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JP393414:dlh
629000-850001

April 9, 2020

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 Tobacco Heating Articles 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., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company (collectively "Complainants") 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 non-confidential Complaint with both non-confidential and confidential exhibits, pursuant to Commission Rule 210.8(a)(1)(i);
2. A non-confidential Statement of Public Interest, pursuant to Commission Rule 210.8(b);
3. Certified copies of the involved United States Patent Nos. 9,839,238 ("the '238 patent"), 9,901,123 ("the '123 patent"), and 9,930,915 ("the '915 patent") listed as Exhibits 1-3 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(i);
4. Certified copies of each of the assignments for the '238, '123 and '915 patents listed as Exhibits 4-6 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(ii);
5. Certified copies of the prosecution histories of the '238, '123 and '915 patents listed as Appendices A, C and E in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(c)(1);

The Honorable Lisa R. Barton
April 9, 2020
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6. Reference documents identified in the prosecution histories of the '238, '123 and '915 patents listed as Appendices B, D and F in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(c)(2);

7. A letter of certification, pursuant to Commission Rules 201.6(b) and 210.5(d), requesting confidential treatment of information appearing in Confidential Exhibits 7, 40, 42, 44, and 49 to the verified non-confidential Complaint.

Because we are filing this complaint electronically, Physical Exhibits 1 to 7, and original certified copies of the '238, '123 and '915 patents and file histories are available upon request.

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

Respectfully submitted,



David M. Maiorana

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

Re: *Certain Tobacco Heating Articles and Components Thereof*

Dear Secretary Barton:

Jones Day represents Complainants, RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company and R.J. Reynolds Tobacco Company (collectively “Complainants”) 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), Complainants respectfully request confidential treatment of Confidential Exhibits 7, 40, 42, 44, and 49 to the Complaint.

The information for which confidential treatment is sought is propriety and not otherwise publicly available. Specifically, Confidential Exhibits 7, 40, 42, 44, and 49 contain proprietary commercial information regarding the tobacco heating articles at issue, Complainants’ patented technology and its infringement by the proposed Respondents, as well as Complainants’ investments and employment activities made in furtherance of its domestic industry under 19 U.S.C. § 1337(a)(3).

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 Complainants; and
- 3) The disclosure of such information could impair the Commission’s ability to obtain information necessary to perform its statutory function.

The Honorable Lisa R. Barton
April 9, 2020
Page 2

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

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "DMM", is positioned above the printed name.

David M. Maiorana

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of

CERTAIN TOBACCO HEATING
ARTICLES AND COMPONENTS
THEREOF

Inv. No. 337-TA-_____

COMPLAINANTS' STATEMENT ON PUBLIC INTEREST

Pursuant to U.S. International Trade Commission ("Commission") Rule 19 C.F.R. § 210.8(b), Complainants RAI Strategic Holdings, Inc. ("RAI"), R.J. Reynolds Vapor Company ("RJR"), and R.J. Reynolds Tobacco Company ("RJRT") (collectively, "Complainants") respectfully submit this Statement on Public Interest with respect to the remedial orders they seek against proposed Respondents Altria Client Services LLC ("ACS"), Altria Group, Inc. ("AGI"), Philip Morris USA, Inc. ("PM USA"), Philip Morris International Inc. ("PMI"), and Philip Morris Products S.A. ("PMP") ("Proposed Respondents").

Complainants seek a permanent, limited exclusion order, specifically directed to Proposed Respondents and their agents, prohibiting from entry into the United States certain tobacco heating articles and components thereof that infringe one or more of U.S. Patent No. 9,839,238 ("the '238 patent"), U.S. Patent No. 9,901,123 ("the '123 patent"), and U.S. Patent No. 9,930,915 ("the '915 patent") (collectively, "the Asserted Patents"). Complainants also seek a cease and desist order pursuant to 19 U.S.C. § 1337(f). The Commission's grant of these remedial orders will serve the public interest.

I. THE REQUESTED REMEDIAL ORDERS ARE IN ACCORD WITH THE PUBLIC INTEREST

There is a strong public interest in protecting intellectual property rights. *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chip, Power Control*

Chips, & Products Containing Same, Including Cellular Telephone Handsets, Inv. No. 337-TA-543, USITC Pub. 4258 (Nov. 2011). As the Commission has noted, “protection of intellectual property rights in the United States provides foreign and domestic businesses alike with a climate of predictability that fosters investment, innovation, and the exchange of technology and associated intellectual property rights.” *Certain Digital Televisions and Certain Products Containing the Same and Methods of Using the Same*, Inv. No. 337-TA-617, Comm’n Op., at 17 (April 2009). The public interest in protecting intellectual property rights can only be precluded in the rarest circumstances. *Certain Baseband Processor Chips*, Comm’n Op., at 153-54 (June 2007). Here, the strong public interest in protecting Complainants’ intellectual property rights outweighs any alleged adverse impact on the public.

A. How The Articles Potentially Subject To The Requested Remedial Orders Are Used In The United States

The infringing products are tobacco heating articles and components thereof, including disposable tobacco sticks, marketed as “the IQOS[®] system.” Proposed Respondents are authorized by FDA to import, offer for sale, and sell the products in the United States and have done so since approximately October 2019.

The IQOS[®] system is part of a category known as “potentially reduced-risk products.” Some such products, like IQOS[®], include tobacco; these are commonly known as “tobacco heating products.” Other such products include a nicotine-containing liquid, and are commonly known as “electronic nicotine delivery systems” or “ENDS.” Still other such products include oral tobacco and nicotine products.

The infringing IQOS[®] system is a tobacco heating product with three components: a holder, disposable tobacco sticks, and a charger. The IQOS[®] holder is an electrically powered and rechargeable unit that holds and heats the disposable tobacco sticks during use to generate a

nicotine-containing aerosol. The IQOS[®] holder includes a casing or housing, control electronics, a battery, and a heating blade. The IQOS[®] holder has an end for receiving the tobacco stick, and it heats the disposable tobacco stick using a ceramic blade, which is pushed into the tobacco stick by the act of inserting the tobacco stick into the holder.

The user turns on the device by a pushbutton switch, which causes the battery to produce and supply electrical current to the heating blade, heating the aerosol forming materials in the tobacco stick, generating an inhalable nicotine-containing aerosol for the user. The temperature of the heating blade is reported not to exceed 350°C, which heats the tobacco below the level of combustion, producing an aerosol.

B. Identification Of Any Public Health, Safety, Or Welfare Concerns Relating To The Requested Remedial Orders

Public health, safety, and welfare concerns do not bar Complainants' requested relief. There is belief among public health officials (and Complainants and Proposed Respondents) that ENDS products may be a potentially reduced-risk alternative to traditional combustible cigarettes. (*See FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, January 2, 2020, <https://www.hhs.gov/about/news/2020/01/02/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes.html>; *How FDA is Regulating E-Cigarettes*, Ned Sharpless, M.D., Acting FDA Commissioner, July 10, 2019, <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes>.) Certain complainants currently sell ENDS products in the U.S. market, as do multiple other companies. Thus, there are ENDS products in the U.S. currently available to adult American smokers looking for a potentially reduced-risk alternative to traditional cigarettes. If the Commission grants Complainants' requested relief regarding the IQOS[®] system, adult American smokers looking for

potentially reduced-risk alternatives could turn to Complainants' ENDS and other products on the market at that time, as discussed below.

One or more Proposed Respondents have stated publicly that ENDS products have the potential to be reduced-risk alternatives to traditional cigarettes. For example, proposed Respondent AGI invested \$12.8 billion in JUUL Labs, Inc., a U.S. ENDS products company. AGI stated that the deal "will accelerate JUUL's mission to switch adult smokers to e-vapor products." (See <http://investor.altria.com/file/Index?KeyFile=396169695>.) Thus, the availability in the U.S. of Complainants' ENDS and other products belies any argument by Proposed Respondents that Complainants' requested relief would harm the public interest by denying adult smokers access to a potentially reduced-risk alternative.

C. Identification Of Like Or Directly Competitive Articles That Complainants, Their Licensees, Or Third Parties Make Which Could Replace The Subject Articles If They Were Excluded

Were the Commission to exclude Proposed Respondents' infringing tobacco heating products and components thereof from entry into the U.S., there are several non-infringing ENDS products available in the U.S. that are directly competitive with the Accused Products. These products include Complainants' VUSE[®] products: VUSE[®] Vibe, VUSE[®] Solo, VUSE[®] Alto, and VUSE[®] Ciro. (www.vusevapor.com). Complainants' Eclipse[®] product is another alternative available in the U.S. Like IQOS[®], Eclipse[®] is a tobacco heating product that heats but does not burn the tobacco. Several oral tobacco and nicotine products are also available in the U.S., including, but not limited to, Camel[®] Snus, Grizzly[®] Snuff, Kodiak[®] Snuff, (www.northerner.com/us), VELO[®] nicotine pouches, REVEL nicotine lozenges, and Nicorette[®] Gum (www.nicorette.com/products/nicorette-gum.html).

Such products would continue to be available to adult American smokers looking for a potentially reduced-risk alternative to traditional combustible cigarettes. Should the Commission

enter an exclusion order in this Investigation, a variety of ready replacement products would remain on the market for public consumption, and so no public harm would result.

D. Whether Complainants, Their Licensees, And/Or Third Parties Have The Capacity To Replace The Volume Of Articles Subject To The Requested Remedial Orders In A Commercially Reasonable Time In The United States

Complainants have sold and will continue to sell potentially reduced-risk alternatives to traditional smoking products in the U.S., unaffected by Complainants' requested relief.

Complainants have the manufacturing capacity to replace the volume of IQOS[®] products subject to the Complainants' requested relief. Complainants will be able to replace the infringing products subject to the requested remedial orders in the U.S. within a commercially reasonable time.

E. How The Requested Remedial Orders Would Impact Consumers

Complainants' requested relief will only potentially affect those consumers who specifically use the infringing IQOS[®] System. The Centers for Disease Control and Prevention estimates that only 13.7% of the U.S. adult population currently smoke traditional combustible cigarettes. *Cigarette Smoking Among U.S. Adults Hits All-Time Low*, <https://www.cdc.gov/media/releases/2019/p1114-smoking-low.html> (Nov. 14, 2019). Thus, the overall impact on U.S. consumers would be relatively small. In any event, Complainants have the capacity to replace the infringing products in the United States with other potentially reduced-risk and other tobacco and nicotine products. The requested remedial orders in this matter will not significantly impact U.S. consumers.

II. CONCLUSION

For the foregoing reasons, there are no public interest concerns that should preclude the issuance of Complainants' requested remedies in this Investigation.

Dated: April 9, 2020

Respectfully submitted,



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RAI Strategic Holdings, Inc.,
R.J. Reynolds Vapor Company, and
R.J. Reynolds Tobacco Company*

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC**

In the Matter of

CERTAIN TOBACCO HEATING
ARTICLES AND COMPONENTS
THEREOF

Inv. No. 337-TA-_____

**VERIFIED COMPLAINT OF RAI STRATEGIC HOLDINGS, INC., R.J. REYNOLDS
VAPOR COMPANY, AND R.J. REYNOLDS TOBACCO COMPANY
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

COMPLAINANTS

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Winston-Salem, NC 27101
Tel: (336) 741-2000

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Winston-Salem, NC 27101
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PROPOSED RESPONDENTS

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Altria Group, Inc.
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EXHIBIT LIST

Ex. No.	Description
1	Certified Copy of U.S. Patent No. 9,839,238
2	Certified Copy of U.S. Patent No. 9,901,123
3	Certified Copy of U.S. Patent No. 9,930,915
4	Certified Copy of Recorded Assignments for U.S. Patent No. 9,839,238
5	Certified Copy of Recorded Assignments for U.S. Patent No. 9,901,123
6	Certified Copy of Recorded Assignments for U.S. Patent No. 9,930,915
7	Licensing Agreements relating to U.S. Patent Nos. 9,839,238, 9,901,123 and 9,930,915 (CONFIDENTIAL)
8	FDA PMTA Authorization Summary of IQOS [®] System
9	<i>Atlanta Business Chronicle</i> article dated May 1, 2019, entitled “Altria Chooses Atlanta To Test Market New FDA-Approved Tobacco Product”
10	Altria/Philip Morris Press Release re FDA Authorization of IQOS [®]
11	<i>Investor’s Business Daily</i> article dated July 19, 2019, entitled “Best Dividend Stocks: Philip Morris, with 5.2% Yield, Bets Big On IQOS”
12	Public Version of Section 3 (Product Description) of MRTPAs on IQOS [®]
13	IQOS User Guide (Section A3.4.1 of PMTAs on IQOS [®])
14	IQOS Quick Start Guide (Section A3.4.2 of PMTAs on IQOS [®])
15	IQOS User Guide (Section A3.4.3 of PMTAs on IQOS [®])
16	FDA Marketing Order Letter re IQOS [®] System Holder and Charger
17	FDA Marketing Order Letter re Marlboro [™] HeatSticks
18	FDA Marketing Order Letter re Marlboro [™] Fresh Menthol HeatSticks
19	FDA Marketing Order Letter re Marlboro [™] Smooth Menthol HeatSticks
20	Philip Morris’s Presentation to Tobacco Products Scientific Advisory Committee on the IQOS Heating System, dated January 24, 2018
21	Philip Morris’s Website re Making Heated Tobacco Products
22	Photographic Images of IQOS [®] System (including IQOS [®] holder, charger, cleaning tool, and Marlboro [™] Heat Sticks)
23	Photographic Images of Pack of 20 Marlboro [™] HeatSticks
24	Photographic Images of Pack of 20 Marlboro [™] Fresh Menthol HeatSticks
25	Photographic Images of Pack of 20 Marlboro [™] Smooth Menthol HeatSticks
26	Clinical Trial NCT01967719
27	Clinical Trial NCT01989156
28	Clinical Trial NCT02396381
29	Clinical Trial NCT02649556
30	November 18, 2016 Philip Morris Letter to the Food and Drug Administration with Modified Risk Tobacco Product Application
31	FDA Press Release re Authorization of IQOS [®]

Ex. No.	Description
32	<i>Wall Street Journal</i> article dated April 30, 2019, entitled “FDA Clears Philip Morris International Heat-Not-Burn IQOS Device For Sale In U.S.”
33	<i>CNBC</i> article dated April 30, 2019, entitled “FDA Clears Philip Morris’ IQOS, Altria Plans To Start Selling Heated Tobacco Device In The US This Summer”
34	Receipt dated October 7, 2019 for purchasing the IQOS® system from the IQOS® store at Lenox Square in Atlanta, Georgia
35	Receipt dated October 7, 2019 for purchasing the IQOS® system from the IQOS® store at Lenox Square in Atlanta, Georgia
36	Receipt dated October 8, 2019 for purchasing the IQOS® system from the IQOS® store at Lenox Square in Atlanta, Georgia
37	IQOS® User Guide
38	IQOS® Quick Start Guide
39	Infringement Claim Chart for U.S. Patent No. 9,839,238
40	Domestic Industry Claim Chart for U.S. Patent No. 9,839,238 (CONFIDENTIAL)
41	Infringement Claim Chart for U.S. Patent No. 9,901,123
42	Domestic Industry Claim Chart for U.S. Patent No. 9,901,123 (CONFIDENTIAL)
43	Infringement Claim Chart for U.S. Patent No. 9,930,915
44	Domestic Industry Claim Chart for U.S. Patent No. 9,930,915 (CONFIDENTIAL)
45	List of Foreign Counterparts to U.S. Patent No. 9,839,238
46	List of Foreign Counterparts to U.S. Patent No. 9,901,123
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48	Altria Group, Inc.’s Second Quarter 2019 Earnings Call Transcript (July 30, 2019)
49	Declaration of Nicholas Gilley (CONFIDENTIAL)
50	Photographic Images of the VUSE® Vibe Device Vapor Pen
51	Photographic Images of the VUSE® Solo Device Vapor E-Cig Power Unit Kit
52	Photographic Images of VUSE® Vibe Menthol Refill Cartridges
53	Photographic Images of VUSE® Vibe Vapor Pen Packaging
54	Photographic Images of VUSE® Solo Vapor E-Cig Power Unit Kit Packaging
55	Photographic Images of VUSE® Vibe Menthol Refill Cartridges Packaging
56	Product Information Guide for the VUSE® Vibe Device Vapor Pen
57	Product Information Guide for the VUSE® Solo Device Vapor E-Cig Power Unit Kit

PHYSICAL EXHIBIT LIST

Ex. No.	Description
PX1	IQOS® System (including IQOS® holder, charger, cleaning tool, and Marlboro™ HeatSticks)
PX2	Pack of 20 Marlboro™ HeatSticks
PX3	Pack of 20 Marlboro™ Smooth Menthol HeatSticks
PX4	Pack of 20 Marlboro™ Fresh Menthol HeatSticks
PX5	VUSE® Vibe Vapor Pen
PX6	VUSE® Vibe Menthol Refill Cartridges
PX7	VUSE® Solo Vapor E-Cig Power Unit Kit

LIST OF APPENDICES

Appx. No.	Description
A	U.S. Patent No. 9,839,238 Certified Prosecution History
B	U.S. Patent No. 9,839,238 Cited References
C	U.S. Patent No. 9,901,123 Certified Prosecution History
D	U.S. Patent No. 9,901,123 Cited References
E	U.S. Patent No. 9,930,915 Certified Prosecution History
F	U.S. Patent No. 9,930,915 Cited References

I. INTRODUCTION

1. RAI Strategic Holdings, Inc. (“RAI”), R.J. Reynolds Vapor Company (“RJR”), and R.J. Reynolds Tobacco Company (“RJRT”) (collectively, “Complainants”) respectfully request that the United States International Trade Commission (“Commission”) institute an investigation into violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by the Proposed Respondents Altria Client Services LLC (“ACS”), Altria Group, Inc. (“AGI”), Philip Morris USA, Inc. (“PM USA”), Philip Morris International Inc. (“PMI”), and Philip Morris Products S.A. (“PMP”) (collectively, “Respondents”).

2. This Complaint is based on Respondents’ unlawful and unauthorized ongoing importation into the United States, sale for importation, and/or sale within the United States after importation of certain tobacco heating articles and components thereof. Respondents’ products infringe at least one or more claims listed below (“Asserted Claims”) of the following U.S. patents (“Asserted Patents”):

U.S. Patent No.	Asserted Claims¹
9,839,238 (Ex. 1)	19*
9,901,123 (Ex. 2)	27*, 28, 29, 30
9,930,915 (Ex. 3)	1*, 2, 5

3. The Asserted Patents are valid and enforceable United States patents, the entire right, title, and interest to which RAI owns by assignment. Exs. 4-6. RJR is an exclusive licensee of the Asserted Patents. Ex. 7. RJRT has conducted (and continues to conduct) research and development and has provided (and continues to provide) technical support for

¹ Independent claims are denoted by *.

products practicing the Asserted Patents. In addition, RJRT has made (and continues to make) investments in plant, equipment, capital, and labor relating to the products practicing the Asserted Patents in the United States.

4. Respondents' activities with respect to the ongoing importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain tobacco heating articles and components thereof, described more fully *infra*, are unlawful under 19 U.S.C. § 1337(a)(1)(B)(i) in that they constitute infringement of the valid and enforceable Asserted Patents.

5. A domestic industry exists in the United States relating to articles protected by the Asserted Patents, described more fully *infra*, as required by Section 337 (a)(2) and defined by Section 337 (a)(3). Complainants' domestic industry includes significant domestic investments in plant and equipment, significant employment of labor and capital, and substantial investments in the exploitation of the inventions claimed in the Asserted Patents, including through research and development and engineering relating to the exploitation of the claimed inventions and articles protected by the Asserted Patents, including Complainants' VUSE[®] Vibe and VUSE[®] Solo products ("Domestic Industry Products" or "D.I. Products"). Exs. 50-57; PX 5-7. Complainants manufacture components of their VUSE[®] Vibe and VUSE[®] Solo products in the United States. *Id.*

6. To remedy Respondents' continuing unfair and unlawful violations of Section 337, Complainants seek, as permanent relief, a limited exclusion order pursuant to 19 U.S.C. § 1337(d) barring from entry into the United States Respondents' products that infringe one or more of the Asserted Claims of the Asserted Patents. Complainants also seek cease and desist orders pursuant to 19 U.S.C. § 1337(f) prohibiting each Respondent from engaging in the

importation into the United States, as well as the sale within the United States after importation, the advertising, marketing, distributing, transferring, operating, testing, updating, supporting, servicing, repairing, or soliciting of products that infringe one or more of the Asserted Claims. Further, Complainants request that the Commission impose a bond upon each Respondent's importation of infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j).

II. THE PARTIES

A. Complainants

7. Complainant RAI is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, N.C. 27101. RAI is the assignee and sole owner of the Asserted Patents.

8. Complainant RJRV is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, N.C. 27101. RJRV is an exclusive licensee of the Asserted Patents and is responsible for developing, distributing, and selling the D.I. Products. Ex. 7.

9. Complainant RJRT is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, N.C. 27101. RJRT provides research and technical support for the D.I. Products and makes significant investments in facilities, equipment, and labor to produce components of the D.I. Products.

B. Respondents

1. Altria Client Services LLC

10. On information and belief, Respondent ACS is a Virginia corporation with offices at 6601 West Broad Street, Richmond, Virginia 23230. On information and belief, ACS is licensed by Respondent PMI to distribute and sell tobacco heating articles and components

thereof, including disposable tobacco sticks, in the United States that infringe the Asserted Patents. Ex. 8 at 10. On information and belief, ACS imports into the United States, sells for importation into the United States, and/or sells within the United States after importation, tobacco heating articles and components thereof, including disposable tobacco sticks, that infringe the Asserted Patents.

2. Altria Group, Inc.

11. On information and belief, Respondent AGI is a Virginia corporation with offices at 6601 West Broad Street, Richmond, Virginia 23230. On information and belief, AGI is a parent entity of ACS and PM USA. Ex. 9. On information and belief, AGI operates in conjunction with the other Respondents with regard to the importation into the United States, sale for importation into the United States, and/or sale within the United States after importation, of tobacco heating articles and components thereof, including disposable tobacco sticks, that infringe the Asserted Patents. Exs. 9-11.

3. Philip Morris USA, Inc.

12. On information and belief, Respondent PM USA is a Virginia corporation with offices at 6601 West Broad Street, Richmond, Virginia 23230. On information and belief, PM USA is licensed by Respondent PMI to distribute, offer for sale, and sell tobacco heating articles and components thereof, including disposable tobacco sticks (the “IQOS[®] system”), in the United States that infringe the Asserted Patents. Exs. 8-9. On information and belief, PM USA imports into the United States, sells for importation into the United States, and/or sells within the United States after importation, tobacco heating articles and components thereof, including disposable tobacco sticks, that infringe the Asserted Patents. According to packaging and other materials submitted to the U.S. Food and Drug Administration (“FDA”), and the packaging and other materials sold by Respondents with the Accused Products in the United States, the IQOS[®]

system and components thereof, including disposable tobacco sticks, are manufactured outside the United States for PM USA. Exs. 8, 12-15.

4. Philip Morris International Inc.

13. On information and belief, Respondent PMI is a Virginia corporation with offices at 120 Park Avenue, New York, New York 10017. On information and belief, PMI is the ultimate parent entity of PMP. On information and belief, PMI operates in conjunction with the other Respondents with regard to the importation into the United States, sale for importation into the United States, and/or sale within the United States after importation, of tobacco heating articles and components thereof, including disposable tobacco sticks, that infringe the Asserted Patents.

5. Philip Morris Products S.A.

14. On information and belief, Respondent PMP is a societe anonyme duly existing under the laws of Switzerland with a corporate address at Quai Jeanrenaud 3, 2000 Neuchâtel, Switzerland. On information and belief, PMP imports into the United States, sells for importation into the United States, and/or sells within the United States after importation, tobacco heating articles and components thereof, including disposable tobacco sticks, that infringe the Asserted Patents. On information and belief, in particular, PMP is a premarket tobacco applicant with FDA for the IQOS[®] system. Ex. 8 at 28; Exs. 16-19. On information and belief, PMP worked in concert with Respondents and others to prosecute and gain FDA authorization for the IQOS[®] system.

III. THE TECHNOLOGY AND PRODUCTS AT ISSUE

A. The Technology

15. The technology at issue generally relates to tobacco heating articles and components thereof, such as disposable tobacco sticks. Complainants are American companies

that lead the industry in research, development, manufacturing, sale, and distribution of products for U.S. adult tobacco consumers seeking alternative sources of nicotine.

16. Traditional combustible cigarettes yield an inhalable smoke that provides flavors and sensations that smokers desire. Complainants' U.S.-based research efforts to invent and develop tobacco heating and vapor articles that produce inhalable aerosols with the desirable flavor and sensory attributes of a traditional cigarette while possibly reducing the smoker's exposure to potentially harmful constituents date back to at least the 1980s and continue today. These efforts have resulted in, *inter alia*, the creation of new and improved methods of generating and applying a heat source to vaporize aerosol-forming materials, such as glycerin, tobacco components, and other flavor sources, without substantial combustion of tobacco constituents, and new and improved heat sources, power sources, aerosol-forming materials, and aerosol delivery systems, critical to providing quality alternative sources of nicotine.

17. Some of those efforts are the subject of the Asserted Patents, U.S. Patent Nos. 9,839,238 ("the '238 patent"), 9,901,123 ("the '123 patent") and 9,930,915 ("the '915 patent").

18. These efforts also have resulted in the commercial introduction of the D.I. Products, including the VUSE[®] Vibe and VUSE[®] Solo products, which include devices that are protected by one or more claims of the Asserted Patents, and the accompanying or related accessories and components.

B. The Accused Products

19. The Accused Products are tobacco heating articles and components thereof that are being imported into the United States, sold for importation into the United States, and/or sold within the United States after importation, by or on behalf of Respondents, that infringe the Asserted Claims of the Asserted Patents. In particular, the tobacco heating articles and

components thereof that infringe one or more of the Asserted Claims of the Asserted Patents are Respondents' IQOS[®] system, including disposable tobacco sticks. Exs. 8, 12-15, 20-25; PX 1-4.

20. On information and belief, Respondents have imported the IQOS[®] system into the United States to conduct clinical studies within the United States. Exs. 26-29. On information and belief, Respondents have also imported the IQOS[®] system into the United States to support their premarket applications with FDA for its IQOS[®] system. Exs. 8, 12, 30. Respondents have imported the IQOS[®] system into the United States for commercial sale, distribution, and marketing, and for selling in the U.S. market after importation. Exs. 9-11, 16-19, 31-36.

1. FDA Authorization

21. On or about May 15, 2017, Respondent PMP, in concert with Respondents, their related entities, or other entities, submitted Premarket Tobacco Product Applications ("PMTAs") seeking FDA authorization for the IQOS[®] system, including disposable tobacco sticks. Ex. 8 at 1, 14; Ex. 16 at 1, 4.

22. On or about April 30, 2019, FDA provided marketing authorization for Respondents' PMTAs on the IQOS[®] system, a tobacco heating article and components thereof, including disposable tobacco sticks. Exs. 16-19. Respondents are now fully authorized by FDA to market and sell within the United States the products specifically authorized by FDA.

23. Prior to filing the PMTAs, on or about November 18, 2016, Respondent PMP, in concert with Respondents, their related entities, or other entities, submitted Modified Risk Tobacco Product Applications ("MRTPAs") seeking FDA authorization for the IQOS[®] system, including disposable tobacco sticks, with claims of reduced exposure or reduced risk. Exs. 30-31. On information and belief, Respondents' MRTPAs are still under FDA review. Ex. 31.

24. On information and belief, from filing the MRTPAs in 2016 and the PMTAs in 2017, through market authorization of the PMTAs in April 2019, and continuing today,

Respondent PMP, in concert with Respondents, their related entities, or other entities, diligently prosecuted the FDA applications. Exs. 8, 10-12, 16-20, 31-33. During the time FDA was considering the PMTAs, Respondent PMP submitted several amendments, including responses to FDA information requests. Ex. 8 at 14.

25. The authorized IQOS[®] system consists of three components: a holder, disposable tobacco sticks, and a charger. Exs. 13-15, 22-25, 37-38. The system is marketed under the IQOS[®] brand name. *Id.* According to FDA documents, the authorized IQOS[®] system is IQOS[®] 2.4, which, on information and belief, is sold in several countries around the world in the same or similar configuration. Exs. 8, 11-15, 20-25.

2. Actual Sales for Importation, Sales After Importation into the United States

26. Since at least October 2019, Respondents have imported into the United States, sold for importation, and/or sold within the United States after importation the FDA-authorized IQOS[®] system. For example, Respondents have imported into the United States and have sold within the United States after importation the IQOS[®] system from stores that they own and operate in Atlanta, Georgia and Richmond, Virginia. *See, e.g.*, Exs. 34-36.

3. The IQOS[®] Holder

27. The IQOS[®] holder is an electrically powered and rechargeable unit designed to hold and heat the disposable tobacco sticks during use to generate a nicotine-containing aerosol. Ex. 8 at 10; Exs. 13-15, 20. The IQOS[®] holder includes a casing or housing, control electronics, a battery as its electrical source, and a heating blade. Ex. 8 at 15-16, 22; Exs. 13-15, 20. The IQOS[®] holder has an end for receiving the tobacco stick. Ex. 8 at 15-16; Exs. 13-15, 20.

28. The IQOS[®] holder heats the disposable tobacco stick using a ceramic blade, which is pushed into the tobacco stick by the act of inserting the tobacco stick into the holder. Ex. 8 at 15-16; Exs. 13, 20.

4. The IQOS[®] Disposable Tobacco Sticks

29. The disposable tobacco sticks are offered in three varieties (one regular and two menthol flavors) and are marketed under or in association with the IQOS[®] brand, as well as the trade name MARLBORO HEATSTICKS. Ex. 8 at 10, 15-19; Exs. 17-19; Ex. 20 at 106; Exs. 21, 23-25; PX 2-4. The tobacco sticks are designed to function with the holder. They are an indispensable component for the proper operation of the IQOS[®] system and have no other function or authorized use. Exs. 16-19; Ex. 8 at 10, 15-19, 62; Exs. 23-25, 37-38; PX 1-4. The IQOS[®] system and the components thereof, including the disposable tobacco sticks, are collectively referred to as the “Accused Products.”

30. The disposable tobacco stick is specially designed and intended for exclusive use with the IQOS[®] holder. Ex. 8 at 10, 15-19, 62; Exs. 16-19; Ex. 20 at 106; Exs. 22-25; PX 1-4. The tobacco stick contains specially processed tobacco made from tobacco powder that has been reconstituted into sheets following the addition of water, glycerin, guar gum, and cellulose fibers. Ex. 8 at 10, 15-19, 62; Ex. 20 at 16; Ex. 21.

31. The IQOS[®] tobacco stick is marketed in three different flavors, regular and two menthol flavors (Smooth Menthol with 1.25 mg menthol per stick and Fresh Menthol with 2.5 mg menthol per stick) to satisfy different consumer preferences. Ex. 8 at 10, 15-19; Exs. 17-19; Exs. 23-25; PX 2-4. The structure and operation across the variety of sticks is otherwise the same. *Id.* The IQOS[®] tobacco stick is specifically designed to function with the IQOS[®] holder to produce an aerosol. Ex. 8 at 10, 15-19, 62; Exs. 16-19; Ex. 20 at 28.

5. The IQOS[®] Charger

32. The IQOS[®] system also includes an IQOS[®] charger for charging and storing the IQOS[®] holder after each use, and an AC power adaptor for recharging the charger. Ex. 8 at 10, 25; Exs. 13-15, 22, 37-38; PX 1. The IQOS[®] charger stores sufficient energy for the use of approximately 20 of the disposable tobacco sticks. Ex. 8 at 10, 15, 25.

33. On information and belief, the IQOS[®] charger, IQOS[®] holder, and IQOS[®] tobacco sticks are packaged in a kit that also contains a tool designed for cleaning the IQOS[®] holder. Ex. 12 at 19-22; Exs. 13-15, 22, 37-38; PX 1.

6. Operation and Manufacture of the IQOS[®] System

34. The IQOS[®] system works as follows in operation: The user inserts a tobacco stick into the holder and turns on the device by means of a pushbutton activated switch. The switch signals to the control electronics, which causes the battery to produce and supply electrical current to the heating blade. The heating blade heats the aerosol-forming materials in the tobacco stick, generating an inhalable nicotine-containing aerosol for the user. The temperature of the heating blade is controlled so that its operating temperature does not exceed 350°C. This allows for heating of the tobacco constituents below the level of combustion, while producing an aerosol containing water, glycerin, and nicotine. Ex. 8 at 14-19; Exs. 13-15, 22, 37-38; PX 1.

35. On information and belief, the Accused Products are manufactured abroad by or on behalf of Respondents and are imported into the United States, sold for importation into the United States and/or sold within the United States after importation, by or on behalf of Respondents. Exs. 9-11, 31-33, 34-36. On information and belief, PMP is responsible for and controls the worldwide design, manufacturing and marketing of the IQOS[®] system, either directly or indirectly through Respondents, their related entities, or other entities, including

manufacturing of the IQOS[®] system or components thereof outside the United States, including at locations in Malaysia, Switzerland, and Italy, for importation into the United States. Ex. 8 at 24, 27; Exs. 22-25. For example, the packaging for the IQOS[®] device purchased from Respondents' store in Atlanta, Georgia, states: "Manufactured for Philip Morris USA, Richmond, VA 23261 . . . Made in Malaysia"; and the packaging for the disposable tobacco sticks purchased from Respondents' store in Atlanta, Georgia, states: "Mfd. for Philip Morris USA, Richmond, VA 23261 . . . Made in Italy." Exs. 22-25, 34-36.

7. Respondents' Instructions for Use of the IQOS[®] System

36. As part of their PMTA submission to FDA, Respondents provided an IQOS[®] Heating System User Guide and IQOS[®] Quick Start Guide. Ex. 8 at 85-86, 98; Exs. 13-15, 37-38. The User Guide provides "comprehensive instructions for use." Ex. 8 at 85; Ex. 37. The Quick Start Guide provides the basic information needed to use the IQOS[®] system. Ex. 8 at 85; Ex. 38.

37. During its review process, FDA found that after reviewing the IQOS[®] Heating System User Guide and IQOS[®] Quick Start Guide, adult smokers were able to charge the IQOS[®] Holder, insert a tobacco stick into the Holder, and heat and consume a tobacco stick. Ex. 8 at 85-86, 98.

38. Thus, Respondents have represented to FDA that they would sell the IQOS[®] system in the United States along with detailed instructions to end users that expressly instruct the end users how to use the IQOS[®] Holder, Charger, and disposable tobacco sticks together to generate an aerosol that the end user inhales.

39. The actual products sold by Defendants in the U.S. include the IQOS[®] Heating System User Guide and IQOS[®] Quick Start Guide. Exs. 37-38; PX 1.

40. Respondents' Accused Products infringe one or more of the Asserted Claims of the Asserted Patents, including at least claim 19 of the '238 patent, claims 27-30 of the '123 patent and claims 1, 2, and 5 of the '915 patent, to the detriment of Complainants and the domestic industry that they have established, and constitute a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on Respondents' unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of the Accused Products.

41. Each of the Accused Products meets each and every limitation of at least one claim of one or more of the Asserted Patents. Complainants' identification of specific models or types of products is not intended, either implicitly or explicitly, to limit the scope of the investigation or the scope of relief to which Complainants are entitled.

IV. THE PATENTS AT ISSUE

42. The Asserted Patents are directed to devices and components thereof that provide adult tobacco consumers with a smoking alternative to traditional cigarettes.

43. The '238 patent has 21 claims: 2 independent claims and 19 dependent claims. Ex. 1 at 20:13-22:33.

44. As further detailed below, at least independent claim 19 of the '238 patent is infringed by Respondents' IQOS[®] system. Ex. 39 (representative claim chart). Complainants reserve the right to assert additional claims upon conducting discovery and as permitted by the Commission.

45. As further detailed below, Complainants' D.I. Products, including the VUSE[®] Solo products, practice at least claims 1-3, 5-11, 13, 15-16, and 18-21 of the '238 patent. Confidential Ex. 40 (representative claim chart).

46. The '123 patent has 30 claims: 3 independent claims and 27 dependent claims. Ex. 2 at 32:50-35:2.

47. As further detailed below, at least independent claim 27 and dependent claims 28-30 of the '123 patent are infringed by Respondents' IQOS® system. Ex. 41 (representative claim chart). Complainants reserve the right to assert additional claims upon conducting discovery and as permitted by the Commission.

48. As further detailed below, Complainants' D.I. Products, including the VUSE® Vibe products, practice at least claims 1-7, 9, 11-19, 21, and 23-26 of the '123 patent. Confidential Ex. 42 (representative claim chart).

49. The '915 patent has five claims: one independent claim and four dependent claims. Ex. 3 at 42:22-47.

50. As further detailed below, at least independent claim 1 and dependent claims 2 and 5 of the '915 patent are infringed by Respondents' IQOS® system. Ex. 43 (representative claim chart). Complainants reserve the right to assert additional claims upon conducting discovery and as permitted by the Commission.

51. As further detailed below, Complainants' D.I. Products, including the VUSE® Solo products, practice at least claims 1-4 of the '915 patent. Confidential Ex. 44 (representative claim chart).

A. U.S. Patent No. 9,839,238

1. Identification of the Patent and Ownership by Complainant

52. RAI owns by assignment the entire right, title, and interest in the '238 patent, entitled "Control Body For An Electronic Smoking Article," which the U.S. Patent and

Trademark Office duly and lawfully issued on December 12, 2017. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '238 patent is attached as Exhibit 1.

53. The '238 patent issued from U.S. Patent Application No. 14/193,961, which was filed on February 28, 2014. The '238 patent expires on April 17, 2036.

54. The '238 patent names Steven L. Worm, Michael Ryan Galloway, Frederic Philippe Ampolini, Randy Lee McKnight, and David Glen Christopherson as inventors (collectively, "the named '238 inventors"). Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each recorded assignment of the '238 patent is attached as Exhibit 4.

55. The named '238 inventors assigned all right, title, and interest in and to the '238 patent to Respondent RJRT. Ex. 4. RJRT assigned its right, title, and interest in and to the '238 patent to Respondent RAI, the current assignee and owner of the '238 patent, on March 17, 2016. *Id.*

56. As a result of the foregoing assignments, RAI is the owner of all right, title, and interest in and to the '238 patent, including the right to enforce, recover damages, and obtain other relief for any infringement of the '238 patent.

57. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '238 patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices A and B, respectively.

2. Non-Technical Description of the '238 Patent²

58. Pursuant to Commission Rule 210.12(a)(9)(vi), the '238 patent generally concerns an electronic smoking article that includes a control body and a removable cartridge. The control

² This description and other non-technical descriptions within this Complaint are for illustrative purposes only. Nothing in any non-technical description is intended, either implicitly

body includes an elongated shell and a coupler that is adapted to connect the control body to the cartridge of the electronic smoking article. Also contained within the shell is an electronic circuit board and a battery.

3. Foreign Counterparts to the '238 Patent

59. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 45 identifies each foreign patent, each foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '238 patent with an indication of the prosecution status of each such patent application.

B. U.S. Patent No. 9,901,123

1. Identification of the Patent and Ownership by Complainant

60. RAI owns by assignment the entire right, title, and interest in the '123 patent, entitled "Tobacco-Containing Smoking Article," which the U.S. Patent and Trademark Office duly and lawfully issued on February 27, 2018. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '123 patent is attached as Exhibit 2.

61. The '123 patent issued from U.S. Patent Application No. 15/286,087, which was filed on October 5, 2016, and claims priority to U.S. Patent Application No. 11/550,634, which was filed on October 18, 2006 and issued as U.S. Patent No. 7,726,320. The '123 patent expires on October 18, 2026.

62. The '123 patent names John Howard Robinson, David William Griffith, Jr., Billy Tyrone Conner, Evon Llewellyn Crooks, and Dempsey Bailey Brewer, Jr. as inventors

or explicitly, to express any position regarding the scope or proper construction of any claim of the Asserted Patents.

(collectively, “the named ’123 inventors”). Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each recorded assignment of the ’123 patent is attached as Exhibit 5.

63. The named ’123 inventors assigned all right, title, and interest in and to the ’123 patent to Respondent RJRT. Ex. 5. RJRT assigned its right, title, and interest in and to the ’123 patent to Respondent RAI, the current assignee and owner of the ’123 patent, on March 17, 2016. *Id.*

64. As a result of the foregoing assignments, RAI is the owner of all right, title, and interest in and to the ’123 patent, including the right to enforce, recover damages, and obtain other relief for any infringement of the ’123 patent.

65. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the ’123 patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices C and D, respectively.

2. Non-Technical Description of the ’123 Patent³

66. Pursuant to Commission Rule 210.12(a)(9)(vi), the ’123 patent generally concerns a smoking article that includes an electrical power source that powers a heater to heat an aerosol-forming material in a disposable portion of the smoking article. The heater may include an elongated portion extending into the aerosol-forming material in the disposable portion of the smoking article. The smoking article may additionally include a switching mechanism that can be manually operated by the user to heat the smoking article.

³ This description and other non-technical descriptions within this Complaint are for illustrative purposes only. Nothing in any non-technical description is intended, either implicitly or explicitly, to express any position regarding the scope or proper construction of any claim of the Asserted Patents.

3. Foreign Counterparts to the '123 Patent

67. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 46 identifies each foreign patent, each foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '123 patent with an indication of the prosecution status of each such patent application.

C. U.S. Patent No. 9,930,915

1. Identification of the Patent and Ownership by Complainant

68. RAI owns by assignment the entire right, title, and interest in the '915 patent, entitled "Smoking Articles and Use Thereof for Yielding Inhalation Materials," which the U.S. Patent and Trademark Office duly and lawfully issued on April 3, 2018. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '915 patent is attached as Exhibit 3.

69. The '915 patent issued from U.S. Patent Application No. 14/737,706, which was filed on June 12, 2015, and claims priority to U.S. Patent Application No. 13/205,841, which was filed on August 9, 2011 and issued as U.S. Patent No. 9,078,473. The '915 patent expires on November 9, 2031.

70. The '915 patent names Steven L. Worm, David Glen Christopherson, Stephen Benson Sears, Dennis Lee Potter, Frederic Philippe Ampolini, and Balager Ademe as inventors (collectively, "the named '915 inventors"). Pursuant to Commission Rule 210.12(a)(9)(ii), a certified copy of each recorded assignment of the '915 patent is attached as Exhibit 6.

71. The named '915 inventors assigned all right, title, and interest in and to the '915 patent to Respondent RJRT. Ex. 6. RJRT assigned its right, title, and interest in and to the '915 patent to Respondent RAI, the current assignee and owner of the '915 patent, on March 17, 2016.
Id.

72. As a result of the foregoing assignments, RAI is the owner of all right, title, and interest in and to the '915 patent, including the right to enforce, recover damages, and obtain other relief for any infringement of the '915 patent.

73. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '915 patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices E and F, respectively.

2. Non-Technical Description of the '915 Patent

74. Pursuant to Commission Rule 210.12(a)(9)(vi), the '915 patent generally concerns a smoking article that includes a reusable control unit that includes an electrical energy source with a projection extending outwardly therefrom, and having a component that forms an electrical connection with electrical contacts on a separate heating member that heats the aerosol forming material in a disposable portion of the smoking article. The component that forms an electrical connection with the electrical contacts is located on the projection extending from the electrical energy source.

3. Foreign Counterparts to the '915 Patent

75. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 47 identifies each foreign patent, each foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '915 patent with an indication of the prosecution status of each such patent application.

D. Licensees Under the Asserted Patents

76. Pursuant to Commission Rule 210.12(a)(9)(iii), copies of the confidential agreements granting a license under the Asserted Patents are included as Confidential Exhibit 7.

V. SPECIFIC INSTANCES OF UNLAWFUL IMPORTATION AND SALE

77. The specific instances of importation of infringing Accused Products set forth below are representative examples of 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.

78. On information and belief, 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, Respondents sell the Accused Products knowing, or having reason to know, that the Accused Products would be subsequently imported into the United States.

79. On information and belief, 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 IQOS[®] system and components thereof, including disposable tobacco sticks. Exs. 9-11, 31-36.

80. Since November 2016, Respondents have been pursuing FDA authorization for commercial marketing and sale of the IQOS[®] system within the United States. As a result, certain information is available to the public regarding the IQOS[®] system. Moreover, by virtue of the FDA regulatory regime, Respondents cannot modify the authorized IQOS[®] product without further FDA authorization.

81. Respondents have also conducted a number of clinical trials on the IQOS[®] system within the United States, in their efforts to commercialize the IQOS[®] system in the United States. Exs. 26-29. In particular, PMP sponsored (1) a clinical trial on the IQOS[®] system identified by protocol number NCT01967719 that started in October 2013 and completed in May 2014; (2) a clinical trial on the IQOS[®] system identified by protocol number NCT01989156 that started in December 2013 and completed in May 2015; (3) a clinical trial on the IQOS[®] system identified by protocol number NCT02396381 that started in March 2015 and completed in August 2017; and (4) a clinical trial on the IQOS[®] system identified by protocol number NCT02649556 that started in September 2015 and completed in December 2017. *Id.* On information and belief, Respondents have imported numerous units of the IQOS[®] system into the United States for use in those clinical trials in the United States.

82. As evidenced by Respondents' FDA submissions, Respondents have conducted several clinical studies on the IQOS[®] system within the United States and provided the results from those studies to support its applications for FDA marketing authorization. Ex. 12 at 163-182. On information and belief, Respondents have imported the IQOS[®] system into the United States for use in those clinical studies in the United States.

83. On information and belief, Respondents have imported numerous units of the IQOS[®] system, including disposable tobacco sticks, and have submitted the units to FDA while pursuing FDA authorization for commercial marketing and sale of the IQOS[®] system within the United States. *E.g.*, Ex. 8 at 14, 25-27.

84. On or about April 30, 2019, FDA granted PMP's PMTAs on the IQOS[®] system, including the IQOS[®] holder, IQOS[®] charger, and IQOS[®] HeatSticks, which include three flavors of HeatSticks: the Marlboro[™] HeatSticks, the Marlboro[™] Fresh Menthol HeatSticks, and the

Marlboro™ Smooth Menthol HeatSticks. Ex. 31. On or about April 30, 2019, Respondents issued a press release announcing FDA authorization and their plan to sell the IQOS® system in the United States in the summer of 2019. Ex. 10; *see also* Exs. 9, 32-33.

85. On July 30, 2019, Respondent AGI held a second quarter earnings call. During that call, Respondent AGI stated:

We expect the first IQOS store to open in Atlanta in September along with other retail touch points including mobile retail units and retail kiosks all restricted to adult smokers. We plan to have the IQOS website live in August where adult smokers will be able to preorder their IQOS devices for pickup at the IQOS Atlanta store. Initially, we expect HeatStick distribution to be in approximately 500 Atlanta area stores. We are very excited to bring IQOS to adult smokers in the U.S....

Ex. 48 at 5-6.

86. Respondents, either individually or acting in concert, manufacture, import, and sell after importation tobacco heating articles and components thereof under certain trade names including IQOS®. The IQOS® system required FDA authorization before it could be marketed in the United States. In their PMTAs for FDA authorization, Respondent PMP represented that Respondents, including PMP, PMI, and related entities, are or would be manufacturing the IQOS® system and components thereof outside the United States, including at locations in Switzerland, Italy, and Malaysia, among other locations outside the United States. Ex. 8 at 24, 27; Exs. 22-25.

87. On information and belief, the IQOS® HeatSticks are manufactured by a PMI entity under the authority of Respondent PMP, and that manufacturing occurs in Italy, or at other locations outside the United States. Exs. 23-25.

88. Respondents have imported their IQOS® system for use and sale in the United States.

89. Respondents have sold and are continuing to sell the IQOS[®] system within the United States after its importation.

90. On July 30, 2019, during its second quarter earnings call, Respondent AGI stated that it expected “the first IQOS store to open in Atlanta in September along with other retail touch points including mobile retail units and retail kiosks all restricted to adult smokers,” and that it plans to “have the IQOS website live in August where adult smokers will be able to preorder their IQOS devices for pickup at the IQOS Atlanta store.” Ex. 48 at 5-6; *see also* Exs. 9-11.

91. Respondents use, offer to sell, and sell the IQOS[®] system from a store that they own and operate in Atlanta, Georgia, since at least October 2019, and from a store they own in Richmond, Virginia since approximately December 2019. Exs. 34-36. In addition, Defendants have sold the infringing tobacco sticks to retailers in both Atlanta, Georgia and in Richmond, Virginia, which retailers sell those products to consumers. The packaging for the IQOS[®] device Defendants sell in the United States recites: “Manufactured for Philip Morris USA, Richmond, VA 23261 . . . Made in Malaysia.” The packaging for the disposable tobacco sticks states: “Mfd. for Philip Morris USA, Richmond, VA 23261 . . . Made in Italy.” For example, the packaging for the IQOS[®] device purchased from Respondents’ store in Atlanta, Georgia, states: “Manufactured for Philip Morris USA, Richmond, VA 23261 . . . Made in Malaysia.” Exs. 22-25.

92. Respondents have imported and are importing the IQOS[®] system that they manufactured abroad into the United States for purposes of commercial marketing and sales. In addition, on information and belief, Respondents have used, or are using, imported IQOS[®] systems in the United States for commercial marketing and sale of the IQOS[®] system in the

United States or for other commercial uses not reasonably related to the development and submission of information for FDA regulatory authorization.

93. On information and belief, Respondents or agents acting at their direction have maintained and continue to maintain a commercially significant inventory of the IQOS[®] system and components thereof in the United States.

VI. UNFAIR ACTS OF RESPONDENTS

A. Infringement

94. Respondents unlawfully import into the United States, sell for importation into the United States, and/or sell within the United States after importation, the Accused Products, of which Respondents are the owner, importer or consignee. The aforesaid acts of Respondents constitute acts of infringement.

1. Direct Infringement

95. Respondents, individually or acting under direction, control, or joint enterprise, directly infringe one or more claims of one or more of the Asserted Patents, by unlawfully importing into the United States, selling for importation into the United States, and/or selling within the United States after importation, the IQOS[®] system, including disposable tobacco sticks. The Accused Products—the IQOS[®] system, including disposable tobacco sticks, infringe, either literally or through the doctrine of equivalents, all the limitations of at least one claim of one or more of the Asserted Patents. Specifically, the Accused Products infringe claims identified in the table below:

U.S. Patent No.	Asserted Claims
9,839,238	19*
9,901,123	27*, 28, 29, 30
9,930,915	1*, 2, 5

2. Indirect Infringement

96. On information and belief, Respondents indirectly infringe the Asserted Patents pursuant to 35 U.S.C. § 271(b) and/or (c) by knowingly and intentionally inducing infringement and/or contributing to the infringement of the Asserted Patents by, among other things, selling in the United States the Accused Products to direct infringers, that include, without limitation, customers and/or end users of those products. Those customers and/or end users of the Accused Products directly infringe one or more claims of one or more of the Asserted Patents.

97. As part of seeking FDA authorization for the IQOS[®] system, Respondents represented to FDA that they would include with the IQOS[®] system detailed instructions directing end users to insert a tobacco stick into the IQOS[®] Holder, and to heat (but not ignite) the tobacco stick to produce an aerosol incorporating tobacco components and/or tobacco-derived components.

98. The products imported into the U.S. and sold by Respondents after importation in the U.S. include the IQOS[®] Heating System User Guide and IQOS[®] Quick Start Guide. Exs. 22, 37-38; PX 1.

99. On information and belief, Respondents have had knowledge of the Asserted Patents. A number of Respondents have cited the '123 patent or its family members during prosecution of their own patents. ACS, for instance, cited U.S. Patent No. 7,726,320 (“the '320 patent”), the ancestor of the '123 patent, during prosecution of its U.S. Patent No. 10,258,087

and U.S. Patent No. D844,221. Likewise, PMP cited U.S. Patent Application Publication No. 2017/0020200, the publication corresponding to the '123 patent, during prosecution of its U.S. Patent No. 9,986,767. It also cited the '320 patent during prosecution of its U.S. Patent No. 10,206,428. Furthermore, a number of Respondents have cited the '915 patent or its family members during prosecution of their own patents. ACS, for instance, cited U.S. Patent No. 9,078,473 ("the '473 patent"), the parent of the '915 patent, during prosecution of its U.S. Patent No. 10,278,424. Likewise, PMP cited the '473 patent, during prosecution of its U.S. Patent No. 10,206,428. ACS cited the U.S. publication of the '238 patent (U.S. Patent Application Publication No. 2015/0245658) during prosecution of its U.S. Patent Nos. D870,375 and 10,021,910. In addition, upon information and belief, Respondents, which are global companies, regularly survey the patent literature for relevant patents and would have encountered the Asserted Patents. Lastly, at the very least, this complaint informs Respondents about the Asserted Patents.

100. On April 9, 2020, Complainants RAI and RJRV filed a complaint in the United States District Court for the Eastern District of Virginia alleging infringement of the Asserted Patents by each of the Respondents. Therefore, for this additional reason, each of the Respondents has knowledge of not only the Asserted Patents but also their infringement of those patents.

101. On information and belief, Respondents actively induce infringement of the Asserted Patents pursuant to 35 U.S.C. § 271(b) through, among other things, the sale in the United States of the Accused Products to direct infringers that include, without limitation, customers and end users of Respondents' Accused Products, with the specific intent that the Accused Products be used in an infringing manner.

102. On information and belief, Respondents encourage customers and end users to use the Accused Products in an infringing manner, by providing a user guide and quick start guide that instruct customers and end users to use the Accused Products in an infringing manner, providing training and/or technical support to customers and end users instructing how to use the Accused Products in an infringing manner, and advertising, marketing, and promoting the use of the Accused Products in an infringing manner. On information and belief, Respondents have had specific intent to infringe the Asserted Patents or were willfully blind to such infringement.

103. On information and belief, Respondents' customers, distributors, resellers, and/or end users of the Accused Products demonstrate or operate the Accused Products in the United States in accordance with the IQOS[®] User Guide that is included with the IQOS[®] system. Assembly and use of the IQOS[®] system and components thereof by direct infringers, such as Respondents' customers, distributors, resellers, and/or end users, operates in a manner that directly infringes the Asserted Patents.

104. On information and belief, Respondents also indirectly infringe the Asserted Patents pursuant to 35 U.S.C. § 271(c) by contributing to the infringement of the Asserted Patents by selling the Accused Products in the United States to direct infringers, including, without limitation, customers and/or end users of the Accused Products, structures and features of which constitute a material part of one or more claims of the Asserted Patents, and are not a staple article of commerce suitable for non-infringing uses, and are especially made and or adapted for use in infringing the Asserted Patents.

105. On information and belief, Respondents possess intent to contributorily infringe the Asserted Patents because they know that the structures and features of the Accused Products

are especially made or adapted for use in an infringement of one or more claims of the Asserted Patents and such features are not a staple article of commerce suitable for non-infringing uses.

106. On information and belief, the direct infringers for Respondents' contributory infringement include, without limitation, customers and end users of the Accused Products, to whom Respondents sell the Accused Products. Respondents contribute to these customers' and end users' infringement by selling the Accused products to them, by advertising and promoting the Accused Products as embodying a material component of the patented inventions, and by encouraging and providing instructions to their customers and end users for using the Accused Products as embodying a material component of the patented inventions.

107. On information and belief, Respondents contribute to the infringement of the Asserted Patents by selling for importation into the United States, importing into the United States, and/or selling within the United States after importation, components, such as the IQOS[®] holder and IQOS[®] HeatSticks, containing infringing functionality of the Accused Products, which are not a staple article or commodity of commerce suitable for substantial non-infringing use. To the contrary, the components are authorized by FDA solely and exclusively for use as part of the IQOS[®] system and are marketed and sold by Respondents solely and exclusively for use as part of the IQOS[®] system. Thus, these components of the IQOS[®] system are especially made or adapted for use in the infringement of the Asserted Patents.

B. Evidence of Infringement

1. The '238 Patent

108. The Accused Products infringe claim 19 of the '238 patent. Pursuant to § 210.12(a)(9)(viii), a chart that applies the independent asserted claim of the '238 patent to the IQOS[®] system is attached hereto as Exhibit 39.

2. The '123 Patent

109. The Accused Products infringe claims 27, 28, 29, and 30 of the '123 patent. Pursuant to § 210.12(a)(9)(viii), a chart that applies the independent asserted claim of the '123 patent to the IQOS[®] system is attached hereto as Exhibit 41.

3. The '915 Patent

110. The Accused Products infringe claims 1, 2, and 5 of the '915 patent. Pursuant to § 210.12(a)(9)(viii), a chart that applies the independent asserted claim of the '915 patent to the IQOS[®] system is attached hereto as Exhibit 43.

VII. HARMONIZED TARIFF SCHEDULE INFORMATION

111. The articles subject to this complaint may be classified under at least the following headings and subheadings of the Harmonized Tariff Schedule (“HTS”) of the United States: 2402.20.8000; 2403.19.2080; 2403.99.2090; 2403.99.3065; 2403.99.9065; 8543.70.9930; 8543.70.9940; 8543.90.8850; 8543.90.8860. These HTS numbers are illustrative only and may not exhaustively reflect the HTS classification of all Accused Products. These HTS numbers are not intended to restrict the scope of this investigation or the scope of relief to which Complainants are entitled.

VIII. THE DOMESTIC INDUSTRY

112. There is a domestic industry as defined under 19 U.S.C. § 1337(a)(3)(A), (B), and/or (C), comprising continuing significant investments in plant and equipment and employment of labor and capital, and continuing substantial investment in exploitation of the Asserted Patents. Moreover, Complainants’ planned future significant and substantial investments in plant and equipment, employment of labor and capital, and exploitation of the Asserted Patents amounts to domestic industry in the process of being established. Specific non-limiting examples of such investments are provided below.

A. Economic Prong

113. Complainants engage in a broad range of qualifying domestic industry activities in the United States directed to articles protected by the Asserted Patents. These articles include the Domestic Industry Products identified in the Declaration of Nicholas Gilley (hereafter “Gilley Decl.”), Confidential Exhibit 49.

114. As discussed below, the Domestic Industry Products, including the VUSE® Vibe and VUSE® Solo products, each practice at least one valid claim of the Asserted Patents. The Domestic Industry Products were, and continue to be, designed, developed, tested, and supported by Complainants in the United States. In addition, Complainants manufacture at least certain components of the Domestic Industry Products in the United States.

115. Complainants have made and continue to make significant investments in plant and equipment directed to Domestic Industry Products that practice the Asserted Patents. Gilley Decl. at ¶¶ 19-40. Those investments in plant and equipment are dedicated to manufacturing, manufacturing support, testing, research, design, development, engineering, product integrity / stewardship / regulatory compliance / support, and various customer support activities focused on the Domestic Industry Products. *Id.*

116. Complainants have made and continue to make significant employment of labor and capital directed to the Domestic Industry Products. Gilley Decl. at ¶¶ 41-54. Those investments in labor and capital are dedicated to manufacturing, manufacturing support, testing, research, design, development, engineering, product integrity / stewardship / regulatory compliance support, and various customer support activities focused on the Domestic Industry Products. *Id.*

117. Complainants further engage in exploitation of the Asserted Patents through their substantial domestic investments in research, design, development, engineering, quality control, testing, engineering, product integrity / stewardship / regulatory compliance support, and various customer support activities relating to the technology covered by the Asserted Patents directed to the Domestic Industry Products. Gilley Decl. at ¶¶ 55-62.

118. A significant and substantial portion of Complainants' technical activities that benefit the Domestic Industry Products takes place in the United States. Gilley Decl. at ¶ 18.

119. Complainants' investments and activities are important to the Domestic Industry Products and represent significant domestic added value, particularly where the protected articles are designed, developed, and manufactured domestically. Gilley Decl. at ¶¶ 63-65.

B. Technical Prong

120. Pursuant to § 210.12(a)(9)(ix), claim charts applying exemplary claims of each of the Asserted Patents to the Domestic Industry Products and evidence cited therein are attached as Confidential Exhibits 40, 42, and 44.

IX. PHYSICAL SAMPLES

121. Physical samples⁴ representative of the Accused Products, namely the IQOS[®] system and refill packs of three varieties of the Marlboro[™] HeatSticks will be submitted as follows:

⁴ Given the Commission's restrictions in response to COVID-19, Complainants will submit the Physical Exhibits when the Commission again permits in-person filings or otherwise provides instructions.

Physical Exhibit	Accused Products
PX1	IQOS [®] system (including IQOS [®] holder, charger, cleaning tool and Marlboro [™] HeatStick)
PX2	Pack of 20 Marlboro [™] HeatSticks
PX3	Pack of 20 Marlboro [™] Smooth Menthol HeatSticks
PX4	Pack of 20 Marlboro [™] Fresh Menthol HeatSticks

122. Physical samples representative of the D.I. Products will be submitted as follows:

Physical Exhibit	D.I. Products
PX5	VUSE [®] Vibe Vapor Pen
PX6	VUSE [®] Vibe Menthol refill cartridges
PX7	VUSE [®] Solo Vapor E-Cig Power Unit Kit

123. As detailed herein and in the attached exhibits, the VUSE[®] Vibe system is protected at least by the '123 patent, and the VUSE[®] Solo system is protected at least by the '238 and '915 patents. The refill cartridges used in these systems are available in tobacco and menthol flavors, but the structure and operation of the cartridges is the same across flavors.

X. RELATED LITIGATION

124. On April 9, 2020, Complainants RAI and RJRV filed a complaint in the United States District Court for the Eastern District of Virginia alleging infringement of the Asserted Patents (and other patents) by each of the Respondents.

XI. RELIEF REQUESTED

125. WHEREFORE, by reason of the foregoing, Complainants respectfully request that the United States International Trade Commission:

- (a) Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the violations by Respondents of Section 337 arising from the importation into the United States, sale for importation, and/or sale within the United States after importation, of Respondents' products that infringe one or more claims of the Asserted Patents.
- (b) Schedule and conduct a hearing, pursuant to 19 U.S.C. § 1337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337 of the Tariff Act of 1930, as amended; and, following the hearing, determine that there has been a violation of Section 337 of the Tariff Act of 1930, as amended;
- (c) Issue a permanent limited exclusion order, excluding from entry for consumption into the United States, entry for consumption from a foreign trade-zone, or withdrawal from a warehouse for consumption, certain tobacco heating articles and components thereof that infringe one or more claims of the Asserted Patents and which are manufactured by or on behalf of, or imported by or on behalf of Respondents, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or

assigns, for the remaining term of the Asserted Patents, except under license of Complainants or as provided by law;

- (d) Issue permanent cease-and-desist orders, pursuant to 19 U.S.C. §1337(f), directing Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with or otherwise on behalf of Respondents, (A) importing or selling for importation into the United States certain tobacco heating articles and components thereof that infringe one or more claims of the Asserted Patents; (B) marketing, distributing, selling, or otherwise transferring, in the United States imported tobacco heating articles and components thereof that infringe one or more claims of the Asserted Patents; (C) advertising imported tobacco heating articles and components thereof in the United States that infringe one or more claims of the Asserted Patents; (D) soliciting U.S. agents or distributors for tobacco heating articles and components thereof that infringe one or more claims of the Asserted Patents; (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of tobacco heating articles and components thereof that infringe one or more claims of the Asserted Patents; (F) testing imported tobacco heating articles and

components thereof in the United States that infringe one or more claims of the Asserted Patents; (G) updating or upgrading imported tobacco heating articles and components thereof in the United States that infringe one or more claims of the Asserted Patents; (H) operating imported tobacco heating articles and components thereof in the United States that infringe one or more claims of the Asserted Patents; or (I) supporting, servicing, and/or repairing imported tobacco heating articles and components thereof in the United States that infringe one or more claims of the Asserted Patents;

- (e) Impose a bond upon any importations or sales of infringing tobacco heating articles and components thereof during the 60-day period for Presidential review, pursuant to 19 U.S.C. § 1337(j); and
- (f) Grant all such other and further relief as the Commission has authority to grant and deems appropriate under the law, based upon the facts complained of herein and as determined by the Investigation.

Dated: April 9, 2020

Respectfully submitted,



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*Counsel for Complainants
RAI Strategic Holdings, Inc.,
R.J. Reynolds Vapor Company, and
R.J. Reynolds Tobacco Company*

VERIFICATION

I, Charles A. Leyes, declare, in accordance with 19 C.F.R. §§ 210.4(c) and 210.12(a), under penalty of perjury, that the following statements are true:

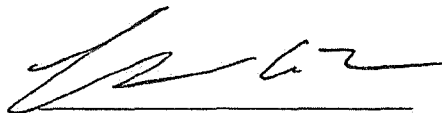
1. I am Assistant Secretary for R.J. Reynolds Tobacco Company ("RJRT") and Vice President and Assistant Secretary for RAI Strategic Holdings, Inc. ("RAISH"). I am duly authorized by RJRT and RAISH to verify the foregoing Complaint Under Section 337 of the Tariff Act of 1930, as Amended.

2. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

3. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the claims and other legal contentions set forth in the Complaint are warranted by existing law or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law.

4. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the allegations of the Complaint Under Section 337 of the Tariff Act of 1930, as Amended are well grounded in fact and have evidentiary support, or where specifically identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

Executed on this 8th day of April, 2020



Charles A. Leyes
Assistant Secretary
R.J. Reynolds Tobacco Company

Vice President and Assistant Secretary
RAI Strategic Holdings, Inc.

VERIFICATION

I, Adin Trbonja, declare, in accordance with 19 C.F.R. §§ 210.4(e) and 210.12(a), under penalty of perjury, that the following statements are true:

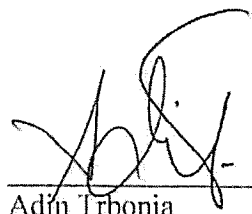
1. I am Vice President and Assistant Secretary for R.J. Reynolds Vapor Company ("RJRV"). I am duly authorized by RJRV to verify the foregoing Complaint Under Section 337 of the Tariff Act of 1930, as Amended.

2. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

3. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the claims and other legal contentions set forth in the Complaint are warranted by existing law or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law.

4. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the allegations of the Complaint Under Section 337 of the Tariff Act of 1930, as Amended are well grounded in fact and have evidentiary support, or where specifically identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

Executed on this 8th day of April, 2020



Adin Trbonja
Vice President and Assistant Secretary
R.J. Reynolds Vapor Company