Inc. (“Flawless Vape Shop”) is a California corporation with a principal address at 5589 E. Santa Ana Canyon Rd, Anaheim, CA 92807. *See* Exhibit 174. On information and belief, Flawless Vape Shop owns and operates flawlessvapeshop.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 805887, Complaint at ¶ 87. “Flawless Vape Shop” is listed as the contact entity on flawlessvapeshop.com. *See* Exhibit 175 at 2. Flawlessvapeshop.com advertises one or more of the Accused Products. *See* Exhibit 176.

4. Flawless Vape Wholesale & Distribution Inc.

Flawless Vape Wholesale & Distribution Inc. is a California corporation with a with a principal address at 5589 E. Santa Ana Canyon Rd, Anaheim, CA 92807. *See* Exhibit 177 at 1. This address is the same as the principal address for Flawless Vape Shop *See* Exhibit 174 at 1. Flawless Vape Wholesale & Distribution Inc. sells products to consumers across the country from the website www.flawlessvapeshop.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 805887, Complaint at ¶ 88. Flawlessvapeshop.com advertises one or more of the Accused Products. *See* Exhibit 176.

5. Thesy, LLC d/b/a Element Vape

Thesy, 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. *See* Exhibit 178 at 1. Element Vape admitted that its fulfillment warehouse is located at that same address. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812423 Respondent Thesy Response to the Notice of Investigation and Complaint at ¶ 91. Element Vape admitted that it sells disposable ENDS devices to consumers in the United States through the website elementvape.com. *Id.* This website advertises one or more of the Accused Products. *See* Exhibit 179.

6. VICA Trading Inc. d/b/a/ Vapesourcing

VICA Trading Inc. d/b/a Vapesourcing (“Vape Sourcing”) is a California corporation with a principal place of business at 3045 Edinger Avenue, Tustin, California 92780. *See* Exhibit 180 at 1. On information and belief, Vape Sourcing sells ENDS, including some or all of the Accused Products, to consumers across the country from the website vapesourcing.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 805887, Complaint at ¶ 92. The website advertises one or more of the Accused Products. *See* Exhibit 181.

7. Ecto World, LLC d/b/a Demand Vape

Ecto World, LLC d/b/a Demand Vape (“Demand Vape”) is a New York limited company with a principal place of business at 2225 Kenmore Ave., Buffalo, NY 14207. *See* Exhibit 182 at 1. On information and belief, Demand Vape sells ENDS through the website demandvape.com. *See* Exhibit 183 at ¶ 24. The website demandvape.com lists 2225 Kenmore Ave., Buffalo, NY 14207 under the contact information. *See* Exhibit 184 at 1. This website advertises one or more of the Accused Products. *See* Exhibit 185.

8. Midwest Goods Inc. d/b/a Midwest Distribution

Midwest Goods Inc. d/b/a Midwest Distribution (“Midwest Goods”) is an Illinois company with a registered address at 1001 Foster Avenue, Bensenville, Illinois 60106. *See* Exhibit 186. Midwest Goods Inc. does business under the assumed name Midwest Distribution Illinois. *See* Exhibits 186 at 2; 43.005. Midwest Distribution appears under the contact information for the website midwestgoods.com. *See* Exhibits 187 at 4; 188 at 1. This website advertises one or more of the Accused Products. *See* Exhibit 189.

III. LEGAL STANDARDS

During the course of an investigation, if the Commission determines that there is reason to believe there is a violation of 19 U.S.C. § 1337, Section 337(e)(1) authorizes the Commission to:

direct that the articles concerned, imported by any person with respect to whom there is reason to believe that such person is violating this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. § 1337(e)(i).

Additionally, “[t]he Commission may grant preliminary relief [under Section 337(e)] to the same extent as preliminary injunctions and temporary restraining orders may be granted under the Federal Rules of Civil Procedure.” 19 U.S.C. § 1337(e)(3). To decide whether to grant such preliminary relief, the Commission applies “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). In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393–94 (2006), the Supreme Court held that courts adjudicating patent disputes should

[REDACTED]

apply “the traditional four-factor framework that governs the award of injunctive relief.”

Accordingly, the Commission considers four factors:

1. Complainant’s probability of success on the merits;
2. Threat of irreparable harm in the absence of the requested relief;
3. The balance of harm between the parties; and
4. The effect, if any, that issuance of the requested temporary relief would have on the public interest.

Certain Dielectric Miniature Microwave Filters and Multiplexers Containing Same, Inv. No. 337-TA-359, Initial Determination (Mar. 17, 1994) (recommending issuance of temporary exclusion order) and Comm’n Order (Apr. 18, 1994) (issuing temporary exclusion order); *see generally Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 865 (Fed. Cir. 2017); (affirming trial court’s grant of motion for preliminary injunction); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930–31 (Fed. Cir. 2012) (same).

IV. THE TRADITIONAL EQUITABLE INJUNCTION FACTORS WEIGH HEAVILY IN FAVOR OF GRANTING REYNOLDS’S REQUESTED TEMPORARY EXCLUSION ORDER

The Proposed Respondents’ infringing products should be excluded from entry during the pendency of the Investigation. As demonstrated below, each of the four traditional equitable injunction factors weighs overwhelmingly in favor of issuing a temporary exclusion order to stop the Proposed Respondents from importing and selling their infringing disposable vaporizer devices to U.S. customers.

A. Reynolds Will Succeed on the Merits

As discussed in detail below, Reynolds will be able to prove infringement, importation, and domestic industry, whereas the Proposed Respondents will be unable to raise a substantial

[REDACTED]

question of invalidity or unenforceability of the Asserted Patents. Accordingly, Reynolds is likely to succeed on the merits.

1. Reynolds Is Likely To Prove Infringement By The Proposed Respondents

Asserted claim 1 of the '202 Patent is directed to an electrically powered, aerosol-generating smoking article that includes an outer housing, a mouthpiece, an electrical power source, an electrical resistance heater, a controller configured to activate current flow through the heater in response to a draw, a storage compartment configured to store liquid aerosol-forming material and arranged such that the liquid aerosol-forming material can be wicked into contact with the heater, and an air passageway where drawn air is combined with the volatilized liquid aerosol-forming material and can be drawn into the mouth of the user. These patented features are embodied in electronic cigarette devices manufactured and distributed by Reynolds, including the U.S. market leader, VUSE® Alto.

The Accused Products are disposable electronic cigarette devices, all of which are manufactured in China and then imported into the United States for sale, either through local vape shops, via online sales, or both. As described below, each of these products infringes claim 1 of the '202 Patent, as well as multiple dependent claims.

(a) Claim Construction Considerations

The claims of the '202 Patent use non-technical language that is not specially or unusually defined in the patent specification. Accordingly, the language of the asserted claims can and should be given its plain and ordinary meaning. To the extent any particular terms do not have plain and ordinary meanings to a lay person, the meaning of such terms should be readily apparent to a person of ordinary skill in the art of vaporizer device design.

[REDACTED]

Additionally, to the extent that Proposed Respondents contend, or the ALJ determines, that the phrase “wicked into contact” requires construction for determination of this Motion, this phrase should be construed to mean “the liquid mixture can be wicked into contact with the heater, or wicked into contact with an area in close proximity to, and exposed to the heat generated by, the heater.” As explained in more detail below, the PTAB applied this construction to the same phrase in the ’202 Patent’s grandparent patent, and the Federal Circuit affirmed the PTAB’s construction.

(b) Infringement By Proposed Respondents

The Accused Products are manufactured and/or imported by dozens of different companies and tend to vary in general shape, appearance, and features offered. *All* of the Accused Products, however, have the same basic internal structure and operation, regardless of the manufacturer or importer. Specifically, all of the Accused Products include an outer casing with a mouthpiece defined at one end, and have a battery, electronics (printed circuit board and/or pressure sensor), e-liquid reservoir, and heater assembly inside the casing. Each of the Accused Products also includes a pressure sensor for initiating the transfer of electrical current to the heater element. When a user draws air through the mouthpiece, a vacuum is created in an end chamber and is detected by the pressure sensor. The sensor then either sends a signal to a PCB, which in turn activates the heating element, or it activates the heating element itself.

Each of the Accused Products also includes an e-liquid reservoir and a heater assembly. The reservoir is a fibrous material that is soaked in e-liquid, and has caps on each end. In some products, the reservoir is contained within a separate plastic container, and in others it is contained within the outer casing. The reservoir includes an opening through the middle, into which the heater assembly is inserted. The Accused Products employ two basic heater assemblies: either a wire mesh or coil that is surrounded by a fibrous wick, or a fibrous wick that



is wrapped with a metal coil. In either case, the wick is in contact with the heater element. The heater element and wick are contained within a tube (often metal), and include a portion of the wick that extends out through an opening in the tube to allow the liquid from the reservoir to be wicked into contact with the heater element.

The Accused Products generally operate as follows: When a user draws air through the mouthpiece of the device, a pressure sensor senses the draw and either initiates current to a heating element that is in contact with a liquid-soaked wick, or sends a signal to a PCB. In the latter configuration, the PCB then initiates a current flow to the heater element that is in contact with a liquid-soaked wick.² The heater element vaporizes the liquid, producing a vapor that is mixed with the drawn air, travels through the tube in the liquid reservoir, and ultimately is drawn out through the mouthpiece and inhaled by the user.

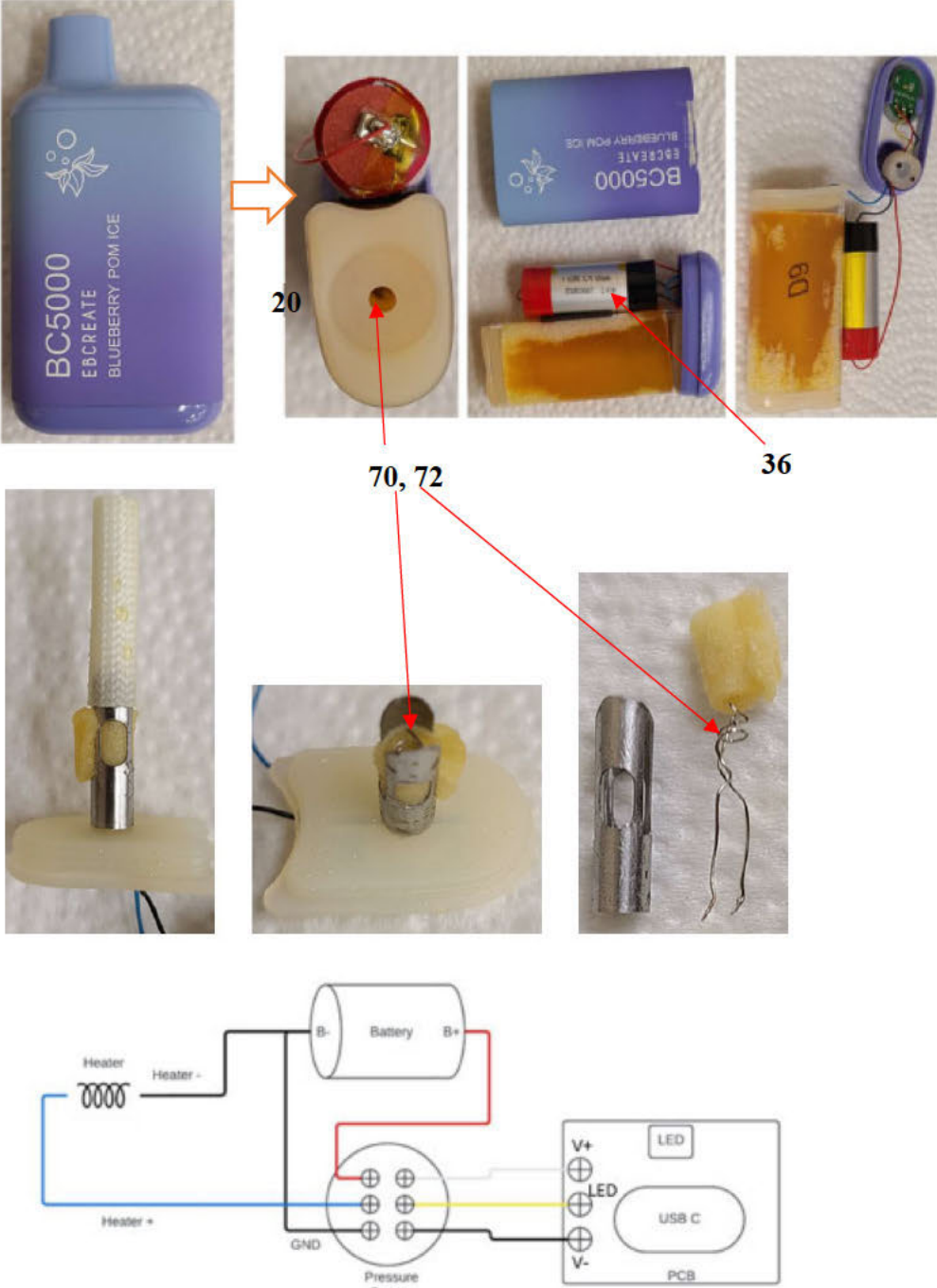
A claim chart demonstrating how one exemplary product —the EBCreate BC5000— infringes claim 1 of the '202 Patent is provided below:

Claim 1	Corresponding Elements in the BC5000 Device
[1-pre] An electrically-powered, aerosol-generating smoking article [10] comprising:	BC5000 is an electrically-powered, aerosol-generating smoking article.

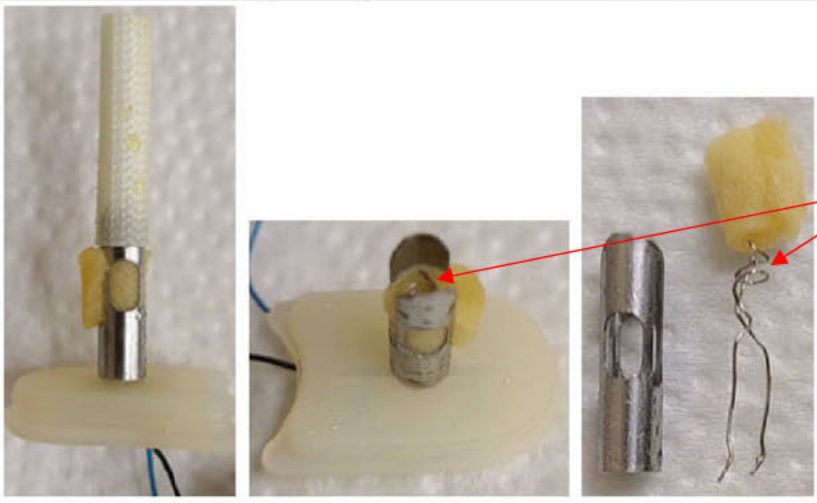
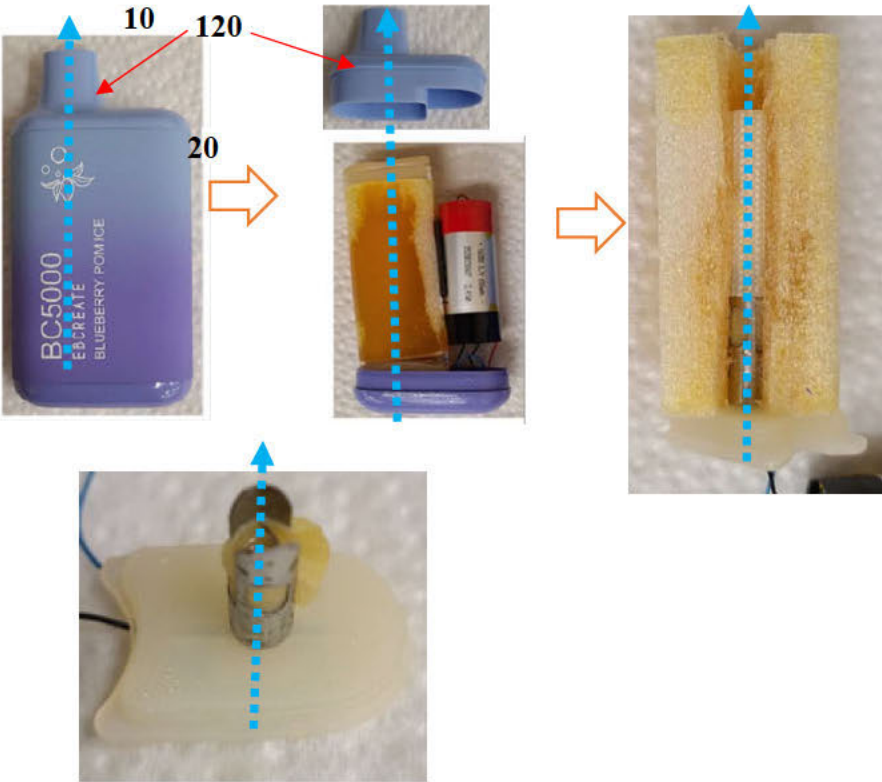
² In some of the Accused Products, the pressure sensor itself also acts as the controller and initiates current to the heater.

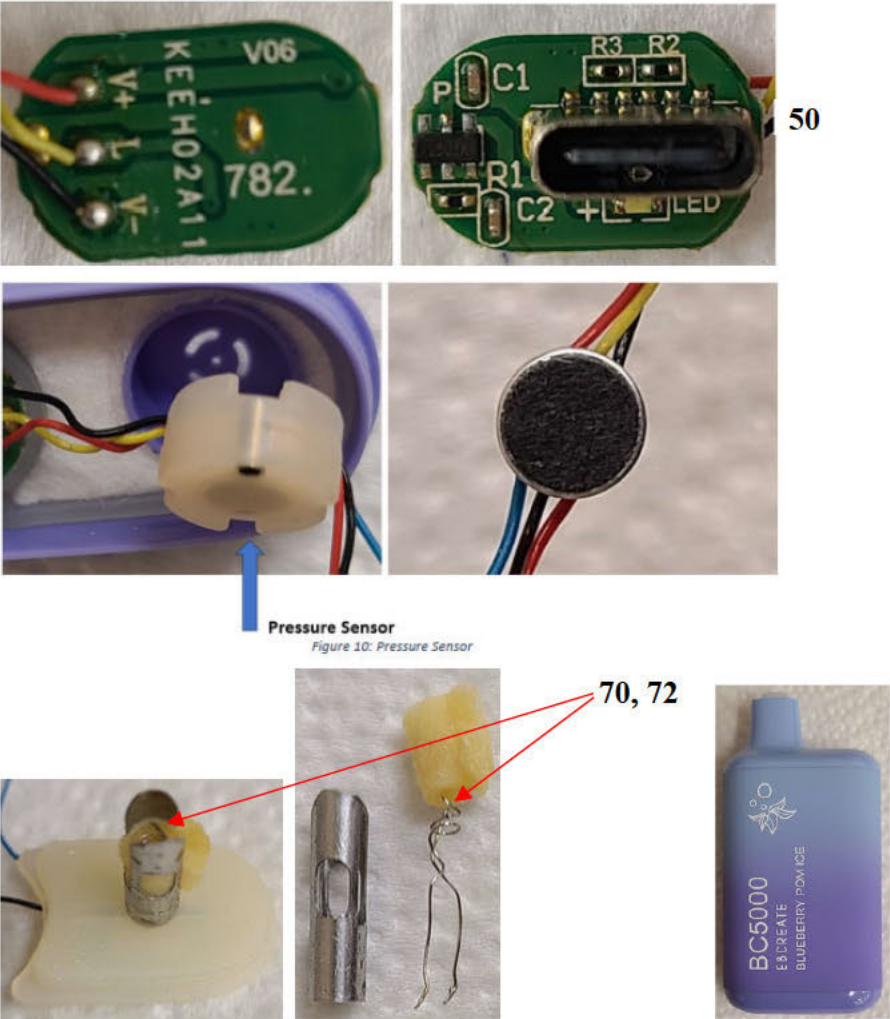
Claim 1	Corresponding Elements in the BC5000 Device
	The image shows the BC5000 product packaging and the device itself. The box is white with blue and pink accents, featuring the BC5000 logo, 'DESIGNER POD DEVICE', 'Designed and Powered by EBCREATE', 'BLUEBERRY POM ICE', and '50S EDITION'. A warning label on the box states: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical.' The device is a blue, rectangular, disposable pod device with a mouthpiece at one end and a base at the other. The device has the BC5000 logo, 'EBCREATE', and 'BLUEBERRY POM ICE' printed on it. 10 Teardown at 4-5.
[1a] an outer housing [20] having two ends [15], [13];	The image shows the BC5000 device with labels 15, 20, and 13. Label 15 points to the mouthpiece, label 20 points to the outer housing, and label 13 points to the base. 15 20 13 Teardown at 5.
[1b] a mouthpiece [120] defined at one of the two ends;	BC5000 has a mouthpiece defined at one of the two ends.

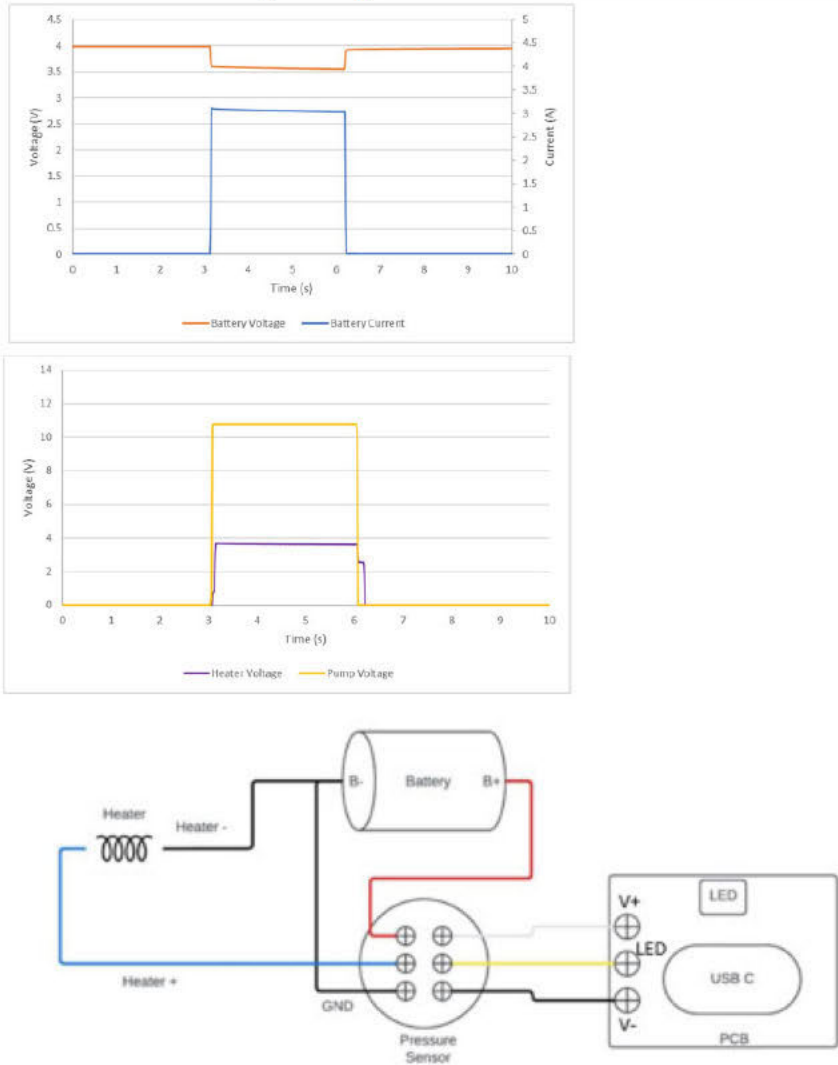
Claim 1	Corresponding Elements in the BC5000 Device
	 The image shows the BC5000 device, a blue rectangular container with a white logo and text: "BC5000", "EBCREATE", and "BLUEBERRY POM ICE". An orange arrow points from the device to its blue cap, which is labeled "12". Teardown at 5-6.

Claim 1	Corresponding Elements in the BC5000 Device
resistance heater being configured for electrical connection with the electrical power source [36]	 Teardown at 5-6, 10-11.
[1e] a storage compartment defined within the outer housing [20], the storage	The storage compartment includes the white/clear component below that holds the liquid aerosol-forming material.

Claim 1	Corresponding Elements in the BC5000 Device
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 [70, 72] to volatilize the liquid aerosol-forming material;	20 The storage compartment also includes the absorbent material that holds liquid and is arranged around the heating wire to wick liquid into contact with the heater.

Claim 1	Corresponding Elements in the BC5000 Device
	 70, 72 Teardown at 5-6, 9-10.
[1f] an air passageway through at least a portion of the outer housing [20], 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 [10] through the mouthpiece [120]; and	The user draws air through the mouthpiece which pulls air through the air passageway (shown in blue, below) within the outer housing. The air combines with the volatilized liquid aerosol-forming material to produce an aerosol that is drawn into the mouth of the user.  Teardown at 5-6, 9-10.

Claim 1	Corresponding Elements in the BC5000 Device
[1g] a controller [50] configured to activate current flow through the electrical resistance heater [70, 72] in response to a draw on the electrically-powered, aerosol-generating smoking article [10].	The controller includes the PCB which activates current through the electrical resistance heater in response to a user drawing on the device and activating the pressure sensor.  Pressure Sensor Figure 10: Pressure Sensor 70, 72 10

Claim 1	Corresponding Elements in the BC5000 Device										
	 <table border="1"> <thead> <tr> <th>Initial Battery Voltage (V)</th> <th>3.98</th> </tr> </thead> <tbody> <tr> <th>Minimum Battery Voltage During Puff (V)</th> <td>3.55</td> </tr> <tr> <th>Maximum Battery Current During Puff (mA)</th> <td>3123</td> </tr> <tr> <th>Maximum Heater Voltage During Puff (V)</th> <td>3.67</td> </tr> <tr> <th>Puff Duration (s)</th> <td>3.14</td> </tr> </tbody> </table>	Initial Battery Voltage (V)	3.98	Minimum Battery Voltage During Puff (V)	3.55	Maximum Battery Current During Puff (mA)	3123	Maximum Heater Voltage During Puff (V)	3.67	Puff Duration (s)	3.14
Initial Battery Voltage (V)	3.98										
Minimum Battery Voltage During Puff (V)	3.55										
Maximum Battery Current During Puff (mA)	3123										
Maximum Heater Voltage During Puff (V)	3.67										
Puff Duration (s)	3.14										
	Teardown at 5, 7-8, 10-11, 13.										

All of the Accused Products infringe claim 1 of the '202 Patent for reasons substantially identical to those demonstrated above. Additionally, all of the Accused Products also infringe at least claims 3-4, 8-11, and 13 of the '202 Patent.³ Claim charts demonstrating how the Accused

³ Some of the Accused Products also infringe claims 12 and/or 15 of the '202 Patent. The claims that each Accused Product infringes are identified in Exhibits 55-104.



Products infringe these claims are attached to the Complaint as Exhibits 55-104. The following table identifies the associated infringement chart(s) for each of the Proposed Respondents and the Accused Products:

Proposed Respondents	Associated Infringement Chart(s)
Breeze Smoke LLC	Exhibit 55 (Breeze Smoke Plus Edition) Exhibit 56 (Breeze Smoke Prime Edition (6000 Puffs)) Exhibit 57 (Breeze Smoke Pro Edition)
Capital Sales Company	Exhibit 55 (Breeze Smoke Plus Edition) Exhibit 56 (Breeze Smoke Prime Edition (6000 Puffs)) Exhibit 57 (Breeze Smoke Pro Edition)
KMT Services LLC d/b/a KMT Distribution and Dank Shop	Exhibit 55 (Breeze Smoke Plus Edition) Exhibit 56 (Breeze Smoke Prime Edition (6000 Puffs)) Exhibit 57 (Breeze Smoke Pro Edition)
Dongguan (Shenzhen) Shikai Technology Co., Ltd.	Exhibit 55 (Breeze Smoke Plus Edition) Exhibit 56 (Breeze Smoke Prime Edition (6000 Puffs)) Exhibit 57 (Breeze Smoke Pro Edition)

Proposed Respondents	Associated Infringement Chart(s)
Vapeonly Technology Co. Ltd.	Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 74 (Lost Mary Off-Stamp) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo)
iMiracle (Shenzhen) Technology Co., Ltd.	Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse)
Guangdong Qisitech Co., Ltd.	Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 76 (RAZ CA6000) Exhibit 78 (RAZ TN 9000) Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse)

Proposed Respondents	Associated Infringement Chart(s)
Fewo Intelligent Manufacturing Limited	Exhibit 58 (EBCreate BC5000) Exhibit 59 (EBCreate BC5000 Thermal Edition) Exhibit 66 (Funky Lands Ti7000) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch)
Nevera (HK) Ltd.	Exhibit 58 (EBCreate BC5000) Exhibit 59 (EBCreate BC5000 Thermal Edition)
Guangdong Cellular Workshop Electronics Technology Co., Ltd.	Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000)
Wonder Ladies Ltd.	Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo)
Sailing South Ltd.	Exhibit 66 (Funky Lands Ti7000)
Marea Morada Ltd.	Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch)
Social Brands, LLC	Exhibit 81 (Space Mary SM8000) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 60 (EBDesign BC5000) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 76 (RAZ CA6000) Exhibit 78 (RAZ TN 9000)
Zhuhai Qisitech Co., Ltd.	Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse)
Shenzhen Han Technology Co., Ltd.	Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo)
Palma Terra Ltd.	Exhibit 74 (Lost Mary Off-Stamp)

Proposed Respondents	Associated Infringement Chart(s)
Shenzhen IVPS Technology Co., Ltd.	Exhibit 84 (Priv Bar Turbo) Exhibit 82 (AL6000) Exhibit 83 (AL9000)
Heaven Gifts International Ltd .	Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo)
Maduro Distributors Inc. d/b/a The Loon	Exhibit 85 (Loon Air) Exhibit 86 (Loon Maxx)
Bidi Vapor, LLC	Exhibit 87 (BIDI Stick Regal)
Kaival Brands Innovations Group Inc.	Exhibit 87 (BIDI Stick Regal)
Kimsun Technology (HuiZhou) Co., Ltd.	Exhibit 88 (Max 1600 puffs)
Shenzhen Yanyang Technology (HuiZhou) Co., Ltd.	Exhibit 89 (Max Air 5000 puffs) Exhibit 90 (Max Flow Mesh 2000 puffs)
Pastel Cartel, LLC	Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 93 (Esco Bars Kilo 4000 puffs)
American Vape Company, LLC	Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 93 (Esco Bars Kilo 4000 puffs)
Affiliated Imports, LLC	Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 93 (Esco Bars Kilo 4000 puffs)
Shenzhen Innokin Technology Co., Ltd.	Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 93 (Esco Bars Kilo 4000 puffs)
Shenzhen Funyin Electronic Technology Co., Ltd.	Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 93 (Esco Bars Kilo 4000 puffs)
Shenzhen LC Technology Co., Ltd.	Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch)
LCF Labs, Inc.	Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch)
Shenzhen Kangvape Technology Co., Ltd.	Exhibit 96 (Kang Vape ONEE - Max 5000) Exhibit 97 (Kang Vape ONEE Stick) Exhibit 98 (Kang Vape ONEE Stick 5200) Exhibit 99 (Kang Vape SMOD Max 6000)
Flumgio Technology Ltd.	Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi) Exhibit 104 (Flum UT Bar)



Proposed Respondents	Associated Infringement Chart(s)
Shenzhen Pingray Technology	Exhibit 91 (Posh Max 2.0)
SV3 LLC d/b/a Mi-One Brands	Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 102 (Flum Mi) Exhibit 100 (Flum Float) Exhibit 101 (Flum Gio) Exhibit 104 (Flum UT Bar) Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch) Exhibit 59 (EBCreate BC5000 Thermal Edition) Exhibit 64 (Elf Bar TE5000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 58 (EBCreate BC5000) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 65 (Elf Bar TE6000) Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 81 (Space Mary SM8000) Exhibit 70 (Geek Bar Pulse) Exhibit 69 (Geek Bar B5000) Exhibit 82 (AL6000) Exhibit 83 (AL9000) Exhibit 93 (Esco Bars Kilo 4000 puffs) Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 74 (Lost Mary Off-Stamp) Exhibit 71 (Lost Mary BM5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 81 (Space Mary SM8000) Exhibit 77 (RAZ DC25000) Exhibit 78 (RAZ TN 9000)



Proposed Respondents	Associated Infringement Chart(s)
Price Point Distributors Inc. d/b/a Price Point NY	Exhibit 55 (Breeze Smoke Plus Edition) Exhibit 56 (Breeze Smoke Prime Edition (6000 Puffs)) Exhibit 57 (Breeze Smoke Pro Edition) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 77 (RAZ DC25000) Exhibit 76 (RAZ CA6000) Exhibit 78 (RAZ TN 9000) Exhibit 80 (RC10000 Touch) Exhibit 84 (Priv Bar Turbo) Exhibit 82 (AL6000) Exhibit 83 (AL9000) Exhibit 81 (Space Mary SM8000) Exhibit 104 (Flum UT Bar) Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi) Exhibit 58 (EBCreate BC5000) Exhibit 59 (EBCreate BC5000 Thermal Edition)



Proposed Respondents	Associated Infringement Chart(s)
Flawless Vape Shop Inc.	Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 84 (Priv Bar Turbo) Exhibit 82 (AL6000) Exhibit 83 (AL9000) Exhibit 80 (RC10000 Touch) Exhibit 61 (EBDesign TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 68 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 104 (Flum UT Bar) Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi) Exhibit 88 (Max 1600 puffs) Exhibit 89 (Max Air 5000 puffs) Exhibit 90 (Max Flow Mesh 2000 puffs) Exhibit 76 (RAZ CA6000) Exhibit 78 (RAZ TN 9000) Exhibit 77 (RAZ DC25000)



Proposed Respondents	Associated Infringement Chart(s)
Flawless Vape Wholesale & Distribution Inc.	Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 84 (Priv Bar Turbo) Exhibit 82 (AL6000) Exhibit 83 (AL9000) Exhibit 80 (RC10000 Touch) Exhibit 61 (EBDesign TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 68 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 104 (Flum UT Bar) Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi)) Exhibit 88 (Max 1600 puffs) Exhibit 89 (Max Air 5000 puffs) Exhibit 90 (Max Flow Mesh 2000 puffs) Exhibit 76 (RAZ CA6000) Exhibit 78 (RAZ TN 9000) Exhibit 77 (RAZ DC25000)



Proposed Respondents	Associated Infringement Chart(s)
Thesy, LLC d/b/a Element Vape	Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 93 (Esco Bars Kilo 4000 puffs) Exhibit 92 (Esco Bars 25000 Mesh) Exhibit 78 (RAZ TN 9000) Exhibit 77 (RAZ DC25000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 74 (Lost Mary Off-Stamp) Exhibit 71 (Lost Mary BM5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 102 (Flum Mi) Exhibit 100 (Flum Float) Exhibit 101 (Flum Gio) Exhibit 104 (Flum UT Bar) Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch) Exhibit 59 (EBCreate BC5000 Thermal Edition) Exhibit 64 (Elf Bar TE5000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 58 (EBCreate BC5000) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 65 (Elf Bar TE6000)



Proposed Respondents	Associated Infringement Chart(s)
VICA Trading Inc. d/b/a/ Vapesourcing	Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 69 (Geek Bar B5000) Exhibit 70 (Geek Bar Pulse) Exhibit 96 (Kang Vape ONEE - Max 5000) Exhibit 97 (Kang Vape ONEE Stick) Exhibit 98 (Kang Vape ONEE Stick 5200) Exhibit 99 (Kang Vape SMOD Max 6000) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi) Exhibit 104 (Flum UT Bar) Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch) Exhibit 68 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000)



Proposed Respondents	Associated Infringement Chart(s)
Ecto World, LLC d/b/a Demand Vape	Exhibit 58 (EBCreate BC5000) Exhibit 59 (EBCreate BC5000 Thermal Edition) Exhibit 66 (Funky Lands Ti7000) Exhibit 71 (Lost Mary BM5000) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 73 (Lost Mary MT15000 Turbo) Exhibit 62 (Elf Bar BC5000 – Malibu) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 64 (Elf Bar TE5000) Exhibit 65 (Elf Bar TE6000) Exhibit 60 (EBDesign BC5000) Exhibit 61 (EBDesign TE6000) Exhibit 68 68 (Funky Republic Ti7000) Exhibit 67 (Funky Republic Fi3000) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 82 (AL6000 by NOVO BAR) Exhibit 83 (AL9000 by NOVO BAR) Exhibit 74 (Lost Mary Off-Stamp) Exhibit 84 (Priv Bar Turbo by SMOK) Exhibit 81 (Space Mary SM8000) Exhibit 78 (RAZ TN 9000) Exhibit 76 (RAZ CA6000) Exhibit 88 (Max 1600 puffs by HYPPE) Exhibit 89 (Max Air 5000 puffs by HYPPE) Exhibit 90 (Max Flow Mesh 2000 puffs by HYPPE) Exhibit 101 (Flum Gio) Exhibit 103 (Flum Pebble) Exhibit 100 (Flum Float) Exhibit 102 (Flum Mi) Exhibit 104 (Flum UT Bar)

Proposed Respondents	Associated Infringement Chart(s)
Midwest Goods Inc. d/b/a Midwest Distribution	Exhibit 84 (Priv Bar Turbo) Exhibit 82 (AL6000) Exhibit 83 (AL9000) Exhibit 91 (Posh Max 2.0) Exhibit 79 (RC1000) Exhibit 80 (RC10000 Touch) Exhibit 81 (Space Mary SM8000) Exhibit 77 (RAZ DC25000) Exhibit 78 (RAZ TN 9000) Exhibit 70 (Geek Bar Pulse) Exhibit 69 (Geek Bar B5000) Exhibit 86 (Loon Maxx) Exhibit 97 (Kang Vape ONEE Stick) Exhibit 98 (Kang Vape ONEE Stick 5200) Exhibit 96 (Kang Vape ONEE - Max 5000) Exhibit 99 (Kang Vape SMOD Max 6000) Exhibit 89 (Max Air 5000 puffs by HYPPE) Exhibit 90 (Max Flow Mesh 2000 puffs) Exhibit 88 (Max 1600 puffs by HYPPE) Exhibit 82 (AL6000 by NOVO BAR) Exhibit 83 (AL9000 by NOVO BAR) Exhibit 94 (Mr. Fog Max) Exhibit 95 (Mr. Fog Switch) Exhibit 72 (Lost Mary MO5000) Exhibit 75 (Lost Mary OS5000) Exhibit 74 (Lost Mary Off-Stamp) Exhibit 63 (Elf Bar Pod King XC5000) Exhibit 71 (Lost Mary BM5000) Exhibit 73 (Lost Mary MT15000 Turbo)

For purposes of this motion only, Reynolds is asserting infringement of claims 1, 4, 9 and 12 of the '202 Patent.

2. Reynolds Is Likely To Prevail Against Any Invalidity Or Unenforceability Defense

The Commission's validity inquiry will start with the asserted claims' presumption of validity. 35 U.S.C. § 282. And they are not likely to be found invalid, because multiple prior attempts to invalidate U.S. Patent No. 9,901,123—the '202 Patent's grandparent, which includes many of the same limitations as the '202 Patent—have all failed. Every claim of the '202 Patent

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requires a limitation that was vigorously litigated with respect to the '123 Patent and found not present in any of the prior art: “aerosol-forming material can be wicked into contact with the electrical resistance heater.” First, respondents in the 1199 Investigation challenged the validity of the “wicked into contact” limitation, and litigated the issue extensively throughout the investigation. Ultimately, those respondents dropped the validity challenge in the middle of the ITC evidentiary hearing. Second, the PTAB and Federal Circuit both examined whether alleged prior art taught the “wicked into contact” limitation and whether the addition of such a limitation would have been obvious, and both found that the previous validity challenges did *not* invalidate the '123 Patent claims.

Reynolds was one of the earliest innovators in electronic cigarette technology. As such, the '202 Patent, like the '123 Patent before it, has an early priority date of October 18, 2006. It is therefore highly unlikely that a Proposed Respondent will uncover never-before-seen prior art that anticipates or renders the '202 Patent claims obvious. Indeed, in addition to the extensive litigation on this patent family, the '202 Patent includes 678 patent citations and 292 non-patent citations, all of which the USPTO considered when deciding whether to issue the '202 Patent.

Any potential validity challenge to the '202 Patent will likely rely on the same or substantially similar prior art, and thus will lack substantial merit because all prior attempts to invalidate the “wicked into contact” limitation have failed, at the ITC, the PTAB, and the Federal Circuit.

(a) Legal Standards

(i) Presumption of Validity

Patents are presumed valid, 35 U.S.C. § 282, and “a defendant seeking to overcome this presumption must persuade the factfinder of its invalidity defense by clear and convincing evidence.” *Microsoft Corp. v. i4i P'ship*, 564 U.S. 91, 97 (2011). “[T]he patent enjoys the same

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presumption of validity during preliminary injunction proceedings as at other stages of litigation.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009). At the preliminary-injunction stage, complainants establish a likelihood of success by showing that a respondent’s validity challenge “lacks substantial merit.” *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1399 (Fed. Cir. 2022); *see also Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). Or, if “the alleged infringer does not challenge validity,” then “the very existence of the patent with its concomitant presumption of validity satisfies the patentee’s burden of showing a likelihood of success on the validity issue.” *Titan Tire*, 566 F.3d at 1377.

(ii) Anticipation

“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.” *Spanion, Inc. v. Int’l Trade Comm’n.*, 629 F.3d 1331, 1356 (Fed. Cir. 2010). Anticipation “can be found only when the reference discloses exactly what is claimed.” *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985). Moreover, to find anticipation a court must determine 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).

(iii) Obviousness

A patent may not be obtained 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.” 35 U.S.C. § 103(a) (pre-AIA); *accord KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is a

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legal conclusion based on underlying facts. *Graham v. John Deere Co.*, 383 U.S. 1, 14, 17-18 (1966).

Obviousness is determined “with reference to a *hypothetical* ‘person having ordinary skill in the art,’” not from the viewpoint of the inventor. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting inventors “possess something ... which sets them apart from the workers of *ordinary* skill”). A POSA “thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights.” *Id.*

Proposed Respondents would have to demonstrate by clear-and-convincing evidence “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). “[H]indsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention” is improper. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012).

(b) Factual Background

The '202 Patent issued as a continuation from an original patent application filed on October 18, 2006. During the course of prosecution of the application for the '202 Patent and earlier continuation patents in this family, the U.S. Patent & Trademark Office considered a wealth of references, including over 1,000 patents, publications, articles, and numerous documents relating to Philip Morris's earlier challenges to the validity of the claimed subject matter at the ITC and the PTAB. On the cover of the '202 Patent itself, under the “References

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Cited” section, the ’202 Patent identifies 617 United States patents and patent publications, 137 foreign patents, and 288 other publications.⁴

The ’202 Patent includes claims similar to those in its grandparent, the ’123 Patent. Both are directed to “[a]n electrically-powered, aerosol-generating smoking article” that includes an “electrical power source” within an “outer housing,” with an “electrical resistance heater” either “powered by” (’123 Patent, claim 1) or “configured for electrical connection with” (’202 Patent, claim 1) the “electrical power source. The ’123 Patent claims “a puff-actuated controller” that is “adapted for regulating current flow through the electrical resistance heater during draw,” while the ’202 Patent claims “a controller configured to activate current flow through the electrical resistance heater in response to a draw.” *Compare* ’123 Patent *with* ’202 Patent. Critically, both patents claim an “aerosol-forming material can be wicked into contact with the electrical resistance heater” such that the aerosol-forming material is “volatilize[d].” *Id.*

The grandparent ’123 Patent was the subject of the 1199 Investigation directed at Philip Morris’s IQOS® product. IQOS® is an electronic cigarette system that heats tobacco without burning it and recently overtook Marlboro as Philip Morris’s leading nicotine brand. Exhibit 284. The ITC found that Philip Morris infringed the ’123 Patent and that the claims of the ’123 Patent had not been proven invalid, and a limited exclusion order should issue against the 1199

⁴ For at least this reason, any attempt by Proposed Respondents to raise an inequitable-conduct defense will also fail. In the 1199 Investigation, despite its best efforts, Philip Morris was only able to muster a single inequitable-conduct defense on the related ’123 Patent. Even then, Chief ALJ Cheney denied Philip Morris’s attempt to add this defense to the investigation, in part because the allegedly non-disclosed reference was discussed repeatedly throughout the specification, demonstrating that adding the defense would have been futile. *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 1199, EDIS Doc. ID No. 722975, Order No. 19 (U.S.I.T.C. Oct. 22, 2020).

respondents. *Certain Tobacco Heating Articles*, Inv. No. 337-TA-1199, EDIS Doc. ID No. 752987, Comm’n Op. at 80.

Philip Morris also challenged the validity of the ’123 Patent’s domestic industry claims (the claims containing the “wicked into contact” limitation) in *inter partes* review (IPR) at the PTAB. *Philip Morris Products SA v. RAI Strategic Holdings, Inc.*, IPR2020-01602, Paper 2 (Sep. 18, 2020) (“IPR Petition”). The PTAB rejected Philip Morris’s challenges and found—under a *preponderance-of-the-evidence* standard—that Philip Morris had not shown the claims to be unpatentable. The Federal Circuit affirmed in full. *Philip Morris Products S.A. v. RAI Strategic Holdings, Inc.*, No. 22-1846, 2023 WL 5970786 at *1 (Fed. Cir. Sept. 14, 2023).

Philip Morris is one of the largest tobacco companies in the world and was represented by a large and competent team of lawyers. It is likely, if not expected, that Philip Morris and its lawyers would have put forth the very best prior art and invalidity arguments they could before the ITC and PTAB to prevent its flagship IQOS® product from being excluded from the United States. But, as explained below, they were unsuccessful.

(c) The Previous ITC Investigation

In the 1199 Investigation, Reynolds asserted the ’123 Patent and relied on claims 1, 4, 6, 11, 13–15, 17, 19, and 23–26 to support its domestic industry. *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, EDIS Doc. ID No. 742491, Initial Determination at 36-37 (U.S.I.T.C. May 14, 2021) (“1199 ID”). Like the claims of the ’202 Patent, each of those domestic industry claims of the ’123 Patent includes the limitation that the “aerosol-forming material can be wicked into contact with the electrical resistance heater.” *Id.* at 7-8; U.S. Patent No. 9,901,123 at claims 1, 15.

In its invalidity contentions, Philip Morris relied on numerous references as allegedly disclosing this limitation. But when the investigation ultimately went to trial, Philip Morris

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relied on only three—and presumably its best—arguments. In its pre-hearing brief, Philip Morris argued that (1) the limitation was disclosed by a product called Ruyan; (2) the limitation was disclosed by CN 2,719,043 to Hon (“the Hon patent” or “Hon”), which Philip Morris contended described a device similar to the Ruyan product; and (3) if neither Ruyan nor Hon disclosed the “wicked into contact” limitation, then it would have been obvious over Ruyan/Hon in view of U.S. Patent No. 2,057,353 (“Whittemore”). *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, EDIS Doc. ID No. 728462, Respondents’ Pre-Hearing Brief at 107-144 (U.S.I.T.C. Dec. 18, 2020) (“Respondents’ Pre-Hearing Brief”). Philip Morris also asserted that the domestic-industry claims were invalid for derivation and a lack of written description. *Id.*

Issues surrounding these arguments, including whether the Ruyan device was even prior art at all, were hotly debated throughout the entire investigation and were the subject of multiple discovery disputes. *Certain Tobacco Heating Articles and Components Thereof*, Inv. No. 337-TA-1199, EDIS Doc. ID No. 728462, Complainants’ Pre-Hearing Brief at 268-325 (U.S.I.T.C. Dec. 18, 2020) (“Complainants’ Pre-Hearing Brief”). But in the middle of the evidentiary hearing, Philip Morris abandoned its invalidity challenges to the domestic-industry claims of the ’123 Patent before the ITC. *Certain Tobacco Heating Articles*, ID at 37-41. Accordingly, Philip Morris failed to invalidate the claims of the Robinson ’123 patent requiring the “aerosol-forming material can be wicked into contact with the electrical resistance heater.” ’123 Patent at claims 1, 15; *Certain Tobacco Heating Articles*, ID at 7-8.

Moreover, even though the ITC did not decide the validity of the domestic-industry claims of the ’123 Patent, during prosecution of the ’202 Patent, Reynolds submitted numerous documents from the 1199 Investigation to the Examiner, including documents related to Philip

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Morris’s challenges to the validity of these claims. For example, Reynolds submitted Philip Morris’s pre-hearing brief, as well as its final invalidity contentions, both of which laid out, in detail, every one of Philip Morris’s invalidity positions with respect to the “wicked into contact” claims. The USPTO still issued the ’202 Patent. So even though the ITC did not ultimately consider Philip Morris’s arguments regarding the ’123 Patent, the USPTO did while prosecuting the application that led to the ’202 Patent.

(d) The Previous IPR

Philip Morris also challenged the validity of the ’123 Patent’s domestic-industry claims in an IPR at the PTAB. Philip Morris put forth substantially similar arguments to those it advanced in the ITC investigation—using the Hon patent as its primary reference, combined with the POSITA’s knowledge as allegedly evidenced by the Ruyan device. IPR Petition at 10-68. And Philip Morris again relied on the same alternative obviousness combination, arguing that it would have been obvious to replace the atomizer described in Hon with the wick and heater arrangement of Whittemore. *Id.* The PTAB rejected both arguments. *Philip Morris Products SA v. RAI Strategic Holdings, Inc.*, IPR2020-01602, Paper 32 (Mar. 30, 2022), attached as Exhibit 285 (“FWD”).

First, the PTAB construed “wicked into contact” to mean that “the liquid mixture can be wicked into contact with the heater, or wicked into contact with an area in close proximity to, and exposed to the heat generated by, the heater.” FWD at 15. Applying this construction, the PTAB agreed with Reynolds that Philip Morris had failed to show how Hon meets this limitation. FWD at 21-25. Specifically, the PTAB held that

Hon, therefore, discloses wicking the liquid mixture in porous body 27 to an area that is separated from Hon’s heating element 26 by atomization cavity wall 25, and that the liquid mixture is exposed to heat produced by heating element 26 only after it is driven through ejection hole 24 by the airflow generated by the user’s draw. In light of these express disclosures in Hon, Petitioner does not

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establish that Hon’s liquid mixture is wicked to an area in ‘close proximity’ to Hon’s heater, as the second part of our claim construction requires.

FWD at 23-24.

With respect to Philip Morris’s obviousness contention, the PTAB again agreed with Reynolds that Philip Morris had not shown that the combination would have been obvious under a preponderance-of-the-evidence standard—a standard of proof even lower than the clear-and-convincing-evidence standard that Proposed Respondents would have to meet in this Investigation. FWD at 27-35. The PTAB noted that Hon expressly taught options for simplifying its device, and that Philip Morris did “not show persuasively that replacing Hon’s atomizer with Whittemore’s wick and heater would have simplified the device as compared with the modifications Hon expressly teaches.” FWD at 27. Philip Morris also relied on statements from a Reynolds teardown report of a Ruyan product, but the PTAB correctly found that the report did not demonstrate that the Ruyan device displayed poor performance in need of improvement, and found that the report actually contradicted Philip Morris’ position that a POSA would have been motivated to replace Hon’s atomizer with Whittemore’s wick and heater. FWD at 29-31. Accordingly, Philip Morris failed again to invalidate the ’123 Patent. FWD at 38.

(e) The Federal Circuit’s Affirmance

The Federal Circuit also reviewed whether the asserted references taught the “wicked into contact” limitation and found that substantial evidence supported the PTAB’s decision to reject Philip Morris’ proposed combination. *Philip Morris Products S.A. v. RAI Strategic Holdings, Inc.*, No. 22-1846, 2023 WL 5970786 at *1 (Fed. Cir. Sept. 14, 2023). The Federal Circuit concluded that the Board reasonably relied on expert testimony and its own analysis of the teardown report of the Ruyan product. Specifically, the “expert testimony to find that Hon’s heater produces more aerosol at higher efficiency while using less power than Whittemore’s wick

[REDACTED]

and heater design” and the Board’s own analysis that “nothing in the RJR teardown report supports a view that the Ruyan device (an implementation of Hon) failed to produce sufficient aerosol that would warrant replacement of the atomizer” provided substantial evidence. *Id.* at *2. The Federal Circuit also held that the Board’s decision was consistent with its analysis in a previous IPR on a different patent that found a POSITA would not replace Hon’s heating element with Whittemore’s. *Id.* at *1.

(f) Conclusion

Despite many years of litigation and multiple attempts at invalidating the ’123 Patent, its validity was confirmed at every instance. The ’202 Patent claims recite the same “wicked into contact” limitation that defeated these prior validity challenges. It is highly unlikely that any patent challenger will find relevant prior art that has not been previously considered by the USPTO due to the nearly 1,000 cited references listed on the ’202 Patent, let alone find prior art before the early priority date of October 2006 that would invalidate the ’202 claims. Moreover, any validity challenge in this investigation would be subject to the clear-and-convincing-evidence standard—a burden *significantly higher* than the preponderance burden Philip Morris failed to meet in the IPR. For these reasons, the ’202 Patent is likely to survive any validity challenge that could conceivably be mounted by the Proposed Respondents in this investigation.

3. Reynolds Will Prove Importation Of The Accused Products

Reynolds will establish specific instances of importation of infringing products by each of the Proposed Respondents.

The specific instances of importation of infringing Accused Products set forth below are representative examples of Proposed Respondents’ unlawful importation into the United States, sale for importation into the United States, and/or sales within the United States after importation of infringing products.

[REDACTED]

On information and belief, Proposed Respondents, either individually or acting in concert, design, develop, evaluate, test, and manufacture or have manufactured Accused Products outside of the United States and are (i) importing into the United States, (ii) selling for importation into the United States, and/or (iii) selling within the United States after importation Accused Products. On information and belief, Proposed Respondents sell the Accused Products knowing, or having reason to know, that the Accused Products would be subsequently imported into the United States.

On information and belief, Proposed Respondents, either individually or acting in concert, knowingly and intentionally direct, authorize, approve, or otherwise participate in the unlawful and infringing conduct alleged herein, including the manufacture, distribution, sale for importation, importation, and/or sale within the United States after importation of the infringing Accused Products and components thereof.

The Accused Products are manufactured overseas, predominantly in China, and then sold for importation into the United States by Proposed Respondents or on their behalf, imported into the United States by Proposed Respondents or on their behalf, and/or sold after importation by Proposed Respondents or on their behalf.

(a) Breeze Proposed Respondents

On information and belief, Breeze Smoke sells for importation, imports, and/or sells after importation the Accused Products. A Breeze Smoke Prime was purchased in the United States. *See* Exhibit 4-1. “Breeze Smoke, LLC” is listed on the packaging of the Breeze Smoke Prime and the packaging indicates “Manufactured in China” and “Sale only allowed in the United States.” *See* Exhibit 6 at 3.

On information and belief, Capital Sales sells for importation, imports, and/or sells after importation the Accused Products. Capital Sales imports, sells, and/or distributes for sale one or

[REDACTED]

more of the Accused Products alone or in partnership with Breeze Smoke via the website capitalcsc.com. *See* Exhibits 111 (indicating contact information for “Breeze Smoke Inquiries – Breeze@capitalcsc.com”); 112 (stating that Capital Sales “is the exclusive distributor for Breeze Smoke.”); 113 (showing the booth location of “Breeze Smoke (distributed by Capital Sales Company” at the National Association of Convenience Stores Show 2022).

On information and belief, KMT Services sells for importation, imports, and/or sells after importation the Accused Products. KMT Services operates the website dankshop.com, through which KMT Services markets Breeze Smoke products, offers Breeze Smoke products for distribution, and/or offers Breeze Smoke products for sale. *See* Exhibits 118 at 8; 117 at 3, note 12.

On information and belief, Shikai Technology sells for importation, imports, and/or sells after importation the Accused Products. A Breeze Smoke Prime was purchased in the United States. *See* Exhibit 4-1. “Dongguan Shikai Technology Co., Ltd” is listed on the packaging of the Breeze Smoke Prime and the packaging indicates “Manufactured in China” and “Sale only allowed in the United States.” *See* Exhibit 6 at 3.

(b) iMiracle Proposed Respondents

On information and belief, Vapeonly sells for importation, imports, and/or sells after importation the Accused Products. Vapeonly is associated with at least one Accused Product that was imported into the United States. *See* Exhibit 121 at 1; 14.

On information and belief, iMiracle (Shenzhen) sells for importation, imports, and/or sells after importation the Accused Products. An EB Design BC5000 was purchased in the United States. *See* Exhibit 14-1. “IMIRACLE (SHENZHEN) TECHNOLOGY CO., LTD.” is listed on the packaging of the EB Design BC5000 and the packaging indicates “Made in China” and “Sale only allowed in the United States.” *See* Exhibit 10 at 4–5.



On information and belief, Guangdong Qisitech sells for importation, imports, and/or sells after importation the Accused Products. An EB Design BC5000 was purchased in the United States. *See* Exhibit 14-1. “GUANGDONG QISITECH CO., LTD.” is listed on the packaging of the EB Design BC5000 and the packaging indicates “Made in China” and “Sale only allowed in the United States.” *See* Exhibit 10 at 4–5.

On information and belief, Fewo Intelligent sells for importation, imports, and/or sells after importation the Accused Products. An EBCreate BC5000 Thermal Edition was purchased in the United States. *See* Exhibit 4-1. “FEWO INTELLIGENT MANUFACTURING LIMITED” is listed on the packaging of the EBCreate BC5000 Thermal Edition and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 9 at 4–5.

On information and belief, Nevera (HK) sells for importation, imports, and/or sells after importation the Accused Products. An EBCreate BC5000 Thermal Edition was purchased in the United States. *See* Exhibit 4-1. “NEVERA (HK) LIMITED” is listed on the packaging of the EBCreate BC5000 Thermal Edition and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 9 at 5.

On information and belief, Guangdong Cellular sells for importation, imports, and/or sells after importation the Accused Products. An EBDesign TE6000 was purchased in the United States. *See* Exhibit 4-1. “GUANGDONG CELLULAR WORKSHOP ELECTRONICS TECHNOLOGY CO., LTD.” is listed on the packaging of the EBDesign TE6000 and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 11 at 6.



On information and belief, Wonder Ladies sells for importation, imports, and/or sells after importation the Accused Products. A Lost Mary OS5000 was purchased in the United States. *See* Exhibit 4-1. “WONDER LADIES LIMITED” is listed on the packaging of the Lost Mary OS5000 and the packaging indicates “Made in China.” *See* Exhibit 25 at 3.

On information and belief, Sailing South sells for importation, imports, and/or sells after importation the Accused Products. A Funky Lands Ti7000 was purchased in the United States. *See* Exhibit 4-1. “SAILING SOUTH Limited” is listed on the packaging of the Funky Lands Ti7000 and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 16 at 4.

On information and belief, Marea Morada sells for importation, imports, and/or sells after importation the Accused Products. A RabBeats RC10000 was purchased in the United States. *See* Exhibit 4-1. “MAREA MORADA LIMITED” is listed on the packaging of the Rabbeats RC10000 and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 29 at 6.

On information and belief, Social Brands sells for importation, imports, and/or sells after importation the Accused Products. A Space Mary SM8000 was purchased in the United States. *See* Exhibit 4-1. “Social Brands” is listed on the packaging of the Space Mary SM8000 and the packaging indicates “MADE IN CHINA” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 31 at 4–5.

On information and belief, Zhuhai Qisitech sells for importation, imports, and/or sells after importation the Accused Products. A Geek Bar Pulse was purchased in the United States. *See* Exhibit 4-1. “Zhuhai Qisitech Co., LTD.” is listed on the packaging of the Geek Bar Pulse as the manufacturer and the packaging indicates that the manufacturer of this product is located

[REDACTED]

in China and states “SALES ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 20 at 4.

On information and belief, Shenzhen Han sells for importation, imports, and/or sells after importation the Accused Products. Shenzhen Han admitted to manufacturing Lost Mary Disposable Vapes in prior litigation. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812394, Respondents Shenzhen Weiboli Technology Co. Ltd, Vapeonly Technology Co. Ltd., Imiracle (Shenzhen) Technology Co., Ltd., Guangdong Qisitech Co., Ltd., and Shenzhen Han Technology Co., Ltd. Response to the Verified Complaint at ¶ 54.

On information and belief, Palma Terra sells for importation, imports, and/or sells after importation the Accused Products. A Lost Mary Off-Stamp SW9000 was purchased in the United States. *See* Exhibit 4-1. “PALMA TERRA LIMITED” is listed on the packaging of the Lost Mary Off-Stamp SW9000 and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 24 at 4–5.

On information and belief, Shenzhen IVPS sells for importation, imports, and/or sells after importation the Accused Products. A NOVO Bar AL6000 was purchased in the United States. *See* Exhibit 4-1. “SHENZHEN IVPS TECHNOLOGY CO., LTD.” is listed on the packaging of the NOVO Bar AL6000 and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 32 at 5.

On information and belief, Heaven Gifts sells for importation, imports, and/or sells after importation the Accused Products. The “brand introduction page” of Heaven Gifts website heavengifts.com advertises the Lost Mary and Elf Bar brands. *See* Exhibit 141 at 2, 4. The Lost Mary and Elf Bar brands include at least one Accused Product imported into the United States. *See* Exhibits 14;24.

(c) Loon Proposed Respondent

On information and belief, Maduro Distributors sells for importation, imports, and/or sells after importation the Accused Products. A Loon Maxx was purchased in the United States. *See* Exhibit 4-1. “The Loon” is listed on the packaging of the Loon Maxx and the packaging indicates “Made in China” and “Sale only allowed in USA.” *See* Exhibit 36 at 4–5.

(d) Bidi Proposed Respondents

On information and belief, Bidi Vapor sells for importation, imports, and/or sells after importation the Accused Products. A Bidi Stick Regal was purchased in the United States. *See* Exhibit 4-1. “Bidi Vapor, LLC” is listed on the packaging of the Bidi Stick Regal and the packaging indicates “MADE IN CHINA” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 37 at 6.

On information and belief, Kaival Brands Innovations sells for importation, imports, and/or sells after importation the Accused Products. Upon information and belief, Kaival Brands Innovations is the “exclusive U.S. distributor of all products manufactured by Bidi Vapor, LLC” including the Bidi Stick Regal. *See* Exhibit 229 at 1. One or more Bidi Stick Regal was imported into the United States. *See* Exhibit 37.

(e) Hyppe Proposed Respondents

On information and belief, Kimsun Technology (HuiZhou) sells for importation, imports, and/or sells after importation the Accused Products. A Hyppe Max was purchased in the United States. *See* Exhibit 4-1. “KIMSUN TECHNOLOGY (HUIZHOU)CO., LTD.” is listed on the packaging of the Hyppe Max and the packaging indicates that the factory for this product is located in China and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 38 at 6.

[REDACTED]

On information and belief, Shenzhen Yangyang sells for importation, imports, and/or sells after importation the Accused Products. A Hype Max Air was purchased in the United States. *See* Exhibit 4-1. Shenzhen Yangyang is listed on the packaging of the Hype Max Air and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 156 at 2.

(f) Esco Bars Proposed Respondents

On information and belief, Pastel Cartel sells for importation, imports, and/or sells after importation the Accused Products. A Esco Bars KILO was purchased in the United States. *See* Exhibit 4-1. “PASTEL CARTEL LLC” is listed on the packaging of the Esco Bars KILO and the packaging indicates “Made in China” and “ONLY FOR SALE IN THE U.S.A.” *See* Exhibit 43 at 6.

On information and belief, American Vape sells for importation, imports, and/or sells after importation the Accused Products. American Vape admitted to selling imported Esco Bar products in a prior litigation. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents’ Response to the Amended Complaint at ¶ 357.

On information and belief, Affiliated Imports sells for importation, imports, and/or sells after importation the Accused Products. Affiliated Imports admitted that it is registered to American Vape Company and acts as American Vape Company’s and Pastel Cartel’s consignee and importer of record for incoming shipments of Esco Bars Disposable Vapes to the United States in a prior litigation. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents’ Response to the Amended Complaint at ¶ 59.

On information and belief, Shenzhen Innokin sells for importation, imports, and/or sells after importation the Accused Products. Shenzhen Innokin admitted that it manufactured certain

[REDACTED]

Esco Bar products in a prior litigation. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents' Response to the Amended Complaint at ¶ 60.

On information and belief, Shenzhen Funyin sells for importation, imports, and/or sells after importation the Accused Products. Pastel Cartel admitted that Shenzhen Funyin "has in the past manufactured some Esco Bars Disposable Vapes" in a prior litigation. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812377, Pastel Respondents' Response to the Amended Complaint at ¶ 61 (admitting to allegations in the Amended Complaint).

(g) Mr. Fog Proposed Respondents

On information and belief, Shenzhen LC sells for importation, imports, and/or sells after importation the Accused Products. A Mr. Fog Max was purchased in the United States. *See* Exhibit 4-1. "Shenzhen LC Technology Co., Ltd." is listed on the packaging of the Mr. Fog Max and the packaging indicates "MADE IN CHINA" and "SALE ONLY ALLOWED IN THE UNITED STATES." *See* Exhibit 44 at 4–5.

On information and belief, LCF Labs sells for importation, imports, and/or sells after importation the Accused Products. A Mr. Fog Switch was purchased in the United States. *See* Exhibit 4-1. "LCF Labs" is listed on the packaging of the Mr. Fog Switch and the packaging indicates "Made in China" and "SALE ONLY ALLOWED IN THE UNITED STATES." *See* Exhibit 45 at 3.

(h) Kangvape Proposed Respondent

On information and belief, Shenzhen Kangvape sells for importation, imports, and/or sells after importation the Accused Products. A KangVape Onee Max was purchased in the United States. *See* Exhibit 4-1. "SHENZHEN KANGVAPE TECHNOLOGY CO., LTD." is

[REDACTED]

listed on the packaging of the KangVape Onee Max and the packaging indicates “Made in China” and “SALE ONLY ALLOWED IN THE UNITED STATES.” *See* Exhibit 46 at 4.

(i) Flum Proposed Respondent

On information and belief, Flumgio Technology Ltd. sells for importation, imports, and/or sells after importation the Accused Products. A Flum Pebble was purchased in the United States. *See* Exhibit 4-1. “Flumgio Technology LTD” is listed on the packaging of the Flum Pebble and the packaging indicates “Made in China” and “Sale only allowed in the USA.” *See* Exhibit 53 at 5.

(j) Posh Proposed Respondent

On information and belief, Shenzhen Pingray sells for importation, imports, and/or sells after importation the Accused Products. A Posh Max 2.0 was purchased in the United States. *See* Exhibit 4-1. “Shenzhen Pingray Technology Co., Ltd.” is listed on the packaging of the Posh Max 2.0 as the manufacturer and the packaging indicates “Made in China” and “Only for sale in USA.” *See* Exhibit 41 at 6.

(k) Distributor Proposed Respondents

On information and belief, SV3 sells for importation, imports, and/or sells after importation the Accused Products. At least one Accused Product was purchased from the website mipod.com/ which is operated by SV3. *See* Exhibit 4-1.

On information and belief, Price Point sells for importation, imports, and/or sells after importation the Accused Products. At least one Accused Product was purchased from the website pricepointny.com which is operated by Price Point. *See* Exhibit 4-1.

On information and belief, Flawless Vape Shop sells for importation, imports, and/or sells after importation the Accused Products. “Flawless Vape Shop” is listed as the contact company

[REDACTED]

on flawlessvapeshop.com and this website advertises one or more of the Accused Products for sale. *See* Exhibits 176.

On information and belief, Flawless Vape Wholesale & Distribution Inc. sells for importation, imports, and/or sells after importation markets and sells products to consumers across the country via the website www.flawlessvapeshop.com. *See Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 805887 Complaint at ¶ 88.

Flawlessvapeshop.com advertises one or more the Accused Products. Flawless Vape Wholesale & Distribution Inc. of the Accused Products. *See* Exhibit 176.

On information and belief, Element Vape sells for importation, imports, and/or sells after importation the Accused Products. Element Vape admitted in a prior litigation that it sells disposable ENDS devices to consumers in the United States through the website elementvape.com. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID No. 812384, Respondent Thesy Response to the Notice of Investigation and Complaint at ¶ 91. Elementvape.com advertises one or more Accused Products for sale. *See* Exhibit 179.

On information and belief, Vape Sourcing sells for importation, imports, and/or sells after importation the Accused Products. Vape Sourcing sells one or more Accused Products to consumers in the United States from the website vapesourcing.com. *See Certain Disposable Vaporizer Devices and Components and Packaging Thereof*, Inv. No. 1381, EDIS Doc. ID No. 805887, Complaint at ¶ 92. This website advertises one or more Accused Products for sale. *See* Exhibit 181.

On information and belief, Demand Vape sells for importation, imports, and/or sells after importation the Accused Products. Demand Vape sells products through the website

[REDACTED]

demandvape.com. *See* Exhibit 184. This website advertises one or more Accused Products for sale. *See* Exhibit 185.

On information and belief, Midwest Goods sells for importation, imports, and/or sells after importation the Accused Products. Midwest Distribution Illinois is an assumed name of Midwest Goods Inc. and “Midwest Distribution Illinois” appears under the contact information for the website midwestgoods.com. *See* Exhibits 43.005; 186; 187 at 4. This website advertises one or more of the Accused Products. *See* Exhibit 189. Midwest Distribution Illinois, through its Managing Director, Mudassir Yasin, recently submitted a Declaration in Federal Court *Midwest Goods Inc., d/b/a Midwest Distribution Illinois v. Breeze Smoke LLC*, No. 1:23-CV-05406, Docket Item #1 at ¶ 1 (N.D. Ill. Aug. 11, 2023) stating that it “is a United States business-to-business (B2B) distributor of vaping devices . . . to other distributors and retail locations,” that it has “thousands of vaping devices . . . for sale, many of which are visible on <https://www.midwestgoods.com/>,” and listing many of the brands encompassed by the Accused Products. *See* Exhibit 230 at ¶¶ 4, 8. Mr. Yasin further stated that, “[o]ver several years, Midwest has purchased thousands of vapes and vape-related product lines from China. In my experience, at least 90% or more of disposable vapes are supplied from China and there are over 100 China suppliers.” *Id.* at ¶ 12.

On information and belief, Proposed Respondents or agents acting at their direction have maintained and continue to maintain a commercially significant inventory of the Accused Products and components thereof in the United States.

On information and belief, Proposed Respondents or agents acting at their direction have maintained and continue to maintain a commercially significant inventory of the Accused Products and components thereof in the United States.

[REDACTED]

4. Reynolds Will Demonstrate A Domestic Industry

For the reasons outlined below, Reynolds will satisfy both the economic and technical prongs of the Commission's domestic industry requirements.

(a) Reynolds Will Again Prove An Economic Domestic Industry ("DI")

Reynolds is not only likely to succeed in proving an economic DI, it has already done so. In the 1199 Investigation discussed above, Reynolds proved the existence of an economic DI with respect to the *exact same* line of products (*i.e.*, VUSE[®] products) it is relying on here to establish economic DI. *See Certain Tobacco Heating Articles*, Inv. No. 337-TA-1199, Order No. 35 at 5 and Comm'n Op. at 12. The presence of an economic DI with respect to the VUSE[®] products was so clear-cut that respondents in the 1199 Investigation stipulated that an economic DI existed. Order No. 35 at 2. That is not surprising given that *Reynolds has invested hundreds of millions of dollars in the DI products*.

As it relates to the issue of economic DI, the only difference between the 1199 Investigation and the facts here is that Reynolds is now relying on *more* products—in fact, all of the products within Reynolds's VUSE[®] line of vapor products—to prove economic DI, which necessarily means the economic DI investments here are even greater than those relied on in the 1199 Investigation. As a result, the case for economic DI is stronger here than it was in the 1199 Investigation. Accordingly, it is not just likely—but virtually certain—that Reynolds will succeed in proving the existence of an economic DI.

(i) Reynolds Has Been Investing In The U.S. Economy For Nearly 150 Years

Reynolds was founded in 1875 in Winston-Salem, North Carolina, by Richard Joshua Reynolds. [REDACTED] Declaration of Robert E. Ferris ("Ferris Decl.") (Exhibit 46) at ¶ 4. Nearly 150 years later, Reynolds is still headquartered in Winston-Salem and is deeply rooted in

[REDACTED]

the U.S. domestic economy. *Id.* Reynolds currently employs thousands of people in the U.S. *Id.* Reynolds's largest plant, formerly known as "Tobaccoville," and now known as the Reynolds Operations Center ("ROC"), is a 2,000,000-square-foot facility located in the town of Tobaccoville, near Winston-Salem. *Id.* Significant manufacturing and production activity for the DI Products takes place in that facility. *Id.* Reynolds also has a significant research and development ("R&D") group in Winston-Salem operating out of its Bowman Gray Technical Center. *Id.* The group primarily responsible for this R&D is the Scientific Research and Development ("SR&D") group, which currently includes more than [REDACTED] employees. *Id.* Reynolds's SR&D Group performs significant R&D activities with respect to the DI Products. *Id.*, ¶¶ 25-44.

(ii) Reynolds Has Always Been A Pioneer In The Discovery And Development Alternatives To Combustible Cigarettes, Including E-Cigarettes

While Reynolds has long been one of the largest tobacco companies in the United States, it is not just a "tobacco" company, and has not been for quite some time. *Id.* at ¶ 5. For many years, Reynolds has been focused on becoming a predominantly smokeless business. *Id.* By 2035, Reynolds's goal is to have at least 50% of its revenue come from noncombustible products. *Id.* To achieve this goal, Reynolds has made significant investments in R&D and commercial manufacture of alternatives to combustible cigarettes. One category of such products in which Reynolds has invested heavily is ENDS or e-cigarettes. *Id.*

Reynolds has been a pioneer in the development of e-cigarettes for almost 15 years. *Id.*, ¶ 6. During that span, Reynolds commercialized four models of VUSE® e-cigarette products that are being relied on for economic DI in this case. *Id.* The VUSE® Solo was the first e-cigarette designed, developed and sold by Reynolds. *Id.*, ¶ 7. Reynolds began developing that product in 2011 and designed and developed it from the ground up. *Id.* In 2013, Reynolds launched the

[REDACTED]

VUSE® Solo, which was the first truly digital e-cigarette ever sold in the U.S. *Id.* The manufacture of the Solo Cartridges, as well as the assembly and packaging of the entire Solo devices, has always been performed in the U.S. *Id.* Similarly, the manufacture of the e-liquid of the VUSE® Solo has always been performed in the U.S. VUSE® Solo was an immediate success as it quickly became the market leader in the e-cigarette category. *Id.*

After VUSE® Solo, Reynolds launched the remaining DI Products, including the VUSE® Vibe, VUSE® Ciro, and VUSE® Alto. *Id.*, ¶ 8. The e-liquid used in the VUSE® Vibe and VUSE® Solo products was developed by Reynolds, and the e-liquid for all VUSE® Products has always been produced in the U.S. *Id.* Currently, Reynolds's VUSE® line is the market leader within the closed system e-cigarette category in the U.S. *Id.*, ¶ 9.

The DI Products comprise the entire line of Reynolds's VUSE® vapor products; they are a key embodiment of Reynolds's commitment to its guiding principles regarding tobacco harm reduction and a cornerstone to Reynolds's future. *Id.*

(iii) Reynolds Will Show That It Meets The Economic DI Requirements Of 19 U.S.C. § 1337(a)(3)(A)-(C)

The economic DI requirement is satisfied when one or more of the statutorily-prescribed economic activities—(i) significant investment in plant and equipment, (ii) significant employment of labor or capital; or (iii) substantial investment in its exploitation, including engineering, research and development, or licensing—have taken place or are taking place with respect to the protected articles. 19 U.S.C. § 1337(a)(3)(A)-(C); *Certain Printing & Imaging Devices & Components Thereof*, Inv. No. 337-TA-690, EDIS Doc. ID No. 444708, Comm'n Op. at 25-26 (U.S.I.T.C. Feb. 17, 2011). The three economic activities are specified in the statute in the disjunctive, meaning that demonstrating the presence of any one economic activity is sufficient to satisfy the economic prong. *Certain Carburetors & Prods. Containing Such*

[REDACTED]

Carburetors, Inv. No. 337-TA-1123, EDIS Doc. ID No. 692517, Comm’n Op. at 7 (U.S.I.T.C. Oct. 28, 2019). Economic DI is analyzed on a case-by-case basis, not according to any rigid mathematical formula. *Certain Batteries & Electrochemical Devices Containing Composite Separators, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-1087, EDIS Doc. ID No. 652457, Order No. 32 at 4 (U.S.I.T.C. Aug. 8, 2018), *aff’d as modified*, EDIS Doc. ID No. 655141, Notice of Comm’n at 2 (U.S.I.T.C. Sept. 7, 2018).

Here, Reynolds will *once again* prove that it satisfies the economic DI requirements under 19 U.S.C. § 1337(a)(3) with respect to the VUSE® DI Products. Reynolds’s significant domestic investments in the DI Products relate to the entire range of activities involved in developing a line of products, launching a line of products, and maintaining a line of products on the market, including:

- research and development (*e.g.*, discovery, design and development; product stewardship, integrity and regulatory compliance; and process / manufacturing engineering);
- domestic manufacture (*e.g.*, manufacture of critical components, assembly and packaging of entire devices, and production of e-liquid); and
- quality control.

Ferris Decl., ¶ 11. With respect to these domestic activities, Reynolds has made significant investments in the U.S. in each of: (1) plant and equipment; (2) labor and capital; and (3) exploitation of the ’202 Patent. *Id.*, ¶ 12.

(1) Reynolds’s Significant Investments In Plant & Equipment

Reynolds has invested hundreds of millions of dollars in plant and equipment with respect to the DI Products (*id.*, ¶ 13), which the Commission has already found satisfies the

[REDACTED]

requirements of economic DI. In the 1199 Investigation, Chief ALJ Cheney found that “it is my initial determination that *Reynolds has shown, with respect to the [VUSE Solo] products... a significant investment in plant and equipment....*” *Certain Tobacco Heating Articles*, EDIS Doc. ID No. 731117, Order No. 35 at 5. That initial determination was not reviewed by the Commission and became final.

The decision in the 1199 Investigation was well-reasoned. For nearly a decade, Reynolds has manufactured cartridges for the VUSE® Solo and assembled and packaged the entire VUSE® Solo devices at the Reynolds Operations Center in Tobaccoville, North Carolina. Ferris Decl., ¶ 14. Sophisticated and expensive equipment is required to manufacture the VUSE® Solo cartridges and assemble and package the devices in the U.S. *Id.*, ¶ 15. Reynolds has invested over [REDACTED] in the purchase of equipment required to produce, assemble and package the VUSE® Solo. *Id.* Examples of equipment purchased include cartridge manufacturing machines, e-liquid filling machines, packaging machines and more. *Id.*

Reynolds also made significant investments in its ROC plant to build a space for the VUSE® Solo cartridges to be manufactured and the devices assembled and packaged. *Id.*, ¶ 16. The facilities used to perform these activities include tooling departments, manufacturing space, automated cartridge assembly and packaging lines, testing facilities, and offices. *Id.* Reynolds invested approximately [REDACTED] building a 70,000 square foot manufacturing space within its Tobaccoville facility to perform these manufacturing, assembly, and packaging activities. *Id.*

Reynolds also makes the e-liquid for all of its VUSE® Products (except VUSE® Alto) at the Reynolds Operations Center. *Id.*, ¶ 17. Reynolds has made significant investments in equipment used to make this e-liquid. *Id.*, ¶ 18. For example, Reynolds invested approximately [REDACTED] in equipment that is installed at the Tobaccoville facility to make e-liquid for

[REDACTED]

VUSE® Products. *Id.* From 2019 through 2023, Reynolds has invested over [REDACTED] operating, maintaining and supporting the manufacturing and production facility for VUSE Products. *Id.*, ¶ 19.

While the e-liquid for the VUSE® Alto is not made at the Reynolds Operations Center, it is made in the U.S. by a third-party manufacturer known as [REDACTED] who produces the e-liquid under the direction and authorization of Reynolds. *Id.*, ¶ 20. Hundreds of millions of VUSE® Alto cartridges are being sold annually in the U.S., and [REDACTED] operates a facility in the U.S. where it makes the e-liquid used in all or substantially all of them. *Id.*, ¶ 21. [REDACTED] has made and continues to make significant investments in plant and equipment relating to the production of e-liquid used in the VUSE® Alto product, and thus Reynolds is indirectly making significant investments in that plant and equipment because those costs are incorporated into the e-liquids that Reynolds purchases through the supply chain. *Id.*

The foregoing exemplary domestic investments in plant and equipment for the VUSE® Products amount to nearly [REDACTED], which does not include the [REDACTED] investments in plant and equipment. *Id.*, ¶ 22. The [REDACTED] investments will be obtained during discovery and will substantially add to the overall investment in plant and equipment already found sufficient to prove economic DI in the 1199 Investigation.

In view of the foregoing, Reynolds will succeed in showing that the plant and equipment investments found sufficient to satisfy the economic DI requirement in the 1199 Investigation are once again sufficient to satisfy the economic DI requirement here.

(2) Reynolds's Significant Investments In Labor & Capital

Reynolds has also invested hundreds of millions of dollars in labor and capital relating to the DI Products. *Id.*, ¶ 23. Based on those investments, Chief ALJ Cheney found in the 1199

[REDACTED]

Investigation that “it is my initial determination that *Reynolds has shown, with respect to the [VUSE Solo] products ... a significant investment in ... employment of labor and capital.*”

Certain Tobacco Heating Articles, EDIS Doc. ID No. 73117, Order No. 35 at 5. That initial determination was not reviewed by the Commission and became final. That decision was well-supported and well-reasoned.

Reynolds’s labor and capital investments for the DI Products largely fall into three categories: (1) research and development; (2) manufacturing, assembly and production; and (3) quality control. Ferris Decl., ¶ 24.

Research & Development. Since at least 2011, Reynolds has been conducting R&D activities in the U.S. related to the DI Products. *Id.*, ¶ 25. These R&D activities are conducted primarily out of the Bowman Gray Technical Center located in Winston-Salem and are performed principally by the group of more than [REDACTED] employees in the SR&D department. *Id.* The R&D activities that Reynolds performs with respect to the DI Products are wide-ranging and include:

- Discovery, design and development;
- Product stewardship / integrity and regulatory compliance; and
- Quality control

Id., ¶ 26.

Discovery, Design and Development

Reynolds began investing in the discovery, design and development of the DI Products as early as 2011. *Id.*, ¶ 27. Reynolds’s initial work included 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

[REDACTED]

Reynolds is also in the process of developing [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Further, Reynolds is also developing another [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From 2019 to through 2023, Reynolds invested over [REDACTED] in labor performing the foregoing activities in connection with the DI Products. *Id.*, ¶ 33.

Product Stewardship, Integrity, and Regulatory Compliance

Product stewardship and integrity for the DI Products covers a wide range of activities at Reynolds, including evaluation of health risks, toxicological studies, chemical stability studies, behavioral studies, clinical studies, non-clinical studies, and more. *Id.*, ¶ 34. Reynolds has a long history of investing in product stewardship and integrity for the DI Products. *Id.* Those

investments date back to Reynolds's development and launch of the first VUSE[®] product (Solo) in 2013. *Id.*

In 2016, much of the product stewardship and integrity work that Reynolds was already performing became mandatory under FDA regulations. In 2016, FDA issued a final regulation, sometimes called the "Deeming Rule," that broadened FDA's authority to regulate products containing nicotine derived from tobacco, including e-cigarettes. *Id.*, ¶ 35. As a result, all "tobacco products" must undergo FDA review and clearance in order to be marketed in the U.S. *Id.* For e-cigarettes, the regulatory pathway to market involved filing a PMTA, and the deadline for filing one was September 2020, for certain e-cigarette products that wished to benefit from an FDA enforcement-discretion policy. Much of the work that Reynolds was already performing as part of its product stewardship and integrity R&D became a requirement for PMTA submissions. *Id.*, ¶ 36.

In October 2019, Reynolds filed its PMTA for VUSE[®] Solo. *Id.* Thereafter, Reynolds filed PMTAs for the remaining VUSE[®] Products, including Alto, Vibe and Ciro. *Id.* Reynolds has received MGOs for tobacco-flavored VUSE[®] Solo, Vibe and Ciro.⁵ *Id.* Reynolds is awaiting a marketing decision for tobacco-flavored VUSE[®] Alto. *Id.*

Based on the requirements that must be addressed in PMTAs, the costs of preparing a PMTA are significant. *Id.*, ¶ 37. For example, in support of its applications for the DI Products, Reynolds conducted numerous non-clinical and clinical studies to evaluate individual health risks among users of VUSE[®] Products; developed an extensive behavioral research program to

⁵ FDA issued MDOs for menthol-flavored VUSE[®] Solo, Vibe and Ciro, but those orders have been stayed by order of the Court of Appeals for the Fifth Circuit. *R.J. Reynolds Vapor Company v. Food & Drug Administration*, 65 F.4th 182, 195 (5th Cir. 2023).

[REDACTED]

assess tobacco-use patterns among purchasers; and performed population modeling and analysis demonstrating the net-population benefit of marketing each product over time. *Id.*

Even though Reynolds has already submitted PMTAs for each of the DI Products, Reynolds's ongoing product stewardship, integrity, and regulatory compliance investments continue to be significant. *Id.*, ¶ 38. For example, Reynolds is routinely required to address the FDA's questions and alleged deficiencies and submit supplemental information to FDA. *Id.*

Reynolds is also subject to reporting requirements imposed by the FDA. *Id.* In addition, Reynolds continues to prepare and submit new PMTAs for modifications and improvements to the DI Products. *Id.*, ¶ 39. As noted above, Reynolds has already submitted a PMTA for [REDACTED]

[REDACTED] In addition, Reynolds has developed [REDACTED] for which Reynolds is preparing new PMTAs. *Id.* Reynolds's ongoing investments in product stewardship, integrity, and regulatory compliance relating to these projects are significant. *Id.*

The bulk of the product stewardship, integrity, and regulatory compliance activities are carried out by Reynolds's Scientific and Regulatory Affairs group located in the Bowman Gray Technical Center in Winston-Salem, North Carolina. *Id.*, ¶ 40. Depending on the year, there are generally at least [REDACTED] Reynolds employees in the U.S. who are engaged in these activities. *Id.*

From 2019 through 2023, Reynolds invested over [REDACTED] in internal labor in the U.S. directed to product stewardship, integrity, and regulatory compliance for the VUSE® Products. *Id.*, ¶ 41.

From 2019 through September 2023, Reynolds invested nearly [REDACTED] in external domestic labor and capital directed to product stewardship, integrity, and regulatory compliance for the VUSE® Products. *Id.*, ¶ 42.

[REDACTED]

From 2013 through 2018, Reynolds invested over [REDACTED] in internal labor in the U.S. directed to product stewardship, integrity, and regulatory compliance for the VUSE® Products. *Id.* at ¶ 43.

From 2013 through 2018, Reynolds invested over [REDACTED] in external labor and capital directed to product stewardship, integrity, and regulatory compliance for the VUSE® Products. *Id.*, ¶ 44.

Investments relating to regulatory compliance, including seeking FDA authorization, are cognizable investments under ITC precedent. Indeed, “[i]f FDA approval is necessary for [complainant] to exploit its invention, ... it follows that expenditures to obtain that approval contribute to the domestic industry.” *Certain Strontium-Rubidium Radioisotope Infusion Sys.*, Inv. No. 337-TA-1110, EDIS Doc. ID 684056, Initial Determination at 142-143 (U.S.I.T.C. Aug. 1, 2019) (finding investments in labor and capital to obtain FDA approval significant under Section 337(a)(3)(B)); *see also Certain Tobacco Heating Articles*, EDIS Doc. ID No. 73117, Order No. 35 at 5; *Certain Tobacco Heating Articles*, EDIS Doc. ID No. 754503, Comm’n Op. at 8, (Oct. 19, 2021); *Certain Electronic Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1139, EDIS Doc. ID No. 697216, Final Initial Determination at 265-266 (U.S.I.T.C. Dec. 13, 2019), EDIS Doc. ID No. 709572, Comm’n Opinion at 8-9 (U.S.I.T.C. May 5, 2020); *Certain Cartridges for Electronic Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1141, EDIS Doc. ID No. 685251, Order No. 38 at 25 (U.S.I.T.C. Aug. 14, 2019); *Certain Minoxidil Powder Salts & Compositions for Use in Hair Treatment*, Inv. No. 337-TA-267, Initial Determination, 1988 WL 582867, at *26 (U.S.I.T.C. Feb. 16, 1988); *Certain Doxorubicin & Preparations Containing Same*, Inv. No. 337-TA-300, 1990 WL 710463, at *64 (U.S.I.T.C. May 21, 1990).

[REDACTED]

Manufacture, Assembly and Production

Reynolds has also made significant investments in domestic labor relating to the manufacture and assembly of VUSE® Products in the U.S. Ferris Decl., ¶ 45. Those investments in labor relate to, among other things, domestic production of the VUSE® Solo cartridges, domestic assembly and packaging of the VUSE® Solo devices, and domestic production of e-liquid used in all of the VUSE® Products. *Id.*

From 2014 through at least part of 2015, Reynolds paid a third-party manufacturer in the U.S. to help make the VUSE® Solo cartridges and assemble and package the devices. *Id.*, ¶ 46. Reynolds's total investment in external labor and capital paid to that third party was approximately [REDACTED]. *Id.*

In 2016, Reynolds moved all of the manufacture of the Solo cartridges and assembly and packaging of the devices to the Reynolds Operations Center in Tobaccoville, NC. *Id.*, ¶ 47. From 2014 through 2019, Reynolds's total investment in internal labor and capital for production, assembly and packaging of the VUSE® Solo products was approximately [REDACTED]. *Id.* From 2020 through 2023, labor associated with the VUSE Products at the ROC production facility was over [REDACTED]. *Id.*

As noted above, the e-liquid for the VUSE® Alto is not made at Reynolds's Operations Center, but is still made in the U.S. by a third-party supplier known as [REDACTED]. [REDACTED] makes significant investments in labor and capital relating to the domestic production of e-liquid used in the VUSE® Alto product. *Id.*, ¶ 48. As explained on [REDACTED] website, "[a]ll [REDACTED] formulations are manufactured for quality and consistency by degreed scientists using only the finest raw materials: USP Kosher Glycerin, USP Kosher Propylene Glycol, and USP Grade Levorotatory Nicotine. *Id.* All materials are independently tested for purity before use in manufacturing." *Id.*

[REDACTED]

Moreover, [REDACTED] website states “[REDACTED] routinely analyzes our finished e-liquids, for their purity, safety and consistency in an A2LA accredited ISO 17025 (3918.01) Analytical Lab. We take pride in our manufacturing process so our customers can be assured of a consistent, high-quality product.” *Id.*, ¶ 49. With respect to quality control, [REDACTED] website further describes multiple activities performed by [REDACTED]. For example, it explains that “[a]s part of our Standard Operating Procedures every batch of incoming raw materials is tested in an accredited analytical laboratory, to verify their original Certificates of Analysis and ensure quality, before being released into production.” *Id.*, ¶ 50. Further, it explains that “[a]ll of our products are traceable back to our suppliers and their original provided certificates of analysis,” “[o]ur flavors have been analyzed and contain no Harmful or Potentially Harmful Constituents (HPHC’s),” and “[o]ur fluids are tested by GC Analytical, an A2LA accredited ISO 17025:2017 (3918.01) Analytical Testing Laboratory, utilizing a GC/MS, GC/FID, LC/MS/MS, HPLC, and an array of other instruments to meet our customers’ needs.” *Id.*

Reynolds is indirectly investing in [REDACTED] labor and capital as those costs are passed through to Reynolds through the supply chain. *Id.* [REDACTED] significant investments in labor and capital relating to the production of e-liquid for the VUSE® Alto will be obtained during early discovery in this case. *Id.*

Quality Control

Reynolds makes significant investments in the DI Products in activities related to quality control. *Id.*, ¶ 52. Reynolds’s quality-control activities are coordinated out of the ROC in Tobaccoville, NC. *Id.*, ¶ 53. The quality-control group performs 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. *Id.*

[REDACTED]

Quality-control personnel also assist with issues on the production floor, develop procedures, and work on quality projects to support the DI Products. *Id.*, ¶ 54.

Reynolds also has a customer-service department that fields customer-service calls relating to VUSE® Products. *Id.*, ¶ 55. Reynolds's quality-control personnel address customer complaints from the customer-service call center, including testing products to address customer complaints, and working with engineering to redesign products as needed to address those complaints. *Id.*

As of October 2023, the quality-control group consisted of approximately [REDACTED] employees located at the Reynolds Operations Center in Tobaccoville. *Id.*, ¶ 56. From 2019 through 2023, Reynolds's investments in quality-control labor relating to the DI Products amounted to more than [REDACTED] *Id.*, ¶ 57.

* * *

Reynolds's total investment in labor and capital relating to the DI Products is more than [REDACTED], not including the labor and capital investment from [REDACTED].

(3) Reynolds's Substantial Investments In Exploitation Of The '202 Patent

Reynolds has made substantial investments in the exploitation of the '202 Patent. All of Reynolds's plant and equipment investments and labor and capital investments are properly included as investments in the exploitation of the '202 Patent. Each category of investments has the necessary nexus to the '202 Patent. The '202 Patent covers the entire line of DI Products, and the plant and equipment and labor and capital investments all relate to the entire line of DI Products or crucial components thereof. The combined investments in plant, equipment, labor and capital that relate to the exploitation of the '202 Patent total more than [REDACTED].

(iv) Reynolds Will Again Succeed in Showing That Its Investments In The DI Products Are Qualitatively and Quantitatively Significant

In the 1199 Investigation, the Commission found that Reynolds's investments in the same VUSE® line of products being relied on here for economic DI were qualitatively and quantitatively significant. *Certain Tobacco Heating Articles*, EDIS Doc. ID No. 754503, Comm'n Op. at 38. Given that the only difference here is that Reynolds is now relying on a broader line of products in the VUSE® family to prove economic DI and, thus, the investments have only increased, there is no doubt that Reynolds will be able to again demonstrate that its investments in the DI Products are both quantitatively and qualitatively significant.

Qualitative Significance. Reynolds's investments related to the DI Products are qualitatively significant. *Id.*, ¶ 58. As noted, Reynolds makes significant investments in the domestic manufacture of e-liquid used in the DI Products. E-liquid is an indispensable component of the DI Products; the DI products cannot be used without it. Further, with respect to VUSE® Solo, Reynolds also invests significantly with respect to the manufacture and production of the cartridges and the assembly and packaging of the Solo devices. As with the e-liquid, the cartridges are critical to producing a saleable product. Without these components, the devices are unusable, and there is no commercially viable product.

In addition to the production-related investments, Reynolds's investments with respect to R&D (*e.g.*, discovery, design and development as well as product stewardship, integrity, and regulatory compliance) and quality control are also qualitatively significant. These non-production activities also relate to critical aspects of the DI Products. Without Reynolds's substantial investments in discovery, design, and development, there would be no DI Products or continued development of those products. Without the product stewardship, the integrity of the DI Products could be compromised. Without the regulatory-compliance investments, Reynolds

[REDACTED]

would never even obtain the marketing authorizations from FDA that are needed to continue selling the DI Products.

The Commission has addressed these facts before and found that such investments are qualitatively significant. In the 1199 Investigation, the Commission found that qualitative significance is demonstrated by the following:

- “Reynolds’s labor and capital investments for VUSE ... relating to product integrity and [FDA PMTA] submissions are important to the potential continued sale of VUSE ... as well as the overall integrity of the product;
- Reynolds’s labor and capital investments in the manufacture of e-liquid used in VUSE Vibe relates to a key component of the VUSE Vibe (the product cannot be used without e-liquid); and
- Reynolds’s 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.”

Certain Tobacco Heating Articles, EDIS Doc. ID No. 754503, Comm’n Op. at 38. Nothing has changed to warrant different conclusions.

Quantitative Significance. Quantitatively, Reynolds’s investments in the DI Products are significant and substantial in absolute terms, amounting to more than [REDACTED]. Reynolds’s investments are also significant and substantial when viewed in context. For example, from 2019 through September 2023, the cost of goods sold for the DI Products was approximately [REDACTED]. Ferris Decl., ¶ 59. The domestic investments during that same approximate time period amounted to more than [REDACTED] (not including the investments from [REDACTED], which is [REDACTED] of the total cost of goods sold during that period, well within the

[REDACTED]

range accepted by the Commission as significant. Given the qualitative nature of the foregoing investments, this is a quantitatively significant percentage.

* * *

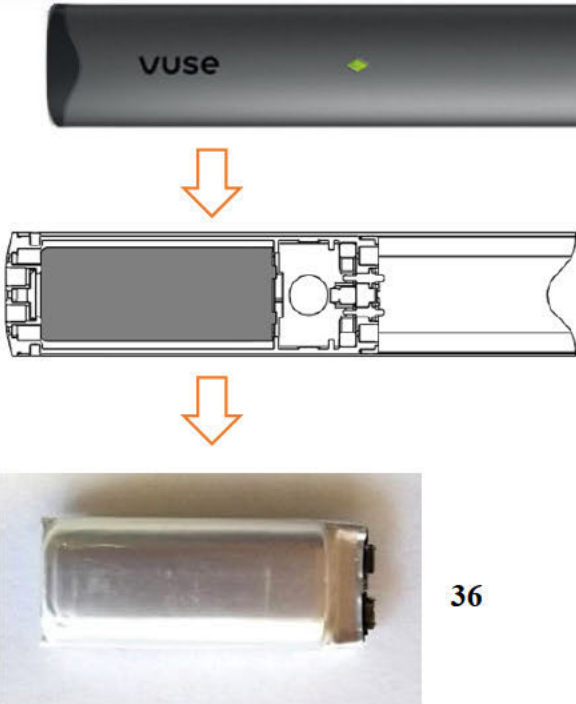
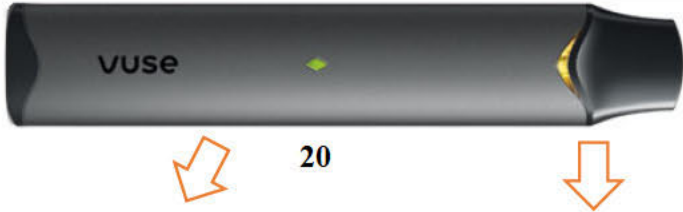
In sum, Reynolds proved in the 1199 Investigation that it makes significant investments in plant, equipment, labor and capital in its VUSE® line of products, which are the DI Products here. Those investments have only increased since the 1199 Investigation. Accordingly, it is certain that Reynolds will succeed again on the issue of economic DI in this case.

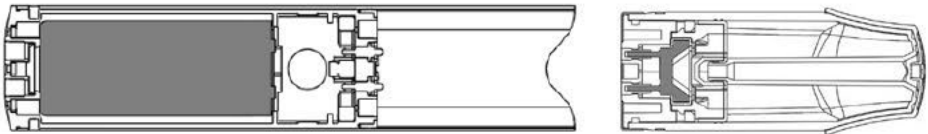
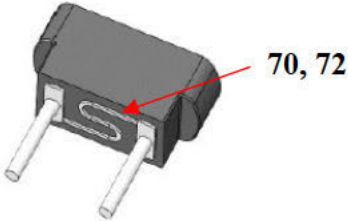
(b) Reynolds Satisfies The Technical Prong

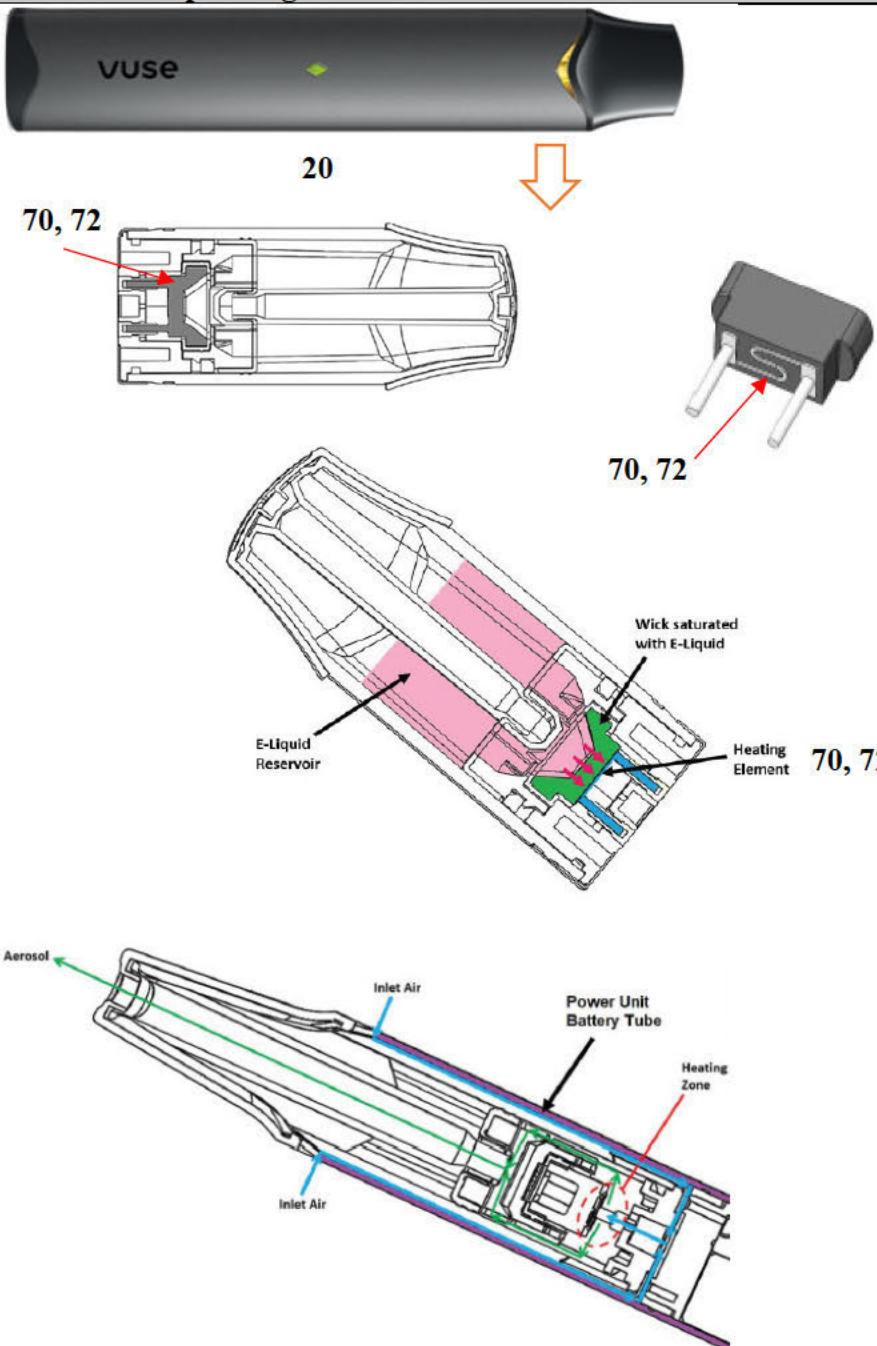
Reynolds also satisfies the technical prong of the domestic industry requirement because each of the VUSE® products described above practices at least one claim of the '202 Patent. An exemplary claim chart demonstrating coverage of the VUSE® Alto product by claim 1 of the '202 Patent is provided below. A claim chart demonstrating coverage of the VUSE® Alto product by claims 1-2, 4-5, 7-10, 13-16, 18-20, 22, 24-26, and 29 of the '202 Patent is contained in Exhibit 225C.⁶ For this motion only, Reynolds is asserting claims 1, 5, 9 and 14 of the '202 Patent for purposes of the t domestic industry technical prong, and it provides the following representative chart showing that the VUSE® Alto practices claim 1 of the '202 Patent.

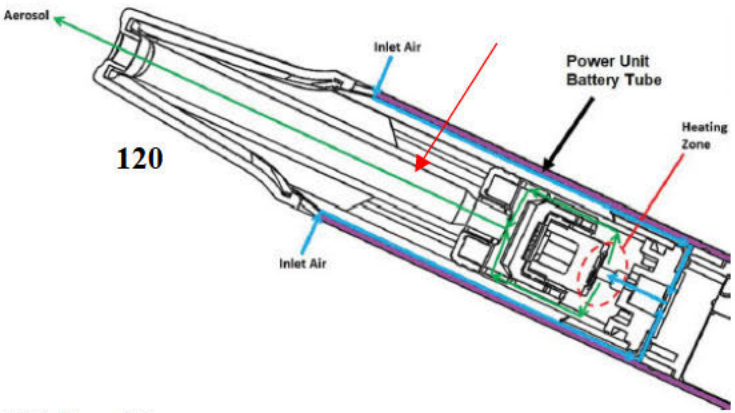
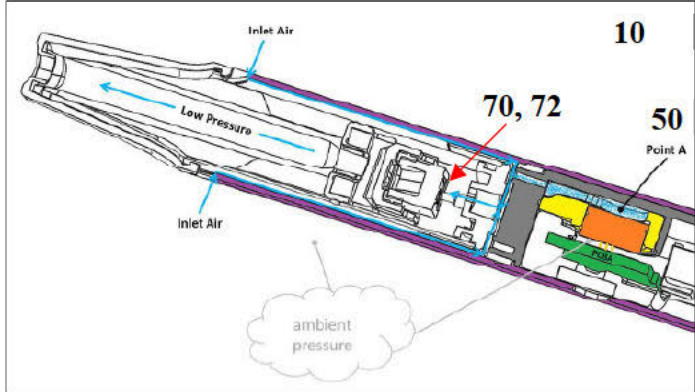
Claim 1	Corresponding Elements in the VUSE® Alto Device
[1-pre] An electrically-powered, aerosol-generating smoking article [10] comprising:	VUSE® Alto is an electrically-powered, aerosol-generating smoking article.  10

⁶ Reynolds's upgraded [REDACTED] [REDACTED] are the same as the VUSE® Alto as relevant to the limitations of the claims of the '202 Patent. Therefore, the upgraded products practice claims 1-2, 4-5, 7-10, 13-16, 18-20, 22, 24-26, and 29 of the '202 Patent for the same reasons described in Exhibit 225C related to the VUSE® Alto product.

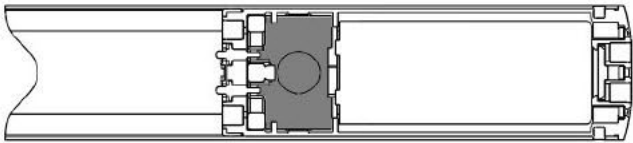
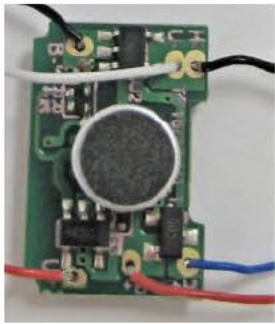
Claim 1	Corresponding Elements in the VUSE® Alto Device
[1a] an outer housing [20] having two ends [15], [13];	 13 20 15 PMTA at 24.
[1b] a mouthpiece [120] defined at one of the two ends;	 12 12 PMTA at 32.
[1c] an electrical power source [36] arranged within the outer housing;	 36 PMTA at 23.
[1d] an electrical resistance heater [70, 72] positioned within the outer housing [20], the electrical resistance heater	 20

Claim 1	Corresponding Elements in the VUSE® Alto Device
being configured for electrical connection with the electrical power source [36]	   36   70, 72  PMTA at 23, 26, 34.
[1e] a storage compartment defined within the outer housing [20], the storage compartment being configured	The storage compartment includes the resevoir and the ceramic wick that are configured for storage of the liquid aerosol-forming material and are arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater.

Claim 1	Corresponding Elements in the VUSE® Alto Device
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 [70, 72] to volatilize the liquid aerosol-forming material;	 The diagrams illustrate the VUSE Alto device and its internal components: Top Diagram: Shows the external view of the device with the brand name "vuse" and a green indicator light. Exploded View: Shows the mouthpiece (labeled 70, 72) and the battery unit (labeled 70, 72) with an orange arrow indicating their assembly. Internal Cross-Section (Mouthpiece): Shows the internal structure of the mouthpiece, including the E-Liquid Reservoir, the Wick saturated with E-Liquid, and the Heating Element (labeled 70, 72). Detailed Cross-Section: Shows the internal components of the device, including the Power Unit Battery Tube, the Heating Zone, and the Inlet Air ports. An Aerosol output is shown at the front.
	PMTA at 34, 37-38.

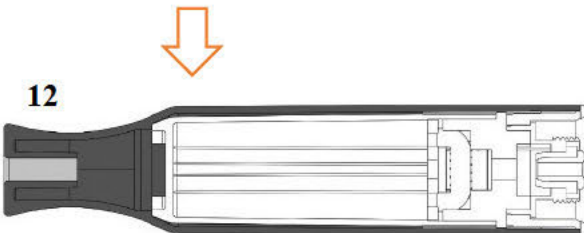
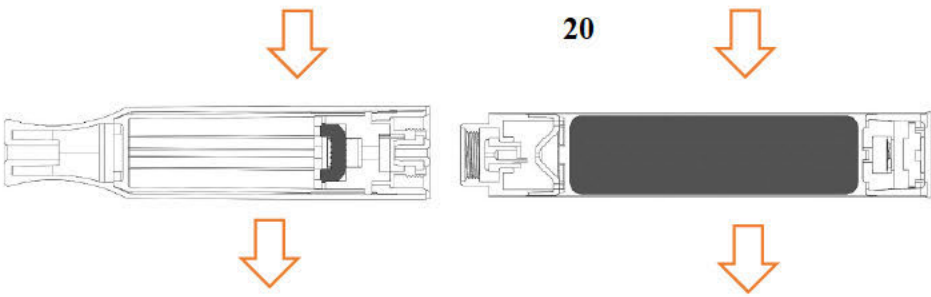
Claim 1	Corresponding Elements in the VUSE [®] Alto Device
[1f] an air passageway through at least a portion of the outer housing [20], the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article [10] through the mouthpiece [120]; and	 PMTA at 37.
[1g] a controller [50] configured to activate current flow through the electrical resistance heater [70, 72] in response to a draw on the electrically-powered, aerosol-generating smoking article [10].	 PMTA at 25.

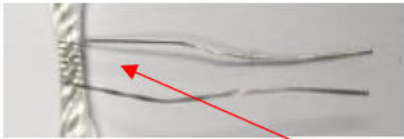
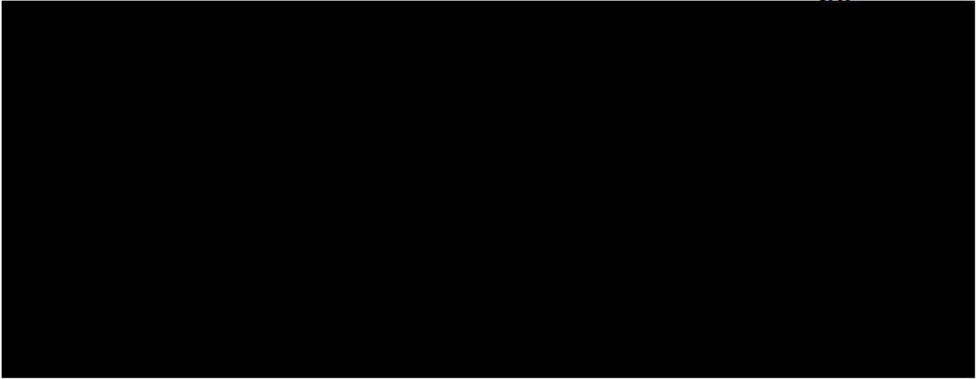


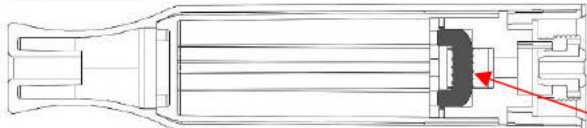
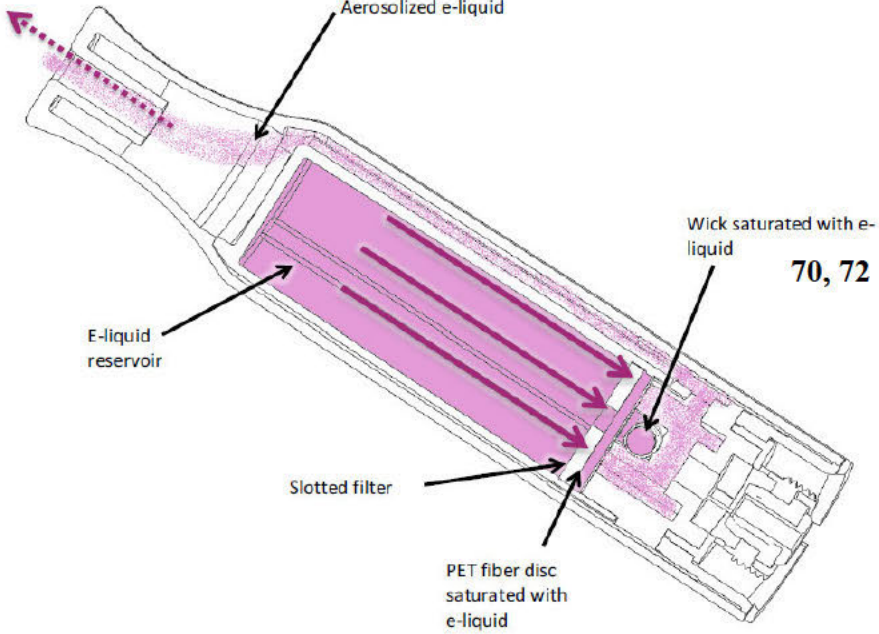
Claim 1	Corresponding Elements in the VUSE® Alto Device	
	PCBA:  The "PCBA", or Printed Circuit Board Assembly, includes the microcontroller, the pressure sensor, the battery-charging IC (integrated circuit), the battery-protection IC, the green LED, and other electronic components mounted to an FR-4 board. The PCBA is connected by pairs of wires to three power unit components: the Battery Cell, the Thimbles, and the Charge PCB. Lead-free solder is used for connecting wires within the power unit. The PCBA senses when a puff occurs, controls power to the heater circuit (Figure H-8), manages battery charging, and provides visual indications via the LED. PMTA at 21.	 50

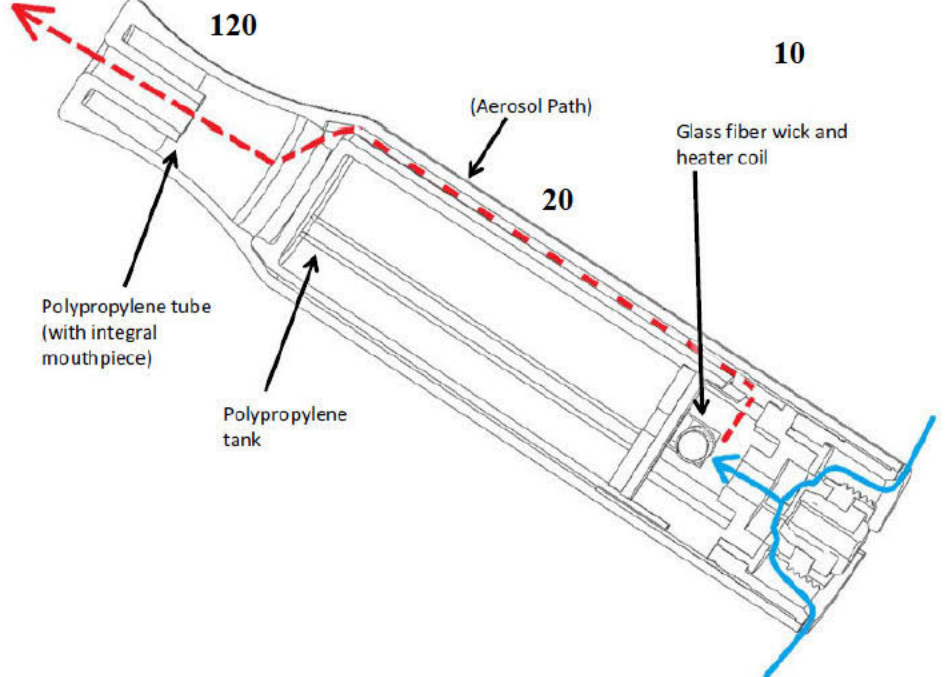
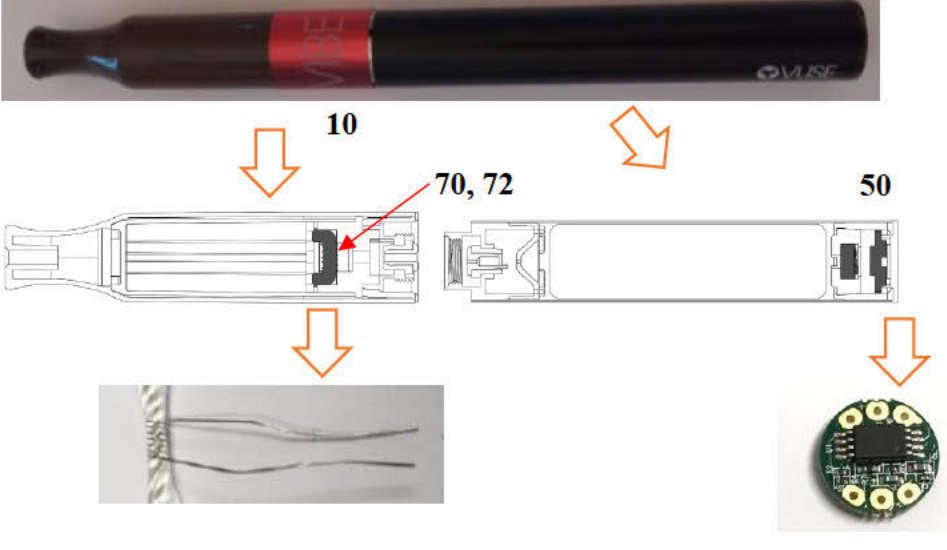
An exemplary claim chart demonstrating coverage of the VUSE® Vibe product by claim 1 of the '202 Patent is provided below. A claim chart demonstrating coverage of the VUSE® Vibe product by claims 1-3, 5-11, 13-27, and 29-30 of the '202 Patent is contained in Exhibit 224C. For this motion only, Reynolds is asserting claims 1, 5, 9 and 14 of the '202 Patent for purposes of the domestic industry technical prong, and it provides the following representative chart showing that the VUSE® Vibe practices claim 1 of the '202 Patent.

Claim 1	Corresponding Elements in the VUSE® Vibe Device	
[1-pre] An electrically-powered, aerosol-generating smoking article [10] comprising:	VUSE Vibe is an electrically-powered, aerosol-generating smoking article.  10	
[1a] an outer housing [20] having two ends [15], [13];	 20  15	

Claim 1	Corresponding Elements in the VUSE® Vibe Device
	PMTA at 16, 20, 32.
[1b] a mouthpiece [120] defined at one of the two ends;	  PMTA at 32.
[1c] an electrical power source [36] arranged within the outer housing;	   PMTA at 20.
[1d] an electrical resistance heater [70, 72] positioned within the outer housing [20], the electrical resistance heater being configured for electrical connection with the electrical power source [36]	 

Claim 1	Corresponding Elements in the VUSE® Vibe Device
	 70, 72 36  PMTA at 20, 33, 41.
[1e] a storage compartment defined within the outer housing [20], 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 [70, 72] to volatilize the liquid aerosol-forming material;	The storage compartment includes the e-liquid reservoir, the PET fiber disk, and the wick that are configured for storage of the liquid aerosol-forming material and are arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater.  20  Polypropylene Tank:  The "Polypropylene Tank" is made of polypropylene and acts as the e-liquid reservoir. The recessed feature on the outer wall provides a path for the aerosol to travel between the tank and tube to the mouthpiece. A slot towards the mouthpiece-end of the part creates an opening for the aerosol passage to continue to the mouthpiece. PET Fiber Disc:  The "PET Fiber Disc" is made from [REDACTED] and absorbs e-liquid from the tank and transfers the e-liquid to the wick. 

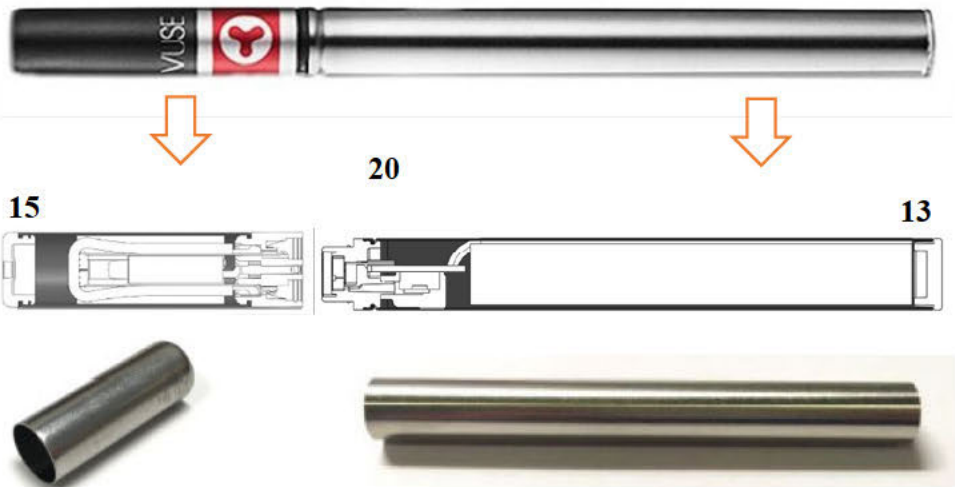
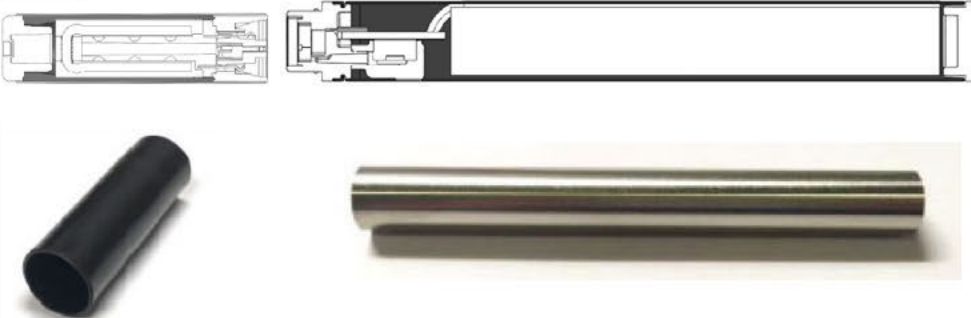
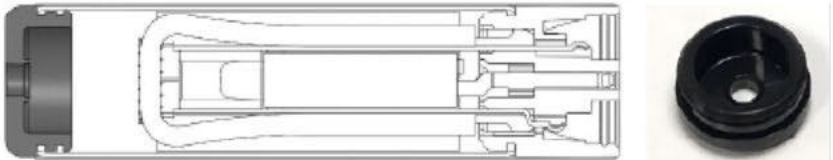
Claim 1	Corresponding Elements in the VUSE® Vibe Device
	Glass Fiber Wick:  The "Glass Fiber Wick" is made from [REDACTED] and absorbs e-liquid from the fiber disc. The e-liquid-saturated wick is in contact with the heater coil.  (shown with heater coil) 70, 72  70, 72 PMTA at 32, 37.

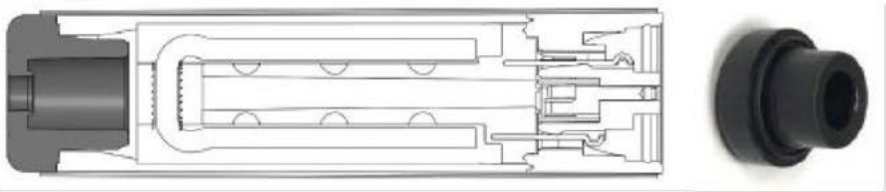
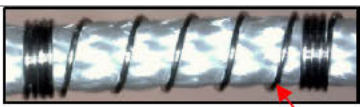
Claim 1	Corresponding Elements in the VUSE® Vibe Device
[1f] an air passageway through at least a portion of the outer housing [20], the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article [10] through the mouthpiece [120]; and	 PMTA at 36.
[1g] a controller [50] configured to activate current flow through the electrical resistance heater [70, 72] in response to a draw on the electrically-powered, aerosol-generating smoking article [10].	

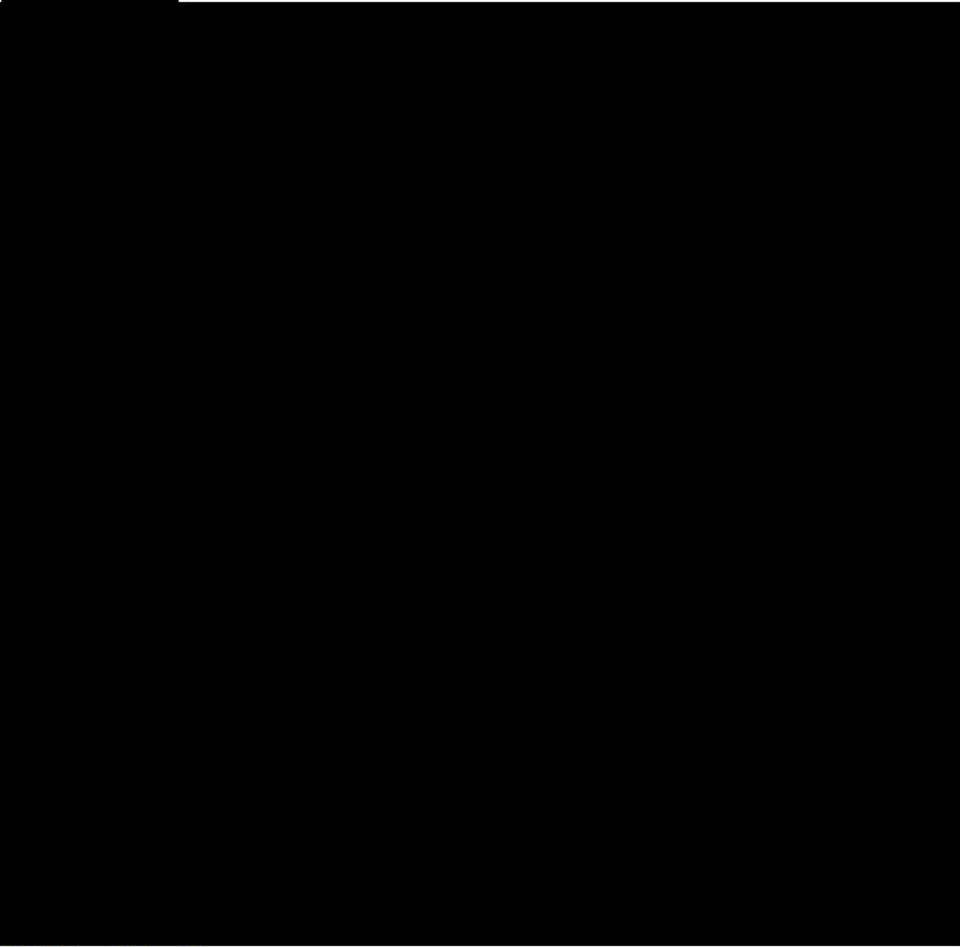
Claim 1	Corresponding Elements in the VUSE® Vibe Device
	The “PCBA” includes the controller, the pressure sensor, two LEDs (light emitting diodes), and other electronic components. The PCBA is connected to the pressure sensor (subcomponent 9a), the battery PCM, and the battery electrode using solder (subcomponent 9b). The PCBA senses a puff, controls power to the heater coil, and regulates battery charging. PMTA at 21, 25, 33.

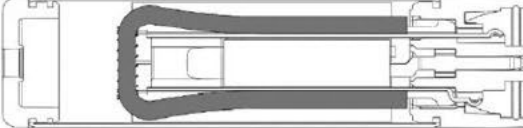
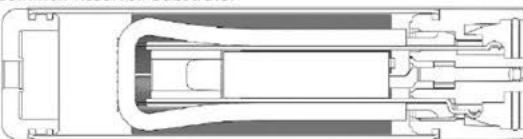
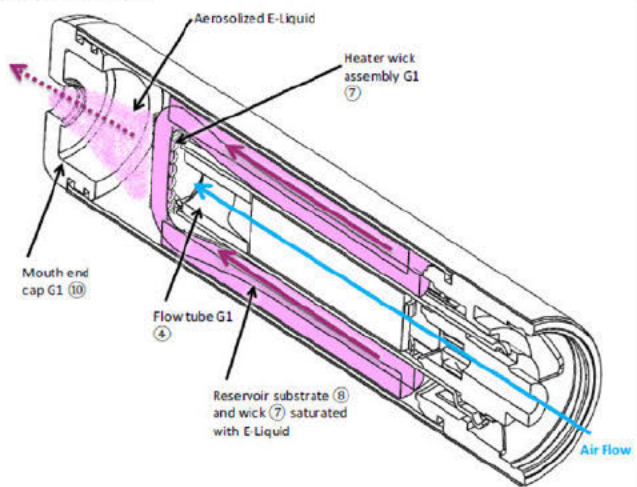
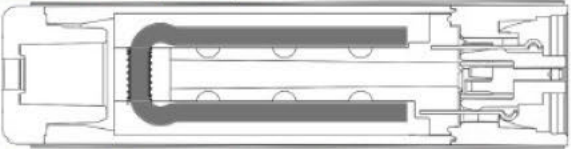
An exemplary claim chart demonstrating coverage of the VUSE® Solo (Generations 1 and 2) product by claim 1 of the '202 Patent is provided below. A claim chart demonstrating coverage of the VUSE® Solo (Generations 1 and 2) product by claims 1-11, 13-27, and 29-30 of the '202 Patent is contained in Exhibit 227C. For this motion only, Reynolds is asserting claims 1, 5, 9 and 14 of the '202 Patent for purposes of the domestic industry technical prong, and it provides the following representative chart showing that the VUSE® Solo practices claim 1 of the '202 Patent.

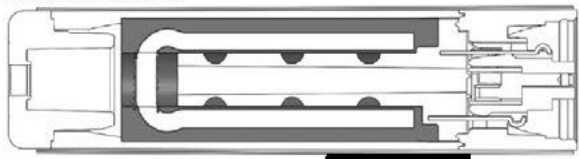
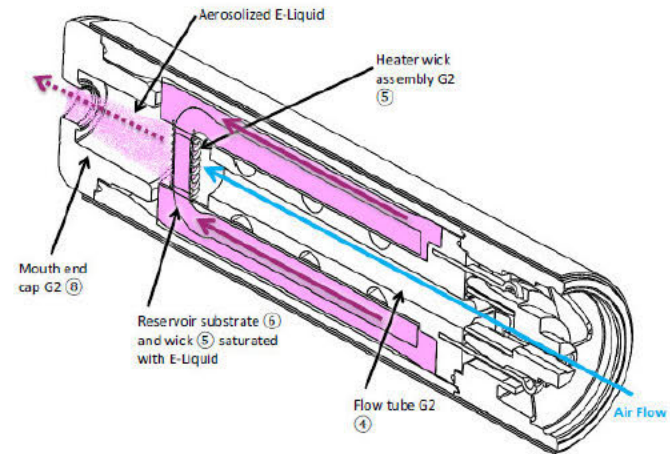
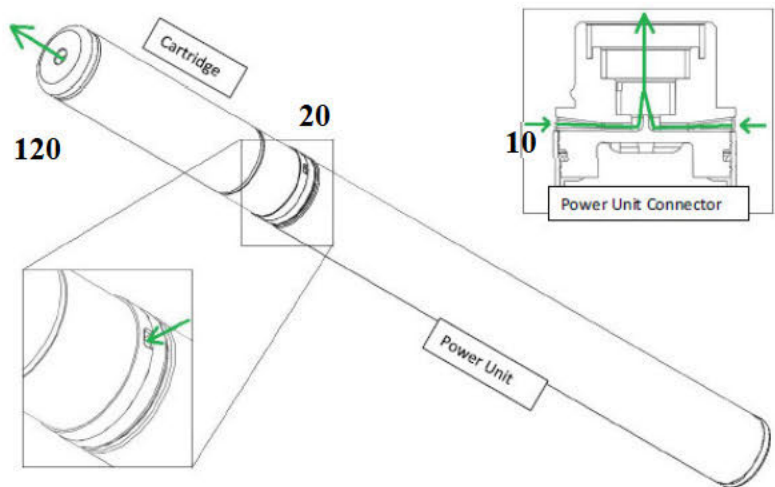
Claim 1	Corresponding Elements in the VUSE® Solo Devices
[1-pre] An electrically-powered, aerosol-generating	VUSE® Solo Devices are electrically-powered, aerosol-generating smoking articles.

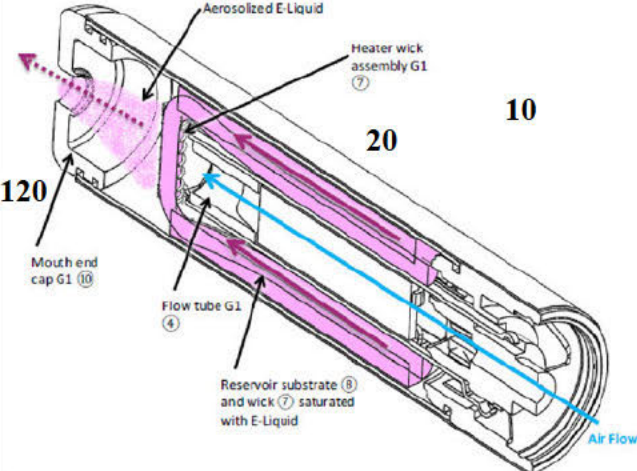
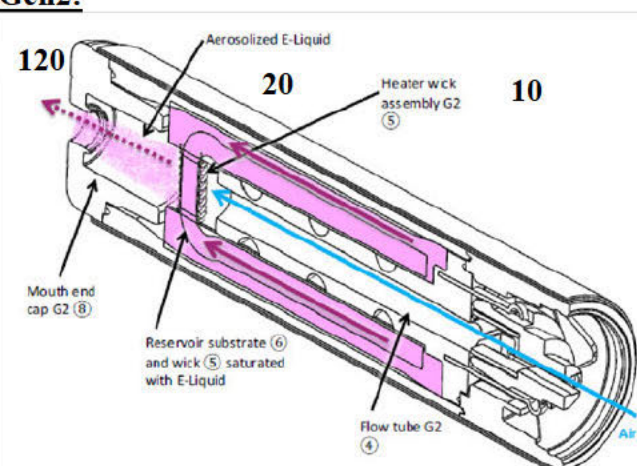
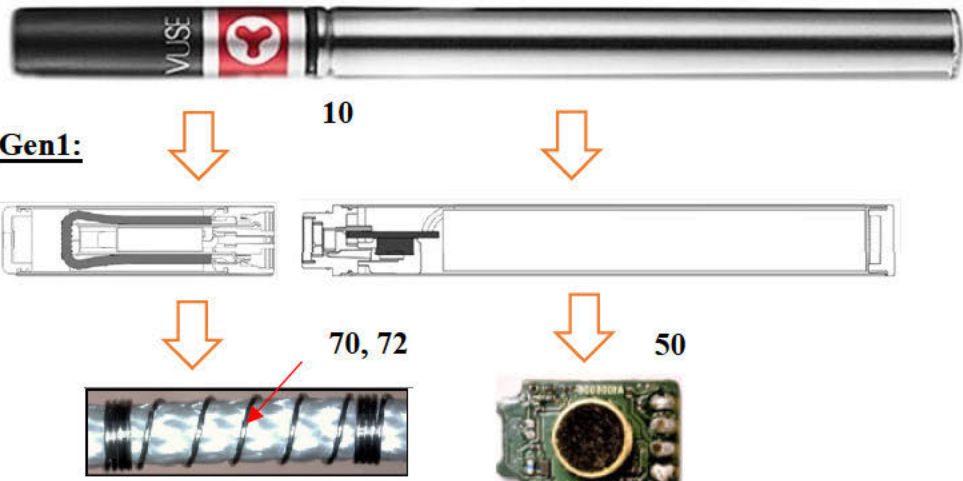
Claim 1	Corresponding Elements in the VUSE® Solo Devices
smoking article [10] comprising:	 10
[1a] an outer housing [20] having two ends [15], [13];	 15 20 13 PMTA at 18, 30. <u>Gen2:</u>  PMTA at 30.
[1b] a mouthpiece [120] defined at one of the two ends;	 <u>Gen1:</u> 120 

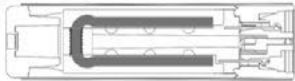
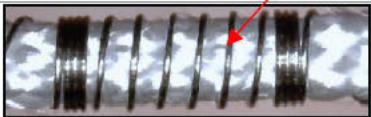
Claim 1	Corresponding Elements in the VUSE® Solo Devices
	PMTA at 30. Gen2: 12  PMTA at 39.
[1c] an electrical power source [36] arranged within the outer housing;	 36   PMTA at 20.
[1d] an electrical resistance heater [70, 72] positioned within the outer housing [20], the electrical resistance heater being configured for electrical connection	 Gen1: 20   70, 72  36

Claim 1	Corresponding Elements in the VUSE® Solo Devices
with the electrical power source [36]	PMTA at 18, 30. Gen2:   70, 72 36 PMTA at 18, 38. Gen 1 and 2:  PMTA at 22, 47.
[1e] a storage compartment defined within the outer housing [20],	The storage compartment includes the common resevoir substrate and heater wick that are configured for storage of the liquid aerosol-forming material and are arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater.

Claim 1	Corresponding Elements in the VUSE® Solo Devices
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 [70, 72] to volatilize the liquid aerosol-forming material;	 20 Gen 1: Heater Wick Assembly G1 Composite:  The "Heater Wick Assembly G1 Composite" is a pre-assembled unit composed of two components: the wick and the heater coil. The wick is braided glass fiber through which the e-liquid travels. The heater is a coil of wire that wraps around the wick to form the heater coil. The heater aerosolizes the e-liquid. Common Reservoir Substrate:  The "Common Reservoir Substrate" is made from [REDACTED] and is wrapped around the flow tube, contacting the wick. The substrate is saturated with 0.5 mL (nominal) of e-liquid after unfilled cartridge assembly, and holds the e-liquid in the finished cartridge. [REDACTED] are also used in the substrate at less than 5% by weight each.  PMTA at 30, 33. Gen2: Heater Wick Assembly G2 Composite:  The "Heater Wick Assembly G2 Composite" is a pre-assembled component composed of two sub-components: the wick and the heater coil. The wick is braided glass fiber through which the e-liquid travels. The heater is a coil of wire that wraps around the wick to form the heater coil. The heater aerosolizes the e-liquid.   

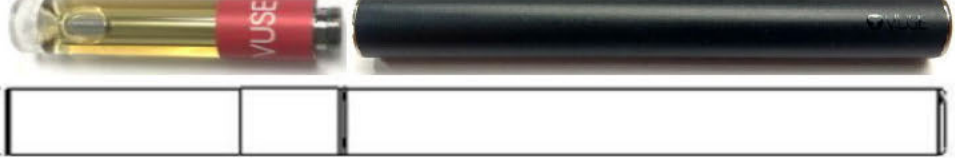
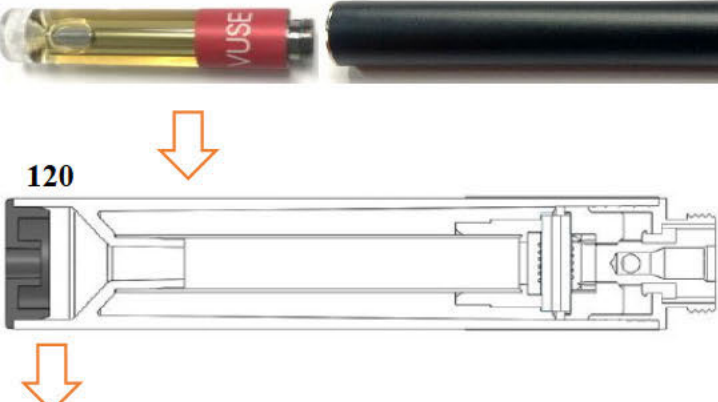
Claim 1	Corresponding Elements in the VUSE® Solo Devices
	Reservoir Substrate G2:  The "Reservoir Substrate G2" is made from [REDACTED] fiber and is wrapped around the flow tube, contacting the wick. The substrate is saturated with 0.5 mL (nominal) of e-liquid after unfilled cartridge assembly, and holds the e-liquid in the finished cartridge. [REDACTED] and [REDACTED] are also used in the substrate at less than 5% by weight each.   PMTA at 38, 39, 41.
[1f] an air passageway through at least a portion of the outer housing [20], 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	<u>Gen1 and 2:</u>  PMTA at 20. <u>Gen1:</u>

Claim 1	Corresponding Elements in the VUSE® Solo Devices
into the mouth of a user of the electrically-powered, aerosol-generating smoking article [10] through the mouthpiece [120]; and PMTA at 33. Gen2:	 PMTA at 33. Gen2:  PMTA at 41.
[1g] a controller [50] configured to activate current flow through the electrical resistance heater [70, 72] in response to a draw on the electrically-powered, aerosol-	 PMTA at 17, 30.

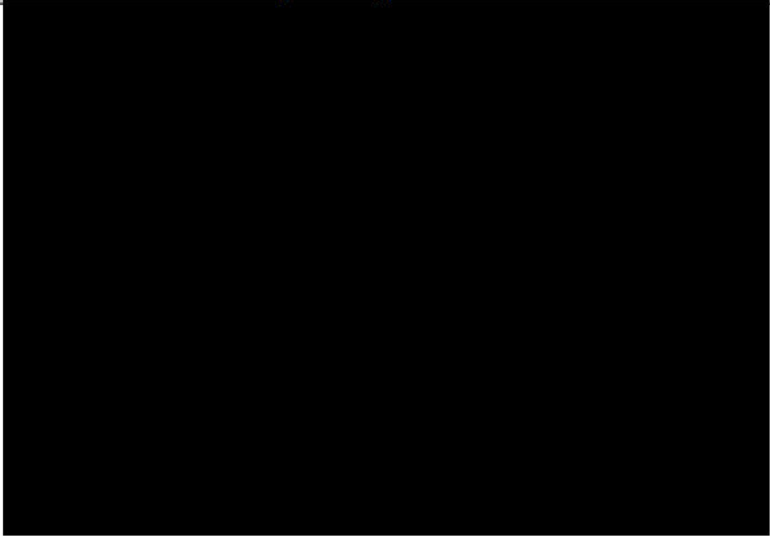
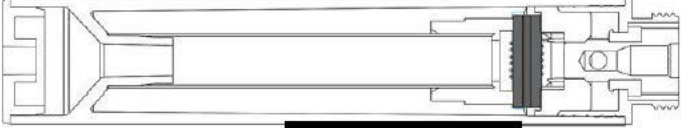
Claim 1	Corresponding Elements in the VUSE® Solo Devices
generating smoking article [10].	Gen2:   PMTA at 17, 38. Gen1 and Gen2: The PCBA holds the pressure sensor, controller, and other electronic components. The PCBA senses a puff, drives the heater coil, regulates battery charging, and authenticates the cartridge. The PCBA receives four leads from the battery assembly (see part #4 "Battery" below for an image of the four leads): • Pressure Sensing – The pressure sensor on the PCBA outputs a signal to the controller whenever it detects a pressure differential. This 'wakes up' the controller and signals the start of a puff. • [REDACTED] • [REDACTED] [REDACTED] PMTA at 17, 24, 47.

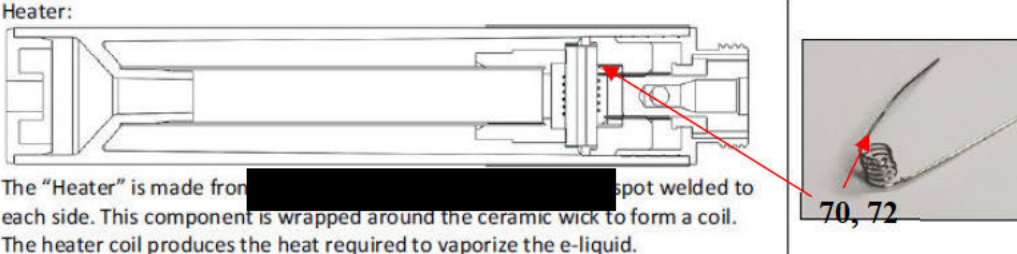
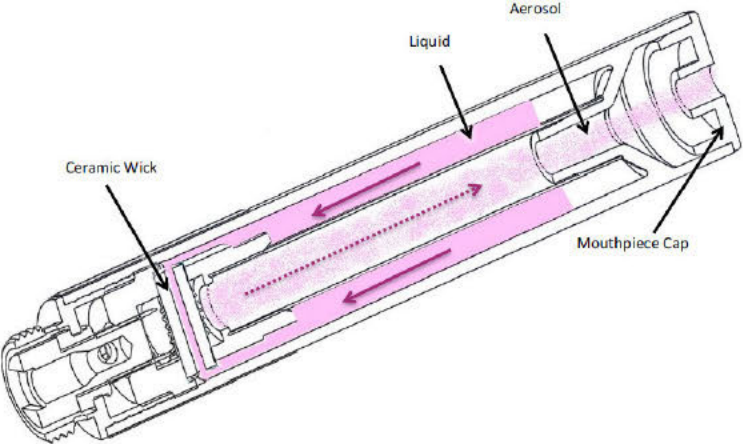
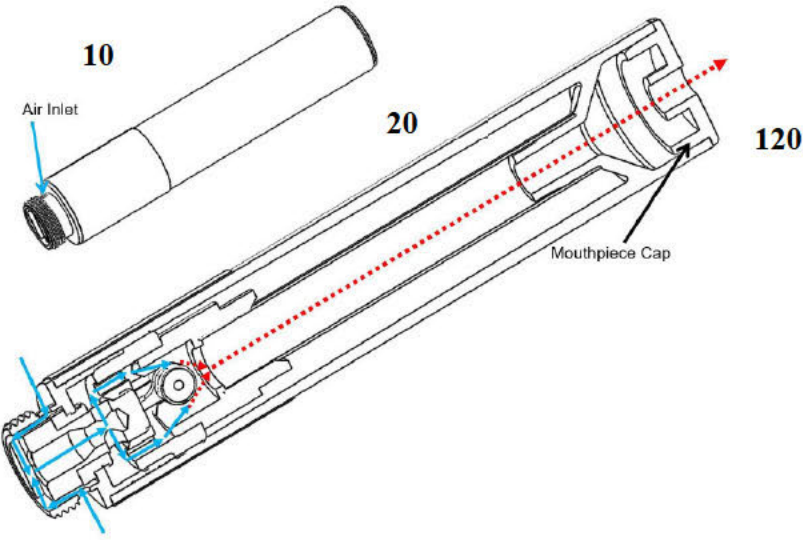
An exemplary claim chart demonstrating coverage of the VUSE® Ciro product by claim 1 of the '202 Patent is provided below. A claim chart demonstrating coverage of the VUSE® Ciro product by claims 1-2, 4-11, 13-22, 24-27, and 29-30 of the '202 Patent is contained in Exhibit 226C. For this motion only, Reynolds is asserting claims 1, 5, 9 and 14 of the '202 Patent for

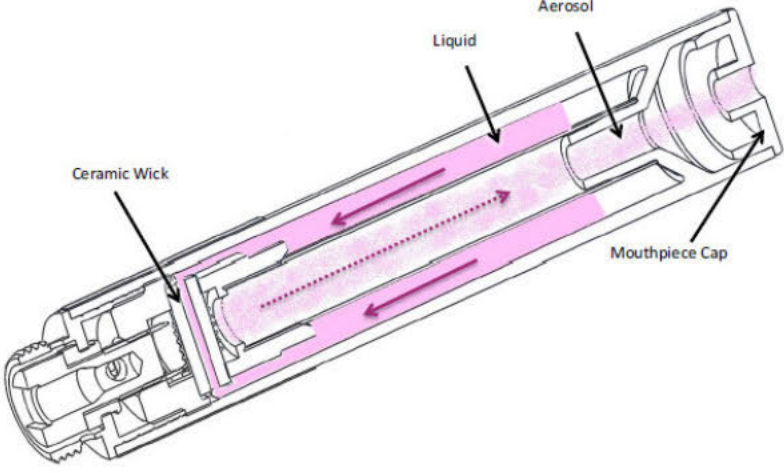
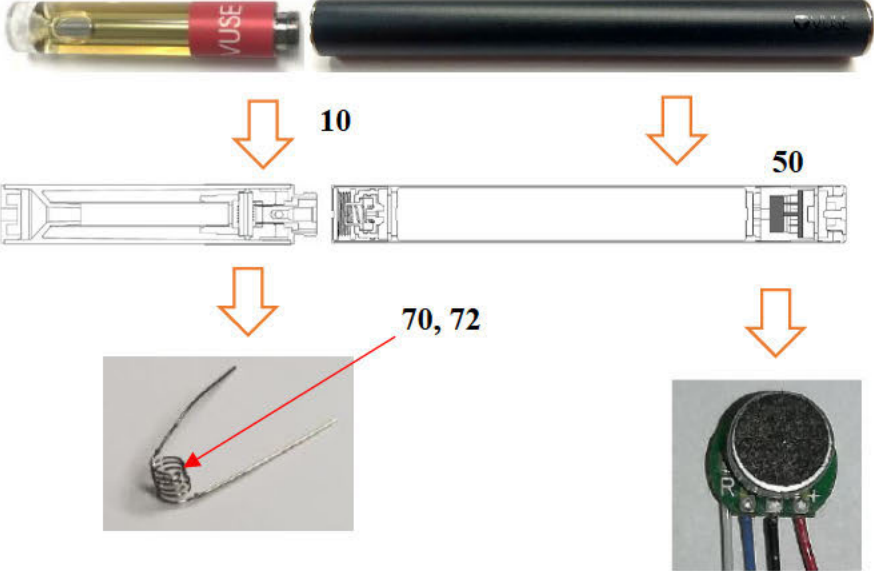
purposes of the domestic industry technical prong, and it provides the following representative chart showing that the VUSE® Ciro practices claim 1 of the '202 Patent.

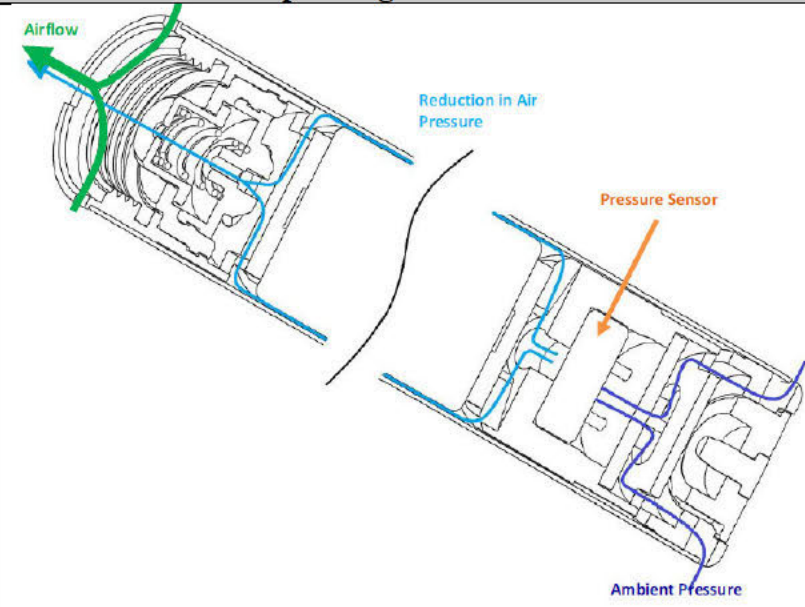
Claim 1	Corresponding Elements in the Vuse Ciro Device
[1-pre] An electrically-powered, aerosol-generating smoking article [10] comprising:	VUSE Ciro is an electrically-powered, aerosol-generating smoking article.  10 PMTA at 15.
[1a] an outer housing [20] having two ends [15], [13];	 20   PMTA at 15, 18, 28.
[1b] a mouthpiece [120] defined at one of the two ends;	 120

Claim 1	Corresponding Elements in the Vuse Ciro Device
	 PMTA at 15, 26.
[1c] an electrical power source [36] arranged within the outer housing;	   PMTA at 15, 19.
[1d] an electrical resistance heater [70, 72] positioned within the outer housing [20], the electrical resistance heater being configured for electrical connection with the electrical power source [36]	    20 36 70, 72

Claim 1	Corresponding Elements in the Vuse Ciro Device
	
[1e] a storage compartment defined within the outer housing [20], 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 [70,	PMTA at 15, 19, 27, 33. The storage compartment includes the plastic cup and the ceramic wick that are configured for storage of the liquid aerosol-forming material and are arranged such that the liquid aerosol-forming material can be wicked into contact with the electrical resistance heater.   20 Plastic Cup:  The "Plastic Cup" is made from [REDACTED]. This component acts as the outer body of the cartridge assembly and the e-liquid reservoir. The transparent outer wall allows visual observation of the e-liquid level. Ceramic Wick:  The "Ceramic Wick" is made from [REDACTED]. This component absorbs e-liquid from the reservoir.  

Claim 1	Corresponding Elements in the Vuse Ciro Device
72] to volatilize the liquid aerosol-forming material;	Heater:  The "Heater" is made from [REDACTED] spot welded to each side. This component is wrapped around the ceramic wick to form a coil. The heater coil produces the heat required to vaporize the e-liquid.  PMTA at 15, 27-28, 30.
[1f] an air passageway through at least a portion of the outer housing [20], the air passageway being arranged so that air drawn into the outer housing combines with volatilized liquid aerosol-forming material to	The air passageway passes through at least a portion of the outer housing and the air combines with the aerosol-forming material at the heater to produce the aerosol. The aerosol is then drawn into the mouth of the user through the mouthpiece. Figure H-12 shows the path of air (blue line) and aerosol (red dashed line) through the cartridge when air is drawn through the mouthpiece cap (upper right in figure). 

Claim 1	Corresponding Elements in the Vuse Ciro Device
produce an aerosol that can be drawn into the mouth of a user of the electrically-powered, aerosol-generating smoking article [10] through the mouthpiece [120]; and	 PMTA at 29.
[1g] a controller [50] configured to activate current flow through the electrical resistance heater [70, 72] in response to a draw on the electrically-powered, aerosol-generating smoking article [10].	 The "Controller" is a commercial off-the-shelf PCB that drives the heater coil and regulates battery charging, among other functions. The controller PCB has a white LED and a pressure sensor component pre-wired as part of the assembly.

Claim 1	Corresponding Elements in the Vuse Ciro Device
	 The diagram illustrates the internal structure of the Vuse Ciro device, showing the flow of air and the location of a pressure sensor. Green arrows indicate the path of airflow from the mouthpiece, through the heating element, and out through the filter. Blue lines represent the internal air passages. A label 'Reduction in Air Pressure' points to a specific area within the device. An orange arrow points to a 'Pressure Sensor' located within the internal air passage. A blue line at the bottom indicates 'Ambient Pressure'. The text 'PMTA at 15, 19, 22, 27.' is located at the bottom left of the diagram area. PMTA at 15, 19, 22, 27.

For the reasons above, and in the claim charts attached to the Complaint as Exhibits 224C-227C, Reynolds will be able to demonstrate that it satisfies the technical prong of the domestic industry requirement.

* * * *

All told, each of these showings demonstrates that Reynolds will succeed on the merits of its claims against the Proposed Respondents.

B. Reynolds Will Be Irreparably Harmed Absent The Requested Temporary Relief

Through their infringement, the Proposed Respondents are irreparably harming more than a decade's worth of Reynolds's work, investment, and its overall plan to move away from combustible cigarettes. The only remedy that can address this irreparable harm is the temporary exclusionary relief sought herein.

Reynolds is in the midst of a major transformation, changing from what was once almost exclusively a smoking tobacco company to a company that plans to predominantly sell non-



smoking products. Exhibit 286. (“Today, the company is focused on paving the way to becoming a predominantly smokeless business. ... By 2035, the company wants 50 percent of its revenue to come from noncombustible products.”). Over the last decade, Reynolds has invested billions of dollars in this transformation, and many hundreds of millions of dollars on the DI products alone. The DI Products, which are considered one of the most effective products for transitioning smokers away from combustible cigarettes, are a key part of Reynolds’s transformation. *See Certain Tobacco Heating Articles*, ID at 120-121 (discussing evidence that “e-cigarettes have proven to be more successful at transitioning smokers off of combustion cigarettes” and have been called “the ‘best’ and ‘most popular—and most successful—quit smoking aids.’”). Reynolds has invested significantly in research and development relating to the DI Products and developed a robust patent portfolio around them. Reynolds has also invested hundreds of millions of dollars abiding by the regulatory requirements for bringing the DI products to market.

The Proposed Respondents are undermining and irreparably harming Reynolds’s decades of work and investment in maintaining its reputation in the eyes of the public and before the FDA. Ferris Decl., ¶ 60. They are stealing Reynolds’s patented technology, having not invested a bit of research or development on their own, placing that patented technology in high-demand products that Reynolds cannot legally sell, improperly and unethically targeting American youth with candy- and dessert-flavored versions of Reynolds’s patented technology, and selling all of these products into the U.S. markets without any effort to invest the tens of millions of dollars necessary to obtain FDA authorization to do so legitimately. *Id.*, ¶¶ 61-62. As just a couple of examples, the following photos of the Accused Products show how Proposed Respondents are

using child-friendly flavors and appealing packaging to target youth in marketing their illicit products:



All of this is creating a tilted playing field in which Reynolds is competing against its own patented technology with both hands tied behind its back. *Id.*, ¶¶ 62-63. Indeed, the importation and sale of illicit disposable vapes in the United States is more pervasive than ever. The Associated Press reported that “the number of unique e-cigarettes on the market has tripled to over 9,000 since 2020, a surge driven almost entirely by Chinese-manufactured disposables.” [Exhibit 287](#). Elf Bar alone reportedly generated U.S. sales of “over \$271 million in the past year.” *Id.* And most of these products come in candy or dessert flavors, which has “made them the favorite tobacco product among teens.” *Id.*

Examples of irreparable harm that Reynolds has suffered as a result of Proposed Respondents’ infringement are vast. They include at least the following:

- **Harm caused by lost sales and market share.** Annually, Reynolds is losing more than \$1.5 billion in sales as a result of infringing disposable vaping devices. In fact, Reynolds is being forced out of market channels altogether because its costs are much higher and it cannot compete with these offshore importers given their higher retail margins.

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- **Harm caused by value erosion.** The Accused Products are underselling Reynolds's DI Products by a significant margin, which is forcing Reynolds out of certain marketing channels and eroding the overall value of the market—a value that Reynolds's intellectual-property leadership should afford it at least for the limited life of the patent. Because of the flood of illegitimate imports, the U.S. market is unlikely to regain that lost value; only an immediate temporary exclusion order can halt the harm of further erosion.
 - **Harm caused by competing against own patented technology used in products Reynolds cannot legally sell that are in high demand.** Reynolds is not only competing against its own patented technology (which has long been known to create irreparable harm by itself), but is competing against products using that technology that Reynolds does not itself sell but that are in high demand. Reynolds never sought marketing authorizations for dessert and candy flavors, but it did seek authorizations for adult-oriented flavored products that adults enjoy. FDA did not authorize those flavors, so Reynolds currently only sells the DI Products with tobacco and menthol flavored e-liquid. Proposed Respondents sell adult-oriented flavors (in addition to the candy- and dessert-flavored vapes), thereby drawing on an adult market using Reynolds's patented technology in which Reynolds cannot compete.
 - **Reputational harm.** Proposed Respondents are using Reynolds's patented technology to target youth. They sell dessert- and candy-flavored e-liquid, in kid-friendly packaging, without any safeguards to prevent youth from accessing the products. These bad acts are poisoning public perception of the entire industry, including reputable market leaders like Reynolds who are playing by the rules.
 - **Harm caused by FDA delays.** The FDA has been overwhelmed with enforcement actions against illicit activity of the Proposed Respondents, and dealing with scores of deficient applications for marketing authorizations covering millions of products, that it cannot give timely attention to meritorious applications, including Reynolds's pending applications. Each passing day that a PMTA for a new Reynolds product remains pending is another day of lost business.
 - **Remaining life of the Asserted Patent will waste away if temporary relief is not granted.** While the '202 Patent only recently issued, it is set to expire in October 2026. Waiting until the conclusion of this investigation to grant exclusionary relief may be a Pyrrhic victory, as there may be little or no exclusionary power left in its Asserted Patent by that point.

Nothing short of the remedy sought here will stop the Proposed Respondents' illicit and infringing behavior and the irreparable harm that Reynolds has and continues to suffer. Indeed, FDA, with all of its resources and support from the Department of Justice and U.S. Customs, has been largely unsuccessful in preventing Proposed Respondents from importing and selling the

[REDACTED]

infringing Accused Products. For example, the Associated Press reported last fall that when FDA initiated enforcement action to block importation of the Elf Bar-branded disposable vapes, the supplier simply changed the product's brand name to "EBCreate, list[ed] different Chinese manufacturers than those targeted by FDA," and kept on importing and selling the same product under the new name in the United States. Exhibits 287, 288. Thus, even if some portion of the harm suffered by Reynolds is quantifiable, Reynolds can never be made entirely whole. If despite its best efforts, even FDA cannot effectively enforce its policies against these China-based Proposed Respondents, Reynolds has no hope of enforcing any monetary award for any portion of the award that can be quantified.

1. FDA's Regulation Of The Domestic Industry and Accused Products

Understanding the extent of Reynolds's irreparable harm requires a basic understanding of how FDA regulates the DI Products and Accused Products. The Tobacco Control Act ("TCA") gave FDA the authority to regulate tobacco products in order "[t]o address public health concerns associated with tobacco use, and use by minors in particular[.]" *American Academy of Pediatrics v. Food & Drug Administration*, 379 F. Supp.3d 461, 468 (D. Md. 2019). In 2016, FDA issued a final regulation, sometimes called the "Deeming Rule," 81 Fed. Reg. 28,973 (May 10, 2016), that broadened FDA's authority to regulate products containing nicotine derived from tobacco, including e-cigarettes, sometimes referred to as electronic nicotine delivery devices ("ENDS"). All "tobacco products" must undergo FDA review and clearance in order to be marketed in the U.S. For e-cigarettes, the regulatory pathway requires filing a pre-market tobacco application ("PMTA"). If FDA determines that the applicant has provided sufficient proof to establish that marketing of the product under review would be "appropriate for the protection of the public health" ("APPH"), FDA will issue a Marketing Granted Order

[REDACTED]

(“MGO”). Exhibit 289. If FDA determines that product does not meet the APPH standard, FDA will issue a Marketing Denial Order (“MDO”). *Id.*

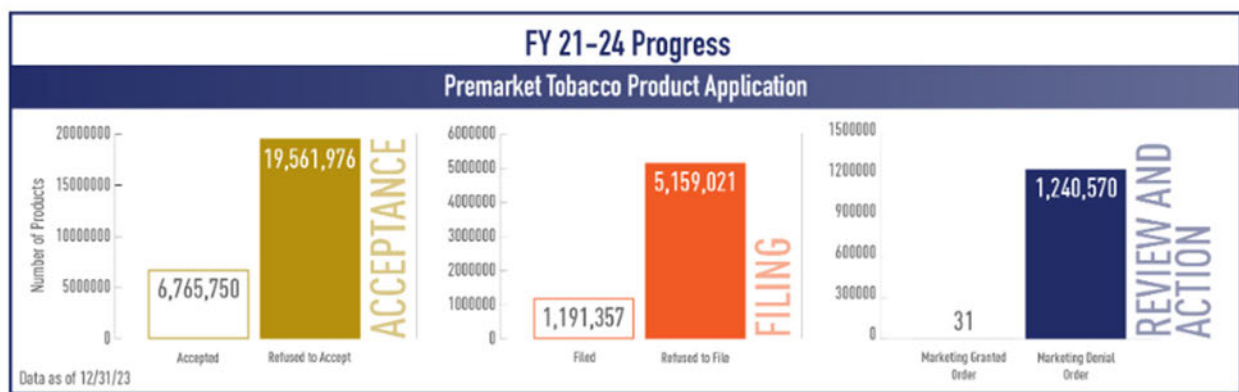
The Deeming Rule brought millions of products under FDA regulation that had not been previously regulated. FDA initially set deadlines for the industry to comply with the newly enacted requirements, but the American Academy of Pediatrics and other health organizations “were alarmed” by FDA’s extensions of the compliance deadlines and sued FDA to compel more expedited deadlines for the newly regulated products. *Am. Academy*, 379 F. Supp.3d at 468-69. The court granted summary judgment for the plaintiffs, finding that FDA had exceeded its authority by extending the compliance deadlines too far into the future. *Id.* at 498. The court ultimately set a deadline of September 9, 2020 for applications for certain e-cigarette products that wished to benefit from an FDA enforcement-discretion policy. *American Academy of Pediatrics v. Food & Drug Administration*, Case No. 8:18-cv-00883-PWG, ECF No. 179 (D. Md. Apr. 3, 2020). The district court also ordered that commercialized products pre-dating the Deeming Rule “for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application,” and FDA “shall have the ability to exempt [new tobacco products on the market as of August 8, 2016] from filing requirements for good cause on a case-by-case basis.” *Am. Academy*, 399 F. Supp.3d at 487.

Given the millions of products covered by the Deeming Rule, it is not surprising that FDA has been bombarded with PMTA submissions. FDA reported that as of December 31, 2023, PMTAs for over 26 million products had been submitted. *See* Exhibit 290. Of those submitted applications, FDA has rejected the vast majority of them. In the first instance, FDA accepted PMTAs for only 6.7 million products; the remainder were not accepted for review. *Id.*

In other words, while PMTAs were submitted for over 26 million products, the applications covering over 19 million products were so facially deficient that FDA refused to even accept them. *Id.* Of the applications covering the remaining 6.7 million products FDA accepted for review, the applications covering approximately five million products were so deficient that FDA refused to review them. *Id.* Ultimately, FDA reviewed PMTAs for over a million products. *Id.* As of December 31, 2023, FDA issued MDOs for 1,240,570 products. *Id.* To date, FDA has not granted a single MGO for any PMTA involving e-cigarettes with flavors other than tobacco.

<https://www.accessdata.fda.gov/scripts/searchtobacco/>.

FDA's progress in processing PMTAs is depicted below:



*The information in this report does not differentiate tobacco products by nicotine source.

Exhibit 290.

As of March 15, 2023, FDA had made determinations on more than 99% of the nearly 26 million products for which PMTAs that have been submitted. Exhibit 291. In its most recent status report, FDA projected that it will take action on all remaining PMTAs from major manufacturers covered by the court's order on or before June 30, 2024. *Am. Academy of Pediatrics v. Food & Drug Admin.*, Civil Action No. 8:18-cv-883-DLB, Dkt. No. 220 at ¶ 2 (D. Md. Apr. 19, 2024).

[REDACTED]

FDA maintains a searchable Tobacco Products Database that allow users to identify tobacco products that may be legally marketed.

<https://www.accessdata.fda.gov/scripts/searchtobacco/>. It also publishes a list of FDA Authorized E-Cigarette Products. Exhibit 292. FDA records show that since 2015, FDA has authorized a total of **45** through the PMTA process. *See* Exhibit 294. Of products issued Marketing Granted Orders, **nine** are Reynolds's ENDS products. *Id.* Three of the four DI Products have received MGOs for the tobacco-flavored products, and a decision on the fourth is expected soon.⁷ Ferris Decl, ¶ 36.

In stark contrast, none of the Accused Products have received MGOs. Exhibit 292. And some of the Proposed Respondents **have received MDOs**⁸ and generally have **not** obtained a stay of enforcement, including Breeze Smoke, LLC⁹ and Shenzhen IVPS Technology Co., Ltd.¹⁰ As to the remaining Proposed Respondents, Reynolds believes that the majority of them have either failed to file a PMTA for their products or filed PMTAs that were so deficient, they were part of the applications covering approximately 25 million products that were rejected by FDA after screening for acceptance and filing. However, public information about filed and pending

⁷ Specifically, on October 12, 2021, FDA issued MGOs for Reynolds's VUSE® Solo Power Unit, VUSE Replacement Cartridge 4.8% G1, and VUSE® Replacement Cartridge 4.8% G2. On May 12, 2022, FDA issued MGOs for Reynolds's VUSE® Vibe Power Units (2 units), VUSE® Vibe Tank Original 3.0%, VUSE® Ciro Power Units (2 units), and VUSE® Ciro Cartridge Original 1.5%. Exhibit 293.

⁸ Current "information on companies that have been issued a marketing denial order (CSV – Last updated 6/6/24)" can be downloaded from FDA's website at <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial>.

⁹ Breeze Smoke challenged the MDO in court, but then voluntarily dismissed the case. *See Breeze Smoke, LLC v. FDA*, Appeal No. 21-3902, ECF No. 40 (6th Cir. Feb. 11, 2022).

¹⁰ Shenzhen IVPS challenged the MDO in court, but did not seek a stay. The case is pending, and most recently, appellant filed its opening brief on May 22, 2024. *Shenzhen IVPS Tech. v. FDA*, Appeal No. 24-60032, ECF No. 67 (5th Cir. May 22, 2024).

[REDACTED]

PMTAs is very limited so Reynolds will not be able to fully determine the regulatory status of the Accused Products without discovery from Proposed Respondents.

2. Reynolds Has Suffered Irreparable Harms

“Irreparable injury encompasses different types of losses ... including lost sales and erosion in reputation and brand distinction.” *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013); *see also Celsis*, 664 F.3d at 930 (“Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.”). Destruction of the patentee’s right to exclusivity in the marketplace, which itself “is an intangible asset that is part of the company’s reputation,” is another form of irreparable harm. *Douglas Dynamics*, 717 F.3d at 1345. “So long as there is a significant threat of harm, a preliminary injunction may issue regardless of the magnitude of the harm.” *QBAS Co., Ltd. v. C Walters Intercoastal Corp.*, No. SACV 10-406 AG (MLGx), 2010 WL 7785955, at *11 (C.D. Cal. Dec. 16, 2010).

(a) All Harm Being Suffered By Reynolds is Irreparable, Even That Which is Quantifiable

Reynolds is suffering a wide range of harms caused by Proposed Respondents’ infringement, a portion of which is quantifiable and portion of which is unquantifiable. On these facts, all harms being suffered by Reynolds—including those that are quantifiable—are irreparable. While quantifiable harms may in theory be recoverable, that is not true here where Proposed Respondents have a long history of successfully evading enforcement actions despite FDA’s best efforts. For example, FDA has initiated numerous enforcement actions to block importation of various disposable vaping devices to no avail. Exhibit [287](#). In fact, Altria Client Services (“Altria”) has commissioned studies in at least California and New York aimed at determining the effectiveness of bans enacted in those jurisdictions. Exhibits 295; 296. In both

[REDACTED]

studies, researchers searched trash discarded in public places and collected packaging from cigarettes and vaping products. *Id.* Altria reported that the California study showed “the flavor ban has had limited effect on the access or demand for flavored e-vapor products ... throughout the entire state.” Exhibit 295. And, “[o]f the e-vapor packs found, almost all (97.9%) were flavored.” *Id.* The results reported from the New York study were similar: “Of the 2,000 discarded vape samples collected, 99% were exported from China, and 99% were flavored—which is outlawed.” Exhibit 296. A survey of New York residents reportedly found that a majority said “government officials were doing a crummy job of enforcing the flavored-vapes ban.” *Id.*

Reynolds cannot expect to be more successful than FDA and various state agencies in enforcing a money judgment outside the country against the elusive Proposed Respondents. Under such circumstances, even quantifiable harm is irreparable. *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) (concluding that evidence of the infringer’s inability to pay damages was a factor that favored a finding of irreparable harm).

(b) Reynolds is Being Irreparably Harmed By Proposed Respondents’ Direct Competition Using Reynolds’s Patented Technology

Direct competition from an infringer selling into the same market is the prototypical form of irreparable harm to a patent owner. *Trebro Mfg, Inc. v. Firefly Equip, LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014) (“Trebro and FireFly are direct competitors selling competing products in this market. Thus, the record strongly shows a probability for irreparable harm”); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) (“Direct competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude.”). As the Federal Circuit explained, when the patentee and accused infringer are “in competition against one another, the

[REDACTED]

patentee suffers harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions.” *Douglas Dynamics*, 717 F.3d at 1345.

For more than a decade, Reynolds has worked tirelessly to develop the DI Products and bring to market non-combustible alternatives that are effective at transitioning adult smokers from traditional cigarettes. Ferris Decl., ¶ 60. It has invested an enormous amount of time, energy and hundreds of millions of dollars doing so. *Id.* The Proposed Respondents are threatening to undermine and destroy all of that work and investment by first taking Reynolds’s patented technology and then forcing Reynolds to compete against its own patented technology but without having done any work or made any investments of its own. *Id.*, ¶ 61. Making matters worse, Proposed Respondents are placing Reynolds’s patented technology in products that Reynolds cannot legally sell, that are largely banned, and that are in higher demand. *Id.*, ¶¶ 62-63. And because Proposed Respondents have not made any investments in research and development or the necessary regulatory investments to obtain marketing authorizations, Reynolds cannot possibly compete head-to-head with Proposed Respondents’ Products. *Id.*, ¶ 64. This creates a very uneven playing field that that is irreparably harming Reynolds. *Id.*

Proposed Respondents’ refusal to incur the added cost of complying with regulatory requirements has caused Reynolds to have to exit an entire and significant distribution channel. *Id.*, ¶¶ 86-94. Until February 2023, Reynolds engaged in delivery sales of the DI Products in accordance with the stringent requirements for delivery sales of tobacco products. *Id.*, ¶¶ 86-88. Reynolds did not use certain common carriers to deliver the products to their customers, including USPS, because those carriers could not make deliveries in compliance with these stringent requirements. *Id.*, ¶ 89. Instead, Reynolds used third-party carriers with much higher shipping rates than common carriers like UPS and USPS. *Id.*, ¶ 90. As a result, Reynolds

[REDACTED]

incurred significant shipping costs (approximately \$20 per package), well in excess of the cost of shipping using USPS. *Id.*

Reynolds also incurred significant costs policing the third-party carriers to ensure that they were complying with the delivery sale requirements, such as checking identification of the person who accepts delivery of the package to ensure that person was over the minimum age required to purchase Reynolds's products. *Id.*, ¶ 93. By early 2023, the cost of complying with the delivery sale requirements had reached a point that it was no longer financially feasible for Reynolds to continue selling its products in the delivery sale market and, at the same time, compete with the Accused Products being sold via delivery sales at a much lower price without the added expense of complying with the associated requirements. *Id.* Accordingly, Reynolds stopped delivery sales of its Products in February 2023. *Id.*, ¶ 94.

Reynolds is also suffering significant irreparable harm by having to compete with products that use Reynolds's patented technology and also incorporate unauthorized flavors that are popular with adult consumers and in high demand, but which Reynolds cannot legally incorporate into its own products. *Id.*, ¶¶ 62-63. This has caused enormous harm to Reynolds. Reynolds's products are much more expensive to bring to market because of its heavy investments in R&D and PMTA costs, and in less demand because Reynolds has complied with FDA's determinations and is not selling products with flavors popular with the youth market. The Proposed Respondents are capitalizing on huge cost savings by infringing and ignoring FDA regulations while also enjoying significant consumer demand—all of which is causing Reynolds substantial and irreparable harm.

(c) Reynolds Is Losing Sales and Market Share Because Of The Infringing Accused Products

Lost sales and lost market share are quintessential examples of irreparable harm. This harm may be particularly acute when the patentee and accused infringer “directly compete for customers in each of the relevant distribution channels,” thereby causing lost sales, lost market share, price erosion, loss of customers, and loss of access to potential customers. *Robert Bosch*, 659 F.3d at 1153-54. Lost market share need not be established by direct evidence; unrebutted circumstantial evidence will suffice to carry the patentee’s burden. *Id.* at 1154. Nor is the patentee’s evidence of irreparable harm undermined by the presence of multiple infringers in the marketplace. *Id.* at 1151 (“the ‘fact that other infringers may be in the marketplace does not negate irreparable harm.’”) (citation omitted). The Federal Circuit explained:

While the existence of a two-player market may well serve as a substantial ground for *granting* an injunction—e.g., because it creates an inference that an infringing sale amounts to a lost sale for the patentee—the converse is not automatically true, especially where, as here, it is undisputed that the patentee has sought to enforce its rights against other infringers in the market.

Id.

Reynolds has seen a significant loss of sales and market share as a result of the Proposed Respondents’ infringing conduct. Reynolds obtains market research data from several independent providers, including Escalent (Grail), MSAi (Marlin) and Kantar (Atlas; Integrated Track), which conduct market surveys of consumers, retail outlets, and summarize the data to provide estimates of sales, market share and usage of adult (21 years old and over) consumers. Ferris Decl., ¶ 65. Reynolds expends significant resources to collect this market research data. Reynolds uses the data in the ordinary course of its business to create market forecasts, analyze trends, and determine the potential effects of changes in the market. Reynolds relies on the data to make important and strategic business decisions. *Id.*, ¶ 66.

[REDACTED]

What this research shows is that the e-cigarette and vaping industry has experienced unprecedented growth in recent years. *Id.*, ¶ 67. Nearly all of that growth, however, can be attributed to increased sales of disposable vaping devices sold by Proposed Respondents. *Id.* In total, disposable vaping device sales have ballooned to over a billion units sold annually. *Id.* While sales of disposable vaping devices are rapidly increasing, sales of Reynolds’s devices and cartridges have been declining and are continuing to decline. *Id.* For example, in 2022, Reynolds sold approximately [REDACTED] cartridges, in 2023 Reynolds sold approximately [REDACTED] cartridges, and Reynolds anticipates fewer than [REDACTED] cartridges in 2024. *Id.*

This disparity in growth between Proposed Respondents and Reynolds is exacerbated by the fact that a typical disposable vaping device contains significantly more e-liquid than a cartridge for the VUSE® Alto product. *Id.*, ¶ 68. Each “unit” of a typical disposable vaping device is the equivalent of 3-5 Reynolds’s Alto cartridges in milliliters. *Id.* And, as consumers are migrating to larger volume disposable devices and seeking more value per milliliter, the disparity between Reynolds’s Alto cartridges and Proposed Respondents’ Products is growing over time which puts pressure on Reynolds’s ability to increase price per milliliter. *Id.*

The dramatic rate at which disposable vaping devices have penetrated the market has caused significant and irreparable harm to Reynolds. *Id.*, ¶ 69. Reynolds’s market data in the channels that Reynolds tracks shows that from May 2023 until February 2024, the total number of retail stores where Reynolds sells its VUSE® Products that are also selling flavored disposable vapes has nearly tripled:

[REDACTED]

[REDACTED]

Id., ¶ 70.

The data also shows Reynolds is losing sales and market share in those sales channels.

Id., ¶ 71. For example, the data from one of Reynolds's customers, Circle K, shows that in June,

2023, Reynolds's market share was [REDACTED] and the flavored disposable vapes share was [REDACTED].

But just six months later, Reynolds's share had dropped by [REDACTED] points to [REDACTED] while the illicit flavored disposable vapes had increased nearly [REDACTED] points to [REDACTED]

[REDACTED]

Id.

[REDACTED]

But this is just the tip of the iceberg because Reynolds estimates, based on the findings of Kantar, that more than 95% of disposable vapes are sold outside of retail stores through newer sales channels (*e.g.*, brick and mortar vape shops), in which Reynolds has not traditionally operated. *Id.*, ¶ 72. The retailers in the markets in which Reynolds operates generally do not take on the risk of selling these illicit products that may not even be the subject of a pending PMTA. *Id.*

As a result, the consumers purchasing disposable vaping devices purchase them at alternative locations, and do not look for their vaping devices in the sales channels in which Reynolds operates. *Id.*, ¶ 73.

If Respondents' Products using Reynolds's patented technology were not on the market, a substantial portion of that industry growth would have gone to Reynolds. *Id.*, ¶ 74. Specifically, based on data collected for Reynolds's Project Atlas through Kantar, for every one disposable vaping device that is forced out of the market, that would result in approximately [REDACTED] closed cartridges being sold in its place based on consumer-claimed research. *Id.*, ¶ 75. More than a billion disposable vaping devices are being sold annually, which means more than [REDACTED] closed cartridges would be sold in place of the disposable vaping devices if they were taken off the market. Of that [REDACTED] cartridges, Reynolds would capture its current fair market share of approximately [REDACTED] of at least [REDACTED] cartridges. Reynolds expects to make [REDACTED] on each of its cartridges. Taking volume times rate, Reynolds conservatively estimates that it suffers [REDACTED] in harm each year that the illicit disposable vaping products are in the market.

The lost market share and sales are not just theoretical or speculative as evidenced by what is happening in Louisiana. In the fall 2023, Louisiana enacted Act 414 of the 2023 Regular Legislative Session. *Id.*, ¶ 76; *see also* Exhibit 297. The Louisiana Office of Alcohol and

[REDACTED]

Tobacco Control’s (“ATC”) is the state agency charged with enforcing the provisions of Act 414. Ferris Decl., ¶ 76.

ATC’s website describes the requirements of Act 414:

[E]very manufacturer of vapor or alternative nicotine products and electronic cigarettes whose products are sold into Louisiana, whether directly or through a wholesale dealer, retail dealer, or similar intermediary or intermediaries, shall execute the certification form and submit it to the ATC with applicable fees and documentation. The initial certification is available in paper and online form. All products properly certified will be posted on ATC’s website beginning November 1, 2023, and updated on the 1st of each month thereafter. Periodic changes or updates may occur. The VAPE Directory will be established and maintained by ATC and will list all certified manufacturers and certified products. NO PRODUCTS may be offered for sale in the State of Louisiana unless the product is listed on the directory and the product meets all other requirements pursuant to law.

Id., ¶ 77.

Even though Act 414 was enacted in the fall of 2023 and was intermittently enforced, Louisiana ATC’s continuous enforcement of the Act did not begin in earnest until March 18, 2024. *Id.*, ¶ 78. As a result of this strict enforcement, Reynolds has seen an approximately [REDACTED] volume growth over the course of the first one to two months. *Id.*, ¶ 79. The following graphs show the dramatic change in Reynolds’s growth in just the few weeks since Louisiana began enforcing Act 414.

[REDACTED]

Id.

Since Louisiana ATC's enforcement of Act 414 as of March 18, 2024, it is the first time the closed e-cigarette category (the category that includes Reynolds's VUSE Products) has experienced an increase in growth in Louisiana in a very long time. *Id.*, ¶ 80. This is concrete evidence of the lost sales and market share that Reynolds is experiencing as a result of Respondents' infringing activities, and powerful evidence of how the temporary exclusion order Reynolds seeks will effectively remedy this wrong. *Id.*

(d) Reynolds is Being Irreparably Harmed by Erosion of Market Value As A Result Of The Infringement.

Price erosion and loss of market position are also irreparable harm that supports injunctive relief. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001).

The Accused Products are sold at average prices ranging from approximately \$10 to approximately \$30, with the price increasing in relation to the amount of vaping fluid contained in each disposable device, the nicotine content, and the quality of the vaping fluid. Exhibit 298. Market research data obtained by Reynolds confirms that the Accused Products undersell

Reynolds's VUSE® Products by a significant margin. Ferris Decl., ¶ 81. In fact, as discussed above, the Proposed Respondents' ability to undersell the VUSE® Products in the delivery sales market forced Reynolds to stop selling via that distribution channel because it was financially unfeasible to compete with the Accused Products. *Id.*, ¶¶ 86-94.

Because Proposed Respondents have not invested in research and development and are not incurring costs to comply with industry regulations, Proposed Respondents' cost of goods sold is much smaller than Reynolds's. *Id.*, ¶ 82. On a per milliliter basis, Proposed Respondents can sell at a lower price that erodes the value per milliliter in the market as well as the overall value of the market. *Id.*, ¶ 83. Because the Proposed Respondents are selling high volume e-liquid vaping devices and eroding the value per milliliter in the market, this puts pressure on Reynolds's ability to extract value with their VUSE Products in the market. *Id.*, ¶ 84. Even if the Proposed Respondents' Products are excluded from the market, Reynolds does not believe the market would regain that lost value. *Id.*, ¶ 85.

For these reasons, the impact of the Accused Products is largely unquantifiable. *Baker Hughes Inc. v. Nalco Co.*, 676 F. Supp. 2d 547, 554 (S.D. Tex. 2009), *aff'd per curiam*, 374 F. App'x 979 (Fed. Cir. 2010) (finding irreparable harm had been established by evidence that the patentee was unlikely to be able to resume elevated pricing of patented goods after discounted sales by infringers, without suffering harm to its good name and ability to conduct business).

(e) Reynolds Is Suffering Irreparable Harm To Its Reputation

Damage to reputation is one of several "valid grounds for finding irreparable harm." *Celsis*, 664 F.3d at 930. "When evaluating reputational injury, 'it is undisputed that such an injury is irreparable; the question is whether this injury will likely occur.'" *RMH Tech LLC v. PMC Indus., Inc.*, 352 F. Supp.3d 164, 201 (D. Conn. 2018) (quoting *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 809 F.3d 633, 648 (Fed. Cir. 2015) (Reyna, J., concurring)). And when

[REDACTED]

infringing activity causes confusion among consumers of the patented product, it causes unquantifiable harm to the patentee's goodwill. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1063 (Fed. Cir. 2010) (affirming district court's determination that patentee "will suffer incalculable harm to its goodwill").

Here, there is no question whether injury to Reynolds's reputation is likely to occur; it has already occurred and is continuing to occur. Despite the fact that Reynolds has received MGOs for several of its tobacco-flavored e-cigarette products, thereby signifying FDA's determination that those products meet the APPH standard, the public has negatively associated and will continue to negatively associate the DI Products (which are targeted for sale only to adults) with the Accused Products (which are sold illicitly and targeted to youth). Ferris Decl., ¶ 95. The conflation of DI Products with the Accused Products brings unwarranted criticism and destroys Reynolds's valuable goodwill in the market. *Id.*, ¶ 96; *see also* Exhibit 299 at 4 (noting an increase over several years in the proportion of U.S. adults who believed that electronic cigarettes were as harmful or more harmful than combustible cigarettes). Reynolds is suffering irreparable harm to its reputation and will continue to suffer this harm until the Accused Products are removed from the market.

The Proposed Respondents are selling disposable vapes containing dessert- and candy-flavored e-liquid, in kid-friendly packaging, without any safeguards to prevent youth from accessing the products. Ferris Decl., ¶ 97. This conduct is unlawful for several reasons: the products infringe Reynolds's patented technology; they are believed to be in violation of FDA regulations because they either failed to file a timely PMTA or the application was rejected as being deficient; and they engage in marketing practices targeting youth in violation of FDA policies. In fact, the latest National Youth Tobacco Survey reported that in 2023, among

[REDACTED]

students reporting current e-cigarette use, 89.4% used flavored products and 25.2% used an e-cigarette daily; the most commonly reported brand was Elf Bar. Exhibit 282.

In contrast to Proposed Respondents' illicit practices, Reynolds is a responsible market participant and innovator. Reynolds has spent millions of dollars researching and developing new technologies, including those protected by the '202 Patent. *See* Section IV.A.4, *supra*. It has also spent tens of millions of dollars preparing and prosecuting successful PMTAs for the DI Products. *Id.* Reynolds's tobacco-flavored VUSE® Solo, Vibe and Ciro have already received MGOs. Exhibit 292. Reynolds's timely filed PMTA for its tobacco-flavored VUSE® Alto is currently under review at FDA. Exhibit 300. Further, Reynolds is committed to preventing underage access to tobacco, vapor, and nicotine products:

We do not want our products in the hands of youth. Period. We remain committed to operating responsibly and working collaboratively with regulators and retail partners. We're using cutting-edge technology, trusted data, and strong marketing controls to improve our tools for underage protection.

Exhibit 301.

Despite Reynolds's best efforts to do the right thing and eliminate youth access to its DI Products, Reynolds's reputation is still being irreparably harmed by the Accused Products and Proposed Respondents' illicit marketing practices. Those practices have created an overall negative public perception of all industry participants, even those acting responsibly. Ferris Decl., ¶ 98. That negative public perception has placed significant political pressure on regulatory agencies that are painting with a broad brush when taking restrictive regulatory action. *Id.*, ¶ 99. Even though Reynolds has pulled from the market its products with flavors other than tobacco and menthol and is committed to preventing underage access to restricted products, Reynolds and its products are frequently found "guilty by association" with the Proposed Respondents' products simply because they operate in the same market. *Id.* FDA has not helped

[REDACTED]

things by being unreasonably restrictive in issuing MGOs. *Id.*, ¶ 100. The data speaks volumes. To date, FDA has reviewed and acted on applications for ***over a million products***, but issued only ***45 MGOs***. Exhibit 294; <https://www.accessdata.fda.gov/scripts/searchtobacco/>. One of Reynolds's competitors, Altria , has urged FDA to “accelerate e-vapor product authorizations to meet adult consumer demand for legal, regulated products.” Exhibit 302.

Reynolds's reputation among retailers of its DI Products is also being irreparably harmed by misconceptions and Proposed Respondents' deceptions in the marketplace about FDA's review of PMTAs. Ferris Decl., ¶ 101. Sellers of illicit e-cigarettes have exploited that full information about which manufacturers' products are subject to timely filed PMTAs that remain pending is not available. *Id.* Sellers like Proposed Respondents can claim to have a pending PMTA, but retailers and distributors cannot verify that representation and therefore cannot reliably distinguish between responsible companies, such as Reynolds, and those that are flouting the rules. *Id.* Therefore, some retailers and distributors take the opposite approach of carrying all products because their PMTA status cannot be verified, which causes Reynolds to have to compete with illicit (and infringing) products that should not be on the market. *Id.*, ¶ 102.

Altria has voiced similar concerns over “[t]he flood of illegal and unregulated e-vapor products from foreign manufacturers flagrantly violating the law and defying FDA's rules[.]” Exhibit 302. To address the problem, Altria urged FDA to publish an up-to-date list of “compliant e-vapor products,” among other suggestions. *Id.* at 2. FDA has since published a list of authorized products, but not a list of all PMTAs that have been filed and their current status. Until all information about pending and resolved PMTAs becomes available, the regulatory status of e-cigarettes will remain unclear, and Reynolds's reputation will continue to be tarnished

[REDACTED]

from being lumped together with bad actors exploiting the lack of clarity. Ferris Decl, ¶¶ 101-102.

(f) Reynolds Is Being Irreparably Harmed Because Delays At FDA Caused By Proposed Respondents Are Causing Lost Business Opportunities

Loss of business opportunities is yet another valid ground for finding irreparable harm. *Celsis*, 664 F.3d at 930. The loss of market opportunities cannot be quantified or adequately compensated, and it, too, is evidence of irreparable harm. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996).

Reynolds is being irreparably harmed by the backlog at FDA created by applicants' submitting PMTAs in bad faith—knowing they would never be granted—solely for the purpose of representing that the applicant has a timely filed PMTA. The evidence of this practice is overwhelming—FDA rejected over 19 million products with PMTAs at its first level screen because they were facially deficient and rejected another more than 5 million products with PMTAs its second level screen, before it engaged in any substantive review of the application. Exhibit 290. Of over 26 million products for which PMTAs were submitted, barely over a million have qualified for review and action. *Id.* The resources that FDA has had to devote to screening out deficient applications and addressing the backlog has caused inordinate delays in FDA's giving attention to meritorious applications.

Moreover, FDA has been preoccupied with enforcement efforts and is expending substantial resources chasing bad actors, including many of the Proposed Respondents. Exhibits 303, 304, 305, and 306. These enforcement distractions take FDA resources away from and slow down the review process. Ferris Decl, ¶¶ 103-110. All of this delay has hampered Reynolds's ability to market current products and bring new products to market, resulting in lost business opportunities and significant irreparable harm. *Id.*, ¶ 110.

3. Reynolds’s Only Meaningful Remedy Is a Temporary Exclusion Order; Without It, Reynolds Will Not Likely Recover For Any Of The Harm It Has Suffered

A patent gives its owner a right to exclude competitors for a limited number of years. *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987). As the Federal Circuit explained, “patent expiration is not suspended during litigation, and the passage of time can work irremediable harm. The opportunity to practice an invention during the notoriously lengthy course of patent litigation may itself tempt infringers.” *Id.* Thus, when an infringed patent “does not have many more years to run,” “the equities weigh heavily against the wrongdoer,” and an exclusionary remedy is especially appropriate. *Id.* at 391 (internal quotation marks omitted). Indeed, “the protection of patents furthers a strong public policy ... advanced by granting preliminary injunctive relief when it appears that, absent such relief, patent rights will be flagrantly violated.” *Id.*

The only meaningful remedy to address the harm Reynolds has suffered by Proposed Respondents’ infringement is a temporary exclusion order granted by the Commission. And Reynolds needs that relief now: The ’202 Patent is a continuation patent in a family of patents claiming priority to October 18, 2006. It only recently issued on March 12, 2024, and Reynolds has moved expeditiously to bring this action and seek temporary relief. That patent will expire on October 18, 2026, and so has relatively little remaining patent life. By the time this investigation concludes in early 2026, any exclusionary remedy issued would be in force for only a few months before the ’202 Patent will expire. And by the time Reynolds could fully prosecute its claims in federal district court to obtain a damages judgment, the ’202 Patent would have long since expired.

Moreover, even if Reynolds were able to successfully obtain a district-court judgment for past damages, it would likely be unable to collect from many or most of the Proposed

[REDACTED]

Respondents. As discussed above, the Proposed Respondents are quick to change brand names on the Accused Products and shift their business to new corporate entities, all to evade FDA's enforcement authority. "[T]he prospect of collecting money damages from a foreign defendant with few to no assets in the United States tips in favor of a finding of irreparable harm."

Bushnell, Inc. v. Brunton Co., 673 F. Supp.2d 1241, 1263 (D. Kan. 2009). As the Federal Circuit has explained, when a patentee may not be able to recover damages for the infringing conduct, this fact supports a finding of irreparable harm warranting an exclusionary remedy. *Robert Bosch*, 659 F.3d at 1155 (concluding that evidence of the infringer's inability to pay damages was a factor that favored a finding of irreparable harm); *Canon, Inc. v. GCC Int'l Ltd.*, 263 F. App'x 57, 62 (Fed. Cir. 2008) (affirming preliminary injunction and noting that even where "money damages against Defendants were awarded, there appears to be a reasonable basis for the district court's finding that there would be little probability that Canon could effect the collection of a money judgment.").

In this case, Reynolds has little hope of being able to enforce money judgments extraterritorially against opponents with extensive experience evading U.S. enforcement efforts and no compunction to play by the rules or respect U.S. authority. *In re Est. of Ferdinand Marcos, Hum. Rts. Litig.*, 25 F.3d 1467, 1480 (9th Cir. 1994) ("[A] district court has authority to issue a preliminary injunction where the plaintiffs can establish that money damages will be an inadequate remedy due to impending insolvency of the defendant or that defendant has engaged in a pattern of secreting or dissipating assets to avoid judgment."); *Aevoe Corp. v. Shenzhen Membrane Precise Electron Ltd.*, No. 2:12-CV-00054-GMN, 2012 WL 1532308, at *5–6 (D. Nev. May 1, 2012) ("[I]t may be difficult or impossible to collect on a money judgment because Defendant currently is a foreign entity and this alone is sufficient to show that Aevoe will likely

[REDACTED]

be irreparably harmed.”). This is yet another source of irreparable harm justifying the Commission to order the requested temporary exclusion orders.

C. The Balance Of The Equities Weighs Strongly In Favor Of Temporary Relief

To obtain a temporary exclusion order, Reynolds must show that “the balance of equities tips in [its] favor.” *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1369 (Fed. Cir. 2017). In assessing this factor, the Commission “must weigh the harm to the moving party if the [exclusionary order] is not granted against the harm to the non-moving party if the [exclusionary order] is granted.” *Id.*

As an initial matter, and as noted above, absent temporary relief, Reynolds is unlikely to obtain any remedy for the harm and damage it has suffered from Proposed Respondents’ infringement. Moreover, the ’202 Patent will expire in October 2026, only a few months after exclusionary remedies would be expected to issue from a full Investigation in early 2026. Waiting until then will strip Reynolds of most of the exclusionary power of its patent. *H.H. Robertson*, 820 F.2d at 390. As noted above, under these circumstance, when an infringed patent “does not have many more years to run,” “*the equities weigh heavily against the wrongdoer*,” and an exclusionary remedy is especially appropriate. *Id.* at 391 (emphasis added; internal quotation marks omitted). Indeed, “the protection of patents furthers a strong public policy ... advanced by granting preliminary injunctive relief when it appears that, absent such relief, patent rights will be flagrantly violated.” *Id.*; see also *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (“absent any other relevant concerns, ... the public is best served by enforcing patents that are likely valid and infringed.”); *Precision Dynamics Corp. v. Typenex Med., L.L.C.*, No. 13-CV-860, 2014 WL 4851542, at *7 (E.D. Wis. Aug. 25, 2014) (“Absent unusual circumstances, the public interest favors granting injunctive relief to preserve

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the exclusionary rights of patentees and thus encourage investment in innovative technology.”) (citations omitted).

In addition, a patent owner faces substantial hardship when it is forced “to compete against its own patented invention.” *Id.* That harm is exacerbated when the accused infringer implements the patentee’s technology in an inappropriate way, thereby damaging the patentee’s reputation in the marketplace. *Douglas Dynamics*, 717 F.3d at 1344-45. In this case, the Proposed Respondents have incorporated Reynolds’s patented technology into unauthorized, illicit, infringing products that Proposed Respondents market to youth at prices far below the price at which Reynolds is able to sell its patented products. Thus, where—as here—a patentee loses the value of its patent as well as suffering irreparable harm from the infringing competition, the balance of equities weighs in favor of granting the temporary exclusion order. *Celsis*, 664 F.3d at 931 (holding no clear error in trial court’s finding that the balance of harms favored patentee in these circumstances).

Compared to Reynolds’s significant interest in enforcing its patent rights, the interests of each of the Proposed Respondents in continuing their infringing and illicit activities is *de minimis*. An accused infringer cannot be heard to complain that a temporary exclusion order could cause it to suffer losses because such losses are the result of “its own calculated risk” in selling an infringing product. *Celsis*, 664 F.3d at 931; *see also Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008) (“[O]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected”) (citation and internal quotation marks omitted).

As discussed in detail above, as a result of the Proposed Respondents’ misconduct, Reynolds has suffered substantial and irreparable harm to its reputation, has lost business

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opportunities, has had to compete against its own patented technology on a very uneven playing field, has lost sales and market share, has lost pricing power, and has seen its prices eroded. This is all happening quickly as the '202 Patent is closing in on expiration. These serious and far-reaching irreparable harms *far outweigh* any harm that any of the Proposed Respondents might allegedly suffer if excluded from selling their illicit, unauthorized disposable vaping products in the U.S. market.

D. The Public Interest Weighs Strongly In Favor Of Temporary Relief

Temporary relief will strongly serve the public interest. Indeed, in addition to the long-standing public policy favoring enforcement of patent rights, other government agencies—including FDA—have already declared that removing Respondents' products from the market serves the public interest. Indeed, these government agencies, including FDA, charged with protecting the domestic public health, safety and welfare are devoting substantial resources to stop the rampant and illicit sales of unauthorized disposable vapes in the United States.

"The Federal Circuit has long held that public policy favors the enforcement of patent rights." *Kolcraft Enter., Inc. v. Chicco USA, Inc.*, No. 09-cv-3339, 2019 WL 4242482, *18 (N.D. Ill. 2019). "The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *ePlus, Inc. v. Lawson Software, Inc.*, No. 09-cv-620, 2011 WL 2119410, at *16 (E.D. Va. May 23, 2011). And, because Respondents' infringement will continue to be profitable absent injunctive relief, the "public interest favors an injunction, as individuals should not be allowed to profit from their bad acts." *Ez-XBRL Sols., Inc. v. Chapke*, No. 17-cv-LMB-TCB, 2018 WL 5808724, at *14 (E.D. Va. Sept. 25, 2018), *report and recommendation adopted*, 2018 WL 5809406 (E.D. Va. Oct. 22, 2018); *see also Monsanto Co. v. Scruggs*, 249 F. Supp.2d 746, 760 (N.D. Miss. 2001) ("The public interest is not served by allowing an infringer to profit at the [patentee's] expense."). The Court should "give[]

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considerable weight to the strong public interest favoring entry of injunctive relief to protect [Reynolds's] patent rights.” *ePlus*, 2011 WL 2119410, at *16.

In this case, however, the public interests served by temporary relief go well beyond preventing unlawful and unfair conduct. FDA and other government bodies have already declared that underage use of candy- and dessert-flavored disposable products like those imported by Proposed Respondents is rampant throughout the United States. California Attorney General Rob Bonta recently explained that disposable vaping manufacturers are using dessert and candy “flavors ... to addict a new generation to nicotine” and that these flavored disposable e-cigarettes are the “driver of the youth vaping crisis.” Exhibit 307. Moreover, in 2023, 2.1 million high school and middle school students reported using vaping devices and ninety percent of them used non-tobacco-flavored products, especially “sweet” flavors like “lemonade, and “gummy bear.” Exhibit 308. “[F]lavored disposable e-cigarettes ... have flooded the market and surged in popularity.” Exhibit 307.

All of this has caused government bodies, including FDA, to declare that Respondents’ products targeting youth are not in the public interest and that removing them actually serves an important public interest. To date, FDA has not granted marketing authorization for any non-tobacco-flavored e-cigarette products, including any candy- and dessert-flavored disposable vaping devices like those at issue here. However, the lack of premarket authorization has done nothing to deter manufacturers of flavored disposable vaping products or to slow the expanding market for these products. In fact, many manufacturers of these products do not even bother to seek authorization. They simply market, distribute, and sell these illicit products, targeting youth in total disregard of the FDA regulations, as though they are lawful products. The harm to the public—especially youth—from these unlawful practices is immense.

[REDACTED]

FDA has initiated numerous enforcement actions to block importation of various flavored disposable vaping devices, but to no avail. Exhibit 387. It has also issued more than 670 warning letters, including to certain Proposed Respondents concerning illegally selling and distributing unauthorized products, including unauthorized disposable vapes. Exhibit 309. Thus, FDA has already determined that these illicit products targeting youth are not serving the public interest. The same finding is warranted here.

V. **THE REQUESTED EXCLUSIONARY ORDERS WOULD NOT HAVE ANY ADVERSE EFFECT ON THE STATUTORY PUBLIC-INTEREST FACTORS**

In determining whether to grant temporary exclusion orders, the Commission considers whether Reynolds's requested relief would have any adverse effects on the statutory public-interest factors: public health, safety, or welfare in the U.S.; competitive conditions in the U.S. economy; the production of like or directly competitive articles in the U.S.; or U.S. consumers. 19 U.S.C. § 1337(e)(1). The Commission also takes into account the strong public interest in protecting valid intellectual-property rights by excluding infringing products. *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (III)*, Inv. No. 337-TA-1076, EDIS Doc. ID No. 679042, Comm'n Op. at 64 (U.S.I.T.C. June 20, 2019). Every discernible public-interest factor favors the granting of temporary injunctive relief here.

The temporary remedial orders Reynolds seeks would promote the public interest by enforcing U.S. patent rights. Further, the products to be excluded are not just infringing products, but as discussed above, they are being unlawfully marketed in the U.S., often by directly targeting youth, outside FDA's scheme of regulatory permissions for these products.

The law does recognize a narrow class of cases where an exclusionary order might "deprive the public of products necessary for some important health or welfare need [such as] energy efficient automobiles, basic scientific research, or hospital equipment," *Spanston, Inc. v.*

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Int'l Trade Comm'n, 629 F.3d 1331, 1360 (Fed. Cir. 2010), but it should go without saying that this is not one of those rare cases where the public interest will provide a reason to deny exclusionary relief. Indeed, the Commission has denied exclusionary relief on public-interest grounds only three times in its history. *Id.* This case is not going to be the fourth.

A. Factor No. 1: Public Health, Safety, Or Welfare In The U.S.

Excluding the Accused Products in this investigation would not negatively impact public health, safety, or welfare in the United States. The Commission has often excluded ENDS and ENDS-related products by limited and general exclusion orders, finding no public health, safety, or welfare concerns weighed against issuing the requested remedies based on the facts in those investigations. *See, e.g., Certain Tobacco Heating Articles*, EDIS Doc. ID No. 754503, Comm'n Op. at 56-64 (granting a limited exclusion order and cease and desist orders); *Certain Elec. Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1139, EDIS Doc. ID No. 709572, Comm'n Op. at 16-18 (U.S.I.T.C. May 5, 2020) (granting limited exclusion orders); *Certain Cartridges for Elec. Nicotine Delivery Sys. & Components Thereof*, Inv. No. 337-TA-1141, EDIS Doc. ID No. 707185, Comm'n Notice (U.S.I.T.C. Apr. 7, 2020) (granting limited exclusion orders against defaulting respondents after briefing on issues including the public interest); *Certain Vaporizer Cartridges & Components Thereof*, Inv. No. 337-TA-1211, EDIS Doc. ID No. 764256, Comm'n Op. at 8-17 (U.S.I.T.C. Mar. 1, 2022) (granting a general exclusion order and cease and desist orders).

In fact, in the 1199 Investigation, the excluded IQOS products, unlike disposable vapes, had obtained FDA authorization after both PMTA and a more rigorous MRTPA review—yet the Commission determined that the public's interest in IQOS was *insufficient* to override the public's interest in enforcing patent rights. In Investigation No. 1139, the Commission found “no evidence” that excluding infringing e-cigarettes would adversely affect the public interest.

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More recently, in pending Investigation No. 1381, the question of whether excluding disposable vapes would adversely affect the public interest was so clear cut that fifteen respondents—many of whom are Proposed Respondents in this investigation—*stipulated* that the remedial orders sought there would not have an adverse impact on any of the statutory public interest factors. *Certain Disposable Vaporizer Devices*, Inv. No. 1381, EDIS Doc. ID 818698, Stipulation. Thus, as the Commission has consistently determined—and the facts here are even more compelling—the requested relief would not raise any public health, safety, or welfare concerns.

B. Factor No. 2: Competitive Conditions In The U.S. Economy

Reynolds sells and has sold its VUSE®-brand e-cigarettes—Solo, Vibe, Ciro, and Alto (collectively, “VUSE® Products”)—in the United States. These products are alternatives to combustible cigarettes for current adult smokers, and they can readily fill any void experienced by current adult smokers from the exclusion of the Accused Products. In addition, current adult smokers can also choose from several other legally marketed ENDS products, as well as a myriad other tobacco and nicotine products that are potentially less risky than cigarettes, that are on the market and that do not fall within the scope of Reynolds’s requested remedial orders. In the 1199 Investigation, the Commission determined that “[t]he evidence presented in this investigation shows that there are numerous like or directly competitive products to IQOS in the United States.” *Certain Tobacco Heating Articles*, EDIS Doc. ID No. 754503, Comm’n Op. at 67. These alternatives include, at least, certain other e-liquid and heat-not-burn products; smokeless tobacco products (such as, Red Man chewing tobacco and Grizzly or Kodiak); snus (Camel Snus); oral tobacco and nicotine products (Velo, ZYN, and on!); and nicotine replacement therapies (Commit, Nicorette and NicoDerm). *Id.* In addition, because the exclusion orders issued in the 1199 Investigation have been rescinded pursuant to the private parties’ settlement agreement (89 Fed. Reg. 18,668 (Mar. 14, 2024)), Philip Morris International

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has announced its intention to relaunch its FDA-authorized IQOS[®] heat-not-burn products in the United States in at least two major markets in 2024. Exhibit 310. Accordingly, adult smokers will be able to obtain replacement products from either Reynolds or third parties if the Accused Products are excluded from the U.S. market.

C. Factor No. 3: Production Of Like Or Directly Competitive Articles In The U.S.

Reynolds has sold and will continue to sell its VUSE[®] Products in the United States, unaffected by Reynolds's requested relief. Reynolds has the capacity to replace any increase in demand from existing adult smokers if the Commission excludes the Accused Products from importation. Ferris Decl., ¶ 111. Reynolds is willing to meet this demand and can do so in a commercially reasonable time, given that it already supplies the industry with significant quantities of ENDS products, as well as oral tobacco and nicotine products. In addition, various third parties currently sell legally marketed ENDS products (as well as myriad other tobacco and nicotine products that are potentially less risky than cigarettes), and, on information and belief, would be able to increase their production capacity to help replace the volume of the Accused Products in a commercially reasonable time. *Certain Vaporizing Devices, Cartridges Uses Therewith, and Components Thereof*, Inv. No. 1368, EDIS Doc. ID No. 799631, Complainant's Public Interest Statement at 4 (U.S.I.T.C. June 30, 2023) ("JLI has more than adequate capacity to replace any demand for the Accused Products with its directly competitive products and can do so in a commercially reasonable timeframe."); *Certain Vaporizing Devices, Cartridges Uses Therewith, and Components Thereof*, Inv. No. 1372, EDIS Doc. ID No. 802888, Complainant's Public Interest Statement at 5 (U.S.I.T.C. Aug. 22, 2023) ("NJOY estimates it could quickly increase its production ..., easily covering JLI's share of the pod market."). And, as noted above, Philip Morris International is planning to relaunch its IQOS[®] products in the United States in

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2024. Accordingly, in the event the requested relief is granted, current adult users of Accused Products in the United States would be able to obtain ENDS, heat-not-burn, or oral tobacco and nicotine products either from Reynolds or third parties, while at the same time the Accused Products would be removed from the market, and American jobs would be potentially increased.

D. Factor No. 4: U.S. Consumers

Reynolds's requested relief would have no adverse impact on U.S. consumers. On the contrary, the requested relief would positively impact and protect U.S. consumers, including furthering goals set by Congress to protect U.S. minors.¹¹ The Accused Products, which are mostly marketed unlawfully and often specifically targeted to minors, are a special concern to Congress, which has urged FDA to increase its enforcement efforts.¹² FDA has already imposed an import ban on Elf Bar brand disposable vapes and issued more than 670 warning letters, including to some of the Proposed Respondents, for illegally selling and distributing unauthorized products, including unauthorized disposable vapes. Exhibit 309.

In contrast to the unregulated flow of the Accused Products into the United States (and particularly towards minors), Reynolds expends significant resources to comply with requirements established for the importation and sale of its products and employs stringent policies and controls to prevent its ENDS devices from getting into the hands of minors. If the Commission grants the requested relief, current adult users would still be able to obtain ENDS and oral tobacco and nicotine products (either from Reynolds or other authorized third parties), but the unfair competition and/or infringing acts associated with the Accused Products (and the

¹¹ See also Exhibit 311 (reporting about congressional hearing in which concerns were raised about the administration's diligence in pursuing intellectual property cases aimed at curbing illegal importation of regulated products, such as disposable vapes).

¹² See, e.g., Exhibits 312; 313.

[REDACTED]

corresponding effects on consumers, including minors) would cease. Accordingly, U.S. consumers would be impacted positively by the requested remedial orders.

* * * *

For these reasons, considering the effect of the requested temporary exclusionary order on the statutory public-interest factors weighs in favor of granting the requested relief. It is well-established that “absent any other relevant concerns, ... the public is best served by enforcing patents that are likely valid and infringed.” *Abbott Labs.*, 452 F.3d at 1348; *Precision Dynamics Corp. v. Typenex Med., L.L.C.*, No. 13-CV-860, 2014 WL 4851542, at *7 (E.D. Wis. Aug. 25, 2014) (“Absent unusual circumstances, the public interest favors granting injunctive relief to preserve the exclusionary rights of patentees and thus encourage investment in innovative technology.”) (citations omitted). It remains extraordinarily rare for the Commission to deny issuing exclusionary orders on public-interest grounds. *Spanson*, 629 F.3d at 1360. This is not a case that presents any facts or circumstances suggesting such a public-interest denial would be merited here. To the contrary, the public interest here is best served by granting the requested temporary exclusion order.

VI. REQUESTED EXCLUSIONARY ORDERS

Through this motion, Reynolds asks the Commission to issue two types of temporary relief: a temporary limited exclusion order directed to all named Respondents and temporary cease-and-desist orders directed to each named Respondent located in the United States.¹³

¹³ In the full Investigation, Reynolds will seek a general exclusion order pursuant to 19 U.S.C. § 1337(d) to exclude from entry into the United States any and all unlicensed disposable vaporizer devices and components thereof that infringe one or more of the Asserted Claims of the Asserted Patent as well as cease and desist orders pursuant to 19 U.S.C. § 1337(f). Complaint, ¶ 6. But for purposes of this motion to obtain temporary relief, Reynolds has named the most prolific and egregious infringers that are causing Reynolds significant and irreparable harm.

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A. Temporary Limited Exclusion Order

Section 337 allows the Commission to enter temporary limited exclusion orders when “the Commission determines that there is reason to believe that there is a violation of this section.” 19 U.S.C. § 1337(e)(1). This remedy is appropriate “unless, after considering [the statutory public interest factors], it finds that such articles should not be excluded from entry.” *Id.* As shown in Section IV.D., *supra*, the public interest factors, as well as past decisions from the Commission, weigh heavily in favor of granting the requested relief. Moreover, the Commission has a “long-standing practice ... to direct its remedial orders to all products covered by the patent claims,” *Certain Dental Implants*, Inv. 337-TA-934, Comm’n Op., 2016 WL 11603664, *28 (U.S.I.T.C. May 11, 2016), even if those products “have not been adjudicated in this investigation.” *Certain Robotic Vacuum*, Inv. No. 337-TA-1057, Comm’n Op., 2019 WL 1292948, *37 (U.S.I.T.C. Feb. 1, 2019).

Because Reynolds has established and will further establish through evidence to be presented at the hearing on this motion that a violation of Section 337 has occurred, a temporary limited exclusion order directed to all named Proposed Respondents is an appropriate remedy.

B. Cease-And-Desist Orders

“[A] cease and desist order is appropriate” when “the record indicates that [Respondents] ha[ve] a commercially significant inventory of infringing product in the U.S.” *Certain Sys. For Detecting & Removing Viruses or Worms, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-510, Comm’n Op., 2005 WL 8153587, at *3 (U.S.I.T.C. Aug. 23, 2005). It is also appropriate when Respondents “have significant domestic operations that could undercut the remedy provided by an exclusion order.” *Certain Arrowheads with Deploying Blades & Components Thereof & Packaging Therefor*, Inv. No. 337-TA-977, Comm’n Op., 2017 WL 11261373, at *10 (U.S.I.T.C. Apr. 28, 2017). Cease-and-desist orders may be issued before the

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conclusion of the Investigation. In appropriate circumstances, like here, the Commission may issue temporary cease-and-desist orders “on any person violating this section, or believed to be violating this section[.]” 19 U.S.C. § 1337(e)(1). Such an order shall issue “directing such person to cease and desist from engaging in the unfair methods or acts involved, unless after considering the effect of such order upon [the statutory public interest factors], it finds that such order should not be issued.” *Id.* Again, as shown in Section IV.D., *supra*, the public interest factors, as well as past decisions from the Commission, weigh heavily in favor of granting the requested relief.

Here, the requested cease-and-desist orders are particularly important given the sheer magnitude of infringing products that are being imported, the potential for the Proposed Respondents to stockpile large quantities of inventory over the next several months, and the documented deceptive practices that the Proposed Respondents have used to circumvent FDA’s and U.S. Customs authorities’ efforts to enforce importation bans against the Accused Products. Without some discovery, Reynolds cannot know the full extent of the existing domestic inventories or the Proposed Respondents’ potential ability to stockpile inventory in the coming months, but the publicly available evidence discussed above shows that the number of unique e-cigarettes on the market is growing exponentially and generating U.S. sales of hundreds of millions of dollars annually. Exhibit [287](#). And, at least some of the Proposed Respondents have a documented track record of importing the Accused Products “under other deceptive practices. They are mislabeled or bundled together with other items in a container.” *Id.*

Unless the temporary remedies issued include temporary cease-and-desist orders, Reynolds will continue to be harmed by continued sales of domestic inventories and any temporary exclusion orders issued by the Commission will be undercut. For these reasons and

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the evidence to be presented at the hearing on this motion, temporary cease-and-desist orders directed to each of the domestic named Proposed Respondents is an appropriate remedy.

VII. BOND REQUIREMENTS

The Commission requires that a movant for temporary relief must address the appropriateness of a bond. 19 C.F.R. § 210.52(b). Under the circumstances, Reynolds should be required to post no bond, or at most a minimal bond. Conversely, Proposed Respondents should be required to post a bond equivalent to 100% of the price of the goods imported, in the event they are permitted to continue importing the accused products. *See Certain Integrated Repeaters, Switches, Transceivers and Products Containing Same*, Inv. No. 337-TA-435, EDIS Doc. ID No. 146901, Comm’n Op. at 32 (U.S.I.T.C. Oct. 8, 2002) (respondents’ bond set at 100% of value of imported goods). This would at least partially compensate Reynolds for the harm done by Proposed Respondents’ importation of infringing products.

A. Reynolds Should Not Be Required To Post A Bond

Under Section 337(e)(2), the Commission “*may* require the complainant to post a bond as a prerequisite to the issuance of an order under this subsection.” 19 U.S.C. § 1337(e)(2) (emphasis added); *see also* 19 C.F.R. §§ 210.52(b)(1), 210.68(a). Thus, the plain language of the statute indicates that ordering a complainant’s bond is within the discretion of the Commission. “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.” 19 C.F.R. § 210.52(c). “The amount of a bond is a determination that rests within the sound discretion of a trial court.” *Sanofi-Synthelabo*, 470 F.3d at 1385. Further, “[t]he 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 v. ZURU Inc.*, 799 F. App’x 823, 837-38 (Fed. Cir. 2020) (citations omitted).

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The most compelling reason for dispensing with a complainant's bond in this case is Reynolds's high likelihood of success on the merits, which, as demonstrated above, is based on Proposed Respondents' clear infringement of the '202 Patent through documented imports, and the extensive domestic industry that Reynolds has created relating to its articles protected by the '202 Patent. This suggests that the likelihood of wrongfully granting injunctive relief is very low. "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." *Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, USITC Pub. 2373, Comm'n Op. at 9 (U.S.I.T.C. Jan. 10, 1990) (refusing to impose a bond on complainants); *see also* H.R. Rep. No. 100-576 at 635-36 (1988) (Conf. Rep.) (legislative history noting the primary purpose of the bond is to prevent the use of a temporary as a tool to harass respondents); *see also Certain Hardware Logic Emulation Sys.*, Initial Determination at 148-50. Because Reynolds is not seeking temporary relief for any improper purpose, and because Reynolds's extremely high likelihood of success on the merits indicates that there is a correspondingly low risk of wrongfully enjoining Proposed Respondents, Reynolds should not be required to pay any bond.

B. No Amount Of Bond Would Be Sufficient To Compensate Reynolds For Irreparable Harm Caused By Continued Importation

If the Commission finds that a temporary exclusion order is warranted, § 337 provides that the Secretary shall refuse entry of the infringing articles. 19 U.S.C. § 1337(e)(1). Section 337 further provides that the articles will be entitled to entry if the respondent pays a bond that is "sufficient to protect the complainant from any injury." *Id.* As discussed above, however, the harm to Reynolds from continued importation by Proposed Respondents cannot be compensated for with monetary damages. *See* Section IV.B., *supra*.



There is likewise no bond amount that will compensate Reynolds for the harm caused by allowing the importation to continue during the pendency of this Investigation. For example, no bond will repair the ongoing damage to Reynolds's reputation, the ongoing delays in getting marketing authorizations to introduce new products, the ongoing loss of pricing power and price erosion, and the loss of distribution channels business opportunities, all of which is being caused by Proposed Respondents. Accordingly, the remedies afforded by a temporary exclusion order are necessary and cannot be replaced by a bond. But if the Commission determines that a bond in lieu of temporary injunctive relief is appropriate, it should be set at 100% of the value of Proposed Respondents' imported products, as is appropriate where the harm to the moving party cannot be quantified. *See, e.g., Certain Integrated Repeaters, Switches, Transceivers & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. 3547, 2001 WL 1769747, at *99-100 (U.S.I.T.C. July 19, 2001) (setting respondent's bond at 100% of value of imported goods); *Certain Flooring Prods.*, Inv. No. 337-TA-443, USITC Pub. 3508, 2001 WL 1693827, at *70-71 (U.S.I.T.C. Nov. 2, 2001).

VIII. CONCLUSION

For the foregoing reasons, Reynolds's Motion for Temporary Relief should be granted, and the Commission should issue a temporary exclusion order preventing Proposed Respondents from further engaging in their unlawful import practices, and temporary cease-and-desist orders preventing Proposed Respondents from further engaging in their unlawful sales of existing inventories.

Dated: June 11, 2024

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Andrea Solomon, hereby certify that on June 11, 2024 copies of Reynolds's Verified Complaint, exhibits, and appendices; Reynolds's Motion for Temporary Exclusion Order, supporting memorandum, and exhibits; letters to the Commission, and required Notice to Respondents, were delivered pursuant to Commission regulations to the following interested parties as indicated:

The Honorable Lisa R. Barton Secretary to the Commission U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W., Room 112 Washington, D.C. 20436	<i>Via</i> EDIS (confidential and nonconfidential versions)
British Embassy Washington 3100 Massachusetts Avenue, NW Washington DC 20008 Embassy of the People's Republic of China in the United States of America 3505 International Pl NW Washington, DC 20008 Hong Kong Economic and Trade Office 1520 18th Street, NW Washington, DC 20036	<i>Via</i> overnight courier (nonconfidential versions only)
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N.T., Hong Kong

Shenzhen Pingray Technology
Floors 2, 3 and 4, Building G
Wanfeng Western Entrepreneurship Park,
Heyi Community, Shajing Street
Bao'an District, Shenzhen
Guangdong Province, China 518125

SV3, LLC d/b/a Mi-One Brands
2303 N 44th Street Unit 2
Phoenix, AZ 85008

Price Point Distributors Inc. d/b/a Price Point NY
500 Smith Street
Farmingdale, NY 11735

Flawless Vape Shop Inc.
5589 E Santa Ana Canyon Rd
Anaheim, CA 92807

Flawless Vape Wholesale & Distribution Inc.
5589 E Santa Ana Canyon Rd
Anaheim, CA 92807

Thesy, LLC d/b/a Element Vape
10620 Hickson Street
El Monte, CA 91731

VICA Trading Inc. d/b/a Vapesourcing
3045 Edinger Avenue
Tustin, CA 92780

Ecto World, LLC d/b/a Demand Vape
2225 Kenmore Ave.
Buffalo, NY 14207

Midwest Goods Inc. d/b/a Midwest Distribution 1001 Foster Avenue Bensenville, IL 60106	
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Dated: June 11, 2024

/s/ Andrea Solomon

Andrea Solomon

Paralegal

JONES DAY

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