

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN TOBACCO HEATING ARTICLES
AND COMPONENTS THEREOF**

INV. NO. 337-TA-1199

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Clark S. Cheney

(May 14, 2021)

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Table of Abbreviations

CC Order	Order No. 28 issued on January 6, 2021
CC Tr.	Transcript of claim construction hearing held September 17, 2020
CDX	Complainants' demonstrative exhibit
CIB	Complainants' initial post-hearing brief
CPB	Complainants' pre-hearing brief
CPX	Complainants' physical exhibit
CRB	Complainants' responsive post-hearing brief
CX	Complainants' exhibit
Dep.	Deposition
FDA	U.S. Food and Drug Administration
JX	Joint Exhibit
MRTTP	Modified risk tobacco product
MRTPA	Modified risk tobacco product application
PMTA	Pre-market tobacco application
PRRP	Potentially reduced risk product
RDX	Respondents' demonstrative exhibit
RIB	Respondents' initial post-hearing brief
RPB	Respondents' pre-hearing brief
RPX	Respondents' physical exhibit
RRB	Respondents' responsive post-hearing brief
RRP	Reduced risk product
RX	Respondents' exhibit

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SDX	Staff's demonstrative exhibit
SIB	Staff's initial post-hearing brief
SPB	Staff's pre-hearing brief
SPMTA	Supplemental pre-market tobacco authorization
SPX	Staff's physical exhibit
SRB	Staff's responsive post-hearing brief
Stip.	Stipulation of the parties
SX	Staff's exhibit
Tr.	Transcript

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In the Matter of

**CERTAIN TOBACCO HEATING ARTICLES
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INV. NO. 337-TA-1199

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Clark S. Cheney

(May 14, 2021)

Pursuant to the Notice of Investigation, 85 Fed. Reg. 29482 (May 15, 2020), and 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i), this is the final initial determination in the matter of *Certain Tobacco Heating Articles and Components Thereof*, Investigation No. 337-TA-1199.

For the reasons stated herein, I have determined that a violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain tobacco heating articles and components thereof based on infringement of U.S. Patent No. 9,901,123 and U.S. Patent No. 9,930,915.

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I. INTRODUCTION

A. Procedural History

On April 9, 2020, complainants RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company (collectively, “Reynolds” or “Complainants”) filed a complaint alleging violations of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tobacco heating articles and components thereof. 85 Fed. Reg. 21020 (Apr. 15, 2020); *see* EDIS Doc. ID 707369. Reynolds submitted a letter supplementing the complaint on April 16, 2020. 85 Fed. Reg. 29482 (May 15, 2020); *see* EDIS Doc. ID 708090.

On May 15, 2020, the Commission instituted Investigation No. 337-TA-1199 to determine:

[W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claim 19 of the '238 patent [U.S. Patent No. 9,839,238]; claims 27–30 of the '123 patent [U.S. Patent No. 9,901,123]; and claims 1, 2, and 5 of the '915 patent [U.S. Patent No. 9,930,915]; and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

85 Fed. Reg. 29482 (May 15, 2020) (“Notice of Investigation”).

The plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “electric tobacco heating device systems and the associated tobacco sticks sold for use with the device systems.” Notice of Investigation; *see also* 19 C.F.R. § 210.10(b)(1).

The Commission also ordered that:

[T]he presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and

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provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1).

Notice of Investigation.

The Notice of Investigation named the following entities as respondents: Altria Client Services LLC, Altria Group, Inc., Philip Morris USA, Inc., Philip Morris International Inc., and Philip Morris Products S.A. (collectively, “Philip Morris” or “Respondents”). *Id.*

The Office of Unfair Import Investigations (“Staff”) is also a party to this investigation. *Id.*

On June 2, 2020, I set the target date for this investigation at sixteen months, which makes this final initial determination due no later than May 14, 2021. Order No. 4 (June 2, 2020).

On July 29, 2020, I granted a motion from Reynolds seeking leave to amend the complaint and notice of investigation to add allegations of infringement of claim 3 of the ’915 patent. Order No. 9 (July 29, 2020), *unreviewed*, Comm’n Notice (Aug. 18, 2020); *see also* 85 Fed. Reg. 52152 (Aug. 4, 2020). Reynolds subsequently filed an amended complaint (“Compl.”). EDIS Doc. ID 716122.

In accordance with the procedural schedule issued as Order Nos. 5 and 10 on June 11, 2020, and July 30, 2020, respectively, the parties submitted a joint chart of proposed claim constructions on August 13, 2020. The parties submitted opening claim construction briefs on August 21, 2020, and responsive claim construction briefs on September 4, 2020. On September 17, 2020, I convened a claim construction hearing.¹ I subsequently issued Order No. 28 (“CC Order”) on January 6, 2021, construing certain disputed claim terms.

¹ The transcript of the claim construction hearing is available as EDIS Doc. ID 721164 and is hereinafter referred to as “CC Tr.”

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On December 14, 2020, I granted a joint motion filed by Reynolds and Philip Morris seeking to terminate this investigation as to named respondents Altria Group, Inc., and Philip Morris International Inc. Order No. 24 (Dec. 14, 2020), *unreviewed*, Comm’n Notice (Jan. 5, 2021).

On January 19, 2021, I granted in part Reynolds’s motion for summary determination that it has satisfied the economic prong of the domestic industry requirement. Order No. 35 (Jan. 19, 2021). Specifically, I determined the economic prong of the domestic industry requirement has been satisfied under 19 U.S.C. §§ 1337(a)(3)(A) and (B) with respect to the ’238 and ’915 patents. *See* Order No. 35, at 5–6. On review, the Commission affirmed that the economic prong is satisfied under 19 U.S.C. § 1337(a)(3)(A) with respect to the ’238 and ’915 patents and provided supplemental analysis. Notice of Commission Determination to Review and Affirm an Initial Determination Granting Summary Determination that the Economic Prong of the Domestic Industry Requirement Is Satisfied (EDIS Doc. ID 734509) (Feb. 18, 2021). The Commission reviewed but took no position as to my findings under 19 U.S.C. § 1337(a)(3)(B). *Id.*

To narrow the issues for the evidentiary hearing, Reynolds and Philip Morris entered into two stipulations regarding undisputed facts. *See* JX-0011C (Stipulation Among the Private Parties to Narrow the Issues for the Evidentiary Hearing) (“Stip.”); JX-0121C (Joint Stipulation Regarding Economic Domestic Industry) (“DI Stip.”).

I held a prehearing conference on January 22, 2021, and convened the evidentiary hearing January 25, 2021. The evidentiary hearing ended on February 1, 2021. *See* Hrg. Tr. 1–1603.

B. The Private Parties

1. Complainants

RAI Strategic Holdings, Inc. is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, North Carolina 27101. Compl. ¶ 7. RAI Strategic Holdings, Inc. is the assignee and sole owner of the patents asserted in this investigation. *See* Compl. Exs. 4, 5, 6.

R.J. Reynolds Vapor Company is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, North Carolina 27101. Compl. ¶ 8. R.J. Reynolds Vapor Company is an exclusive licensee of the patents asserted in this investigation and is responsible for developing, distributing, and selling the products on which Reynolds relies to show satisfaction of the domestic industry requirement. *See id.*

R.J. Reynolds Tobacco Company is a North Carolina corporation with its principal place of business located at 401 North Main Street, Winston-Salem, North Carolina 27101. Compl. ¶ 9. R.J. Reynolds Tobacco Company provides research and technical support for the products on which Reynolds relies to show satisfaction of the domestic industry requirement. *See id.*

2. Respondents

Altria Client Services LLC is a Virginia corporation with offices at 6601 West Broad Street, Richmond, Virginia 23230. Response of Respondents Altria Client Services LLC, Altria Group, Inc., and Philip Morris USA, Inc., to the Amended Complaint and Notice of Investigation (“Philip Morris Resp. to Compl.”) ¶ 10 (EDIS Doc. ID 717980) (Aug. 24, 2020).

Philip Morris USA, Inc. (“Philip Morris USA”) is a Virginia corporation with offices at 6601 West Broad Street, Richmond, Virginia 23230. *Id.* ¶ 12. Philip Morris USA imports and

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sells after importation certain accused IQOS® systems and disposable tobacco sticks into the United States. *Id.*

Philip Morris Products S.A. (“Philip Morris Products”) is organized under the laws of Switzerland with an address of Quai Jeanrenaud 3, 2000 Neuchâtel, Switzerland. *Id.* ¶ 14. Philip Morris Products has imported into the United States and sold for importation into the United States certain accused IQOS® system products and disposable tobacco sticks. *Id.* Philip Morris Products is a premarket tobacco applicant with United States Food and Drug Administration (“FDA”) for the accused IQOS® systems and disposable tobacco sticks, and Philip Morris Products consulted with Altria Client Services LLC and Philip Morris USA to obtain FDA authorization in the United States. *Id.*

C. The Asserted Patents

Reynold asserts claims under three patents in this investigation: the ’123 patent, the ’915 patent, and the ’238 patent (collectively, the “Asserted Patents”).

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

The ’123 patent, titled “Tobacco-Containing Article,” issued on February 27, 2018, and names John Howard Robinson, David William Griffith, Jr., Billy Tyrone Conner, Evon Llewellyn Crooks, and Dempsey Bailey Brewer, Jr. as inventors. JX-0002 (“’123 patent”) at cover page. The ’123 patent issued from application no. 15/286,087, filed on October 5, 2016, and claims priority to application no. 11/550,634, which was filed on October 18, 2006, and issued as U.S. Patent No. 7,726,320. *Id.* The ’123 patent expires on October 18, 2026. *Id.*

The ’123 patent is assigned to RAI Strategic Holdings, Inc. ’123 patent at cover page; Compl. Ex. 5.

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Reynolds asserts claims 27–30 of the '123 patent against Philip Morris. *See* Notice of Investigation; CIB at 18. To prove satisfaction of the technical prong of the domestic industry requirement, Reynolds relies on claims 1, 4, 6, 11, 13–15, 17, 19, and 23–26 of the '123 patent. *See* CIB at 43. The claims at issue in this investigation read as follows:

1. An electrically-powered, aerosol-generating smoking article comprising:

an electrical power source within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

at least one electrical resistance heater powered by said electrical power source;

a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw, the controller comprising a sensor adapted for sensing draw on the smoking article by a user; and

a rod-shaped carrier device engaged with the mouth-end of the tubular outer housing and comprising a cartridge providing a liquid storage compartment containing a mixture comprising a tobacco extract and an aerosol-forming material absorbed within an absorbent fibrous material, the cartridge having a generally tubular shape and adapted for airflow therethrough;

wherein the rod-shaped carrier device is operatively positioned such that, during draw, the mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater and volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

4. The smoking article of claim 3, wherein the flavoring agent comprises menthol.

6. The smoking article of claim 1, wherein the mixture comprises essentially pure nicotine, extracts composed predominantly of nicotine, or formulations composed predominantly of nicotine.

11. The smoking article of claim 1, wherein the cartridge is electrically conductive.

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13. The smoking article of claim 1, wherein the mixture comprises glycerin, tobacco extract, and a flavoring agent.

14. The smoking article of claim 1, wherein the absorbent fibrous material is in contact with the electrical resistance heater.

15. An electrically-powered, aerosol-generating smoking article comprising:

- an electrical power source in the form of a battery within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

- at least one electrical resistance heater powered by said electrical power source;

- a puff-actuated controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater during draw, the controller comprising a sensor adapted for sensing draw on the smoking article by a user; and

- a rod-shaped carrier device removably engaged with the mouth-end of the tubular outer housing and comprising a cartridge providing a liquid storage compartment containing a mixture comprising a tobacco extract comprising nicotine and an aerosol-forming material selected from glycerin, propylene glycol, or a mixture thereof, the mixture absorbed within an absorbent wicking material, the cartridge having a generally tubular shape and adapted for airflow therethrough;

- wherein the rod-shaped carrier device is operatively positioned such that, during draw, the mixture comprising the tobacco extract and the aerosol-forming material can be wicked into contact with the electrical resistance heater and volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

17. The smoking article of claim 16, wherein the flavoring agent comprises menthol.

19. The smoking article of claim 15, wherein the mixture comprises essentially pure nicotine, extracts composed predominantly of nicotine, or formulations composed predominantly of nicotine.

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23. The smoking article of claim 15, wherein the cartridge is electrically conductive.

24. The smoking article of claim 15, wherein the absorbent wicking material is in contact with the electrical resistance heater.

25. The smoking article of claim 15, wherein the absorbent wicking material is positioned in proximity to the at least one electrical resistance heater.

26. The smoking article of claim 15, wherein an air passageway extends along the length of the cartridge.

27. An electrically-powered, aerosol-generating smoking article comprising:

- an electrical power source in the form of a battery within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

- at least one electrical resistance heater powered by said electrical power source, wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing;

- a controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater; and

- a cigarette-type device removably engaged with the mouth-end of the tubular outer housing and comprising a tobacco segment circumscribed by a wrapping material and comprising a tobacco material and an aerosol-forming material, wherein the elongated portion of the resistance heating element extends into the tobacco segment when the cigarette-type device is engaged with the mouth-end of the outer housing, such that during draw, aerosol-forming material can be volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

28. The smoking article of claim 27, wherein the cigarette-type device further comprises a filter element downstream from the tobacco segment.

29. The smoking article of claim 27, further comprising an actuation mechanism in the form of a switching mechanism that can be manually operated by the user in order to heat the cigarette-type device.

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30. The smoking article of claim 27, wherein the electrical resistance heating element provides surface region temperatures of at least 200° C. and less than 600° C. such that the tobacco material does not burn during use.

'123 patent at claims 1, 4, 6, 11, 13–15, 17, 19, and 23–30.

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

The '915 patent, titled “Smoking Articles and Use Thereof for Yielding Inhalation Materials,” issued on April 3, 2018, and names Steven L. Worm, David Glen Christopherson, Stephen Benson Sears, Denis Lee Potter, Frederic Phillipe Ampolini, and Balager Ademe as inventors. JX-0003 (“’915 patent”) at cover page. The '915 patent issued from application no. 14/737,706, filed on June 12, 2015, and claims priority to application no. 13/205,841, which was filed on August 9, 2011, and issued as U.S. Patent No. 9,078,473. *Id.* The '915 patent expires on November 9, 2031. *Id.*

The '915 patent is assigned to RAI Strategic Holdings, Inc. '915 patent at cover page; Compl. Ex. 6.

Reynolds asserts claims 1, 2, 3, and 5 of the '915 patent against Philip Morris. *See* Notice of Investigation; Order No. 9 (July 29, 2020), *unreviewed*, Comm’n Notice (Aug. 18, 2020); CIB at 56. To prove satisfaction of the technical prong of the domestic industry requirement, Reynolds relies on claims 1 and 3 of the '915 patent. *See* CIB at 70. The claims at issue in this investigation read as follows:

1. A reusable control unit for use with a disposable smoking article, the reusable control unit comprising a control housing including:

a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source that includes a projection extending outwardly therefrom and that includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member; and

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a control unit section that houses a power source, a switching component that actuates flow of electrical current from the electrical energy source to the electrical heating member, and a flow regulating component that regulates a previously initiated current flow from the electrical energy source to the electrical heating member, wherein the component that forms an electrical connection with the electrical contacts is located on the projection.

2. The reusable control unit of claim 1, wherein the power source includes a battery.
3. The reusable control unit of claim 1, wherein the electrical energy source includes a capacitor.
5. The reusable control unit of claim 1, wherein the switching component comprises a pushbutton.

'915 patent at claims 1–3 and 5.

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

The '238 patent, titled “Control Body for an Electronic Smoking Article,” issued on December 12, 2017, and names Steven L. Worm, Michael Ryan Galloway, Frederic Phillipe Ampolini, Randy Lee McKnight, and David Glen Christopherson as inventors. JX-0001 (“’238 patent”) at cover page. The '238 patent issued from application no. 14/193,961, filed on February 28, 2014, and expires on April 17, 2036. *Id.*

The '238 patent is assigned to RAI Strategic Holdings, Inc. '238 patent at cover page; Compl. Ex. 4.

Reynolds asserts independent claim 19 of the '238 patent against Philip Morris. *See* Notice of Investigation; CIB at 76. To prove satisfaction of the technical prong of the domestic industry requirement, Reynolds relies on claims 1, 3, 5, 6, 8–11, 19, and 20 of the '238 patent. *See* CIB at 95. The claims at issue in this investigation read as follows:

1. A control body for an electronic smoking article, the control body comprising:

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an elongated shell with an interior, a proximal end, and an opposing distal end;

a coupler having a body end in engagement with the proximal end of the shell and having an opposing connector end configured to releasably engage a cartridge;

an electrical power source;

an electronic circuit board positioned within the shell interior between the electrical power source and the coupler;

and an air pressure sensor attached to the electronic circuit board;

wherein the shell has a central axis therethrough from the proximal end to the distal end, and wherein the electronic circuit board is oriented substantially parallel to the central axis of the shell;

wherein the shell interior includes a normal air pressure space and a pressure reduction space, and wherein a first end of the pressure sensor is in fluid communication with the pressure reduction space and a second end of the pressure sensor is in fluid communication with the normal air pressure space; and

wherein the body end of the coupler forms a wall, the opposing connector end of the coupler has a cavity, and the coupler includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the body end of the coupler to be in fluid communication with the pressure reduction space.

3. The control body according to claim 1, comprising a sealing member configured to form an air tight seal around the air pressure sensor and the second end of the pressure channel and thus define the pressure reduction space that encompasses the opening at the second end of the pressure channel and the first end of the pressure sensor.

5. The control body according to claim 1, wherein the coupler includes an air inlet channel in fluid communication with the cavity.

6. The control body according to claim 5, wherein the air inlet channel is formed entirely within the coupler body.

8. The control body according to claim 5, wherein the coupler has a longitudinal axis extending from the body end to the opposing connector end, and wherein the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler.

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9. The control body according to claim 8, wherein the first end of the pressure channel is spatially separated from the air inlet channel so as to be relatively nearer the connector end of the coupler.

10. The control body according to claim 1, comprising an ambient air flow pathway extending from the exterior of the coupler, through the coupler body, and through the cavity.

11. The control body according to claim 1, wherein the electronic circuit board includes a microprocessor, and wherein the microprocessor is configured to establish electrical current flow from the electrical power source when the air pressure sensor detects a reduced pressure in the pressure reduction space relative to the air pressure in the normal air pressure space.

19. A control body for an electronic smoking article, the control body comprising:

an elongated shell with an interior, a proximal end, and an opposing distal end;

a coupler formed of an elongated body having a first end that forms a wall and that engages the proximal end of the shell and a second end that comprises a cavity configured to releasably engage a cartridge, wherein the coupler includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler, wherein the coupler includes an air inlet channel in fluid communication with the cavity and an air inlet aperture in an exterior surface of the coupler, and wherein the coupler has a longitudinal axis extending from the first end to the second end, and the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler; and

a microprocessor.

20. The coupler according to claim 19, wherein the first end of the pressure channel is spatially separated from the air inlet channel so as to be relatively nearer the second end of the coupler.

'238 patent at claims 1, 3, 5, 6, 8–11, 19, and 20.

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D. The Accused Products

Reynolds accuses the Philip Morris IQOS 2.4, IQOS 3, and IQOS 3.1 Duo systems and HeatSticks (collectively, “Accused Products” or “IQOS”) of infringing the ’123, ’915, and ’238 patents. *See* CIB at 6.

E. The Domestic Industry Products

Reynolds relies on its VUSE line of products to prove satisfaction of the domestic industry requirement. *See* CIB at 4–6. VUSE Solo and VUSE Vibe are electronic nicotine delivery systems consisting of a power unit and closed e-liquid cartridges. CX-0947C.12; CX-0948C.15.

Reynolds began developing the VUSE Solo in [REDACTED], releasing disposable beta versions in 2012, a reusable product known internally as “G1” in 2013, and a reusable “G2” version in [REDACTED]. Hrg. Tr. 76:21–78:4; CX-0934C. In early 2015, Reynolds launched VUSE Evigo, which was later renamed Vibe. Hrg. Tr. 78:5–20; CX-0934C.

Reynolds asserts that the VUSE Solo G1 and G2 devices are articles protected by the ’915 patent, that the VUSE Solo G2 devices are articles protected by the ’238 patent, and that the VUSE Vibe devices are articles are protected by ’123 patent. CIB at 4.

II. JURISDICTION & IMPORTATION

A. Subject Matter Jurisdiction

Section 337 of the Tariff Act prohibits the importation, the sale for importation, or the sale after importation of articles that infringe a valid and enforceable patent if an industry exists in the United States relating to articles protected by the patent. 19 U.S.C. §§ 1337(a)(1)–(2). Reynolds’s Amended Complaint states a cause of action under section 337 by alleging that Philip Morris imports, sells for importation, and sells after importation certain tobacco heating articles and components thereof that infringe the Asserted Patents. *See* Compl. at 23–28.

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No party has contested the Commission's subject matter jurisdiction over this investigation. Indeed, Reynolds and Philip Morris stipulated that the Commission has subject matter jurisdiction over this investigation pursuant to 19 U.S.C. § 1337. Stip. ¶ 132.

The Commission, therefore, has subject matter jurisdiction over this investigation.

B. Personal Jurisdiction

By filing the Amended Complaint and participating in the investigation, Reynolds has consented to personal jurisdiction at the Commission. *See Certain Cutting Tools for Flexible Plastic Conduit & Components Thereof*, 337-TA-344, Initial Determination at 4, *not reviewed*, Comm'n Determination Not to Review an Initial Determination Finding a Violation of Section 337 (Oct. 28, 1993), USITC Pub. No. 2719 (Jan. 1994). Philip Morris has stipulated that the Commission has personal jurisdiction over each of the respondents. Stip. ¶ 133. I therefore find that the Commission has personal jurisdiction over all parties. *See, e.g., Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, Initial Determination at 4–5 (May 16, 2005) (unreviewed in relevant part).

C. Importation

To prove a violation of section 337 by any particular respondent, the complainant must show that the respondent engaged in “[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee” of products accused of infringement. 19 U.S.C. §§ 1337(a)(1)(A)–(B). Philip Morris has stipulated that the Accused Products have been imported into the United States. Stip. ¶¶ 111–118, ¶ 131. I therefore find that the importation requirement of section 337 has been satisfied.

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D. *In Rem* Jurisdiction

Philip Morris has stipulated that the Commission has *in rem* jurisdiction over the Accused Products. Stip. ¶ 134. I therefore find the Commission has *in rem* jurisdiction over the Accused Products in this investigation. *See Sealed Air Corp. v. Int’l Trade Comm’n*, 645 F.2d 976, 985–86 (C.C.P.A. 1981) (noting the Commission has jurisdiction over imported goods).

E. Standing

Philip Morris does not dispute Reynolds’s ownership of the Asserted Patents. The record demonstrates that Reynolds has standing in this investigation due to its ownership by assignment of the Asserted Patents. *See* Compl. Exs. 4–6.

III. LEGAL PRINCIPLES

A. Claim Construction

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff’d*, 517 U.S. 370 (1996). Claim construction resolves legal disputes between the parties regarding claim scope. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1319 (Fed. Cir. 2016).

Evidence intrinsic to the application, prosecution, and issuance of a patent is the most significant source of the legally operative meaning of disputed claim language. *See Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit explained in *Phillips*, courts must analyze each of these

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components to determine the “ordinary and customary meaning of a claim term” as understood by a person of ordinary skill in the art at the time of the invention. 415 F.3d at 1313.

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). “[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314; see *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (“In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’”). The context in which a term is used in an asserted claim can be “highly instructive.” *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Id.* at 1316. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.” *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, “[t]he construction that stays true to the claim language and most naturally aligns with the

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patent’s description of the invention will be . . . the correct construction.” *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Id.* at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* “The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence.” *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

B. Infringement

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard “requires proving that infringement was more likely than not to have occurred.” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Direct Infringement

“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). “Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is no literal infringement as a matter of law.” *Bayer AG v.*

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Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000). Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008).

2. Induced Infringement

“[A] violation of Section 337 may arise from an act of induced infringement.” *Suprema, Inc. v. Int’l Trade Comm’n*, 796 F.3d 1338, 1351 (Fed. Cir. 2015). Section 271(b) of the Patent Act states: “Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). “To prevail on a claim of induced infringement, in addition to inducement by the defendant, the patentee must also show that the asserted patent was directly infringed.” *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002). “Section 271(b) covers active inducement of infringement, which typically includes acts that intentionally cause, urge, encourage, or aid another to directly infringe a patent.” *Arris Group v. British Telecomms. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011). Liability for inducement requires proof that the party had “knowledge that the induced acts constitute patent infringement.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

3. Contributory Infringement

A party is liable for contributory infringement if it “offers to sell or sells within the United States or imports into the United States . . . a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.” 35 U.S.C. § 271(c). “[T]o prevail on contributory infringement in a Section 337 case, the complainant must show *inter alia*: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after

importation within the United States, the accused components that contributed to another's direct infringement." *Spansion*, 629 F.3d at 1353.

C. Validity

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft*, 131 S. Ct. at 2242.

1. Anticipation

Under 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, 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." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

2. Obviousness

Under 35 U.S.C. § 103, a patent may be found invalid as obvious if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Because obviousness is determined at the time of invention, rather than the date of litigation, "[t]he great challenge of the

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obviousness judgment is proceeding without any hint of hindsight.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011).

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417–18 (2007). Thus, based on a combination of several prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

Obviousness is a determination of law based on underlying determinations of fact. *Star Scientific*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level and content of the prior art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR*, 550 U.S. at 399 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are referred to collectively as the “*Graham* factors.” Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* When present, secondary considerations “give light to the circumstances surrounding the origin of the subject matter sought to be patented,” but they are not dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l*, 618 F.3d 1294, 1304–06 (Fed. Cir. 2010). For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and

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the merits of the claimed invention. *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372–73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

3. Written Description

The issue of whether a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112 is a question of fact. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1188 (Fed. Cir. 2012). The hallmark of the written description requirement is the disclosure of the invention. *See Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The test for determining the sufficiency of the written description in a patent requires “an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Id.* “The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Id.*

4. Indefiniteness

Pursuant to 35 U.S.C. § 112, a patent specification “shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” Section 112 requires “that a patent’s claims, viewed in light of the specification and prosecution history inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A patent claim that is indefinite is invalid. 35 U.S.C. § 282(b)(3)(A).

D. Domestic Industry

For a patent-based complaint, a violation of section 337 can be found “only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *John Mezzalingua Assocs., Inc. v. Int’l Trade Comm’n*, 660 F.3d 1322, 1331 (Fed. Cir. 2011). The domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm’n Op. at 12–14, USITCPub. No. 4120 (Dec. 2009).

1. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

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

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Because the statutory criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *See InterDigital Commc’ns*, 707 F.3d at 1303 n.4; *Certain Variable Speed Wind*

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Turbines and Components Thereof, Inv. No. 337-TA-376, Comm’n Op. at 15, USITC Pub. No. 3003 (Nov. 1996).

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 8, USITC Pub. No. 2949 (Jan. 1996). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.” *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more valid claims of the patent. *See id.*; *Spancion*, 629 F.3d at 1349; *Certain Vision-Based Driver Assistance System Cameras and Components Thereof*, Inv. No. 337-TA-907, Comm’n Op. at 36, USITC Pub. No. 4866 (Feb. 2019). It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op. at 38, USITC Pub. No. 4005 (May 2008).

IV. LEVEL OF ORDINARY SKILL IN THE ART

In my earlier claim construction order, I declined to make findings about the level of ordinary skill in the art because the claim construction analysis would not differ under the competing proposals offered by the parties. CC Order at 10.

At the evidentiary hearing, only Reynolds’s experts, Mr. Alarcon and Mr. Clemens, offered a definition of a person of ordinary skill in the art. Hrg. Tr. 159:4–17, 1502:16–24; *see*

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CDX-0001C.1; CDX-0002.2. Each testified that a person of ordinary skill in the art at the time of the alleged inventions of each of the Asserted Patents would have had a Bachelor's degree in mechanical engineering, electrical engineering, chemistry, physics, or a related field, and three to four years of industry experience. Hrg. Tr. 159:4–17, 1502:16–24. Alternatively, each expert testified that a person of ordinary skill in the art would have had a Master's degree in those same fields and one to two years of industry experience. Hrg. Tr. 159:4–17, 1502:16–24. Mr. Alarcon and Mr. Clemens also testified that a person of ordinary skill in the art would have been familiar with electrically powered smoking articles and their components and underlying technologies or similar components and technologies. Hrg. Tr. 159:4–17, 1502:16–24.

Philip Morris did not offer a position as to the level of ordinary skill in the art during the evidentiary hearing or in its initial post-hearing brief.

As the testimony of Mr. Alarcon and Mr. Clemens as to the level of ordinary skill in the art is unrebutted, I therefore adopt their definition of a person of ordinary skill in the art at the time of the alleged inventions of each of the Asserted Patents.

V. THE '123 PATENT

A. Claim Construction

There are no claim construction disputes for the '123 patent that need resolution. *See* CC Order at 8 n.5.

B. Infringement

Reynolds asserts claims 27–30 of the '123 patent against Philip Morris. *See* CIB at 18. As discussed further below, the record evidence demonstrates that the Accused Products infringe these claims.

1. Claim 27

Philip Morris has stipulated that the Accused Products satisfy most limitations of claim 27 of the '123 patent. Stip. ¶ 76. The limitations that remain in dispute are emphasized below:

27. An electrically-powered, aerosol-generating smoking article comprising:

an electrical power source in the form of a battery within *a tubular outer housing having a mouth-end and an end distal to the mouth-end*;

at least one electrical resistance heater powered by said electrical power source, *wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing*;

a controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater; and

a cigarette-type device removably engaged with the mouth-end of the tubular outer housing and comprising a tobacco segment circumscribed by a wrapping material and comprising a tobacco material and an aerosol-forming material, wherein the elongated portion of the resistance heating element extends into the tobacco segment when the cigarette-type device is engaged with the mouth-end of the outer housing, such that during draw, aerosol-forming material can be volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

Id.

For the reasons set forth below, I find that the Accused Products satisfy these limitations and infringe claim 27 of the '123 patent.

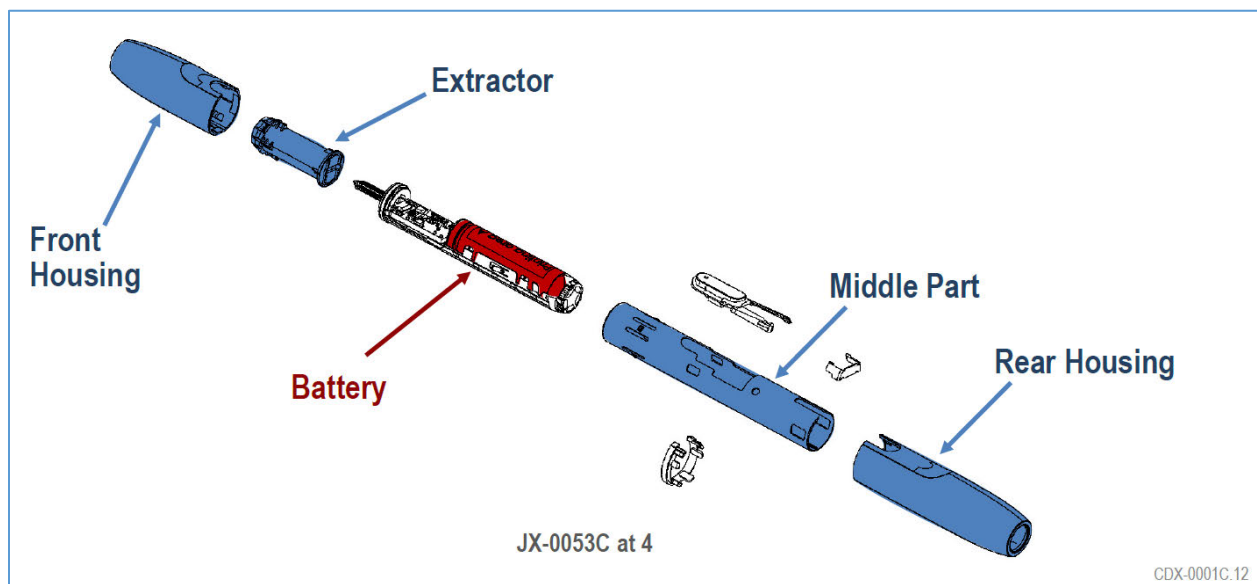
a) **“a tubular outer housing having a mouth-end and an end distal to the mouth-end”**

The second limitation of claim 27 requires “an electrical power source in the form of a battery within a tubular outer housing having a mouth-end and an end distal to the mouth-end.”

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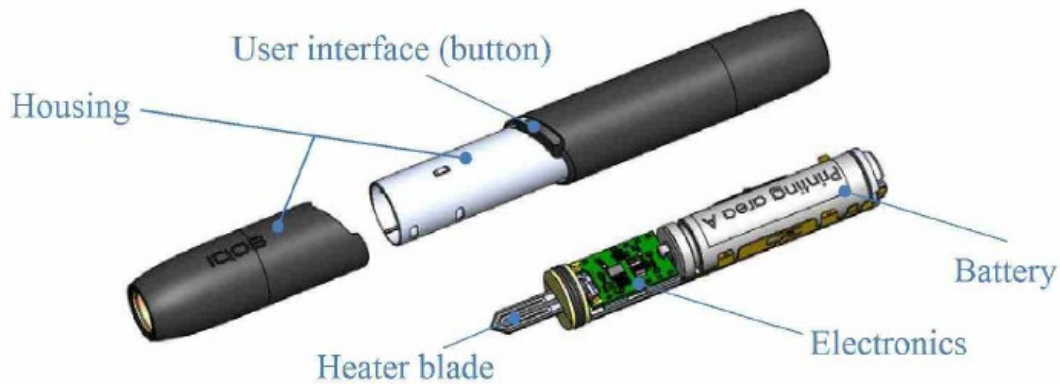
The record evidence demonstrates that the Accused Products meet this limitation because each has an electrical power source (a battery) located within a tubular outer housing having a mouth-end (that holds the tobacco stick) and a distal end (that holds the battery).

For IQOS 2.4, the claimed tubular outer housing consists of the front housing, extractor, middle part, and rear housing, which are identified in blue below; the battery, which is identified in red, is contained within the tubular outer housing.



CDX-0001C.12 (illustrating JX-0053C at 4).

The IQOS 3 and IQOS 3.1 Duo have a construction similar to that of the IQOS 2.4. A figure from Philip Morris's supplemental premarket tobacco authorization for IQOS 3 submitted to the FDA, reproduced below, identifies the front housing, rear housing, middle part and extractor as the "Housing."



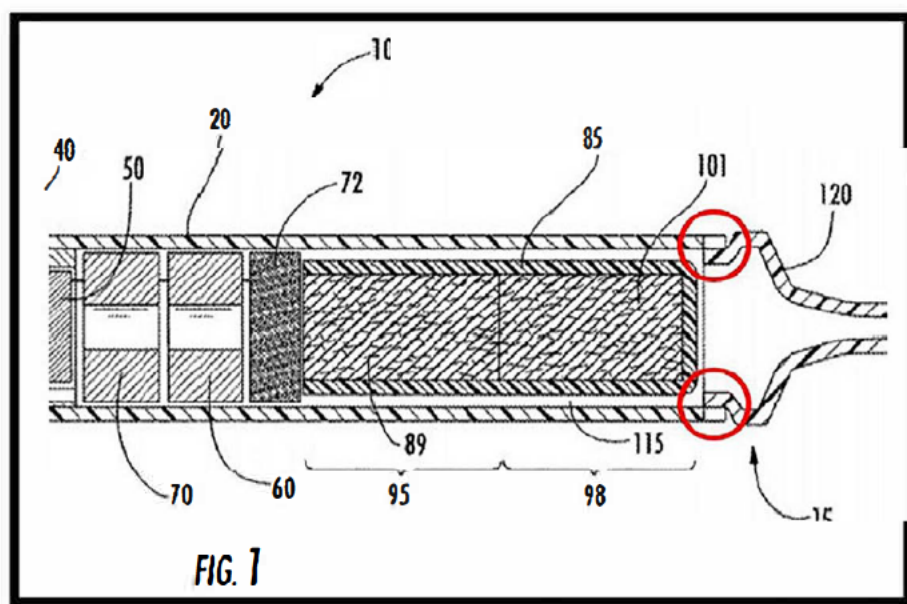
CX-0592C at 5.

In each of the IQOS 2.4, IQOS 3 and IQOS 3.1 Duo, the front housing, extractor, middle part, and rear housing components are tubular in shape, “outer” to the interior components, and house the interior components. Accordingly, the front housing, extractor, middle part, and rear housing together comprise the claimed “tubular outer housing.” The claimed “mouth-end” is the end closest to the extractor, which engages with the tobacco stick, and the claimed “end distal to the mouth-end” is the opposite end, which is closest to the battery.

Philip Morris argues that the Accused Products do not satisfy the “tubular outer housing” limitation because claim 27 requires that the tubular outer housing have (1) a battery within it, (2) a controller within it, and (3) a mouth-end that engages with a cigarette-type device, and that “no single structure of the accused IQOS devices meets those three requirements.” *See* RRB at 25–36. Philip Morris’s non-infringement argument fails because it is based on the false premise that the claimed “tubular outer housing” must be a single structure and cannot be comprised of multiple components or sub-structures.

Philip Morris’s argument is contradicted by the express disclosure of the ’123 patent specification. The ’123 patent states that “[i]f desired, the outer housing can possess an aesthetically pleasing cover (not shown)” and that the “outer container 20 of the smoking article 10

can possess an end cover or cap 35.” ’123 patent at 19:46–66. The patent also states: “As shown the outer housing 20 includes a mouth-end 15 and an end 13 distal to the mouth-end.” *Id.* at 19:59–61. Figures 1–3 of the ’123 patent show that the mouth-end 15 portion of the outer housing can include “a mouth-end piece 120” component that is separate, “typically removable,” and at least partially internal to another portion of the outer housing 20. *Id.* at 24:4–18, Figs. 1–3. As an example, Figure 1 is reproduced below, with red annotations showing where the mouth-end 15 is internal to another portion of the outer housing 15.



’123 patent at Fig. 1 (red annotation added).

Philip Morris also argues that one “cannot mix the [Accused Products’] front housing (part of the outermost housing) with separate and distinct internal housings (e.g., the extractor and middle part) and treat them collectively as the same ‘tubular outer housing’” for purposes of an infringement analysis, contending that “[t]hose are three different housings.” RRB at 31. Philip Morris’s noninfringement argument is belied by its own documents it submitted to the FDA. As discussed above, the supplemental premarket tobacco authorization submitted to the FDA for the

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IQOS 3 identifies the front housing, rear housing, middle part and extractor as the “Housing.” CX-0592C at 5. This document states that the “Holder (shown with the housing removed in the figure below) is designed to hold the *HeatStick* and heat it upon user initiation in a controlled and repeatable manner.” *Id.* (emphasis original). Similarly, the premarket tobacco authorization submitted to the FDA for the IQOS 2.4 PMTA also refers to the front housing, extractor, middle part, and rear housing collectively as the “Casing,” and this document shows the casing removed from the interior components of the heating blade, control electronics, and battery. CX-0572C at 19.

Therefore, for the reasons set forth above, I find that the Accused Products satisfy the claim 27 limitation “a tubular outer housing having a mouth-end and an end distal to the mouth-end.”

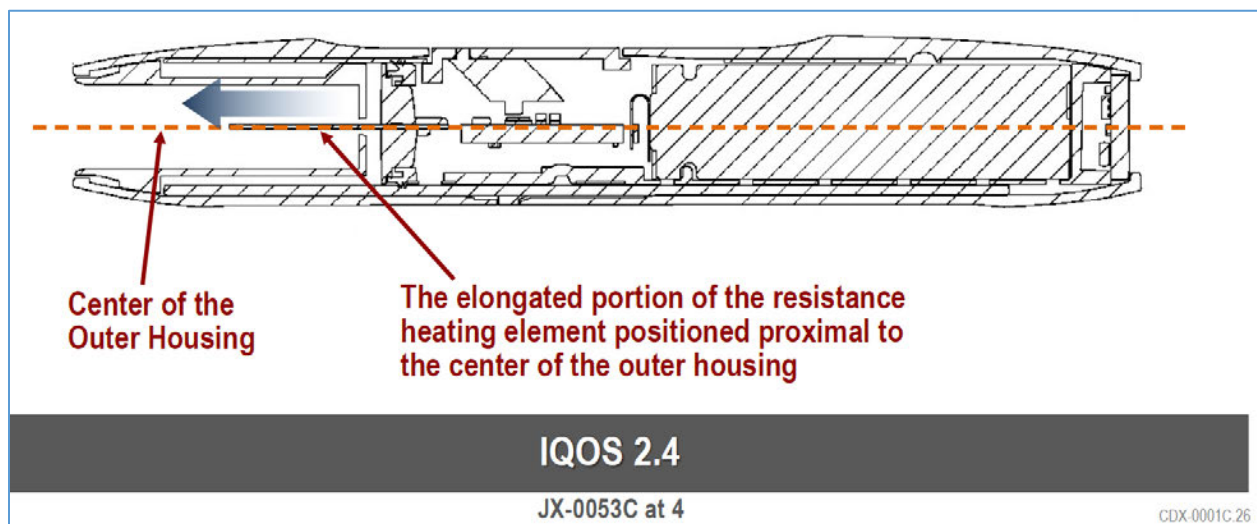
b) “wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing”

The fourth limitation of claim 27 requires that “at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing.” The record evidence shows that the Accused Products satisfy this limitation because at least a portion of the resistance heating element in the Accused Products is elongated and extends downstream toward the mouth-end of the outer housing, and because the elongated portion of the resistance heating element is positioned proximal to the center of the outer housing. Philip Morris failed to argue in its post-hearing responsive brief that this claim limitation is not satisfied; the

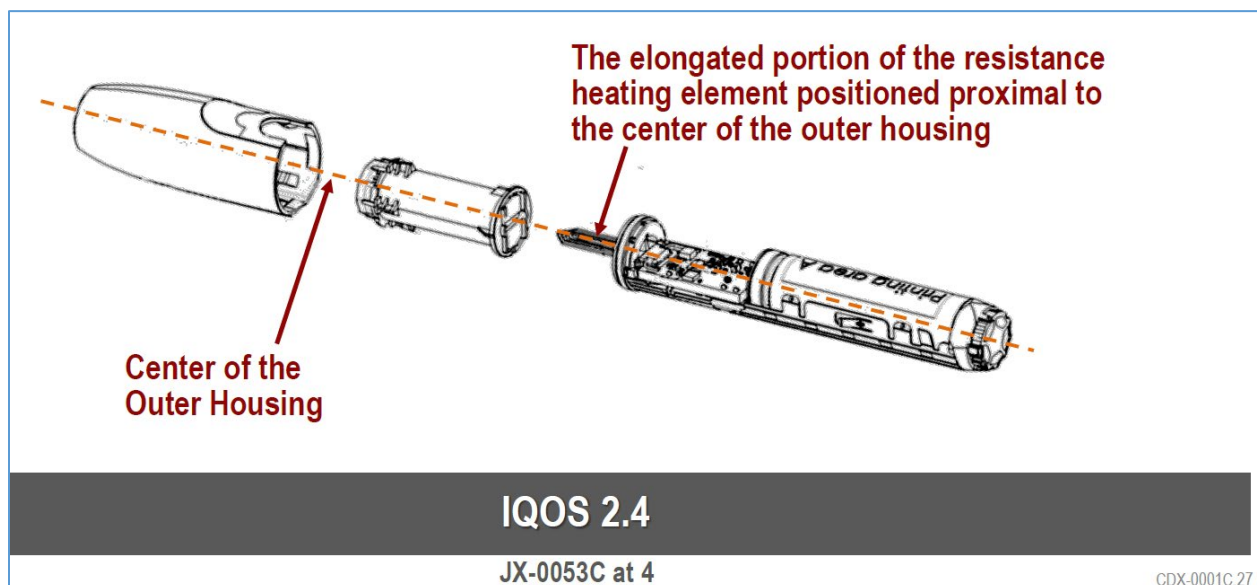
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evidence adduced by Reynolds on this issue is therefore deemed unopposed. *See* RRB at 25–41; Order No. 8 at Ground Rule 14.2 (July 27, 2020).

Documents showing section and assembly views of the IQOS 2.4, reproduced below, demonstrate that at least a portion of the resistance heating element is elongated and extends downstream towards the mouth-end of the outer housing and is positioned proximal to the center of the outer housing.

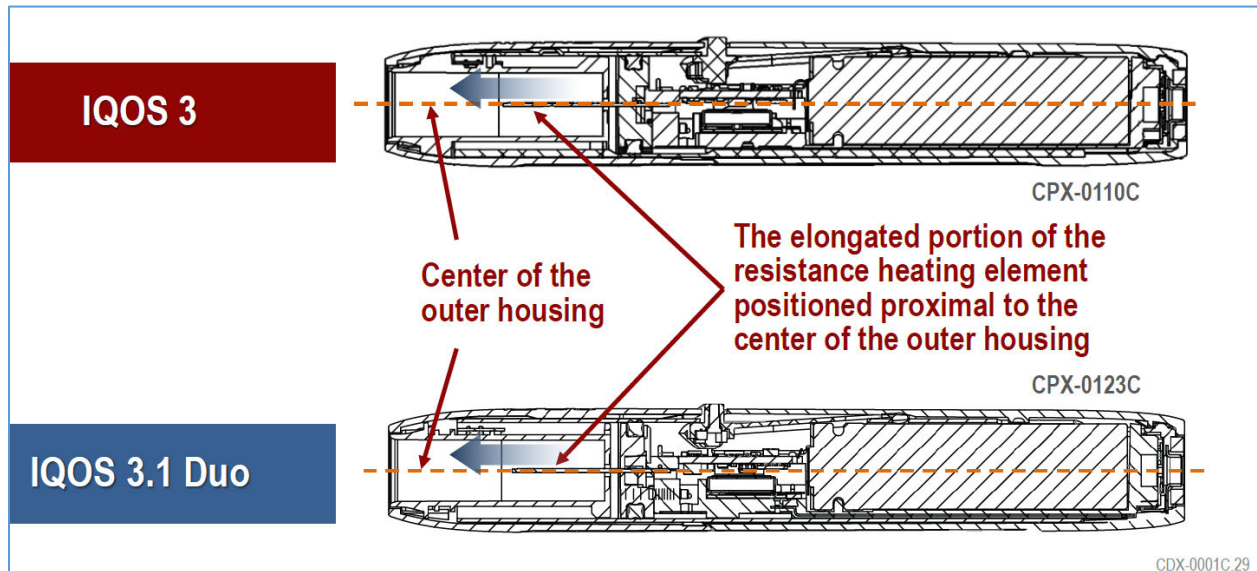


CDX-0001C.26 (illustrating JX-0053C.4).



CDX-0001C.26 (illustrating JX-0053C.4).

As illustrated below, the IQOS 3 and IQOS 3 Duo likewise include a portion of the heating element that is elongated, extends towards the mouth-end of the outer housing, and is proximal to the center of the outer housing.



CDX-0001C.29 (illustrating CPX-0110C and CPX-0123C); CX-0755C.

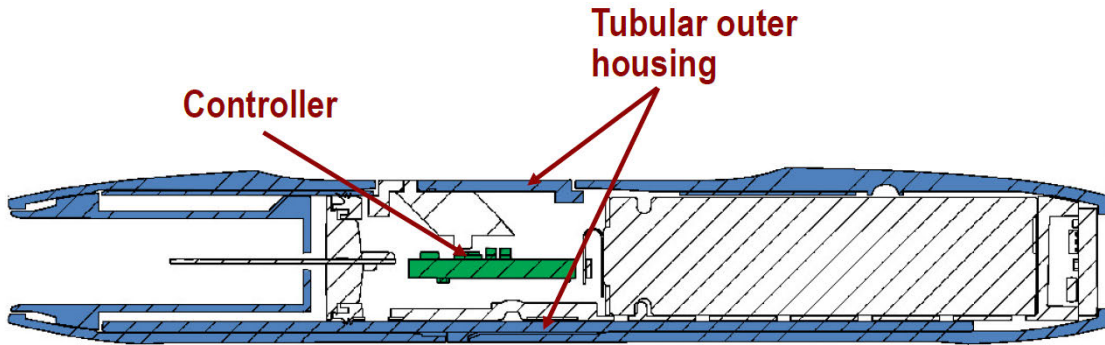
I therefore find that the Accused Products satisfy the claim 27 limitation “wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing.”

c) “a controller within the tubular outer housing”

The sixth limitation of claim 27 requires “a controller within the tubular outer housing.” Philip Morris has stipulated that the Accused Products include a controller. Stip. ¶ 76. Philip Morris’s only argument as to this limitation is whether the controller is in the “tubular outer housing,” because, as discussed above, Philip Morris contends the multiple tubes in the IQOS products do not form that housing. RRB at 26–36. I resolved the housing question against Philip

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Morris above. As shown in the illustration below, that controller is located within the claimed tubular outer housing.

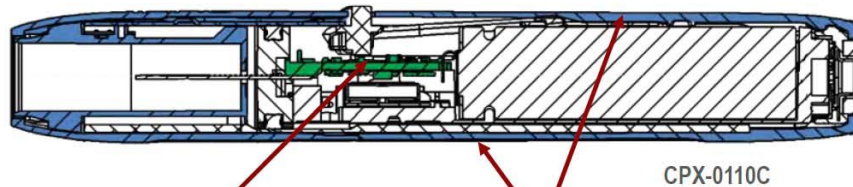


IQOS 2.4

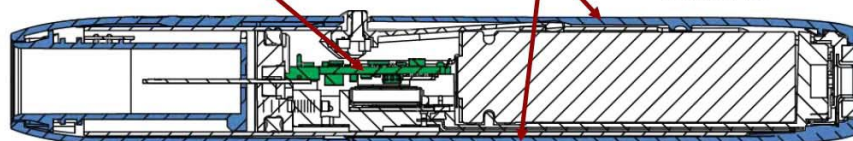
JX-0053C at 4

CDX-0001C.31

IQOS 3



IQOS 3.1 Duo



CDX-0001C.32

CDX-0001C.31–32 (annotating JX-0053C at 4, CPX-0110C, and CPX-0123C).

I therefore find that the Accused Products satisfy the claim 27 limitation “a controller within the tubular outer housing.”

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d) “a cigarette-type device removably engaged with the mouth-end of the tubular outer housing”

The seventh limitation of claim 27 requires “a cigarette-type device removably engaged with the mouth-end of the tubular outer housing.” Philip Morris has stipulated that the accused tobacco stick, or HeatStick, is a cigarette-type device. Stip. ¶ 76. Philip Morris admits that the HeatSticks are inserted into the extractor of the Accused Devices, but it contends that the extractor is not part of the claimed tubular outer housing. *See* Hrg. Tr. 1050:9–16.

For all the reasons discussed above, the claimed “tubular outer housing” in the Accused Products consists of the front housing, extractor, middle part, and rear housing. I therefore find that the Accused Products satisfy the claim 27 limitation “a cigarette-type device removably engaged with the mouth-end of the tubular outer housing.”

2. Claims 28–30

Claims 28–30 all depend from independent claim 27. ’123 patent at claims 28–30. Philip Morris does not dispute that the accused IQOS products meet the additional limitations of these dependent claims and does not assert any independent noninfringement bases with regard to these claims. Stip. ¶¶ 77–79; RIB at 41. As claim 27 of the ’123 patent has been found to be infringed, and the presence of the additional limitations of claims 28–30 in the IQOS products is undisputed, the record evidence demonstrates that dependent claims 28–30 of the ’123 patent are also infringed.

3. Indirect Infringement

Reynolds argues that respondents Philip Morris USA and Philip Morris Products induce infringement and contribute to infringement of claims 27–30 of the ’123 patent by, among other things, selling in the United States at least the IQOS 2.4 system to other direct infringers. CIB at

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41–43 (citing JX-0011C ¶¶ 111–13, 117, 128–30; CX-0030C at 16–47, 49–59; JX-0094C (Manson Dep.) at 61:3–62:18, 64:22–65:14 (explaining that Philip Morris USA imports and sells IQOS and HeatSticks for eventual sale to consumers)). Reynolds argues that those other direct infringers include, for example, customers and end users of IQOS 2.4. *Id.* (citing JX-0011C ¶¶ 128–30; CX-0030C at 16–47, 49–59; JX-0094C (Manson Dep.) at 61:3–62:18, 64:22–65:14). Reynolds also argues that because IQOS 2.4 infringes the asserted claims of the '123 patent, use of the IQOS 2.4 by customers and end users also constitutes direct infringement. *Id.*

Philip Morris's only argument against a finding of indirect infringement is that IQOS does not directly infringe the '123 patent; Philip Morris does not contest the evidence adduced by Reynolds as to the actions of Philip Morris USA and Philip Morris Products that support a finding of indirect infringement. *See* RRB at 41.

[REDACTED]

[REDACTED] CX-0025C at 112; CX-0030C at 143. In addition, Philip Morris USA and Philip Morris Products had a specific intent to infringe at least because they have been aware of Reynolds's allegations that the IQOS 2.4 infringes the '123 patent since the filing of the complaint in this investigation, which included claim charts demonstrating how IQOS 2.4 infringes the asserted claims of the '123 patent.

The evidence shows that Philip Morris USA and Philip Morris Products encourage customers and end users to use the Accused Products in an infringing manner. Philip Morris USA and Philip Morris Products distribute IQOS 2.4 Kits with a User Guide and Quick Start Guide that instruct the user to insert a Marlboro HeatStick into the IQOS 2.4 Holder. JX-0092 at 56:11–13; CX-0582C at 14; CX-0583C at 5; *see also* Stip. ¶¶ 111–13, 117, 128–30. Philip Morris USA and Philip Morris Products not only provide training and technical support to customers and end users,

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instructing them how to use the Accused Products in an infringing manner, they also advertise, market, and promote the use of the Accused Products in an infringing manner. CX-0546; CX-0583C; CX-0594C; CX-0073.

The evidence also shows that Philip Morris USA and Philip Morris Products contribute to infringement of the '123 patent by customers and end users of IQOS 2.4 by importing and selling components, such as the IQOS 2.4 holder and Marlboro HeatSticks, that contain infringing functionality and are not a staple article or commodity of commerce suitable for substantial non-infringing use. *See* Stip. ¶¶ 111–13, 117, 128–30; CX-0030C at 16–47, 49–59; JX-0094C at 61:3–62:18, 64:22–65:14. Indeed, the HeatSticks are specifically designed for use with the Accused Products and are not suitable for substantial non-infringing use. *See* Hrg. Tr. 167:19–23.

I therefore find that Reynolds has shown that Philip Morris USA and Philip Morris Products both induce and contribute to the infringement of claims 27–30 of the '123 patent with respect to the IQOS 2.4 products.

C. Technical Prong of the Domestic Industry Requirement

Reynolds argues that the VUSE Vibe practices claims 1, 4, 6, 11, 13–15, 17, 19, and 23–26 of the '123 patent. CIB at 43–47. Philip Morris has stipulated that the VUSE Vibe practices all limitations of these claims except for one part of one limitation of independent claims 1 and 15. Stip. ¶¶ 86–89. The limitation for claim 1 remaining at issue is “absorbed within an absorbent fibrous material” and the limitation for claim 15 remaining at issue is “the mixture absorbed within an absorbent wicking material.” *See* Hrg. Tr. 239:17–24, 250:17–251:8, 252:13–253:4; Stip. ¶¶ 86–89. Philip Morris failed to argue that the VUSE Vibe product does not practice the '123 patent in its post-hearing responsive brief; Reynolds’s arguments that the technical prong is

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satisfied for the '123 patent are therefore deemed unopposed. *See* RRB at 25–41; Order No. 8 at Ground Rule 14.2.

The record evidence demonstrates that the VUSE Vibe product practices the claim 1 limitation “absorbed within an absorbent fibrous material” and the claim 15 limitation “the mixture absorbed within an absorbent wicking material.” The VUSE Vibe includes a PET fiber disc and glass fiber wick that absorb and are saturated with e-liquid; the PET fiber disc and glass fiber wick are therefore the claimed “absorbent fibrous material” and “absorbent wicking material.” *See* Hrg. Tr. 240:9–12, 242:5–243:15, 252:1–3; CX-0948C.32–33. The PET fiber disc and glass fiber wick are contained within the liquid storage compartment in the VUSE Vibe. *See* Hrg. Tr. 244:17–250:11, 252:13–20; CX-0948C.32–33, .66.

I therefore find that Reynolds has demonstrated that the VUSE Vibe practices claims 1, 4, 6, 11, 13–15, 17, 19, and 23–26 of the '123 patent, thereby satisfying the technical prong of the domestic industry requirement.

D. Validity

Philip Morris argues that asserted claims 27–30 of the '123 patent are rendered obvious by U.S. Patent No. 5,249,586 (RX-0073) (hereinafter “Morgan”) in view of the general knowledge of a person of ordinary skill in the art. RIB at 25–40. Reynolds has stipulated that Morgan is prior art under 35 U.S.C. § 102(b) and that Morgan discloses each limitation of claims 27–30 except one. Stip. ¶¶ 81–83. According to Reynolds, Morgan does not disclose the claim 27 limitation “[an] elongated portion of the resistance heating element positioned proximal to the center of the outer housing.” CRB at 6.

Philip Morris does not dispute that Morgan fails to disclose “[an] elongated portion of the resistance heating element positioned proximal to the center of the outer housing,” but
instead

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argues that “it would have been obvious to use a centered heater in the Morgan device because it is undisputed that centered heaters were well known before the priority date of the ’123 patent.” RIB at 25. Philip Morris argues that “[t]he state of the art from 1992 (Counts-962, RX-0005) through 2006 (Adams, RX-00745 and Park, RX-0079) taught not just centered heaters, but also their advantages, including simplicity, reliability, reduced cost, and thermal efficiency.” RIB at 25–26. Philip Morris also argues that the ’123 patent “states that the selection of heating elements was a ‘matter of design choice’ and would be ‘readily apparent’ to a [person of ordinary skill in the art].” RIB at 35 (citing ’123 patent at 29:32–50; Hrg. Tr. 1076:2–25). Philip Morris therefore argues that “a [person of ordinary skill in the art] would have been motivated to implement Morgan using a centered heater as the predictable solution from the narrow list of known and available design choices.” RIB at 27, 35–36, 40–41.

Before discussing the merits of Philip Morris’s obviousness argument, I first address an evidentiary objection that arose during the hearing. Reynolds and Staff raised concerns that Philip Morris was advancing an obviousness combination of Morgan in view of Adams, a combination that Philip Morris allegedly told the U.S. Patent and Trademark Office it would not assert in this investigation. Hrg. Tr. 1031–1045:15. The objection was raised in view of statements made during Philip Morris’s opening statements regarding the of Morgan and Adams, as well as demonstratives disclosed by Philip Morris’s expert the evening before he was to testify. Hrg. Tr. 1033:5–16, 1043:20–1044:13. After Reynolds and Staff raised their objections, Philip Morris represented that it would not argue the obviousness combination of Morgan in view of Adams and that it would instead argue only that Morgan rendered the ’123 patent obvious in view of the knowledge of a person of ordinary skill in the art, which would include knowledge of certain references, such as Adams and others, that disclose central heaters. *See* Hrg. Tr. 1040:5–24.

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In its post-hearing rebuttal brief, Reynolds maintains its argument that Philip Morris should be precluded from relying on Morgan in combination with Adams:

Respondents attempt to defend their gamesmanship by asserting the fiction that using Adams as a secondary reference (as asserted at the [Patent Trial and Appeal Board]) is somehow distinct from using Adams as evidence of the general knowledge of a [person of ordinary skill in the art]. This is certainly not consistent with opening trial as they did by describing Adams as a “key” reference “[o]n invalidity,” and it is nothing more than sneaking an argument through the back door that Respondents expressly and strategically abandoned to try to save their case at the [Patent Trial and Appeal Board] from *Fintiv* denial.

CRB at 29–30; *see also id.* at 26–30.

With respect to Reynolds’s continuing objection, Staff takes the position that

Respondents[’] obviousness arguments here do not contravene Respondents’ representations to the U.S. Patent and Trademark Office because ultimately Respondents did not offer evidence that the claims of the ’123 Patent are obvious in view of the combination of Morgan and Adams. Rather, Respondents only advance the obviousness position that the claims were rendered obvious by Morgan in view of the knowledge of a [person of ordinary skill in the art] consistent with their invalidity contentions and the expert reports in this Investigation.

SIB at 72 n.5.

Having considered the parties’ positions, I hereby deny Reynolds’s request that Philip Morris be precluded from relying on the Morgan reference in view of the knowledge of a person of ordinary skill in the art. I now turn to the substantive merits of Philip Morris’s obviousness case.

Philip Morris’s obviousness argument hinges upon passages from the ’123 patent stating that “[s]election of battery and resistance heating elements can vary, and can be a matter of design choice” and “[s]election of the power source and resistance heating elements can be a matter of design choice.” *See* RIB at 35 (citing ’123 patent at 29:32–50). The ’123 patent does not state,

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however, that the arrangement and positioning of those resistance heating elements are matters of design choice. Instead, the design choices described in the '123 patent relate to the amount of resistance in the resistance heating elements and the voltage and current provided by the power sources. *See* Hrg. Tr. 1508:22–1510:1. This passage does not support Philip Morris's argument, that "a [person of ordinary skill in the art] would have been motivated to implement Morgan using a centered heater as the predictable solution from the narrow list of known and available design choices." *See* RIB at 27, 35–36, 40–41.

In addition, Morgan itself shows that it would not have been obvious to modify Morgan to include a centered heater. Morgan teaches the benefit of having multiple heaters, circumferentially-spaced away from the center, such that each heating element can be heated individually, in sequence, and so that no portion of the tobacco would be heated more than once. *See* Morgan at 5:18–25, 5:61–65. Specifically, Morgan teaches that the multiple heaters permit "each respective heater 23 to provide an individual charge of tobacco flavor substance." Morgan at 5:61–65. Morgan also teaches that its placement of the heaters circumferentially around the device away from the center—"distributed substantially uniformly around the circumference of cavity"—serves to accomplish the goal of avoiding "reheating and the production of undesired compounds and off tastes." Morgan at 5:18–25. In view of these teachings, a person of ordinary skill in the art would not have been motivated to modify Morgan to include a centered heater.

This lack of motivation to combine is further described when Morgan recognizes that placing the heating elements away from the center is an inefficient use of the tobacco because the tobacco "in the center" is "never heated to deliver flavor to the smoker." Morgan at 7:1–5. Rather than solving this problem by including a heating element that was proximal to the center as Philip Morris's hypothetical person of ordinary skill would have done, Morgan instead maintains the

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heater elements spaced away from the center and solves the problem in a different way. Morgan removes the tobacco from the center and puts in its place a non-tobacco “fiber bundle” surrounded by a layer of metallic foil with a slurry of tobacco coated onto it. Morgan at 6:63–7:10.

Therefore, for the reasons set forth above, I find that Philip Morris has failed to show by clear and convincing evidence that Morgan in view of the general knowledge of a person of ordinary skill in the art renders obvious claims 27–30 of the ’123 patent.

VI. THE ’915 PATENT

A. Claim Construction

I construed the disputed terms “a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source” and “electrical energy source” as part of the claim construction order issued as Order No. 28. *See* CC Order at 10–18. I hereby incorporate the discussion of those terms on pages 10–18 of Order No. 28 as part of this initial determination.

B. Infringement

Reynolds asserts claims 1, 2, 3, and 5 of the ’915 patent against Philip Morris. *See* CIB at 56. As discussed further below, the record evidence demonstrates that the Accused Products infringe these claims.

1. Claim 1

Philip Morris has stipulated that the Accused Products satisfy some limitations of claim 1 of the ’915 patent. Stip. ¶ 59. The limitations that remain in dispute are emphasized below:

1. A reusable control unit for use with a disposable smoking article, the reusable control unit comprising a control housing including:

a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source that includes a projection extending outwardly therefrom and that

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includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member; and

a control unit section that houses a power source, a switching component that actuates flow of electrical current from the electrical energy source to the electrical heating member, and a flow regulating component that regulates a previously initiated current flow from the electrical energy source to the electrical heating member, *wherein the component that forms an electrical connection with the electrical contacts is located on the projection.*

Id.

As discussed in further detail below, the record evidence demonstrates that the Accused Products satisfy all limitations and thus infringe claim 1.

a) “a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source”

Claim 1 requires “a receiving end” and “a control unit section.” As illustrated below, the Accused Products each have a cap (the claimed “receiving end”) that receives a HeatStick (the claimed “disposable smoking article”) and couples the HeatStick with the middle part and rear housing (together, the claimed “control unit section”). *See* Hrg. Tr. 195:11–196:18. Because HeatSticks cannot be reused, they are the consumable element of the Accused Products and are therefore the claimed “disposable smoking article.” *See* Hrg. Tr. 198:4–12.

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CDX-0001C.40; CX-0939C at 21; JX-0064C at 50.

The figures below illustrate how the engaging end of the HeatStick is inserted into the receiving end of the holder. *See Hrg. Tr. 197:2–20.*



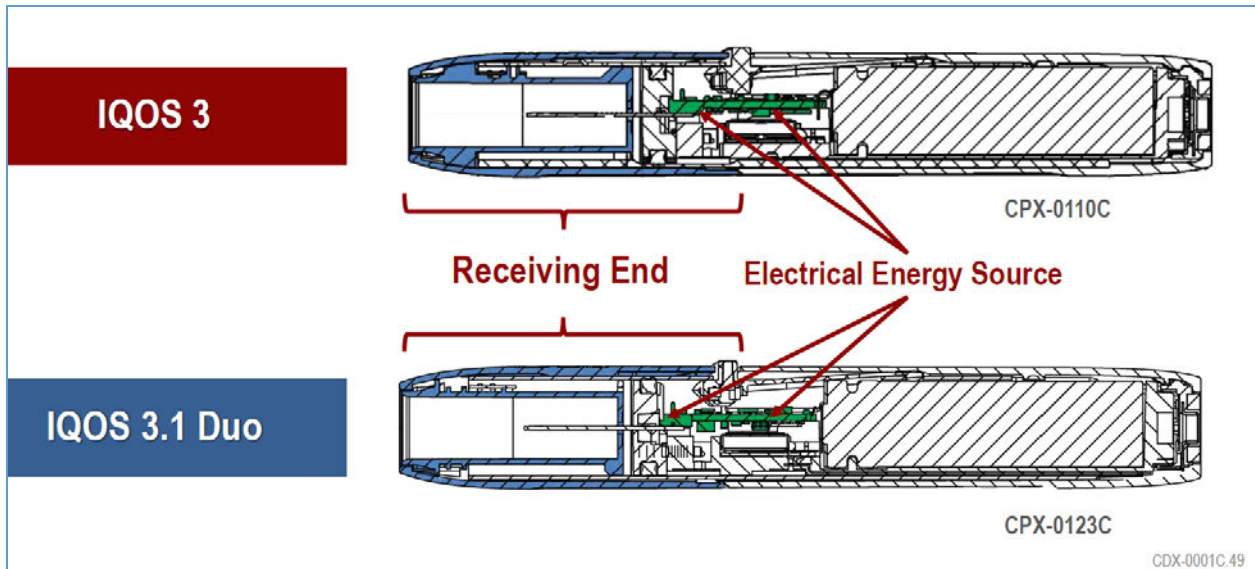
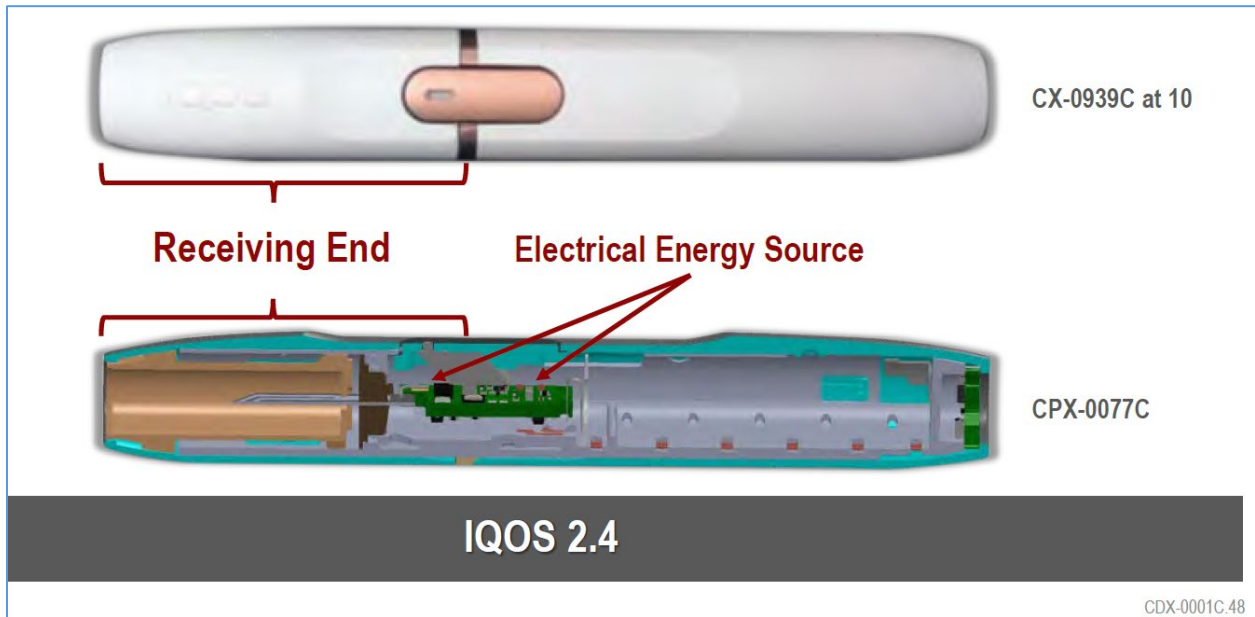
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CDX-0001C at 41–42; CX-0572C at 3; JX-0064C at 47; CX-0073 at 32.

As shown in the illustrations below, the Accused Products include an electrical energy source in the form of a printed circuit board assembly (annotated green) including the printed circuit board, electrical components, and heater wires.² The printed circuit board assembly is partially within the receiving end of the Accused Products, thus satisfying the limitation “having an electrical energy source.” *See* Hrg. Tr. 200:1–201:9; CPX-0077C.

² The structure and function of the printed circuit board assembly is discussed in more detail in the next section.

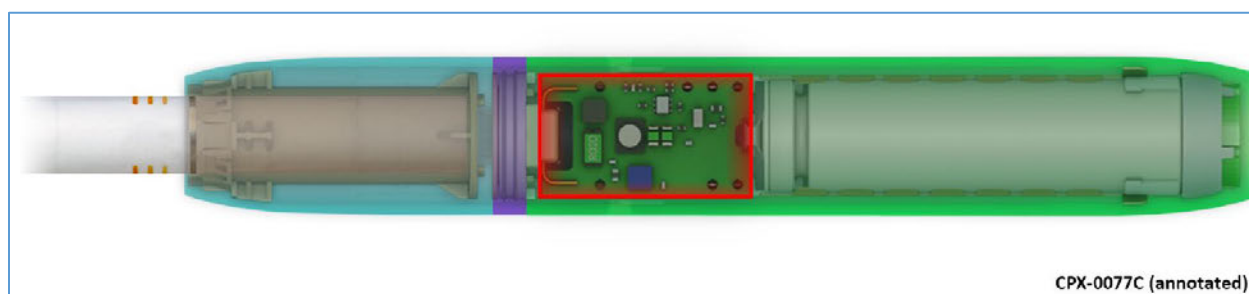


CDX-0001C at 48–49; CX-0939C; CPX-0077C; CX-0755C; CPX-0110C; CPX-0123C.

Philip Morris contends that in the Accused Devices the boundary between the “receiving end” and “control unit section” is not located between the front and rear housings (shown in figure below), but rather at the location of the heater overmold. *See* RRB at 42–55. In particular, Philip Morris’s expert Mr. Flolid takes the position that the receiving end of the Accused Products stops at an isolation barrier at the end of the heating chamber, arguing that no part of the HeatStick can

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be received by any part of the alleged control housing that extends beyond this point. *See* RRB at 42–55; Hrg. Tr. 817:15–818:22, 917:10–918:20. Philip Morris therefore argues that that the portion of the device extending beyond the heating chamber cannot be part of the “receiving end.” To illustrate this argument, Mr. Flolid provided the slide below showing that the heating chamber (annotated aqua) and the electronics chamber (annotated green) are separated by the isolation barrier (annotated purple). Hrg. Tr. 817:15–818:22.



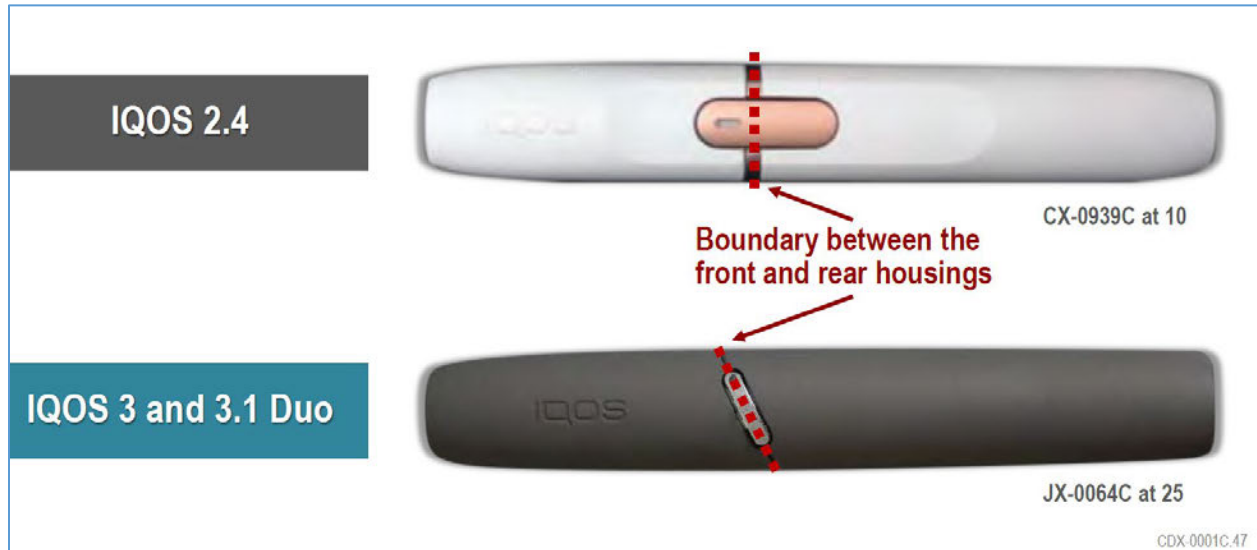
RDX-0003C at 40.

This argument raised by Philip Morris and its expert Mr. Flolid is not persuasive. The term “receiving end” is a term of orientation; it is the end of the device that receives a disposable smoking article and has an electrical energy source. As oriented in Mr. Flolid’s diagram, the end of the IQOS device that receives the HeatStick and has the electrical energy source is the left end. The presence of additional structures neither required nor prohibited by the claims, such as an “isolation barrier” or an aerosol-retaining “heating chamber,” do not negate the fact that the end of the device that receives the HeatStick is the “receiving end.” *Mannesmann Demag Corp. v. Engineered Metal Prods.*, 793 F.2d 1279, 1282–83 (Fed. Cir. 1986) (“The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure.”).

The patent claim does not delineate a boundary between the “receiving end” and any other structure. But even if the claim were to have such a requirement, the evidence demonstrates that

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the “receiving end” in the IQOS products extends at least to boundary between the front and rear housings, as illustrated below.



CDX-0001C.47.

The record evidence demonstrates that the “cap” of the Accused Devices, which comprises the combined front housing and extractor, receives the disposable HeatStick. *See* Hrg. Tr. 197:2–20, 200:1–201:9. Reynolds’s expert Mr. Alarcon testified: “[Users] pull on the cap, which includes the front housing and the extractor, and that disengages the HeatStick from the holder.” Hrg. Tr. 190:22–25. Additionally, the Quick Start guides for the Accused Products illustrate the “cap” as the end of the device that encompasses the front housing and extractor and that receives the disposable HeatStick. CX-0594C at 4; CX-0583C at 6; CX-0448 at 6; *see* Hrg. Tr. 424:7–430:3. The more detailed User Guide also refers to the front housing and extractor collectively as the “cap” and instructs that the cap end of the device receives the disposable HeatStick. *See* CX-0451 at 14, 16, 19; CX-0450 at 9, 11, 14. An internal Philip Morris document further illustrates the integral nature of the front housing and the extractor. CX-0605C at 11. That document shows a cross-sectional view of the IQOS device and labels the front housing as the

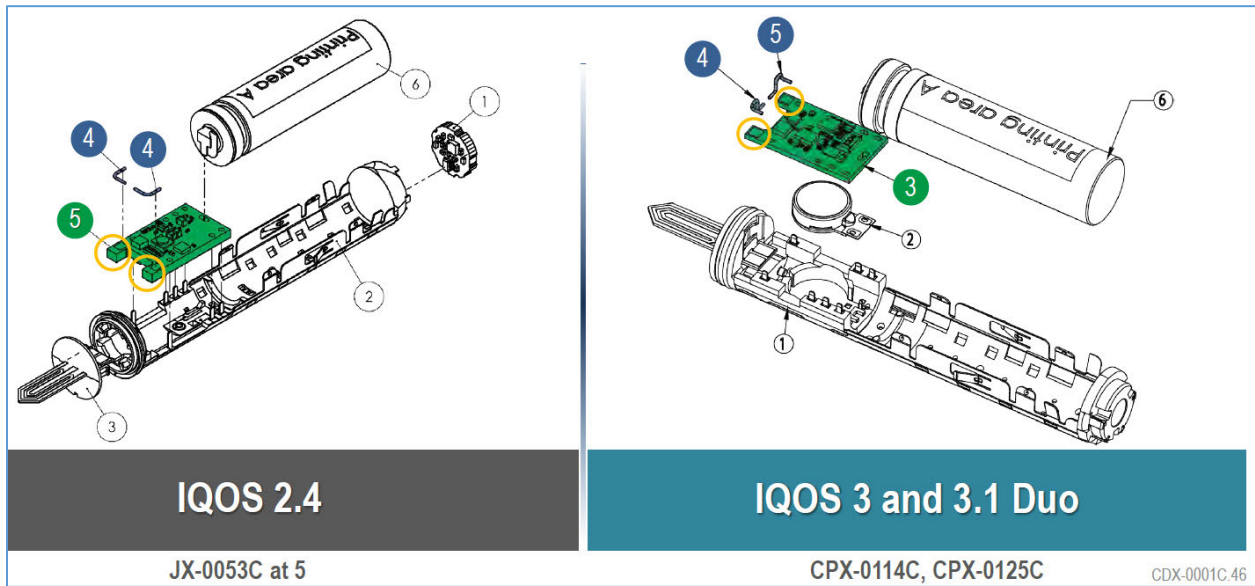
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“Device Outer casing wall” and the extractor as the “Device Inner casing wall.” *Id.*; *see* Hrg. Tr. 424:7–430:3. The figure illustrates this structure receiving the disposable HeatStick. CX-0605C at 11.

For the reasons discussed above, I find that the Accused Products satisfy the claim 1 limitation “a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source.”

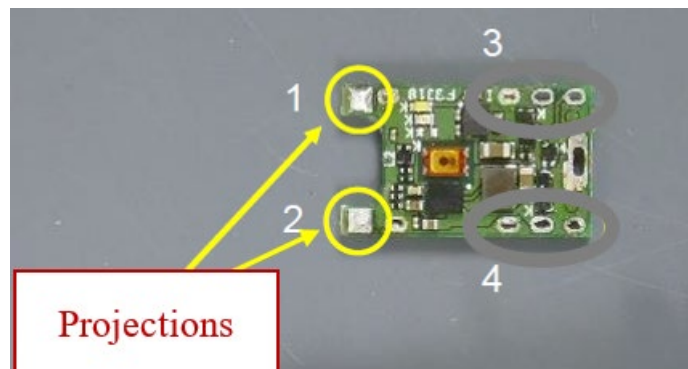
b) “an electrical energy source that includes a projection extending outwardly therefrom and that includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member . . . wherein the component that forms an electrical connection with the electrical contacts is located on the projection”

As shown in the figures below, the Accused Products have an electrical energy source in the form of a printed circuit board assembly (annotated green). The assembly includes the printed circuit board, electrical components, and heater wires. *See* Hrg. Tr. 199:3–18. The assembly connects at one end to the battery and connects at the other end to the electrical resistance heater. *See* JX-0090C at 161:2–9, 167:17–25; Hrg. Tr. 441:1–13. The assembly provides electrical current and energy from the battery to the electrical resistance heater. *See* JX-0090C at 57:22–25; JX-0090C at 82:20–83:3; CX-0592C at 7–9. Two projections (circled in orange) extend outwardly from the assembly. *See* Hrg. Tr. 199:3–18.



CDX-0001C at 46.

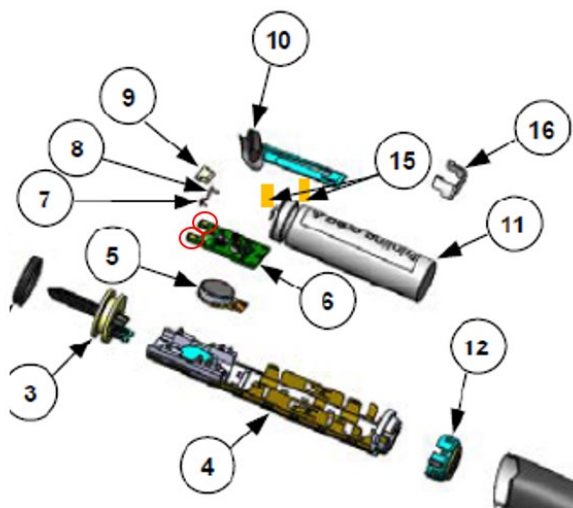
A teardown report of the IQOS 3 shown below demonstrates that printed circuit board assemblies in that product include two projections extending outwardly, and that each projection includes a solder pad for connecting to the heater wires. *See Hrg. Tr. 432:6–433:16.*



JX-0064C at 58. This teardown report states that “wires bridge between the [printed circuit board] and the base of the heater blade,” and Reynolds’s expert Mr. Alarcon testified that those “wires are soldered to connect the projections to the . . . corresponding contacts on the heater blade” to “provide the electrical connection between the heating element and the [printed circuit board].” JX-0064C at 57–58; Hrg. Tr. 432:6–433:16.

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Similarly, a portion of a document submitted to the FDA describing the IQOS 3 demonstrates that the projections (circled in red below) of the printed circuit board assembly, which is shown below as item 6, include left and right heater wire mounts, which are shown below as items 7 and 8 respectively. CX-0591C at 7; *see* Hrg. Tr. 433:17–435:6. The document also provides: “Both heater wires (heater wire surface mount left and right) are 3 mm wide and long metal parts, which connect the heating element (overmolded heater seal) to the electronic controls on Heater PCB.” CX-0591C at 15. Mr. Alarcon testified that this disclosure also demonstrates that the heater wires provide for transmission of electrical current from the printed circuit board assembly to the heater blade. Hrg. Tr. 434:8–435:6.



CX-0591C at 7.

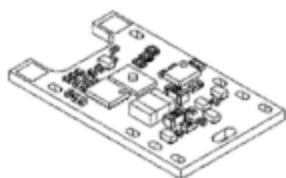


Figure 7: Heater PCB



Figure 15: Heater wire surface mount left (a) and right (b)

CX-0591C at 10–15.

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Mr. Alarcon also testified that, in the Accused Products, electrical current is transmitted from the battery through the printed circuit board to heater wires and the heater blade. Hrg. Tr. 435:7–437:5, 440:5–441:13; CDX-0001C.46; JX-0053C; CPX-0114C; CPX-0125C. He testified these structures “allow for the transmission of electrical current from the battery to the heating member in the accused IQOS devices.” Hrg. Tr. 435:7–437:5.

This is additionally confirmed by the teardown report of the IQOS 3, which Mr. Alarcon testified indicates that “electrical current is flowing from the power source of the battery . . . through the PCB, which is on the microcontroller, and it’s involved in controlling the current that’s passed to the heater.” Hrg. Tr. 437:6-438:7; CX-939C; CX-039C at 34.

Based on the record evidence described above, the printed circuit board assembly, with its electrical components and heater wires, “provides for transmission of electrical current from the power source to the heating member.” I therefore find that the Accused Products satisfy the “electrical energy source that includes a projection extending outwardly therefrom and that includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member . . . wherein the component that forms an electrical connection with the electrical contacts is located on the projection” limitation of claim 1 of the ’915 patent.

Philip Morris argues that the Accused Products do not include the claimed “electrical energy source” because no “wiring or other contact connected to the heating blade *is inserted into* any part of the [printed circuit board] or heater wires.” See RRB at 61 (emphasis added); *see also id.* at 55–62. Philip Morris notes that at the claim construction stage of the investigation I construed an “electrical energy source” to mean a “receptacle that provides for transmission of electrical current from the power source to the heating member.” CC Order at 18. Philip Morris

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maintains that the word “receptacle” in my construction requires wiring or an electrical contact to be “inserted” into something else. *See* RRB at 61.

I find Philip Morris’s argument lacks merit. At the claim construction stage of this investigation, Philip Morris chose to rest on an assertion that the phrase “electrical energy source” was indefinite. *See* CC Order at 16–18. I rejected the indefiniteness argument, and the only remaining construction urged on the record at that time is the one I adopted, which used the word receptacle. *Id.* at 18. The adopted construction was consistent with the patent specification, which teaches that “the electrical energy source may function as a more literal receptacle in that the contacts are not permanently inserted therein but only make an electrical connection with the electrical energy source when the cartridge 300 is inserted into the receiving chamber 210 sufficiently so that the contacts are moved into electrical connection with the electrical energy source.” ’915 patent at 23:33–55. The specification thus does not limit the electrical energy source to a configuration requiring something be inserted into something else. Instead, the specification describes more generally an “electrical connection with the electrical energy source” and provides a number of exemplary embodiments. *See, e.g., id.* at 23:49–55 (“[T]he projection 225 can function as an extension of the electrical energy source in that electrical leads 222 (as seen in FIG. 9) are present on the projection, and the electrical heating member 400 receives electrical energy from the electrical energy source only when the electrical heating member (or a portion thereof) makes contact with the electrical leads.”). Thus, the term “receptacle” in my construction must be, and is, consistent with the manner in which the inventors used the term. As the inventors used the term, a receptacle may “only make an electrical connection”; it need not have contacts “inserted therein.” *Id.*

In any event, a tribunal may engage in “rolling claim construction” and revisit or alter its interpretation of the claim terms “as its understanding of the technology evolves.” *Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002). To the extent my earlier construction

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did not resolve the dispute Philip Morris now raises about a receptacle and about inserted connectors, I reiterate that the term in the claim is “electrical energy source,” not “receptacle.” It is the words of the claim itself that matter; “the name of the game is the claim.” *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998) (citing Giles Sutherland Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 Int’l Rev. Indus. Prop. & Copyright L. 497, 499 (1990)). The language of claim 1 does not require something be inserted into the claimed electrical energy source, and nothing in the specification limits the electrical energy source to a structure into which connectors are inserted.

Philip Morris’s argument also relies on a declaration Reynolds’s expert Mr. Alarcon submitted (CX-0435) at the *Markman* hearing stage of this investigation. Mr. Alarcon’s declaration is evidence extrinsic to the ’915 patent file wrapper, and I did not rely on it when construing the term “electrical energy source” in my claim construction order because the intrinsic evidence amply informed the correct construction of the term. CC Order at 16–18; *see Phillips*, 415 F.3d at 1317. I also decline to use Mr. Alarcon’s declaration now to further “construe” my construction, as the intrinsic evidence does not suggest that the claimed invention requires “wiring or other contact connected to the heating blade” to be “inserted into any part of the [printed circuit board] or heater wires.”

In sum, for the reasons discussed above, I find that the Accused Products satisfy the claim 1 limitation “an electrical energy source that includes a projection extending outwardly therefrom and that includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member . . . wherein the component that forms an electrical connection with the electrical contacts is located on the projection.”

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2. Claims 2, 3, and 5

Claims 2, 3, and 5 all depend from independent claim 1. '915 patent at claims 2, 3, and 5. Philip Morris does not dispute that the accused IQOS products meet the additional limitations of dependent claims 2 and 5. Stip. ¶ 59.

The additional limitation of claim 3 is “wherein the electrical energy source includes a capacitor.” '123 patent at claim 3. The evidence shows that the Accused Products each include a capacitor located on the printed circuit board, which is part of the claimed electrical energy source. CX-600C; CX-848C; CX-863C; *see* Hrg. Tr. 209:2–210:20; CDX-0001C.61–62. The Accused Products therefore satisfy the additional limitation of claim 3.

As claim 1 of the '915 patent was shown to be infringed in the discussion above, the undisputed record evidence demonstrates that dependent claims 2, 3, and 5 of the '915 patent are also infringed.

3. Indirect Infringement

Reynolds alleges that respondents Philip Morris USA and Philip Morris Products induce infringement and contribute to infringement of claims 1–3 and 5 of the '915 patent. CIB at 70.

[REDACTED]

[REDACTED]

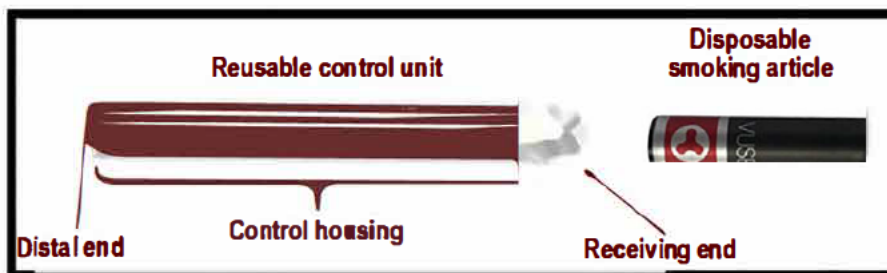
CX-0025C at 112; CX-0030C at 143.

For the same reasons discussed in Section V.B.3 above, the evidence shows that Philip Morris USA and Philip Morris Products indirectly infringe claims 1–3 and 5 of the '915 patent with respect to the IQOS 2.4 device.

C. Technical Prong of the Domestic Industry Requirement

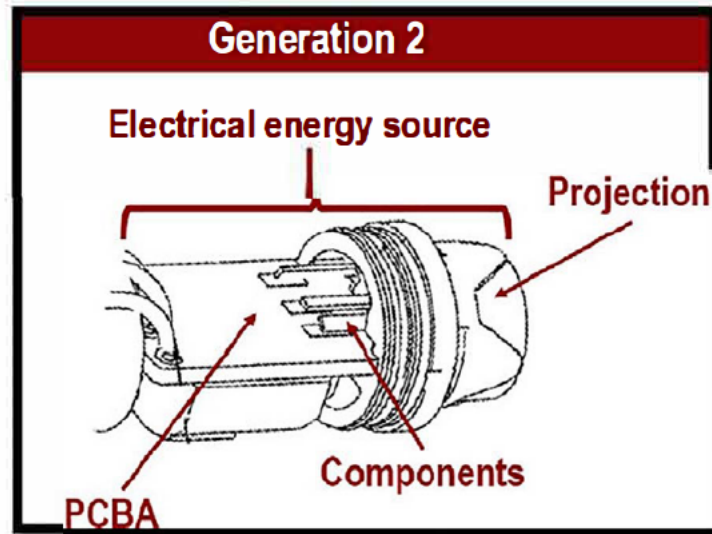
Reynolds argues that the VUSE Solo G1 and G2 practice claims 1 and 3 of the '915 patent. CIB at 70–75. Philip Morris has stipulated that Solo G1 and G2 practice all limitations of these claims except whether Solo G1 and G2 have “a receiving end for receiving an engaging end of the disposable smoking article and having at least a portion of an electrical energy source” as recited in claim 1. Stip. ¶ 70. Philip Morris’s only technical prong argument for the '915 patent is that “the un rebutted evidence establishes that the electrical energy source in Complainants’ Vuse Solo Gen. 1 and 2 DI products are indistinguishable from the electrical energy source in the [alleged prior art] Accord devices.” RRB at 62. But, to paraphrase the noninfringement law, a technical prong defense “cannot be proved by comparing [the domestic industry] product to the prior art.” *See Zenith Elecs. Corp. v. PDI Commc’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008).

As shown below, the record evidence demonstrates the VUSE Solo G1 and G2 have “a receiving end for receiving an engaging end of the disposable smoking article and having at least a portion of an electrical energy source” as recited in claim 1. The VUSE Solo G1 and G2 each have a metal tube, which comprises the control housing recited in the preamble to claim 1, and the end of the metal tube that connects to the engaging end of the cartridge through the black connector (shown below) is the receiving end. *See Hrg. Tr.* 254:25–255:6.

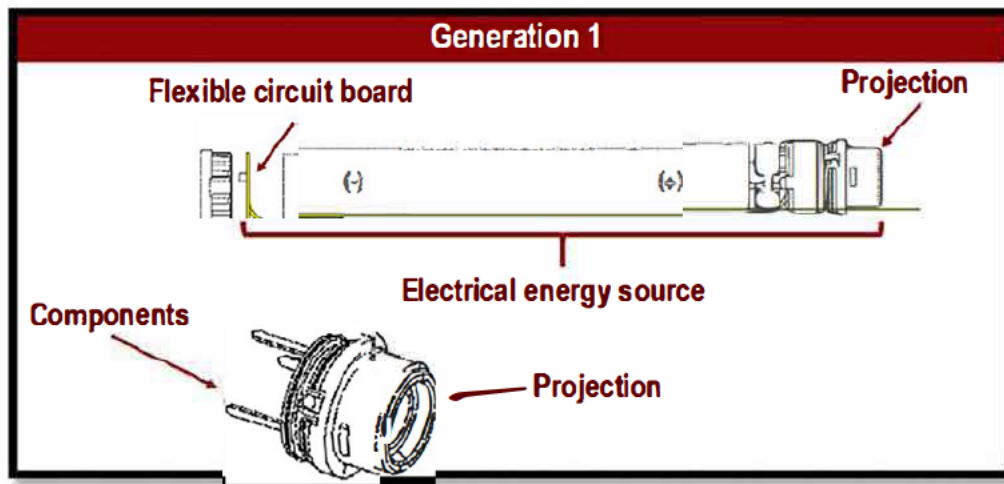


CX-0947C.12; CDX-0001C.1 12.

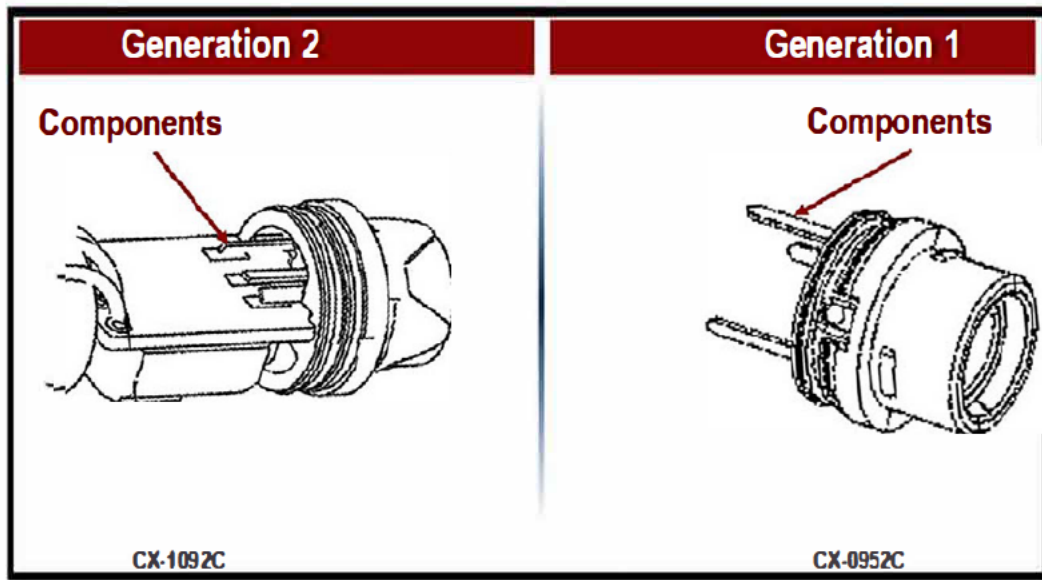
As illustrated in the figures below, the claimed electrical energy source comprises a circuit board, electrical pins, and the black connector. *See Hrg. Tr. 255:18 256:25.*



CX-1092C.2; CDX-0001C.114.



CX-0952C; CDX-0001C.115.



CDX 0001C.116.

At the hearing, Reynolds's expert Mr. Alarcon demonstrated how at least a portion of the electrical energy source is within the receiving end. Hrg. Tr. 257:1 16.

Philip Morris failed to explain in its post hearing responsive brief why the foregoing evidence fails to demonstrate a “receiving end” and “electrical energy source” in the VUSE Solo G1 and G2. *See* RRB at 62. Reynolds's technical prong showing for the '915 patent is therefore deemed unopposed. Order No. 8 at Ground Rule 14.2. The unrebutted record evidence demonstrates that the VUSE Solo G1 and G2 practice claims 1 and 3 of the '915 patent, thereby satisfying the technical prong of the domestic industry requirement.

D. Validity

Philip Morris alleges that claims 1 3 and 5 of the '915 patent are anticipated or rendered obvious by two devices alleged to be prior art, the Accord JLI and the Accord K. RIB at 44 -66. Philip Morris also alleges that the term “electrical energy source” is indefinite, thereby rendering claims 1 and 3 invalid. *See id.* at 66.

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Philip Morris's invalidity arguments are addressed in turn below.

1. The Accord Devices

a) Accord JLI

The Accord JLI is an electronic heat-not-burn tobacco device developed by Philip Morris. *See* Hrg. Tr. 774:3–775:18. The record evidence establishes that the Accord JLI device is prior art under 35 U.S.C. §§ 102(a) and (b) (pre-AIA). In late 2002, over eight years before the August 9, 2011, priority date for the '915 patent, the Accord JLI was offered for sale, sold, and publicly used in the United States through two principal channels: (1) retail sales and (2) an upgrade program offered to existing Accord customers. Hrg. Tr. 775:22–776:15. Retail sales took place at approximately 150 stores around Richmond, Virginia. Hrg. Tr. 776:1–15, 777:5–12; JX-0058 at -8837; JX-0105C (Burton Dep.) at 37:10–39:14. By June 2003, 57 Accord JLI kits had been sold out of these stores. JX-0045 at -2586; Hrg. Tr. 778:21–779:15. Reynolds does not dispute that the Accord JLI device is prior art to the '915 patent. *See* CRB at 31–48.

The central dispute about the Accord prior art is the “electrical energy source.” Philip Morris argues that the Accord JLI's heater printed circuit board (or “horizontal printed circuit board”) and heater connector with socket contacts satisfies the “electrical energy source” limitation of claim 1. *See* RIB at 55–56. Philip Morris also argues that the heater connector is the claimed projection and that it extends outwardly from the heater/horizontal printed circuit board. *See id.* at 51–53, 55–56. But the record evidence fails to support Philip Morris's arguments.

Philip Morris introduced into evidence a photograph (reproduced below) of the Accord JLI with its battery removed; the photograph allegedly shows the back side of the heater/horizontal printed circuit board. *See* Hrg. Tr. 785:19–25.



RX-0030. This photograph fails to show a heater connector as a projection extending outwardly from the printed circuit board.

Philip Morris's expert Mr. Flolid testified that "the back side of the [heater/horizontal] board" is visible in the photograph and asserted, without corroborating evidence, that "the heater connector's on the other side." Hrg. Tr. 923:17–20. Mr. Flolid pointed to solder joints on the printed circuit board and implied that the heater connector must therefore be attached to the non-visible side of the printed circuit board, but such an inference based on uncorroborated testimony does not constitute clear and convincing evidence. Even though the photograph may show solder joints, it does not show that the solder joints are connected to leads from the heater connector or that the heater connector projects outwardly from the printed circuit board.

Philip Morris adduced another photograph of the Accord JLK in support of its invalidity argument, but this photograph also fails to show that the Accord JLK satisfies the "electrical energy

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source” limitation. This second photograph (reproduced below) shows only a portion of the heater connector and does not show the alleged heater/horizontal printed circuit board.



RX-0033. The photograph fails to show what is on the other side of the heater connector and thus fails to support Philip Morris’s assertion that the heater connector is attached to and/or projects from the heater/horizontal printed circuit board.

Perhaps in view of the lack of evidence showing the internal structure of the Accord JLI, Philip Morris attempts to bootstrap an invalidity case by asserting that the Accord JLI and Accord K are materially the same and that documents showing the internal structure of the Accord K can be relied upon for factual findings about the internal structure of the Accord JLI. *See, e.g.*, RIB at 49 (citing Hrg. Tr. 800:23–801:2, 800:23–801:2; RX-0752C (Flolid Witness Stmt.) at Q27–28, Q40 (“[T]he relevant aspects of the JLI and K are materially the same for purposes of my analysis.”). To support this assertion Philip Morris relies on evidence provided by its former employee Doug Burton, who testified that the Accord JLI and Accord K “are very much

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alike because the configuration is essentially the same, parts are in the same place.” Hrg. Tr. 800:23–801:2.

Mr. Burton’s testimony as to the alleged similarities between the Accord JLI and Accord K is vague and uncorroborated. He failed to provide clear and convincing evidence that the heater connector and heater/horizontal printed circuit board in Accord JLI and Accord K are the same. The validity analysis involves a consideration of how these components are electrically connected, and Mr. Burton’s testimony does not address these internal connections. *Cf. Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (unless the prior art shows every element of the claim “*arranged or combined in the same way as recited in the claim*,” it cannot be said to prove prior invention of the thing claimed” (emphasis added)).

For the reasons set forth above, I find that Philip Morris has failed to show by clear and convincing evidence that the Accord JLI satisfies the ’915 claim limitation “electrical energy source.” Philip Morris has thus failed to demonstrate that the Accord JLI anticipates claims 1–3 of the ’915 patent.

Philip Morris has also failed to demonstrate that the Accord JLI renders obvious claim 5 of the ’915 patent for similar and additional reasons. First, the Accord JLI does not disclose the claimed “electrical energy source,” and Philip Morris has not explained how it would have been obvious to bridge “the differences between the claimed invention and the prior art” from evidence lacking that claimed feature. *See* 35 U.S.C. § 103. Additionally, even if the Accord JLI did disclose the claimed “electrical energy source,” there is no evidence or explanation showing that it would have been obvious to combine a structure having all of the features of claim 1 with a pushbutton. *See* RIB at 65–66 (arguing that adding a pushbutton to the Accord JLI would have

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been obvious). *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (rejecting a “conclusory” obviousness argument “untethered to any supporting evidence”).

b) Accord K

The Accord K is an electronic heat-not-burn tobacco device developed by Philip Morris. *See* Hrg. Tr. 774:3–775:18. Philip Morris alleges that the Accord K anticipates claims 1–3 of the ’915 patent and renders obvious claim 5 of the ’915 patent. *See* RIB at 41–65. Reynolds disputes that the Accord K is prior art to the ’915 patent, which has a priority date of August 9, 2011. *See* CRB at 31–35.

Doug Burton, a former employee of respondents Philip Morris USA and Altria Client Services LLC, testified at the hearing regarding his work on the Accord K. *See id.* Mr. Burton testified that Philip Morris USA held a series of consumer research events in Miami, Florida, to demonstrate and distribute the Accord K in the late-2005 to early-2006 timeframe. Hrg. Tr. 788:19–789:8. A moderator purportedly demonstrated the Accord K, which at the time was marketed as the “Parliament NXT Smoking System,” to event attendees. RX-0699.2; Hrg. Tr. 790:7–18, 789:19–22; JX-0046 at 6, 12. Attendees purportedly “were invited to participate in extended trial research for approximately 1 week and were given [an Accord K] kit.” RX-0699.2. Accord K kits purportedly were distributed to over 600 attendees, and recipients purportedly “were encouraged to use it as if they had purchased it . . . and show it off to their friends to [] hopefully generate interest around the product.” JX-0046 at 6; Hrg. Tr. 789:23–790:1, 790:19-25; CX-2026C at -8979.

Mr. Burton also testified:

[T]here was only one Accord K. We didn’t build a special one for Miami. We didn’t build a special one for Felix at [Philip Morris International Inc.] to look at. And [] by purpose of its existence, the technical file [RX-0064]

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has to describe what we intended to sell and in this case what we distributed for consumers [re]search.

Hrg. Tr. 807:7–12.

Although Mr. Burton’s testimony might establish that devices known as Accord K were in public use in Miami by no later than 2006, Philip Morris has failed to show that the Accord K devices used in Miami are the same Accord K devices described in the technical documents that Philip Morris uses to support its invalidity arguments. Indeed, Mr. Burton himself admitted: “[I]f you look at those documents, you will not see written anywhere this is the one that you’re going to take to Miami.” Hrg. Tr. 807:22–24.

“The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony.” *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999). The Supreme Court recognized over one hundred years ago that “[w]itnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information.” *Washburn & Moen Mfg. Co. v. Beat ’Em All Barbed-Wire Co.*, 143 U.S. 275, 284 (1892).

“Mere testimony concerning invalidating activities is received with further skepticism because such activities are normally documented by tangible evidence such as devices, schematics, or other materials that typically accompany the inventive process.” *Finnigan Corp.*, 180 F.3d at 1366–67; *see also Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1373 (Fed. Cir. 1998) (a “paper trail of virtually all commercial activity” is now “ubiquitous,” such that it is “rare indeed that some physical record (e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other

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contemporaneous record) does not exist.”); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 60 (1923) (testimony of prior public use “falls short of being enough to overcome the presumption of novelty from the granting of the patent” when “there is not a single written record, letter or specification of prior date to [the patentee's] application that discloses any such discovery by anyone . . .”).

Mr. Burton’s testimony is no more corroborated than testimony found insufficient in the cases above. I find that Philip Morris has failed to demonstrate, by clear and convincing evidence, that the Accord K is prior art to the ’915 patent. *See Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1361 (Fed. Cir. 2001) (an accused infringer bears the burden by proving by clear and convincing evidence that a reference is prior art). For this reason, Philip Morris has failed to demonstrate that the Accord K anticipates claims 1–3 or renders obvious claim 5 of the ’915 patent.

2. Indefiniteness

Philip Morris argues that the claim term “electrical energy source,” which is recited in asserted claims 1 and 3 of the ’915 patent, is indefinite. *See* RIB at 66. This argument is a renewal of the argument Philip Morris raised at the *Markman* claim construction hearing. *See, e.g.*, CC Order at 17–18. Philip Morris’s indefiniteness argument is denied at least for the same reasons set forth in my claim construction order. Accordingly, Respondents have not shown the claim to be indefinite. *Nautilus*, 134 S. Ct. at 2129.

VII. THE ’238 PATENT

A. Claim Construction

I construed the disputed terms “shell,” “pressure channel,” “air inlet channel,” and “the first end of the pressure channel is spatially separated from the air inlet channel relative to the

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longitudinal axis of the coupler” as part of the claim construction order issued as Order No. 28. See CC Order at 19–31. I hereby incorporate the discussion of those terms on pages 19–31 of Order No. 28 as part of this initial determination.

B. Infringement

Reynolds asserts claim 19 of the ’238 patent against Philip Morris. See CIB at 76. As discussed further below, the record evidence demonstrates that the Accused Products do not infringe this claim.

Philip Morris has stipulated that the Accused Products satisfy some limitations of claim 19 of the ’238 patent. Stip. ¶ 2. The limitations that remain contested are identified with bolded italic typeface below:

19. A control body for an electronic smoking article, the control body comprising:

an elongated shell with an interior, a proximal end, and an opposing distal end;

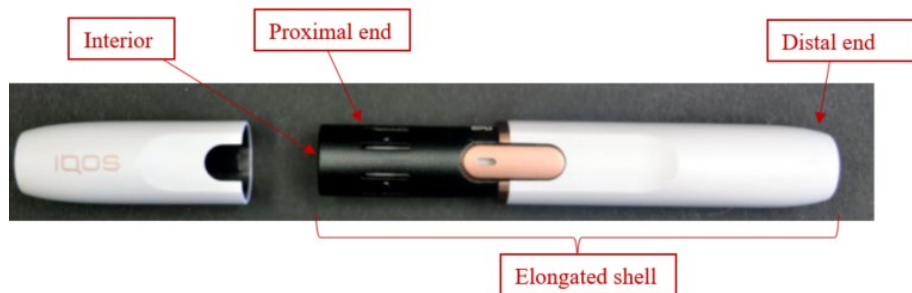
a coupler formed of an elongated body having a first end ***that forms a wall and that engages the proximal end of the shell*** and a second end that comprises a cavity configured to releasably engage ***a cartridge, wherein the coupler includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler,*** wherein the coupler includes an air inlet channel in fluid communication with the cavity and an air inlet aperture in an exterior surface of the coupler, and wherein the coupler has a longitudinal axis extending from the first end to the second end, and ***the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler;*** and

a microprocessor.

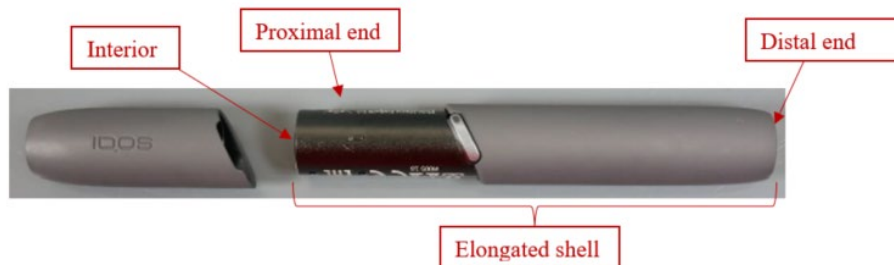
Id.

1. “an elongated shell with an interior, a proximal end, and an opposing distal end”

As seen in the image below, the IQOS 2.4 has an elongated shell with an interior, a proximal end, and an opposing distal end.



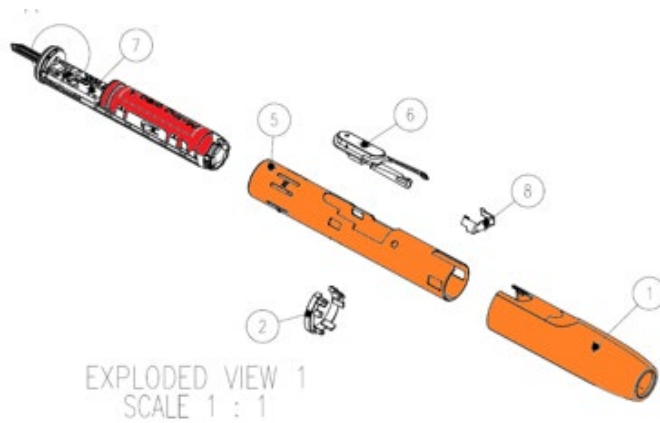
See CX-0939C at 21 (annotations added); JX-0053C at 4; Hrg. Tr. 212:1–213:18; CDX-0001C.66–67. Similarly, for the IQOS 3 and 3.1 Duo, the following image shows that these devices also include an elongated shell with an interior, a proximal end, and an opposing distal end.



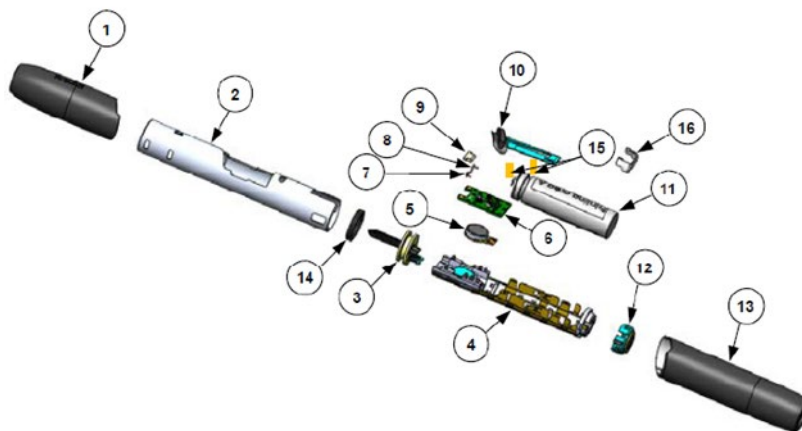
See JX-0064C at 50 (annotations added); Hrg. Tr. 212:1–213:18; CDX-0001C.67–68.

In the Accused Products, the elongated shell includes the “middle part” and “rear housing.” Reynolds’s expert Mr. Alarcon provided a demonstrative slide, reproduced below, that shows the IQOS 2.4’s “middle part” and “rear housing” colored orange. Hrg. Tr. 212:1–213:18; CDX-0001C.66–68; CX-572C; CPX-0076C; JX-0053C at 4. He colored in red a battery housed in the interior of the elongated shell, which is the power source. *Id.*

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Id. For the IQOS 3 and 3.1 Duo, Mr. Alarcon provided an illustration (reproduced below) identifying the “middle part” and “rear housing” of the claimed “elongated shell” as items 2 and 13, respectively, while the power source, or battery, is item 11. *See* Hrg. Tr. 407:13–408:10; CX-0591C at 7.



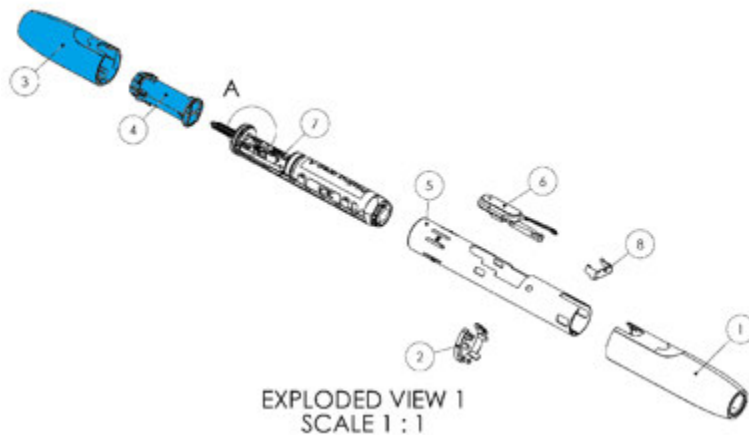
Id.

Philip Morris does not dispute that the Accused Products have “an elongated shell with an interior, a proximal end, and an opposing distal end.” *See* RRB at 5–25; Order No. 8 at Ground Rule 14.2 (finding forfeiture if an issue is not raised in post-hearing briefing). I therefore find that the Accused Products satisfy this limitation of claim 19 of the ’238 patent.

2. “a coupler . . . having a first end that forms a wall and that engages the proximal end of the shell”

Claim 19 recites “a coupler formed of an elongated body having a first end that forms a wall and that engages the proximal end of the shell.” Philip Morris has stipulated that the Accused Products include “a coupler formed of an elongated body having a first end” and “a second end that comprises a cavity to releasably engage.” Stip. ¶ 2. As discussed below, the record evidence demonstrates that the Accused Products also have a coupler with “a first end that forms a wall and that engages the proximal end of the shell.”

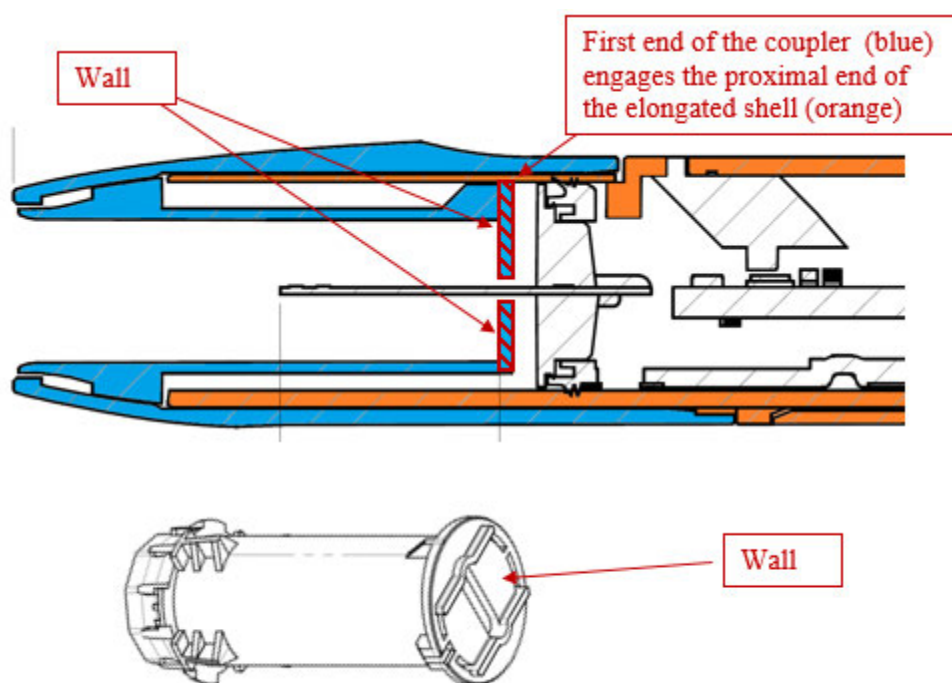
As shown in the below slide prepared by Reynolds’s expert Mr. Alarcon, the coupler includes the front housing and extractor, both depicted in blue. *See* Hrg. Tr. 214:2–215:24; CDX-0001C.71.



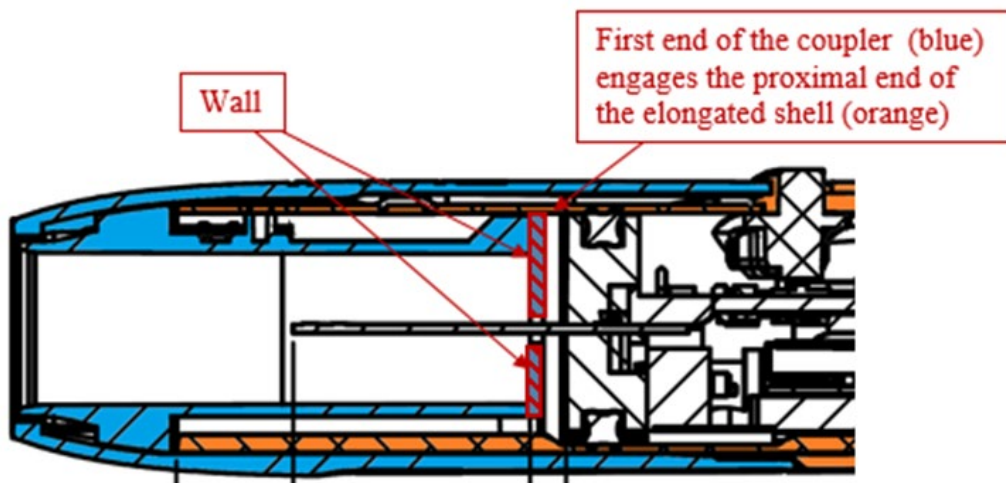
JX-0053C at 4; CPX-0076C.

Mr. Alarcon provided another slide (reproduced below) showing that the first end of the coupler (blue) forms a wall (red) and engages the proximal end of the shell (orange). Hrg. Tr. 214:2–215:24; CDX-0001C.71.

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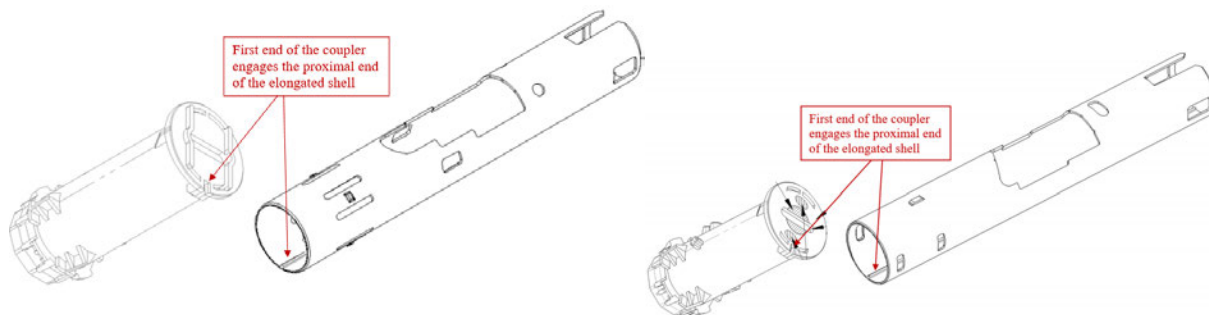
JX-0053C at 4; CPX-0070C; CPX-0076C; CX-0641C.



CX-0755C; CPX-0110C.

Mr. Alarcon testified that, in the Accused Products, both the front housing and the extractor of the coupler engage the proximal end of the shell. *See* Hrg. Tr. 214:2–219:18; CDX-0001C.70–76. Based on his investigation of the devices, Mr. Alarcon testified that the front

housing engages the middle part to hold the parts together, and the extractor rotationally engages the middle part to prevent the coupler from rotating relative to the proximal end of the elongated shell. *Id.* The images below further demonstrate the engagement between the first end of the coupler and the proximal end of the shell.



CPX-0070C; CPX-0072C; CPX-0113C; CPX-0105C; CPX-0103C.



CX-0583C at 5-6; CX-0448 at 5-6; JX-0064C at 47.

Philip Morris does not dispute that the Accused Products have “a coupler . . . having a first end that forms a wall and that engages the proximal end of the shell.” *See* RRB at 5–25; Order No. 8 at Ground Rule 14.2 (finding waiver if an issue is not addressed in post-hearing briefing). I therefore find that the Accused Products satisfy this limitation of claim 19 of the ’238 patent.

3. “configured to releasably engage a cartridge”

The undisputed record evidence shows that the Accused Products have “a second end that comprises a cavity configured to releasably engage” a HeatStick. CX-0572C at -5498; *see* Hrg.

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Tr. 219:22–220:23, 225:19–226:1; CDX-0001C.78. HeatSticks are disposable tobacco sticks specifically designed for use in the Accused Products. CX-0572C.3. The parties dispute whether a HeatStick is a “cartridge” as that term is used in the ’238 patent. CIB at 85–87 (HeatSticks are cartridges); SIB at 32–34 (HeatSticks are not cartridges); RRB at 18 (same).³

Staff takes the position that “cartridge,” as that term is used in the ’238 patent, refers to the cartridges of vaping devices and does not encompass disposable tobacco sticks. SIB at 33 (citing RX-0748C at Q30). Staff identifies portions of the ’238 specification that describe a cartridge as including “an atomizer 132 comprising a resistive heating element 134 (e.g., a wire coil) configured to produce heat and a liquid transport element 136 (e.g., a wick) configured to transport a liquid.” *See id.* (citing ’238 patent at 7:46–49); *see also* ’238 patent at 8:21–37 (“the cartridge 104 includes a reservoir layer 144 comprising layers of nonwoven fibers formed into the shape of a tube encircling the interior of the outer body 126 of the cartridge”), 11:39–44 (“cartridge 204 can be formed of a cartridge shell 203 enclosing the reservoir housing 244 that is in fluid communication with a liquid transport element 236 adapted to wick or otherwise transport an aerosol precursor composition stored in the reservoir housing to a heater 234”). Staff further argues that cartridges for vaping devices described in contemporaneous publications generally include “a solution (or e-liquid storage area),” an “aerosol generator or atomizer,” and/or “a wick/heater as aerosol generator [and] gauze saturated with e-liquid.” SIB at 33 (citing RX-0237.1–2; RX-0223.1; RX-0221.9 at 5:30–36; RX-0226.4 ¶ 7; RX-0239.7 at 1:58–2:34).

Conversely, Reynolds takes the position that the ’238 specification does not limit the claimed “cartridge” to requiring components such as an e-liquid reservoir and a heater wrapped

³ Philip Morris does not offer an independent argument as to why a HeatStick is not the claimed “cartridge” but instead relies on arguments put forward by Staff. *See* RRB at 18.

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around a wick. *See* CIB at 86 (citing Hrg. Tr. 221:15–222:24). Reynolds argues the '238 specification “states that any components in the cartridge are ‘representative,’ and by using terms like ‘can be’ and ‘may be,’ and stating that these examples ‘are not intended to limit the scope of the cartridge,’ the patentees made this clear.” ’238 patent at 11:35–49.

In view of the teachings of the '238 patent, I find that the term “cartridge” recited in claim 19 is not limited to a component of an electronic cigarette or vaping device comprising, for example, an e-liquid reservoir and a wick/heater to generate an aerosol. The following passage from the '238 patent is instructive:

In another embodiment *substantially the entirety of the cartridge may be formed from one or more carbon materials*, which may provide advantages in terms of biodegradability and absence of wires. In this regard, the heating element may comprise a carbon foam, the reservoir may comprise carbonized fabric, and graphite may be employed to form an electrical connection with the battery and controller.

'238 patent at 9:7–14 (emphasis added).

As taught in the above passage, the claimed cartridge need not include e-liquid or heating wires. The “entirety of the cartridge” can be comprised of “one or more carbon materials,” which describes exactly the composition of the accused HeatSticks. CX-0572C.3.

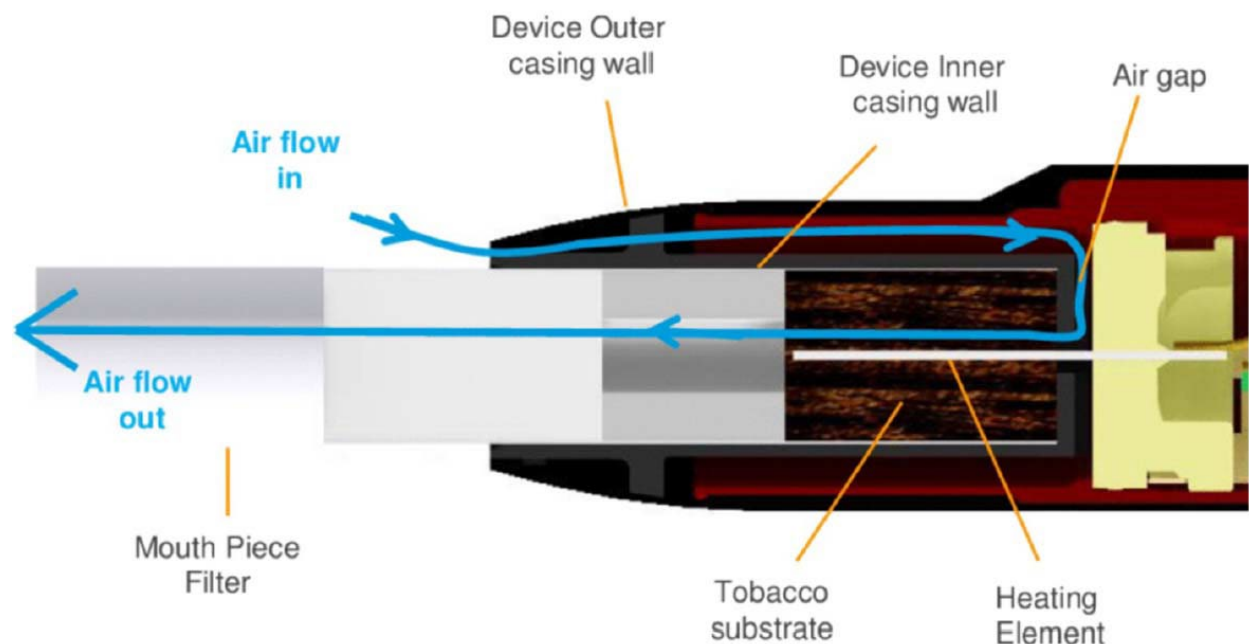
I therefore find that the Accused Products satisfy the claim 19 limitation “configured to releasably engage a cartridge.”

4. **“the coupler includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler”**

Reynolds contends that coupler in the Accused Products each have “a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler.” CIB at 88–91. Reynolds’s argument is

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better understood in view of the illustration below, which is taken from a Philip Morris internal document and shows the path of air flowing through the Accused Products when the user inhales:



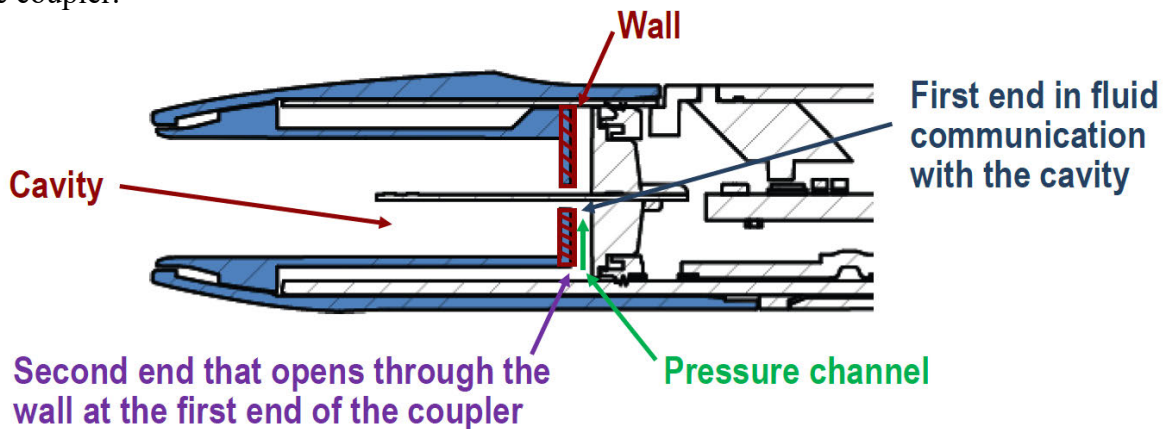
CX-0605C at 11

CX-0605C at 11.

As illustrated above, when a user takes a puff on an Accused Product, air flows in through air inlet opening located towards the mouth end of the device. JX-0095C (Zuber Dep.) at 62:9–63:5; JX-0090C (Holzherr Dep.) at 120:8–16, 122:2–4. The air then flows through the space between the outer surface of the extractor and the middle part. JX-0095C (Zuber Dep.) at 63:6–9. Next the air flows through the wall between the bottom of the extractor and the middle part. *Id.* at 63:10–20. Then the air flows through the space between the bottom of the extractor and the overmold of the heater, through the slit around the heater blade, through the tobacco stick, and into the user's mouth. *Id.* at 63:21–64:16. There is a pressure differential between where air enters the Accused Products and where air enters the user's mouth, and that pressure change is distributed along the entire length of the blue line. Hrg. Tr. 1016:7–1018:5.

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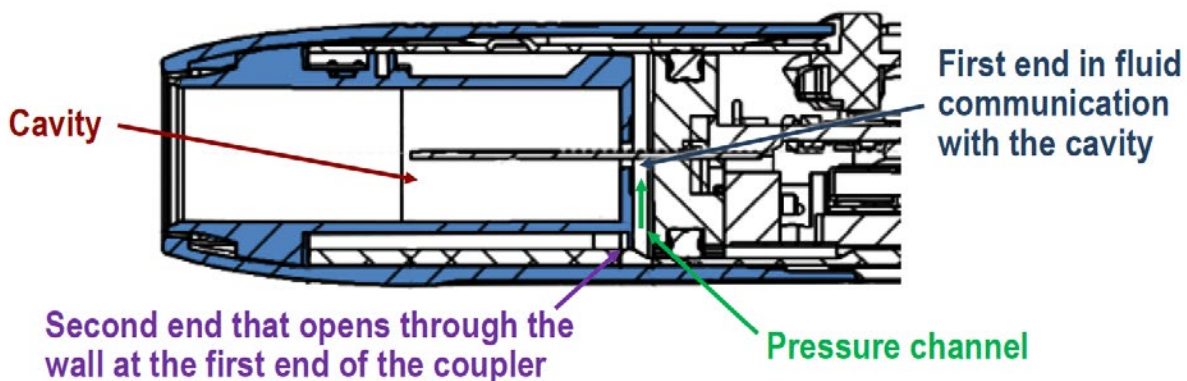
Reynolds has identified a portion of the air path through the Accused Products to be the “pressure channel” recited in claim 19. The figures below show in green the portion Reynolds asserts to be the pressure channel, and also illustrate Reynolds’s argument that the Accused Products have “a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler.”



IQOS 2.4

CPX-0076C

CDX-0001C.84



IQOS 3 and 3.1 Duo

CPX-0110C

CDX-0001C.85

CDX-0001C.84–85; *see* CIB at 91.

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I first address the question of whether the portion of the air flow pathway identified by Reynolds in green in the illustrations above satisfy the “pressure channel” limitation of claim 19. The record evidence shows there is a pressure differential across the entirety of the air flow pathway. Hrg. Tr. 1016:7–1018:5. Thus there is a pressure differential between the first and second ends of the alleged pressure channel. That alleged pressure channel is therefore a passageway that communicates a change in pressure. Hrg. Tr. 226:20–227:20; *see* CC Order at 24 (the plain and ordinary meaning of “pressure channel” is “passageway communicating a pressure change”). Accordingly, I find Reynolds has demonstrated that the Accused Products have a “pressure channel” as claimed in claim 19 of the ’238 patent.

Nevertheless, Reynolds has failed to adduce evidence demonstrating that the coupler in the Accused Products “includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler” because the pressure channel does not “open[] through the wall at the first end of the coupler.” Rather, as seen in the figures above and discussed in testimony provided by Philip Morris’s expert Dr. Slocum and Reynolds’s expert Mr. Alarcon, the pressure channel (green arrow) is entirely behind the wall, which is formed by the base of the extractor. The pressure channel therefore does not have “a second end that opens *through* the wall.” *See* JX-0053C at 4; CPX-0215C at 5; CX-0755C; Hrg. Tr. 361:14–363:6, 1000:6–1001:11.

Reynolds argues that “[t]he second end of the pressure channel opens through the peripheral radial slits in the wall at the first end of the coupler,” but this argument is not supported by the record. *See* CIB at 88 (citing Hrg. Tr. 227:3-11). Reynolds’s expert Mr. Alarcon was unable to offer an opinion regarding whether the radial slits in the extractor are part of the pressure channel; he likened the slits in the wall to “the door jam[b]” between the “air inlet channel” and

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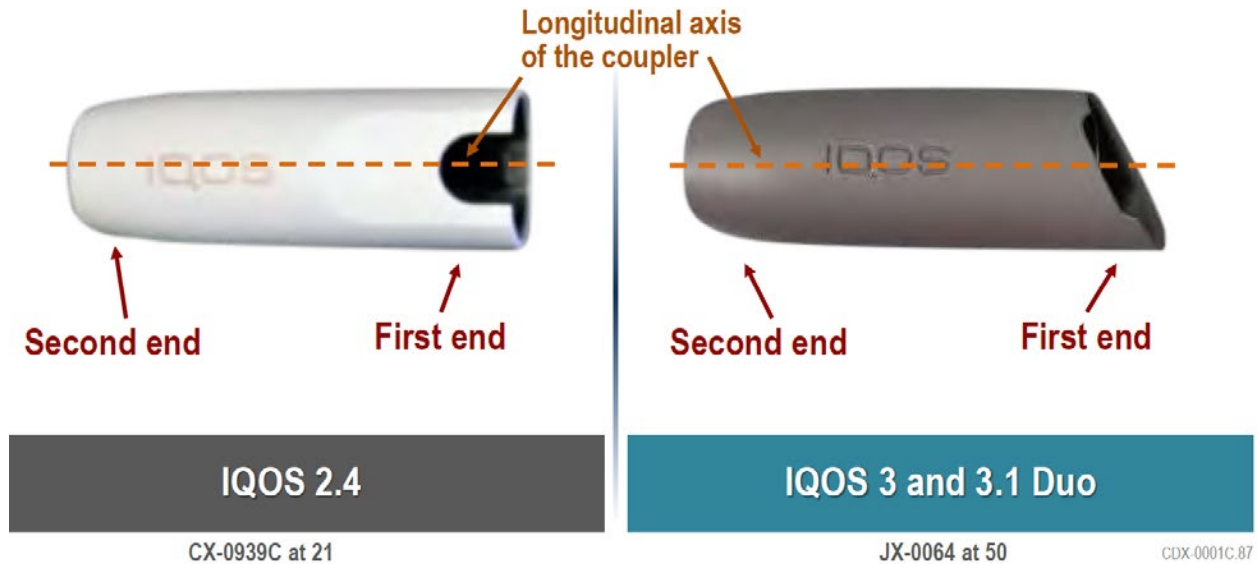
the “pressure channel” and would not offer “a hard opinion” regarding where in that region the “air inlet channel” ended and the “pressure channel” began. *See* Hrg. Tr. 416:2–417:21; *see also* CIB at 95 (“The pressure channel is within the coupler to the right-hand side of the base of the extractor. The base of the extractor forms a boundary between the air inlet channel and the pressure channel, with a transition region in the radial slots of the base of the extractor.”) (citing Hrg. Tr. 226:20–23; Hrg. Tr. 228:15–229:5). Reynolds has thus failed to establish that the pressure channel in the Accused Products “opens *through* the wall at the first end of the coupler.”

Accordingly, I find that the Accused Products do not satisfy the claim 19 limitation “the coupler includes a pressure channel extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler.”

5. “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler”

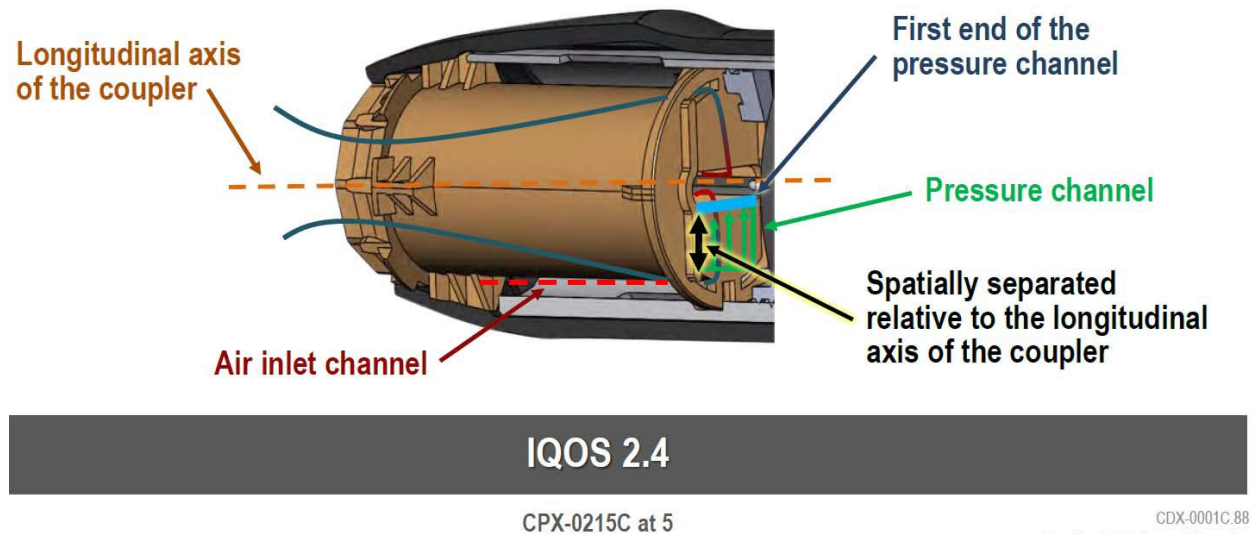
The record evidence demonstrates that the Accused Products satisfy the claim 19 limitation “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler.” The illustrations below show the longitudinal axis of the coupler. *See* Hrg. Tr. 231:11–20.

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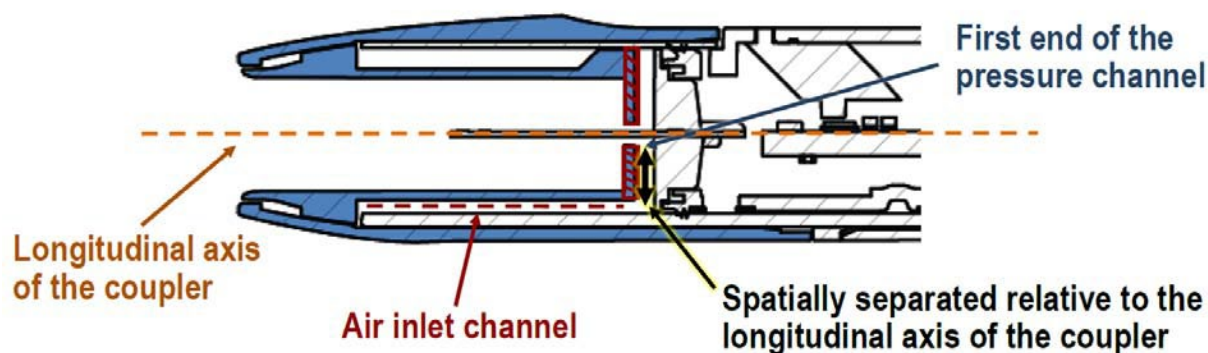


CDX-0001C.87.

The first end of the pressure channel, which is the end of the pressure channel closest to the heater, is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler. *See Hrg. Tr. 231:21–233:22.* The figures below illustrate this spatial separation in the Accused Products.



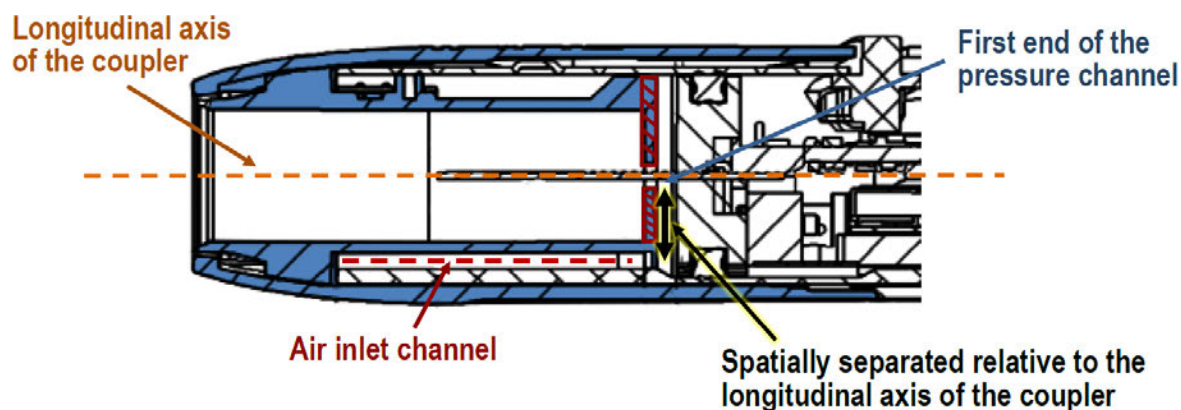
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IQOS 2.4

CPX-0076C

CDX-0001C:89



IQOS 3 and 3.1 Duo

CPX-0110C

CDX-0001C:91

CDX-0001.88–89, .91.

I therefore find Reynolds has demonstrated that the Accused Products satisfy this limitation of claim 19 of the '238 patent.

In sum, because Reynolds has not demonstrated that the accused IQOS devices have the claimed “pressure channel” that “opens through the wall at the first end of the coupler,” I find the IQOS products do not infringe claim 19 of the '238 patent.

C. Indirect Infringement

Reynolds alleges that respondents Philip Morris USA and Philip Morris Products induce infringement and contribute to infringement of claim 19 of the '238 patent. CIB at 95. [REDACTED]

[REDACTED]

[REDACTED] CX-0025C at 112.

Liability for both induced and contributory infringement requires an underlying act of direct infringement. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 923 (2014). Because the evidence fails to show that any of the Accused Products directly infringe claim 19 of the '238 patent, I find that Reynolds has failed to show that Philip Morris USA and Philip Morris Products indirectly infringe claim 19 of the '238 patent with respect to the IQOS 2.4 device.

D. Technical Prong of the Domestic Industry Requirement

Reynolds argues that the VUSE Solo G2 practices claims 1, 3, 5, 6, 8–11, 19, and 20 of the '238 patent. CIB at 95–101. Philip Morris has stipulated that the VUSE Solo G2 practices all limitations of these claims except for one limitation on each of claims 1, 8, and 9.⁴ Stip. ¶¶ 11–25. The limitation for claim 1 remaining at issue is “extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the body end of the coupler to be in fluid communication with the pressure reduction space,” the limitation for claim 8 remaining at issue is “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler,” and the limitation for claim 9 remaining at issue is “wherein the first end of the pressure channel is spatially separated from the

⁴ The disputed limitations in claims 1 and 8 are also found in claim 19.

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air inlet channel so as to be relatively nearer the connector end of the coupler.” *See* Hrg. Tr. 262:3–17, 268:11–269:5, 272:20–23, 274:1–12; Stip. ¶¶ 11–25.

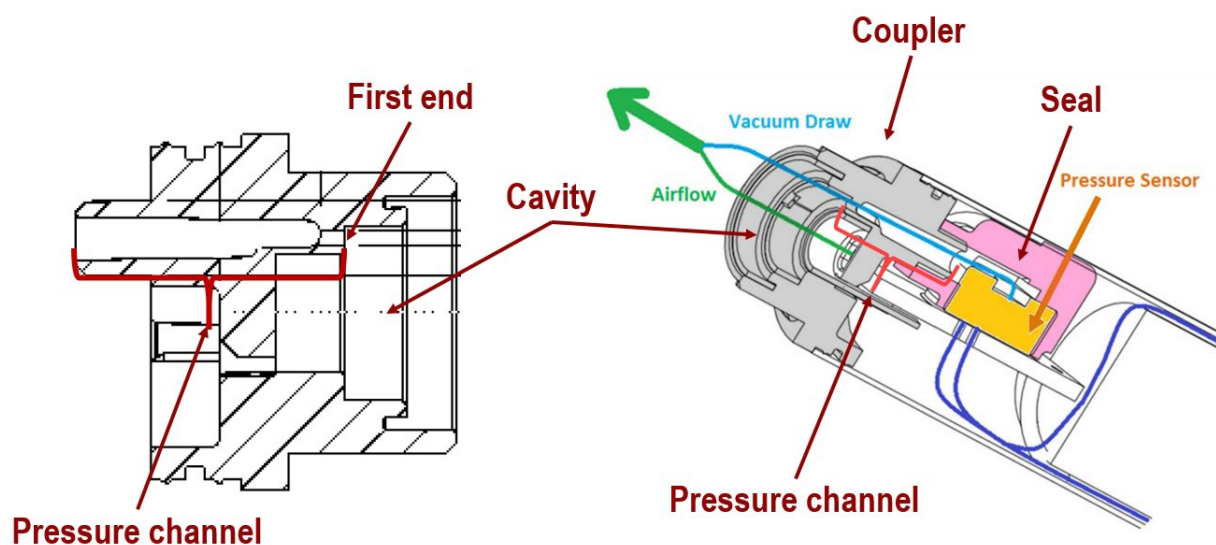
Philip Morris failed to argue that the VUSE Solo G2 does not practice the ’238 patent in its post-hearing responsive brief; Reynolds’s arguments that the technical prong is satisfied for the ’238 patent are therefore deemed unopposed. *See* RRB at 5–25; Order No. 8 at Ground Rule 14.2.

As discussed in further detail below, in view of the undisputed record evidence, I find that Reynolds has demonstrated that the VUSE Solo G2 practices claims 1, 3, 5, 6, 8–11, 19, and 20 of the ’238 patent, thereby satisfying the technical prong of the domestic industry requirement.

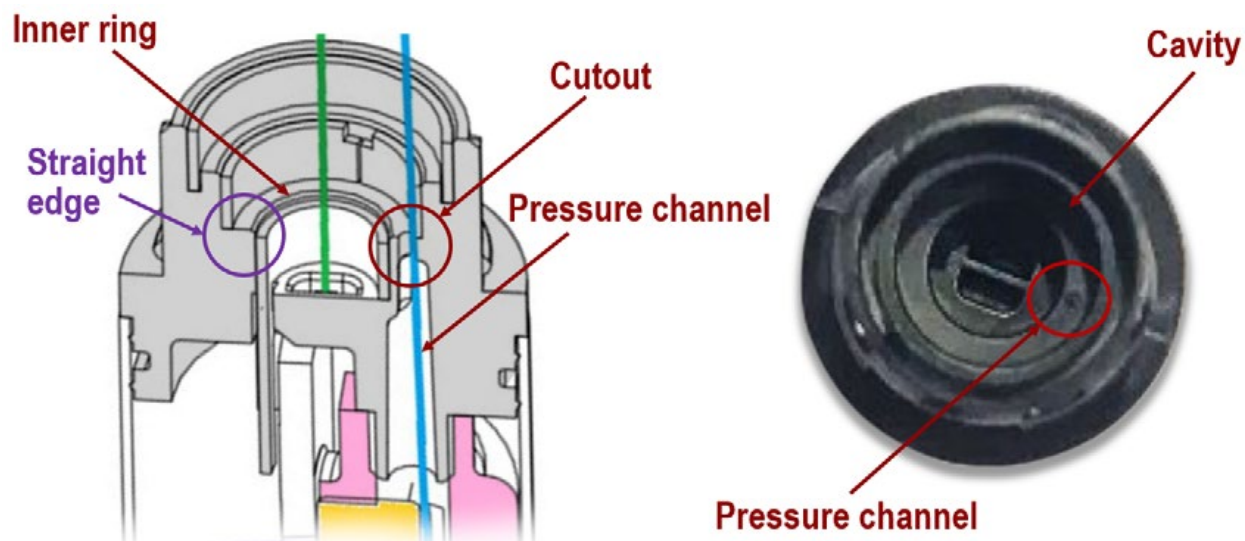
1. **“extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the body end of the coupler to be in fluid communication with the pressure reduction space”**

The undisputed record evidence demonstrates that the coupler in the VUSE Solo G2 includes a pressure channel “extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the body end of the coupler to be in fluid communication with the pressure reduction space.”

As illustrated below, the first end of the pressure channel opens into the cavity and is therefore in fluid communication with the cavity. *See* Hrg. Tr. 263:14–265:24. Reynolds’s expert Mr. Alarcon testified that the VUSE Solo G2 would not function if the first end of the pressure channel were not in fluid communication with the cavity. Hrg. Tr. 265:25–266:7.

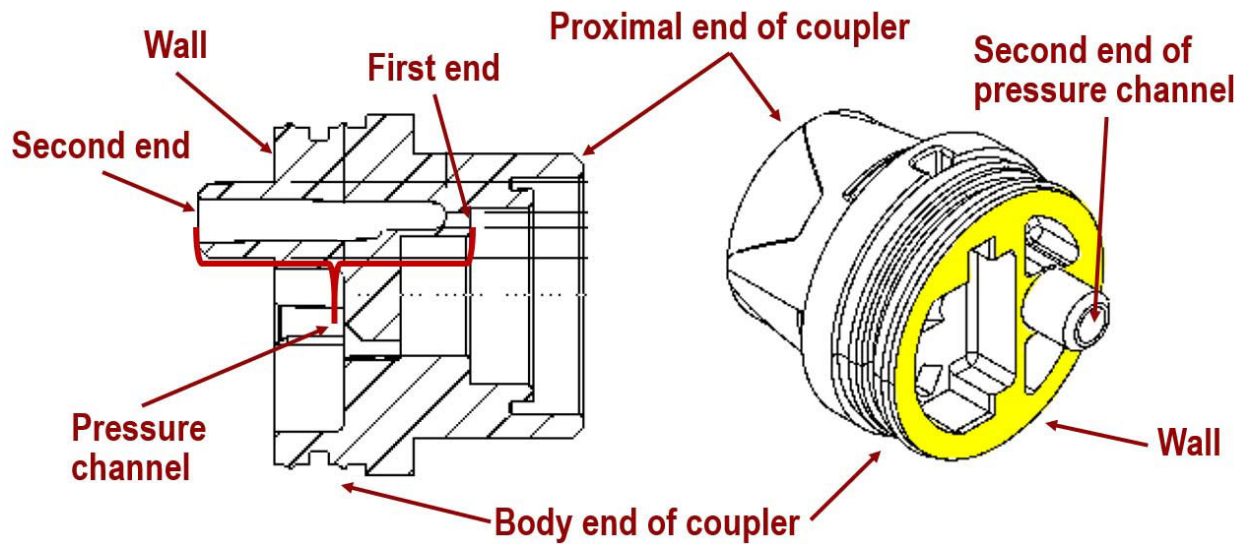


CX-1077C; CX-0947C.20–21; *see also* CDX-0001C.125.



CX-0947C.16, 20–21; *see also* CDX-0001C.126.

The second end of the pressure channel opens through the wall at the body end of the coupler, which is the end closest to the control body of the device. *See* Hrg. Tr. 266:8–24.



CX-1077C; *see also* CDX-0001C.127.

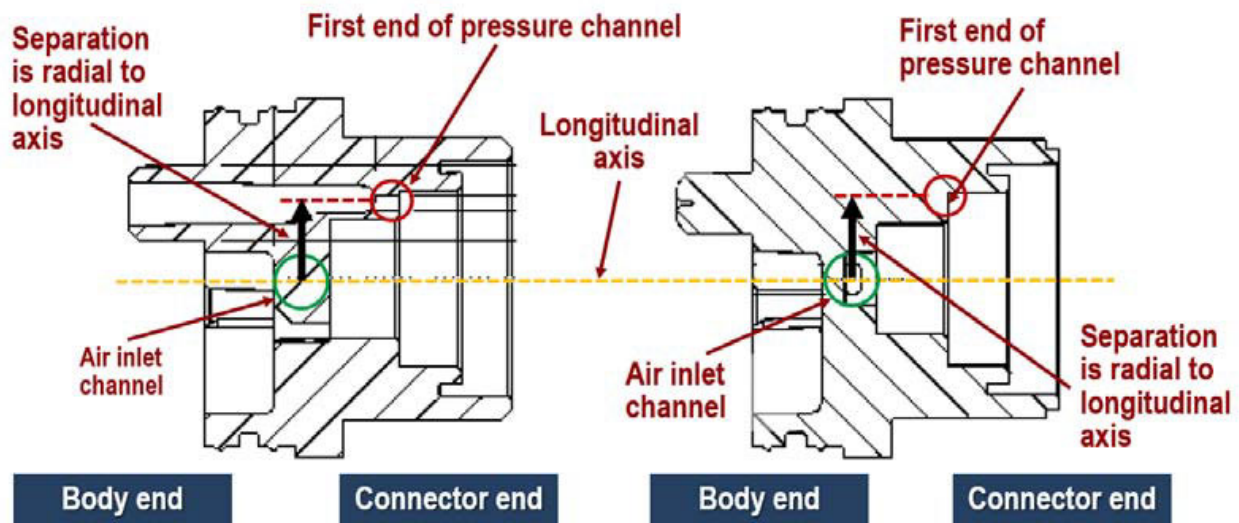
The second end of the pressure channel is in fluid communication with the pressure reduction space, which is the space within the airtight seal that surrounds the pressure sensor and the second end of the pressure channel. CX-0947C.21; *see* Hrg. Tr. 267:1–19. Reynolds’s expert Mr. Alarcon testified that the VUSE Solo G2 would not function if the second end of the pressure channel were not in fluid communication with the pressure reduction space because the sensor would not be able to detect a pressure change. Hrg. Tr. 267:20–268:3.

I therefore find that the VUSE Solo G2 practices the claim 1 and claim 19 limitation “extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the body end of the coupler to be in fluid communication with the pressure reduction space.”

2. “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler”

The undisputed record evidence demonstrates that coupler in the VUSE Solo G2 includes a pressure channel “wherein the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler.”

As illustrated below, there is spatial separation between the first end of the pressure channel and the air inlet channel in a direction radial to, or measured from, the longitudinal axis. *See* Hrg. Tr. 270:21–25.



CX-1077C; *see also* CDX-0001C.131.

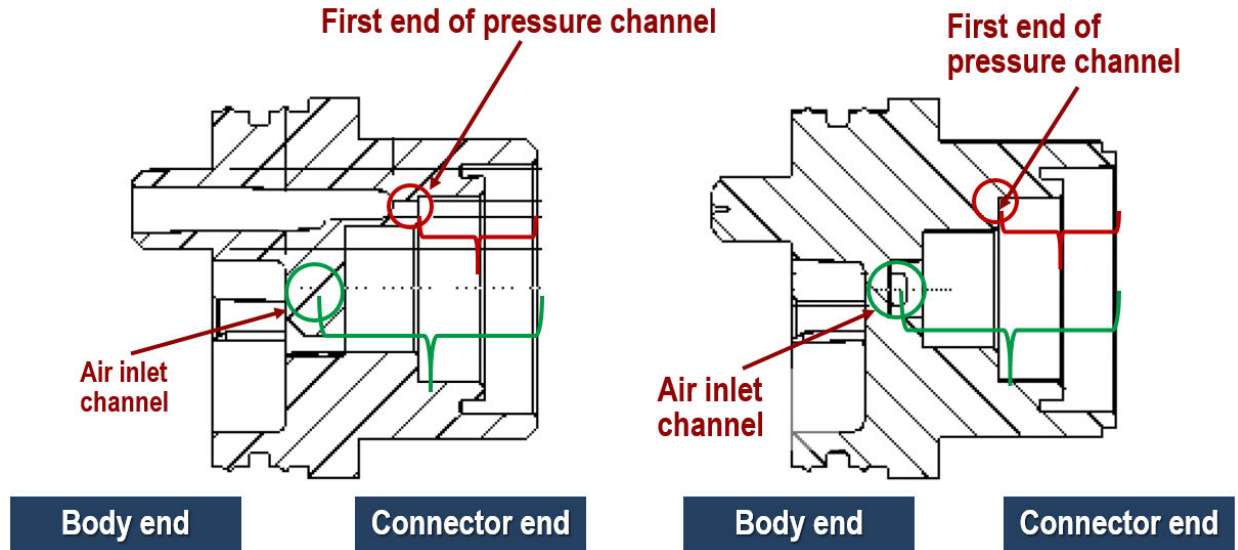
I therefore find that the VUSE Solo G2 practices the claim 8 and claim 19 limitation “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler.”

3. “wherein the first end of the pressure channel is spatially separated from the air inlet channel so as to be relatively nearer the connector end of the coupler”

As illustrated below, the undisputed record evidence demonstrates that the coupler in the VUSE Solo G2 includes a pressure channel wherein the first end of the pressure channel is spatially

separated from the air inlet channel so as to be relatively nearer the connector end of the coupler.

See Hrg. Tr. 271:5–272:19.



CX-1077C; *see also* CDX-0001C.133.

I therefore find that the VUSE Solo G2 practices the claim 9 limitation “wherein the first end of the pressure channel is spatially separated from the air inlet channel so as to be relatively nearer the connector end of the coupler.”

E. Validity

Philip Morris alleges that claim 19 of the ’238 patent is anticipated by two prior art publications, U.S. Patent Application Publication No. 2011/0036346 (RX-0220) (hereinafter “Cohen”) and U.S. Patent No. 8,499,766 (RX-0221) (hereinafter “Newton”). RIB at 6–22. Reynolds has stipulated that both these references are prior art, and that each discloses many of the limitations of claim 19. Stip. ¶¶ 3–10.

Philip Morris also alleges that claim 19 of the ’238 patent is invalid for lack of written description under my construction of the term “pressure channel.” RIB at 22–25.

Philip Morris’s invalidity arguments are addressed in turn below.

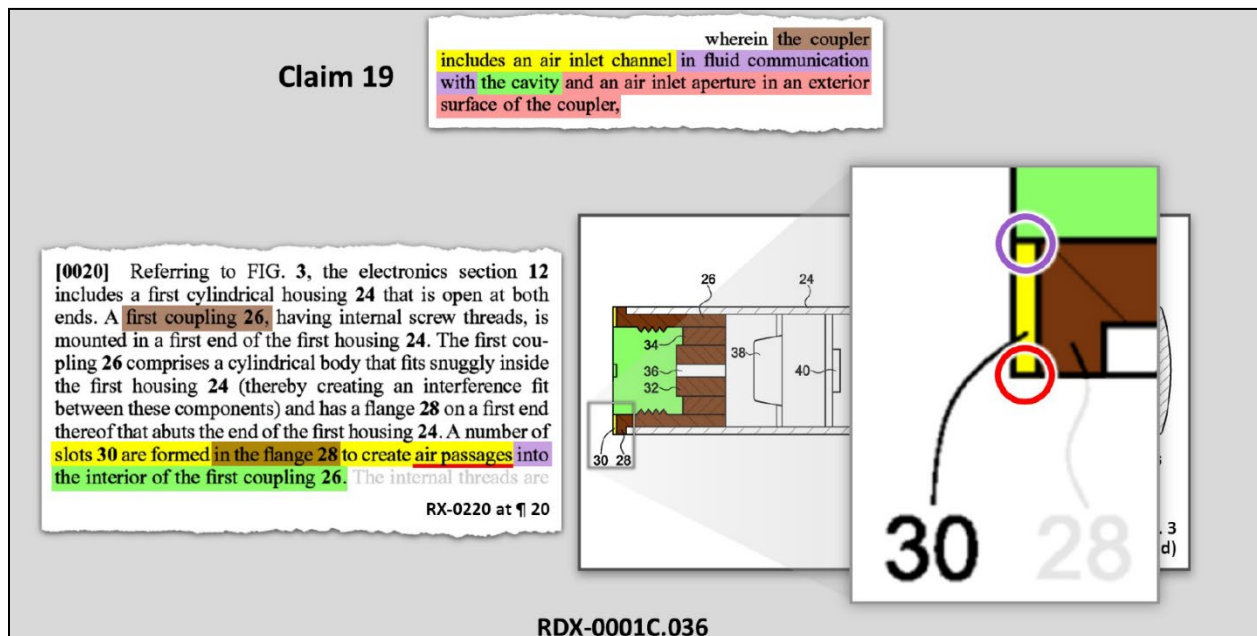
1. Cohen

Reynolds has stipulated that Cohen discloses most limitations of claim 19 of the '238 patent. Stip. ¶ 6. The only limitation Reynolds argues Cohen does not disclose is “wherein the coupler includes an air inlet channel in fluid communication with the cavity and an air inlet aperture in an exterior surface of the coupler.” *See id.* The evidence shows, however, that Cohen discloses the “air inlet channel” limitation and claim 19 is therefore anticipated.

Cohen teaches the following with respect to Figure 3:

The first coupling 26 comprises a cylindrical body that fits snugly inside the first housing 24 (thereby creating an interference fit between these components) and has a flange 28 on a first end thereof that abuts the end of the first housing 24. A number of *slots 30 are formed in the flange 28 to create air passages into the interior of the first coupling 26.*

RX-0220 ¶ 20 (emphasis added). Thus, Cohen discloses an air inlet channel (“air passages” of slots 30 in flange 28) that are in fluid communication (“air passages into”) with the coupler’s cavity (interior of the first coupling 26). This configuration is illustrated in Figure 3 of Cohen, which is reproduced below with annotations:



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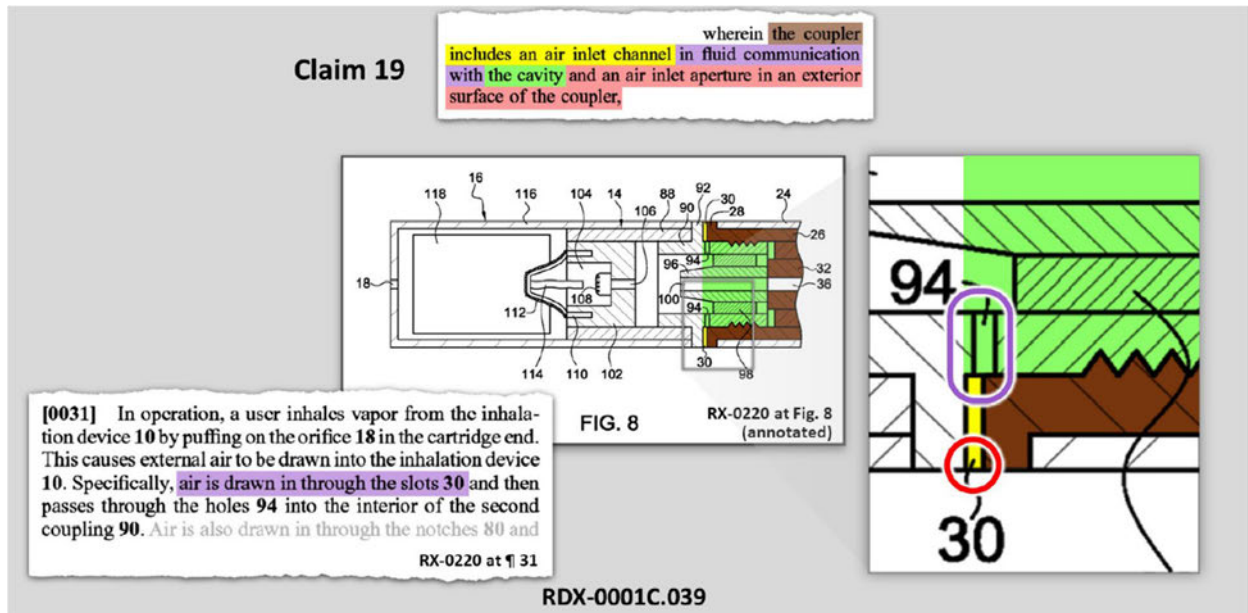
RDX-0001C.036 (annotating RX-0220 at Fig. 3).

Cohen's disclosure is confirmed by testimony from Reynold's expert Mr. Clemens, who admitted that: (1) Cohen's first coupling 26 discloses a "coupler," (2) the "open space . . . in the interior of the first coupling 26" is "a cavity," (3) "one end of the slots 30 is open to the interior of the coupling, and the other end of slot 30 is open to the end of the flange," and (4) "slots 30 in the first coupling 26 create an air passage into the interior of the first coupling." *See* Hrg. Tr. 1532:15–1535:8.

Reynolds takes the position that the slots 30 disclosed in Figure 3 of Cohen are not the claimed "air inlet channel in fluid communication with the cavity" because no cartridge or atomizer is shown in Figure 3 and because no air actively flows through slots 30 if a cartridge is not present. *See* CRB at 50. Reynolds argues that "[s]lots 30 are ***not adapted to*** distribute drawn, ambient air through the smoking article (including the coupler) when atomizing unit 14 is not present and not coupled to first housing 24. . . . Rather, slots 30 are completely open to the air, cannot distribute air to any particular location, and thus would not be considered an 'air inlet channel.'" *Id.* (emphasis original).

Reynolds's argument is not persuasive because claim 19 recites only "a control body for an electronic smoking article" and does not require the presence of a cartridge. In addition, claim 19 does not does not require that air be actively flowing through the air inlet channel. *Cf.* Hrg. Tr. 1006:11–14 (testimony from Mr. Alarcon stating that claim 19 could be infringed by a device that is merely sitting on a table). Reynolds's argument to the contrary is contradicted by the explicit teaching of Cohen that the slots 30 "create air passages into the interior of the first coupling 26." Cohen ¶ 20.

Figure 8 of Cohen and the accompanying text also teaches the disputed “air inlet channel” limitation of claim 19. In Figure 8 (reproduced with annotations below), slots 30 extend through first coupling 26 to be in fluid communication with the exterior surface of the coupler on one end, and with the cavity on the other. *See* Hrg. Tr. 1006:15–1008:9.



RDX-0001C.39 (annotating Cohen Fig. 8).

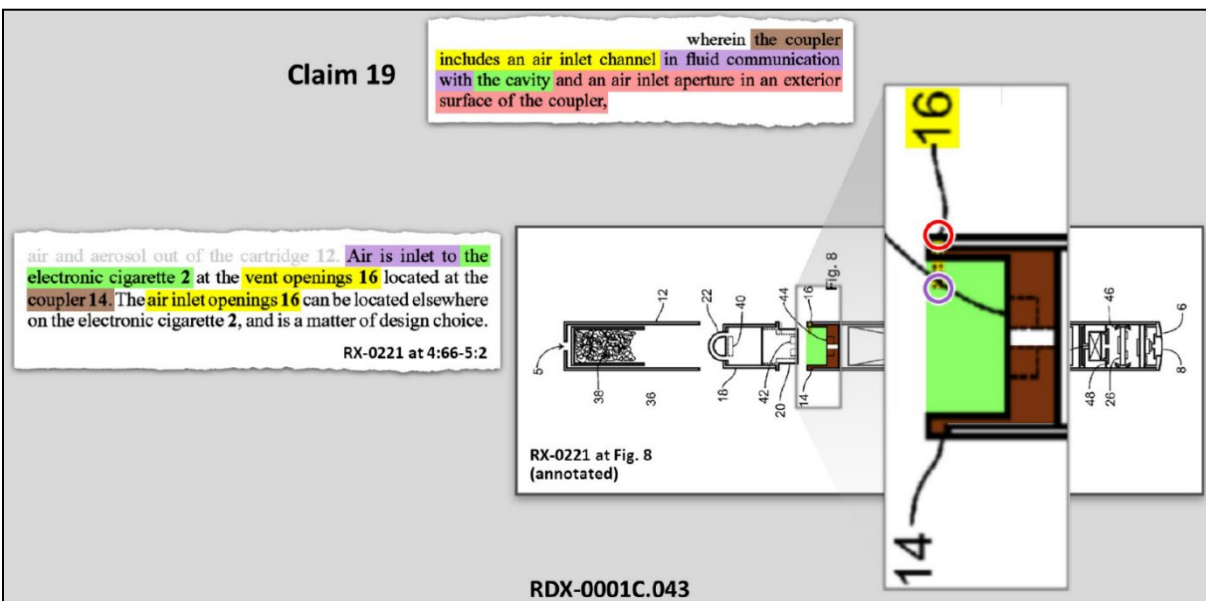
Reynolds disputes that Figure 8 discloses the “air inlet channel” limitation, arguing that air is drawn into the interior of “second coupling 90” rather than “first coupling 26.” *See* CRB at 52–54. Reynolds’s argument notwithstanding, Figure 8 nevertheless discloses this limitation because “second coupling 90” is nested inside “first coupling 26” and slots 30 remain in fluid communication with the cavity of first coupling 26, whether directly or indirectly. *See* Hrg. Tr. 1006:15–1008:9; *see also* Hrg. Tr. 359:21–360:1.

For the reasons set forth above, I find that Philip Morris has shown, clearly and convincingly, that asserted claim 19 of the ’238 patent is anticipated by Cohen.

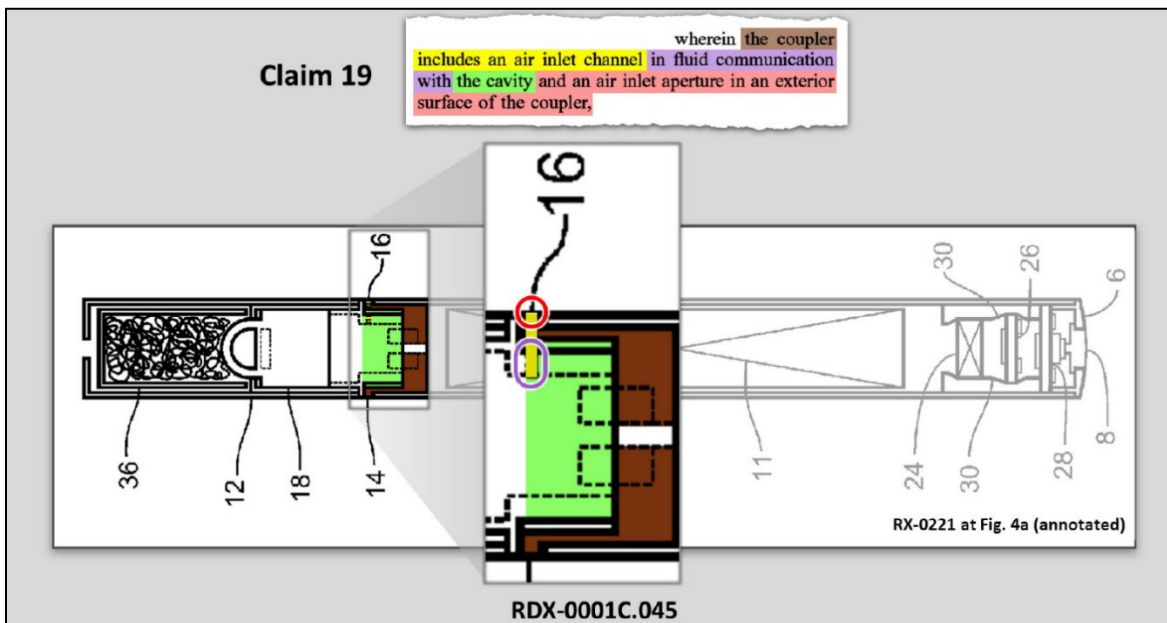
2. Newton

Reynolds has stipulated that Newton discloses motion limitations of claim 19 of the '238 patent. Stip. ¶ 8. The only limitation Reynolds argues Newton does not disclose is “wherein the coupler includes an air inlet channel in fluid communication with the cavity and an air inlet aperture in an exterior surface of the coupler.” *See id.* The evidence shows, however, that Newton discloses the “air inlet channel” limitation and claim 19 is therefore anticipated.

Newton teaches that “[a]ir is inlet to the electronic cigarette 2 at the vent openings 16 located at the coupler 14,” allowing “fresh air [to be] inlet to the atomizer assembly 18 through vent openings 16.” Newton at 4:66–5:2; 5:45–58. These “vent openings 16” are also referred to as “air inlet vents 16.” *Id.* at 4:45–54. In addition, Figures 8 and 4a, shown below with color annotations, confirm that air inlet vents / vent openings 16 (highlighted in yellow) within coupler 14 (highlighted in brown) serve as an air inlet channel in fluid communication with an aperture at the exterior of the device and with the cavity of the coupler (highlighted in green). *See* Hrg. Tr. 1008:10–1011:16.



RDX-0001C.043 (annotating Newton Fig. 8).



RDX-0001C.045 (annotating Newton Fig. 4a).

The evidence therefore shows that the “air inlet vents 16” / “vent openings 16” disclosed in Newton satisfy the claim 19 limitation “an air inlet channel in fluid communication with the cavity.”

Reynolds’s argument that Newton does not disclose an air inlet channel is similar to the argument they made with respect to Cohen:

Inlet vents 16 are *not adapted to* distribute drawn, ambient air through the smoking article (including the coupler) when atomizer assembly 18 is not present and not coupled to elongated portion 10. . . . Rather, inlet vents 16 are completely open to the air (Newton Figure 3), cannot distribute air to any particular location, and thus would not be considered an air inlet channel.

CRB at 59.

Reynolds’s argument with respect to Newton is unpersuasive for the same reasons discussed above with respect to Cohen.

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For the reasons set forth above, I therefore find that Philip Morris has shown, clearly and convincingly, that asserted claim 19 of the '238 patent is anticipated by Cohen.

As for Philip Morris's obviousness argument based on Newton alone, "a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for anticipation is the epitome of obviousness." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (internal quotation marks and citations omitted). Accordingly, I find that Philip Morris has shown, clearly and convincingly, that asserted claim 19 of the '238 patent is also invalid under 35 U.S.C. § 103.

3. Lack of Written Description

Philip Morris argues that asserted claim 19 of the '238 patent is invalid for failing to satisfy the written description requirement of 35 U.S.C. § 112. RIB at 6, 22–24. Specifically, Philip Morris argues that (1) a person of ordinary skill in the art would not understand the inventors to have possessed a "pressure channel" without a "pressure sensor" in accordance with my construction of "pressure channel" and (2) there is no written description for an "air inlet channel" directly connected to a "pressure channel." *Id.* As discussed below, Philip Morris has failed to show by clear and convincing evidence that the inventors lacked possession of the claimed invention at the time the application was filed. *Ariad Pharm*, 598 F.3d at 1351.

The '238 patent specification teaches at least one embodiment having a pressure channel without an accompanying pressure sensor:

In other embodiments, a control body for an electronic smoking article can comprise an elongated shell with an interior, a proximal end, and an opposing distal end. The control body further can comprise a coupler formed of an elongated body having a first end that forms a wall and that engages the proximal end of the shell and a second end that comprises a cavity configured to releasably engage a cartridge, wherein the coupler includes *a pressure channel* extending between a first end that is in fluid communication with the cavity and a second end that opens through the wall at the first end of the coupler, wherein the coupler includes an air inlet

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channel in fluid communication with the cavity and an air inlet aperture in an exterior surface of the coupler, and wherein the coupler has a longitudinal axis extending from the first end to the second end, and the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler. The control body further can comprise one or more additional components, such as a power source, a microprocessor or other control component, or the like. In some embodiments, the first end of the pressure channel in the coupler can be spatially separated from the air inlet channel so as to be relatively nearer the second end of the coupler.

'238 patent at 3:14–36 (emphasis added).

In addition, Figure 8 of the '238 patent illustrates an embodiment without a pressure sensor:

The embodiment of a control body 802 illustrated in FIG. 8 comprises an electronic circuit board 806 positioned within a shell 801 between a battery 810 and a coupler 824. The electronic circuit board 806 is configured lengthwise such that it is substantially parallel with a central axis of the shell 801. The electronic circuit board 806 comprises a first LED 812*a* and a second LED 812*b*. Further, in the illustrated embodiment, the coupler 824 is light transmissive such that light from the first LED 812*a* and/or light from the second LED 812*b* is visible external to the control body through the coupler. The coupler may be formed, for example, from a translucent thermoplastic material. The control body 802 further can include an input element, such as a pushbutton 861, which can be adapted to activate power delivery from the power source in the control body to a heater, such as in an attached cartridge (see FIG. 2). The input element alternatively can be adapted to active a further control function of the device, such as described in greater detail below.

'238 patent at 18:51–19:2.

Despite not having a pressure sensor, the embodiment in Figure 8 nevertheless contains a “pressure channel” as that term has been construed. *See* CC Order at 24–25 (construing “pressure channel” to mean “passageway communicating a pressure change”). As discussed above in connection with the infringement analysis of the “pressure channel” limitation, when a user draws air through the embodied invention, there is a pressure differential across the entirety of the air

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flow pathway. That air flow pathway is therefore a passageway that communicates a change in pressure. *See* Section VII.B.4 (citing Hrg. Tr. 226:20–227:20, 1016:7–1018:5).

Philip Morris’s contention that “there is no written description for an ‘air inlet channel’ directly connected to a ‘pressure channel’” is likewise lacking in merit. *See* RIB at 23. Philip Morris’s argument relies mainly on the ’238 patent’s teaching of spatial separation between the pressure channel and air inlet channel to prevent backflow. *See id.* at 24. Yet, claims 8 and 19 (and their dependent claims) require only that “the *first end* of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler.” ’238 patent at claims 8 and 19 (emphasis added). The ’238 patent therefore does not teach or claim that the entirety of the pressure channel and air inlet channels be spatially separated, just that the first end of the pressure channel be spatially separated from the air inlet channel. This type of spatial separation is described in the ’238 patent specification. *See, e.g.*, ’238 patent at 2:47–3:36, 7:22–34, 9:21–41, 12:6–34, 15:32–19:2.

For these reasons, Philip Morris has failed to prove by clear and convincing evidence that claim 19 of the ’238 patent is invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112.

VIII. ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT

A. The ’238 and ’915 Patents

As noted above, I issued an initial determination on January 19, 2021, granting Reynolds’s motion for summary determination that the economic prong of the domestic industry requirement has been satisfied in part, determining that the economic prong has been satisfied with respect to the ’915 and ’238 patents. Order No. 35. The Commission affirmed my finding on summary determination that “[Reynolds satisfies] the economic prong of the domestic industry requirement

under 19 U.S.C. 1337(a)(3)(A) for the '238 patent and the '915 patent.” EDIS Doc. ID 734509 at 3.

B. The '123 Patent

Reynolds and Philip Morris stipulated that Reynolds made domestic investments in plant and equipment and labor and capital connected to the VUSE Vibe product alleged to practice the '123 patent. DI Stip. ¶¶ 4, 9. Although Philip Morris does not dispute a domestic industry exists under 19 U.S.C. § 1337(a)(3)(B) with respect to the VUSE Vibe, it argues that a domestic industry does not exist under 19 U.S.C. § 1337(a)(3)(A). DI Stip. ¶ 2, 8; RRB at 68–69.

Staff takes the position that Reynolds has demonstrated a domestic industry for the '123 patent under 19 U.S.C. §§ 1337(a)(3)(A) and (B). SIB at 112–16.

1. Reynolds’s Investments in Plant and Equipment

Reynolds and Philip Morris stipulated that “Reynolds has invested approximately [REDACTED] in domestic plant and equipment used to manufacture e-liquid for the VUSE Vibe.” DI Stip. ¶ 9. As stipulated, Reynolds’s domestic investments in plant and equipment include the following items:

- [REDACTED] invested in purchasing new equipment to make e-liquid for VUSE Vibe at Reynolds’s manufacturing facility in [REDACTED] and to modify space there to address environmental regulations, building codes, and production of hazardous waste (CPX-0196C; CDX-0004C.10–CDX-0004C.14); and
- [REDACTED] invested in purchasing equipment to make e-liquid for VUSE Vibe at Reynolds’s [REDACTED] facility (CPX-0135C; CDX-0004C.15–CDX-0004C.17).

Id.

Despite stipulating to the amount of Reynolds’s investments in plant and equipment, Philip Morris argues that Reynolds does not satisfy the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(A). *See id.*; RRB at 68 (arguing Reynolds has failed to

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show quantitative significance of its investments). Nevertheless, the record evidence demonstrates that Reynolds's domestic investments in plant and equipment for the VUSE Vibe product are both qualitatively and quantitatively significant.

Reynolds's investments are qualitatively significant because all of the proprietary e-liquid used in the VUSE Vibe product is made in the United States. Hrg. Tr. 605:8–606:6, 700:25–701:9, 1180:1–4 (Philip Morris's expert is not aware of any e-liquid produced outside the United States). It is undisputed that the VUSE Vibe product does not operate without e-liquid and that Reynolds does not sell any VUSE Vibe cartridges that do not include e-liquid. *See* Hrg. Tr. 602:13–603:3, 605:8–606:6, 1180:5–11 (Philip Morris's expert testifying that VUSE products cannot operate without e-liquid). Therefore, Reynolds's investments here are qualitatively significant because they are critical to producing a saleable product. *See Certain Electronic Nicotine Delivery Systems and Components Thereof*, Inv. No. 337-TA-1139, Initial Determination at 270 (Dec. 13, 2019) (unreviewed in relevant part).

Reynolds's domestic investments in plant and equipment for the VUSE Vibe product are also quantitatively significant. Reynolds's economic expert Dr. Mody compared Reynolds's domestic investments in plant and equipment to the total amount of Reynolds's foreign and domestic spending on the cost of goods and services (COGS) required to produce the patented products. *See* Hrg. Tr. 603:4–604:13; CDX-0004C.41. Reynolds's total cost of goods and services, foreign and domestic, is [REDACTED]. *Id.* The domestic spend of [REDACTED] is approximately [REDACTED] of the total. *Id.* That is a quantitatively significant investment. Moreover, Reynolds's domestic investments in plant and equipment for the Vibe products are quantitatively significant when compared to the sales revenue generated from those investments. The domestic spend of [REDACTED] is equivalent to [REDACTED] of the [REDACTED] in total U.S. sales of the Vibe Products

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from 2016 to the second quarter of 2020. *See* Hrg. Tr. 602:13–603:3; CDX-0004C.39. That is a quantitatively significant investment.

In view of the stipulated facts discussed above, I find that Reynolds has demonstrated significant investments of plant and equipment with respect to the VUSE Vibe product alleged to practice the '123 patent. I therefore find that Reynolds has satisfied the economic prong of the domestic industry requirement for the '123 patent under 19 U.S.C. § 1337(a)(3)(A).

2. Reynolds's Employment of Labor and Capital

Reynolds and Philip Morris stipulated that “Reynolds has made at least [REDACTED] in domestic investments in labor and capital, as defined under 19 U.S.C. § 1337(a)(3)(B), relating to Reynolds's VUSE Vibe product, which Reynolds contends practices one or more claims of the '123 Patent.” DI Stip. ¶ 3. As stipulated, Reynolds's domestic investments in labor and capital include the following items:

- [REDACTED] in PMTA external labor and capital;
- [REDACTED] in product integrity and submissions internal labor;
- [REDACTED] in domestic oversight of foreign manufacture internal labor;
- [REDACTED] in product discovery and development internal labor; and
- [REDACTED] in manufacture of e-liquid internal labor.

Id. ¶ 4.

Reynolds and Philip Morris also stipulated that Reynolds's investments in labor and capital are “qualitatively and quantitatively significant under 19 U.S.C. § 1337(a)(3)(B) and demonstrate[] an economic domestic industry for the VUSE Vibe product.” DI Stip. ¶ 5. As stipulated, qualitative significance is demonstrated by the following analyses:

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- Reynolds's domestic investments in labor and capital associated with the VUSE Vibe amount to at least approximately [REDACTED] of the total foreign investment in VUSE Vibe (*see, e.g.*, CPX-0208C; CPX-0173C; CPX-0209C; CDX-0004C.41); and
- Reynolds's domestic investments in labor and capital associated with the VUSE Vibe amount to at least nearly [REDACTED] of the total domestic sales of the VUSE Vibe product (*see, e.g.*, CPX-0208C; CPX-0173C; CPX-0209C; CDX-0004C.39).

Id. ¶ 6.

As further stipulated, quantitative significance is demonstrated by the following analyses:

- Reynolds's labor and capital investments for VUSE Vibe relating to product integrity and submissions are important to the potential continued sale of VUSE Vibe 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 and OEM oversight relating to VUSE vibe are important to the development and oversight of a commercial product sold in the United States.

Id. ¶ 7.

In view of the stipulations between Reynolds and Philip Morris and the uncontested record evidence outlined above, I find that Reynolds has demonstrated significant investments of labor and capital with respect to the VUSE Vibe product alleged to practice the '123 patent. I therefore find that Reynolds has satisfied the economic prong of the domestic industry requirement for the '123 patent under 19 U.S.C. § 1337(a)(3)(B).

3. Reynolds's Investment in Exploitation of the '123 Patent

Reynolds also argues that it has satisfied the economic prong of the domestic industry requirement for the '123 patent under 19 U.S.C. § 1337(a)(3)(C). CIB at 48–50. Philip Morris opposes a finding that the domestic industry is satisfied under this provision of the statute, and Staff takes no position on Reynolds's argument. RRB at 68–69; SIB at 112–16; SRB at 21.

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Reynolds argues that its [REDACTED] expenditure related to a voluntary market withdrawal is an investment to exploit the patented technology of the '123 patent and is both qualitatively and quantitatively significant. CIB at 49–50. However, Reynolds did not present evidence showing a nexus between its withdrawal investments and exploitation of the '123 patent. *See id.* This failure of proof is fatal to Reynolds's argument that it satisfies the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(C) for the '123 patent. *See Certain Integrated Circuit Chips & Prod. Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 38 (Aug. 22, 2014).

I therefore find that Reynolds has failed to demonstrate substantial investment in the exploitation of the '123 patent.

C. FDA Approval of the Domestic Industry Products

At the hearing, Stacy Erlich, Philip Morris's expert in the field of FDA law and the regulation of tobacco and nicotine products, testified that "all e-cigarette products are illegal . . . because none of them have pre-market authorization." Hrg. Tr. 1478:5-8. This testimony prompted me to ask the parties whether Reynolds's VUSE Vibe and Solo products can properly support a domestic industry if they have not yet been authorized by FDA. Hrg. Tr. 1591:16–18. The parties subsequently addressed this issue in post-hearing briefs. *See* CIB at 50–54; RRB at 62–68; SRB at 16–21. Having considered the arguments presented by the parties, I have concluded that the regulatory status of the VUSE Vibe and Solo products do not preclude a finding that the domestic industry requirement is satisfied in the context of this investigation.

Interpretation of section 337 begins with the statutory text, giving terms "their ordinary meaning." *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013). Here, section 337(a)(3) clearly defines when a domestic industry exists:

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

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3) (emphasis added).

The statute instructs that a domestic industry “shall be considered to exist” if there are significant or substantial investments in the United States of the types enumerated. The statutory criteria for a domestic industry are met in this investigation: as discussed above, I have found that both the technical prong and the economic prong of the domestic industry requirement have been satisfied for all of the Asserted Patents. The statutory text does not suggest that other considerations—like regulatory approval status—can negate the existence of an industry when the statutory criteria are met.

This determination accords with the Commission’s treatment of a similar issue in *Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, USITC Pub. No. 5025 (Feb. 2020) (“*Strontium-Rubidium Systems*”). There, the respondent argued that there was no domestic industry for a medical device that had not been approved by the FDA at the time of the filing of the complaint. The ALJ rejected that argument and noted that in several prior investigations the Commission had credited expenditures made prior to FDA approval in its domestic industry analysis. *Strontium-Rubidium Systems*, Initial Determination at 132–34, 141–42 (citing *Certain Minoxidil Powders, Salts, and Compositions for Use in Hair Treatment*, Inv. No. 337-TA-267, Comm’n Op. at 1–2 (Sept. 23, 1988);

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Certain Salinomycin Biomass and Preparations Containing Same, Inv. No. 337-TA-370, USITC Pub. No. 2978 (July 1996), Initial Determination at 128 (not reviewed); *Certain Diltiazem Hydrochloride and Diltiazem Preparations Containing Same*, Inv. No. 337-TA-348, USITC Pub. No. 2902 (June 1995), Initial Determination at 120–28 (unreviewed in relevant part)). The ALJ in *Strontium-Rubidium Systems* followed the reasoning in those earlier determinations and found a domestic industry to exist despite the lack of FDA approval. *Id.*, Initial Determination at 135, 147. The ALJ found that articles protected by the patent had been manufactured by the time the complaint was filed. *Id.* Even though those articles could not be sold commercially in the United States, significant capital had been invested domestically and significant domestic labor had been employed to manufacture the articles domestically. *Id.*, Initial Determination at 147, 149. The Commission affirmed the ALJ’s finding of a domestic industry. *Id.*, Comm’n Op. at 26.

Here, the VUSE domestic industry is on no worse footing than the domestic industry in *Strontium-Rubidium Systems*. Indeed, the facts of record in this investigation make an even stronger case for finding a domestic industry: whereas the medical devices in *Strontium-Rubidium Systems* were not available on the commercial market, the VUSE products at issue here are actually being sold. Moreover, the FDA has been notified of the VUSE products through regulatory applications (*see, e.g.*, CX-2097), and the FDA has not initiated enforcement to remove the products from the market.

In sum, the regulatory status of the VUSE products does not negate my determination that the statutory criteria for the existence of a domestic industry have been met.

IX. CONCLUSIONS OF LAW

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this investigation.
2. The importation requirement has been satisfied.
3. Claims 27–30 of the ’123 patent have been infringed.

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4. Claims 1–3 and 5 of the '915 patent have been infringed.
5. Claim 19 of the '238 patent has not been infringed.
6. The technical prong of the domestic industry requirement has been satisfied with respect to the '123, '915, and '238 patents.
7. The economic prong of the domestic industry requirement has been satisfied with respect to the '123, '915, and '238 patents.
8. Claims 27–30 of the '123 patent have not been shown invalid by clear and convincing evidence.
9. Claims 1–3 and 5 of the '915 patent have not been shown invalid by clear and convincing evidence.
10. Claim 19 of the '238 patent has been shown invalid as anticipated in view of the prior art.
11. Claim 19 of the '238 patent has not been shown invalid as failing to satisfy the written description requirement of 35 U.S.C. § 112.

X. FINDINGS OF FACT WITH RESPECT TO THE PUBLIC INTEREST

Before issuing a remedy for a violation of section 337, the Commission must consider the effect of the remedy on the following statutory public interest factors: (1) the public health and welfare; (2) competitive conditions in the United States economy; (3) the production in the United States of articles that are like or directly competitive with those that are the subject of the investigation; and (4) United States customers. *See* 19 U.S.C. §§ 1337(d)(1), (f)(1). The Commission must weigh these effects against the strong public interest favoring the protection of U.S. intellectual property rights by excluding infringing imports. *Certain Magnetic Data Storage*

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Tapes and Cartridges Containing the Same (III), Inv. No. 337-TA-1076, Comm’n Op. at 64 (June 20, 2019).

Only in rare circumstances will the Commission determine that the public interest considerations outweigh the patent holder’s rights. *See Spansion*, 629 F.3d at 1359–60 (Fed. Cir. 2010). The Commission has entirely declined to issue a remedy after finding a violation only three times, and has never done so since 1984. *Id.* at 1360 (listing investigations). In each of those three cases, the exclusion order was denied because inadequate supply within the United States—by both the patentee and domestic licensees—meant that an exclusion order would deprive the public of products necessary for some important health or welfare need: energy efficient automobiles, fundamental scientific research, or hospital equipment. *Id.*

In this investigation, the Commission delegated to me the task of gathering and evaluating evidence concerning the effect any remedy in this investigation might have on the statutory public interest factors. 85 Fed. Reg. at 29482–29483. This evidence included written comments submitted by members of the public as well as testimony and documents presented at trial. *See, e.g.*, EDIS Doc. IDs 708590, 708977, 708978, 708979, 708981, 708983, 708985, 708986, 708987, 708988, 708990, 709114; CX-0042; CX-0052; CX-0083; CX-0100; CX-0101; CX-0180C; CX-0181C; CX-0183C; CX-0190C; CX-0191C; CX-0193; CX-0201; CX-0207C; CX-0208C; CX-0243C; CX-0253C; CX-0257C; CX-0262C; CX-0271; CX-0281C; CX-0296; CX-0320C; CX-0330; CX-0336; CX-0337; CX-0338; CX-0341; CX-0342; CX-0364C; CX-0373; CX-0374C; CX-0385; CX-0390; CX-0395; CX-0409; CX-0444; CX-0458; CX-0468; CX-0506; CX-0507; CX-0508; CX-0509; CX-0522; CX-0524; CX-0525; CX-0528; CX-0529; CX-0537C; CX-0552; CX-0606C; CX-0607C; CX-0611; CX-0612; CX-0614C; CX-0695C; CX-0703C; CX-0715C; CX-0739C; CX-0746C; CX-0752C; CX-0786; CX-0787; CX-0790; CX-0792; CX-0876;

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CX-0877C; CX-0880C; CX-0889; CX-0894; CX-0895; CX-0901; CX-1015; CX-1170; CX-1202; CX-1204; CX-1205; CX-1207; CX-1216; CX-1265; CX-1284; CX-1320; CX-1322; CX-1336; CX-1364; CX-1367; CX-1368; CX-1379; CX-1380; CX-1412; CX-1420; CX-1447; CX-1465; CX-1546; CX-1563; CX-1817; CX-1840; CX-1881; CX-1882; CX-1898C; CX-1899; CX-1916; CX-1917; CX-1922; CX-1923; CX-1933; CX-1939; CX-1942; CX-1944; CX-1945; CX-1946; CX-1947; CX-1948; CX-1949; CX-1950; CX-1951; CX-1953C; CX-1954C; CX-1955C; CX-1956C; CX-1957C; CX-1958C; CX-1960; CX-2047; CX-2054; JX-0015; JX-0016; JX-0017; JX-0018; JX-0019; JX-0020; JX-0021; JX-0022; JX-0023; JX-0024; JX-0025; JX-0026; JX-0027; JX-0028; JX-0029; JX-0030; JX-0031; JX-0032; JX-0034; JX-0035; JX-0036; JX-0037; JX-0038; JX-0039; JX-0040C; JX-0048C; JX-0049C; JX-0051; JX-0052; JX-0054; JX-0055; JX-0056; JX-0057; JX-0060C; JX-0067; JX-0068; JX-0069; JX-0070; JX-0071; JX-0072; JX-0073; JX-0074; JX-0076; JX-0079; JX-0081; JX-0082; JX-0083; JX-0084; JX-0085; JX-0086; JX-0099C; JX-0102C; JX-0112C; JX-0115C; RX-0312; RX-0315; RX-0316; RX-0324; RX-0325; RX-0370C; RX-0430C; RX-0431C; RX-0432C; RX-0433C; RX-0434C; RX-0435C; RX-0436C; RX-0437C; RX-0438C; RX-0439C; RX-0440C; RX-0441C; RX-0442C; RX-0443C; RX-0444C; RX-0445C; RX-0446C; RX-0447C; RX-0448C; RX-0449C; RX-0450C; RX-0451; RX-0452; RX-0453; RX-0454; RX-0455C; RX-0456C; RX-0457C; RX-0458; RX-0459; RX-0460; RX-0461; RX-0486; RX-0630; RX-0637; RX-0639; RX-0640; RX-0662; RX-0668.

A. The Public Health and Welfare

Philip Morris, the maker of the accused IQOS devices, argues that remedial orders barring entry of imported IQOS products would adversely impact the public health and welfare. Philip Morris claims that IQOS helps smokers of traditional combustion cigarettes “move away, and stay away,” from combustion cigarette smoking. RIB at 58. Philip Morris notes the FDA has found

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that “a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies” examining the effects of IQOS use. RIB at 69 (citing JX-0034 at -2335-36). Philip Morris claims an exclusion order amounts to “depriving current and future users of the health benefits of IQOS.” *See* RIB at 71. Reynolds and Staff disagree.

I find the evidence overwhelmingly shows that excluding the IQOS products will not “deprive the public of products necessary for some important health or welfare need.” *Cf. Spansion*, 629 F.3d at 1360. As described below, this conclusion is based on scientifically reliable information from expert and independent government authorities, including the FDA and the U.S. Surgeon General.

1. Tobacco use harms the public health and welfare

IQOS is a tobacco product regulated by the FDA. JX-0018 at 1, 3. A user inserts a HeatStick into the IQOS device. JX-0034 at 16. The HeatStick contains a tobacco plug made from ground tobacco powder. *Id.* The IQOS device heats the tobacco plug and produces an aerosol that the user inhales. *Id.* The FDA has reviewed extensive data about the IQOS product, its uses, and its effects. At the conclusion of that review, the FDA reiterated, in unequivocal terms, “All tobacco products are potentially harmful and addictive.” JX-0018 at 2. It made no exception to that statement for IQOS. The FDA specifically stated that, although IQOS products are permitted for sale in the United States, the FDA has not determined “these products are safe or ‘FDA approved.’” *Id.*

The body of evidence demonstrating harm from tobacco use is overwhelming. The Surgeon General warns, “Tobacco smoke contains a deadly mix of more than 7,000 chemicals; hundreds are harmful, and about 70 cause cancer.” RX-0315.8; CX-1294 at 1. One out of every

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three cancer deaths in the United States is linked to cigarette smoking. RX-0315.12. Smoking is the number one cause of lung cancer. *Id.* Tobacco smoke also causes cancer of the voice box, mouth and throat, esophagus, pancreas, bladder, stomach, colon and rectum, liver, cervix, and kidney, as well as acute myeloid leukemia. *Id.* Smoking harms “nearly every organ of the body.” *Id.* Smoking is the leading cause of chronic obstructive pulmonary disease (“COPD”), and smoking increases the risk of stroke. RX-0315.10-11. Tobacco smoke and nicotine are harmful to reproductive health and are linked to pregnancy complications, preterm birth, low birth weight, some birth defects, decreased fertility in both women and men, and erectile dysfunction. RX-0315.13; CX-1284.

Tobacco smoking is the leading cause of preventable disease and death in the United States. RX-0315.5. Sixteen million Americans live with a serious disease caused by smoking. *Id.* But harms from tobacco are not equally distributed across society. RX-0315.5. Cigarette smoking remains highest among people with mental health conditions; people of low socioeconomic status; people without health insurance; Medicaid enrollees; lesbian, gay, bisexual, and transgender adults; people with disabilities or limitations; and American Indians and Alaska Natives. *Id.*; *see also* JX-0057 at 2–5, 15–17, 22–23 (similar inequities in Great Britain). Disadvantaged people are overrepresented in the 480,000 Americans who die from smoking each year. RX-0315.5. Smoking-related illness costs the national economy \$300 billion each year. *Id.*

2. The FDA found IQOS exposes users to carcinogens and is expected to cause them harm

Philip Morris represented to this tribunal that the IQOS system heats tobacco to release nicotine “without combusting the tobacco and exposing the consumer to the dangerous carcinogens and harmful chemicals created by combustion.” RIB at 2. This statement is at best

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extremely misleading. The FDA unequivocally stated “the use of the IQOS system clearly still exposes users to HPHCs [harmful and potentially harmful constituents], and would be expected to cause harm.” JX-0034 at 44. Many of the same dangerous carcinogens and harmful chemicals created by full tobacco combustion are also created by heating tobacco in the IQOS device. According to Philip Morris’s own testing, aerosols inhaled from the IQOS system contain known and potential carcinogens that are equivalent to about 18% of the concentration of such chemicals in the smoke of a combustion cigarette. JX-0034 at 24–25. The IQOS aerosol also has four possible or probable human carcinogens and numerous other chemicals “of toxicological concern” not found in typical combustion cigarette smoke. *Id.* The FDA found that “consuming 10 Heatsticks exposes users to levels of carcinogenic and reproductive toxicant HPHCs [harmful and potentially harmful constituents], acetaldehyde, acetamide, acrylamide, ammonia, catechol, formaldehyde, mercury, and propylene oxide that are *comparable to smoking 1-3 cigarettes.*” *Id.* at 42 (emphasis added).

It is true the FDA has found that “the available scientific evidence shows that the IQOS system produces lower concentrations of many harmful and potentially harmful constituents (HPHCs) compared to cigarette smoke.” JX-0034 at 9. But carcinogens and other harmful constituents are still present; it just takes more puffs to inhale the same dangerous quantities found in combustion cigarette smoke. *Id.* at 42.

And then there is nicotine, the highly addictive chemical in tobacco. CX-1284. While Philip Morris managed to reduce the overall concentration of dangerous chemicals in the IQOS aerosol, it ensured that systemic nicotine exposure—the nicotine received by the body—from IQOS remains at addictive levels similar to those produced by combusted cigarettes. JX-0034 at 52, 54. Another addictive compound in the IQOS aerosol, anabasine, is 26-33% *higher* in IQOS

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aerosols than in the combustion cigarette smoke when normalized by nicotine concentration. *Id.*; RX-0486.2. The FDA found the levels of nicotine in the IQOS product will “sustain addiction in nicotine-dependent populations and, in non-users, can have a similar risk of initiation and developing addiction as combusted cigarettes.” JX-0034 at 41. “A similar risk of initiation” means that IQOS presents the same risk as traditional cigarettes for inducing non-smokers to start an addictive, harmful, and potentially deadly tobacco habit. After reviewing the addiction evidence, the FDA found “no support for a general claim about reduced risk of harm” connected to IQOS use. *Id.*

According to the FDA, “nicotine can change the way the brain works, causing cravings for more of it.” CX-1284 at 2. If pregnant women use tobacco products, nicotine can cross the placenta and result in premature labor; low birth weight; respiratory failure at birth; and even sudden infant death syndrome (SIDS). *Id.* The FDA found that nicotine from IQOS poses the same risks to the fetus as nicotine from traditional cigarettes. JX-0034 at 42. Nicotine exposure during adolescence can disrupt normal brain development and may have long-lasting effects, such as increased impulsivity and mood disorders. CX-1284 at 2. The FDA found that nicotine from IQOS “may pose potentially negative effects on the developing brain in youth.” JX-0034 at 42, 44. Because of nicotine’s powerfully addictive nature and profound effects on the developing brain, the FDA and the Surgeon General both unequivocally state that “no tobacco products are safe for youth to use.” CX-1284 at 2; RX-0315.16. That includes IQOS.

3. The FDA did not find IQOS would provide a potential benefit to the population as a whole

Philip Morris points out that, due to the lower levels of harmful chemicals in IQOS aerosols, the FDA predicted that “a measurable and substantial reduction in morbidity or mortality

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among individual tobacco users is reasonably likely in subsequent studies.” RIB at 69 (quoting JX-0034). But the FDA stated multiple times in its review that “the benefits of reducing exposure to harmful and potentially harmful chemicals require *complete cessation of combusted cigarette smoking*.” See, e.g., JX-0034 at 13 (emphasis added). Unfortunately, that is not how most people use IQOS. According to Philip Morris’s own data, “dual use with combusted cigarettes is the predominant pattern of IQOS use,” with only 5.8% of IQOS users in the United States completely switching from combustion cigarettes. *Id.* at 60, 62. In fact, the only witness who testified in this investigation about personally using the IQOS system admitted that he still smokes combustion cigarettes. Hrg. Tr. 1262:15–24. Thus, while an “individual tobacco user[]” may benefit from transitioning completely to IQOS, the FDA concluded that the findings of prevalent dual use “do not provide strong support for the potential benefit to the population as a whole.” *Id.* at 60.

The FDA also pointed out that there is not necessarily a linear relationship between reduced exposure to harmful chemicals and reduced harm to IQOS users. For example, while lung cancer and COPD generally have linear dose-response relationships with smoking, cardiovascular disease has a non-linear relationship with smoking. JX-0034 at 41. Even low levels of exposure to tobacco, such as a few cigarettes per day, occasional smoking, or exposure to secondhand tobacco smoke are sufficient to substantially increase risk of cardiac events. *Id.* Thus, while a reduction in smoking may decrease risk of some diseases, it may not decrease risk of other tobacco-related diseases. *Id.*

4. Philip Morris has marketed IQOS to youth in contravention of its own policies and FDA restrictions

Philip Morris avers in this investigation, as it did to the FDA, that “IQOS is intended to move a smoker away from [combustion cigarettes] to a less harmful means of enjoying tobacco.”

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RIB at 81. But the full record evidence tells another story. “Tobacco companies make their money by selling tobacco.” JX-0057 at 188. Companies like those in this investigation recognize that “disruptive technology . . . should be harnessed to protect the core business of selling tobacco, exploited to expand tobacco markets or developed as an opportunity to make nicotine products attractive to non-smokers.” *Id.* As researchers at Stanford University bluntly put it, “if [Philip Morris] were serious about achieving a ‘smoke-free world,’ it would halt its aggressive worldwide marketing of Marlboro, and its other major tobacco brands, and also curtail its generously funded political lobbying efforts to suppress governmental actions to protect public health.” CX-1412 at 9.

There is evidence that Philip Morris intends to use IQOS to addict new tobacco users and expand its market, not just transition existing smokers. The majority of smokers are between the ages of 30 and 60 with lesser prevalence among other age groups. CX-1412 at 7. According to researchers at Stanford University, if Philip Morris intended to reach an audience of middle-aged smokers, its marketing message “would be delivered by a middle-age smoker describing how IQOS helped them with their cigarette smoking addiction.” *Id.* Instead, “IQOS advertisements are dominated by chic, attractive young models, especially females, in fashionable dress and elegant poses.” *Id.* Also, according to the Stanford researchers, the marketing channels favored by the 30- to 60-year old demographic are printed magazines and newspapers (or their digital equivalents), television, and radio. *Id.* at 8. But instead of those channels, Philip Morris entered into a \$6.5 million agreement with Vice Media, which describes itself as the “Fast growing, #1 youth media company in the world.” *Id.* at 9. IQOS marketing is most heavily present in social media channels such as Instagram, which have a strong youth bias. *Id.* An internal Philip Morris document gives the following example of an Instagram post that follows IQOS brand guidelines:

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“Our photo shows twenty-something friends hitting the town with the city lights at their backs” with the caption “Bright lights, big city...and your #iQOS, #nyc.” *Id.* at 67–68.

Just two months after the FDA imposed “stringent restrictions” on marketing IQOS to young people “via websites and through social media platforms,” Philip Morris was caught paying young people to market IQOS on Instagram. *See* JX-0018 at 3 (announcing FDA restrictions on youth marketing); CX-1015 (Reuters report). Reuters investigative reporters found Philip Morris paid a 21-year-old Instagram influencer to post about IQOS, in violation of its stated company policy that prohibits marketing tobacco products with “models who are or appear to be under the age of 25.” CX-1015. The influencer plugged IQOS while posing in “seductive photos of herself drinking wine, swimming and posing with little clothing in luxurious settings.” *Id.* And that influencer was not the only young person hired by Philip Morris to push IQOS. Reuters found Philip Morris had paid young social media influencers in Japan, Italy, Switzerland, Russian, and Romania. *Id.* When confronted with the Reuters reporting, Philip Morris admitted it had violated its own policies and, in response, supposedly suspended its global social media marketing campaign. *Id.* But around this same time, in May 2019, Philip Morris promoted IQOS as a sponsor of Tel Aviv University’s Student Day, an activity the Stanford researchers called “clearly youth-oriented.” CX-1412 at 8, 16. And notwithstanding its promise to change its practices after the Reuters story broke, the record shows “youth appealing marketing [of IQOS] continues worldwide.” *Id.* at 11.

Ninety percent of traditional cigarette smokers start smoking before the age of 18. CX-1015 at RJRITC_001247128. Youth who have never used tobacco products are more

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interested in trying IQOS than combustion cigarettes. *See* CX-1265. The risk to non-smoking youth presented by IQOS is real, and it is of concern to the FDA. JX-0018 at 3.⁵

5. Comments from members of the public do not support denial of a remedy

As discussed in Order No. 39 issued on March 12, 2021, Philip Morris coordinated the filing of comments under the signatures of doctors and others when the Commission requested comments from the public in this investigation. As described below, those comments are unreliable primarily because they are anecdotal and fail to account for the scientific evidence evaluated by the FDA. They are also tainted by bias introduced by Philip Morris.

At a public preliminary conference, I asked Philip Morris about the relationship between it and the signatories on certain public interest comments. 6/10/20 Tr. at 59:7–11. Counsel for Philip Morris responded that “there is not that high level of coordination that I believe the Court assumes” and that Philip Morris was “just trying to facilitate the mechanics of filing” the public interest statements as “an administrative courtesy.” 6/10/20 Tr. at 59:7–23, 62:6–10. As would become clear during the investigation, that statement from Philip Morris’s counsel was not true. The record contains evidence that Philip Morris employees exchanged many emails, drafts, and edits with persons who submitted public interest comments in this investigation. *See* CX-2054. Philip Morris also provided direct and in-kind contributions to many of the commenters. That evidence is reviewed below.

⁵ Philip Morris submitted research studies evaluating the potential for uptake of IQOS among every age demographic except youth. JX-0034 at 65. This omission caused some concern in the FDA review process. *Id.*

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a) Dr. Gunther

Dr. Julie Gunther practices medicine at a clinic called SparkMD in Boise, Idaho. In early 2019, a lobbyist named Jay Keese told Dr. Gunther that the IQOS heat-not-burn products at issue in this litigation might help patients overcome addiction to smoking combustion cigarettes. Hrg. Tr. 1208:15-1209:13. Mr. Keese told Dr. Gunther that Philip Morris was inviting physicians and others to learn more about the IQOS product on a five-day, all-expenses-paid trip to Philip Morris facilities in Switzerland and Italy. Hrg. Tr. 1209:14–1210:1; 1216:18–1217:1; 1218:10–17. Dr. Gunther told Mr. Keese she was intrigued. Hrg. Tr. 1209:16-17.

From the beginning, Dr. Gunther suspected something was going to be asked of her in exchange for the trip. Hrg. Tr. 1209:16-17. When she inquired about the quid pro quo, she was told that after learning about IQOS on the trip she would be asked to give her “forthright opinion about what a clinician who takes care of her people thinks about this product.” Hrg. Tr. 1209:23–1210:9. Dr. Gunther accepted the offer. *Id.*

Dr. Gunther was then contacted by William Muller, a representative of Phillip Morris. Hrg. Tr. 1214:20–1215:1. Mr. Muller coordinated Dr. Gunther’s travel to Europe, a trip that occurred in April of 2019. Hrg. Tr. 1214:20–1215:1, 1233:16–17. The five-day trip involved a couple of hours talking about tobacco harm reduction. JX-0099C at 284:1–13. The tour participants did not see much on the facilities tour, “just looking into the windows” at the facility. JX-0099C at 284:14–21. And not everything on the trip was related to learning about IQOS. When Philip Morris gave Dr. Gunther the choice of visiting a Philip Morris factory in Bologna or a Ferrari factory in the same city, she chose to visit the Ferrari factory. Hrg. Tr. 1218:10–19.

Mr. Muller then asked Dr. Gunther to write an article for a publication called RealClear Health. Hrg. Tr. 1215:9-15. He provided a suggested draft of the article to Dr. Gunther. Hrg. Tr.

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1215:16–1217:17, 1234:20–1235:3. Dr. Gunther testified that she thought the suggested draft “was garbage” but an article under Dr. Gunther’s name was published in RealClear Health in July 2019. Hrg. Tr. 1223:21–23, 1236:8–17; CX-1944C.

During her April 2019 trip to Europe, Dr. Gunther met Ondrej Koumal, director of communications and engagement at Philip Morris. Hrg. Tr. 300:5–24; 1218:4–9; 1227:15–17. Later in 2019, Mr. Koumal invited Dr. Gunther to travel from Boise on an all-expenses-paid trip to a Formula One race in Austin, Texas, on Halloween weekend. JX-0099C at 292:7–293:1; Hrg. Tr. 1223:18–20. She sat in a sponsored box during the race at the invitation of Philip Morris. Hrg. Tr. 1220:12–16. She was also invited to a concert and to hear motivational speakers during her trip to Austin. Hrg. Tr. 1220:17–19. Dr. Gunther remembers interacting with Mr. Koumal during the trip and after. Hrg. Tr. 1227:18–1228:2.

In April 2020, Philip Morris reached out to Dr. Gunther again, this time through Mr. Koumal, and asked her to make a public interest statement in this investigation. JX-0067; Hrg. Tr. 1223:24–1224:2; 1227:4–8. Mr. Koumal sent Dr. Gunther a draft comment for the Commission based on the article published under her name in RealClear Health. JX-0067. Dr. Gunther testified at her deposition that she knew that the draft was “what they prefer is said” about IQOS. Hrg. Tr. 1230:6–1231:3. Dr. Gunther emailed Mr. Koumal back an edited version of the draft, and Mr. Koumal responded that he would send her HeatSticks for her father’s IQOS device when they became available. CX-1942C. Some of the wording in the public interest comments Philip Morris ultimately filed on behalf of Dr. Gunther is different than the draft it sent her, but the overall message is the same. A comparison of a few passages demonstrates this point, with differing language emphasized:

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Language Suggested by Philip Morris JX-0067	Language in Dr. Gunther's filed comments EDIS Doc. ID 708987
If I can't help people quit all of the way ...can I help them quit part way? Does shifting towards the road of cessation move people through the hardest first part of change? Leading a conversation that looks towards cessation as a matter of incremental change differs from the long-held culture of saying that smoking is deleterious for health and quitting is the only option. The absolutism of that strategy towards cessation has been and remains woefully ineffective.	I began to think, if I can't help people quit all the way...can I help them quit part way? Does shifting towards the road of cessation move people through the hardest first part of change? Leading a conversation that looks towards cessation as a matter of incremental change differs from the long-held culture of saying that smoking is deleterious for health and quitting is the only option. The absolutism of that strategy towards cessation has been and remains woefully ineffective.
Is continuing a harmful habit that can be modified to be less harmful, better than no change at all? As a physician and daughter of a smoker, I think it is.	Is continuing a harmful habit that can be modified to be less harmful better than no change at all? As a physician and daughter of a smoker, I think it is.
That is why taking away IQOS - the only novel alternative nicotine product reviewed by the US Food and Drug Administration and found to be appropriate for the protection of public health - as a tool to help patients on this road to behavioral change is disturbing.	Taking away the IQOS - the only novel alternative nicotine product reviewed by the U.S. Food and Drug Administration and found to be appropriate for the protection of public health - would be a massive step backward in U.S smoking reduction.
To change the absolutist strategy towards cessation, a wide choice of potentially reduced risk products is needed. Excluding IQOS would be a step in the wrong direction.	To change the absolutist strategy towards cessation, a wide choice of potentially reduced-risk products is needed. Excluding IQOS as a product available to US smokers would be a step in the wrong direction.

There is no evidence in the record that, before submitting her comments, Dr. Gunther personally reviewed the FDA findings summarized in my analysis above. In particular, Dr. Gunther does not address the FDA findings that (1) “the use of the IQOS system clearly still exposes users to [harmful and potentially harmful constituents], and would be expected to cause

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harm” (JX-0034 at 44); (2) studies showing prevalent dual use of IQOS and combustion cigarettes “do not provide strong support for the potential benefit to the population as a whole” (*id.* at 60); and (3) IQOS presents the same risk of addiction to non-smokers as combustion cigarettes, “thereby providing no support for a general claim about reduced risk of harm” (*id.* at 41). Her comments about her own patients are anecdotal, in contrast to the extensive scientific studies about IQOS reviewed by the FDA. For at least these reasons, I give Dr. Gunther’s public interest comments little weight.

Additionally, the record demonstrates that Dr. Gunther’s comments may have been influenced by bias. She has accepted travel gifts and attorney services from Philip Morris valued in the many thousands of dollars. I discount the weight of her comments for this additional reason.

b) Dr. Nikan Khatibi

The Commission also received public comments on relief in this investigation from another physician, Dr. Nikan Khatibi, who, like Dr. Gunther, took Philip Morris up on its offer of paid trips to Europe and to the Formula One race in Austin. JX-0099C at 281:6-12; Hrg. Tr. 307:7-21. Philip Morris sent Dr. Khatibi a draft statement for submission to the Commission. Hrg. Tr. 302:3-6; CX-0787. As discussed in Order No. 39, attorneys paid by Philip Morris filed a statement under Dr. Khatibi’s signature with the Commission. The submission to the Commission with Dr. Khatibi’s signature is identical, word-for-word, with the draft Philip Morris emailed him. *Compare CX-0787 with EDIS Doc. ID 708979.*

I find Dr. Khatibi’s public interest comments to lack credibility. The weight of the evidence surrounding the submission raises serious doubts as to whether Dr. Khatibi has personal knowledge of the matters asserted therein. Additionally, like Dr. Gunther, there is no evidence

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that Dr. Khatibi personally considered the FDA findings about the potential harms of IQOS summarized above.

c) Other Filers of Public Comments

The American Conservative Union, the American Vaping Association, Consumer Advocates for Smoke-free Alternatives Association (“CASAA”), the Progressive Policy Institute, and Nextera Healthcare also submitted public interest comments. Like Dr. Gunther and Dr. Khatibi, the people who submitted public interest comments on behalf of these organizations took trips to Europe paid for by Philip Morris. JX-0099C at 279:17–282:2.

The record shows Philip Morris wrote the original draft for the comments from CASAA. *Id.* at 176:9–177:21; 179:9–19. Beyond the trip to Europe, [REDACTED] *Id.* at 242:12–16.

The record further contains comments from the Reason Foundation. Philip Morris paid for a representative from that group to attend the Formula One race in Austin, and [REDACTED] JX-0099C at 242:17–20, 294:10–20. The Reason Foundation submitted comments after Philip Morris asked. *Id.* at 77:15–22.

The record also contains a submission from an organization called TechFreedom. EDIS Doc. ID 708988. The record shows Philip Morris edited the statement submitted by TechFreedom and removed references to certain studies. *See, e.g.*, JX-0099C at 139:17–141:2. Philip Morris also discussed with TechFreedom how much publicity the TechFreedom submission should receive. *Id.* at 147:3–148:9.

The Smoke-Free Alternatives Trade Association (“SFATA”) also submitted public interest comments. EDIS Doc. ID 708986. The record indicates Philip Morris provided edits to SFATA’s

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comments and engaged in negotiations with SFATA about what should stay in the comments and what should be left out. *See, e.g.*, JX-0099C at 203:10–205:6, 212:24–213:14.

The record also contains a comment from the Schizophrenia and Related Disorder Alliance of America (“SARDAA”). [REDACTED] JX-0099C at 244:7–11. Like other commenters, that organization submitted its statement at the behest of Philip Morris. *Id.* at 77:23–78:4

As discussed in Order No. 39, the comments under the signatures of these entities were all filed by attorneys paid for by Philip Morris, and Philip Morris paid for their legal representation during the course of the investigation.

Given the record of extensive coordination between Philip Morris and these commenters, I do not find their comments to be objective. As with Dr. Gunther and Dr. Khatibi, there is no evidence that these entities considered the FDA findings about the potential harms of IQOS that I have credited above. For all of these reasons, I give these public interest comments little weight in formulating my recommendation on remedy.

d) Congressman George Holding

Congressman George Holding also submitted comments relating to the public interest. EDIS Doc. ID 709114. Congressman Holding represented, until January 2021, a tobacco-producing district in North Carolina. JX-0099C at 299:1–16.

Congressman Holding submits that removing IQOS from the market would have an adverse impact on the public interest. EDIS Doc. ID 709114. He notes IQOS has been authorized for sale by the FDA and argues that smokers need access to a wide range of products to reduce the harm of smoking. *Id.* Congressman Holding also submits that exclusion of IQOS runs counter to the intent of Congress laid out in the 2009 Tobacco Control Act, which in his view provided a

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pathway for products like IQOS to come to U.S. market. *Id.* He points out that the FDA determined that IQOS is “appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes.” *Id.* Congressman Holding relies on a Philip Morris earnings report stating that IQOS has “conversion rates of approximately 71%.” *Id.* He also cites materials submitted to the FDA stating that IQOS outsells Marlboro in Japan. *Id.* Congressman Holding also made economic arguments that I address below.

With respect to public health and welfare, it is unclear whether Congressman Holding had the benefit of reviewing the full FDA findings relating to IQOS that are in the record of this investigation. The FDA findings on conversion rates to IQOS contradict the statements from Philip Morris that Congressman Holding cites. The FDA stated that “dual use with combusted cigarettes is the predominant pattern of IQOS use,” with only 5.8% of IQOS users in the United States completely switching from combustion cigarettes. JX-0034 at 60, 62. The FDA reiterated that without “*complete cessation of combusted cigarette smoking*,” IQOS users will not experience a reduction in harm. *See, e.g.*, JX-0034 at 13 (emphasis added). The multiple studies considered by the FDA show prevalent dual use of IQOS and combustion cigarettes and “do not provide strong support for the potential benefit to the population as a whole.” *Id.* at 60. Additionally, the FDA concluded, after examining extensive data, that IQOS presents the same risk of addiction to non-smokers as combustion cigarettes, “thereby providing no support for a general claim about reduced risk of harm.” *Id.* at 41.

The limited data cited by Congressman Holding does not give the full picture of the harms and potential benefits presented by IQOS. The FDA findings, on the other hand, give scientific consideration to all relevant materials of record. I therefore give more weight to the FDA findings.

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6. Combustion cigarette smokers have safer options than IQOS, and those options have been proven effective in reducing harm

The record demonstrates that the number of smokers in the United States has been steadily declining for five decades, long before the introduction of IQOS to the U.S. market. RX-0315.4. Clearly, IQOS is not the only path to reduced tobacco harm. The record identifies safer ways than IQOS to help combustion cigarette smokers transition away from harmful cigarette smoke. The Surgeon General issued a report describing “evidence-based strategies” for quitting smoking. RX-0315.5. It includes five nicotine replacement therapies, such as patches, gum, and lozenges, that have been shown to be effective for helping adults quit smoking based on scientific evidence reviewed by the FDA. RX-0315.15. Two non-nicotine medications, varenicline and bupropion, have been found by the FDA to reduce cravings for nicotine and help smokers quit. *Id.* The Surgeon General also advises that combining medication and counseling “can more than double one’s chances of successfully quitting.” RX-0315.14. These scientifically validated interventions would remain available to all smokers if the IQOS products are excluded from the U.S. market, and none have the carcinogenic chemicals produced by IQOS.

7. Public Health Conclusion

Based on the factual findings above, I have determined that the scientific evidence entered into the record of this investigation shows that excluding the IQOS products will not adversely affect the public health and welfare as a whole. Other therapies to reduce tobacco use have been found by the FDA to be effective, and those alternatives do not cause harm by exposing users to carcinogens. There is even reason to conclude that excluding the IQOS devices may have a positive effect in preventing youth from taking up tobacco use for the first time with the IQOS device. The public health and welfare facts do not weigh against entry of a remedy.

B. The Production of Like Articles in the United States

Philip Morris argues that there is no IQOS substitute on the U.S. market because there is no other aerosolized tobacco product with the kind of FDA authorizations IQOS has received. RIB at 71. It also suggests that no other products provide nicotine delivery with the same efficiency, taste, and sensory experience as IQOS. RIB at 81–83.

Philip Morris applies too stringent a test for like articles. Section 337 directs the Commission to evaluate the continued availability of “like or directly competitive articles in the United States.” *See* 19 U.S.C. § 1337(d)(1). Commission precedent supports consideration of other non-infringing alternatives in the market, even when those alternatives are not exactly the same as the accused products. *See, e.g., Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Comm’n Op. at 66 (June 20, 2019) (looking to the “total data storage market” and finding that the accused magnetic tape products “account for only a small share of the total data storage market and continue to face steep competition from hard disk drives and memory technologies”); *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*, Inv. No. 337-TA-1012, Comm’n Op. at 143–44 (Apr. 2, 2018) (stating that “while Sony insists the relevant market should be narrowed to LTO-7 tapes, its own witness admitted that all storage media directly compete with Sony’s LTO-7 tapes,” including optical media and hard disk drives).

The tobacco companies feuding in this investigation, and others, have ensured there is no shortage of like tobacco products delivering nicotine to U.S. consumers. For example, Reynolds’s VUSE heat-not-burn product is available on the U.S. market, as described in my domestic industry findings. Reynolds’s Eclipse product also remains on the market. Hrg. Tr. 65:6–15. Additional Eclipse products are the subject of FDA marketing orders. Hrg. Tr. 66:6–12, 467:23–468:22,

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1437:5–11, 1438:6–20. Philip Morris’s expert on the regulation of products under the FDA’s jurisdiction, Ms. Ehrlich, testified that the “FDA has never taken the position that there are not other substitutes for IQOS.” Hrg. Tr. 1442:20–25.

In the smokeless tobacco category, Philip Morris sells a broad range of products under the Skoal® and Copenhagen® brand names. Dr. Murrelle testified that Kodiak and Grizzly are additional examples of available smokeless tobacco products, and that the Skoal, Copenhagen, Kodiak, and Grizzly products all currently have FDA authorization to remain on the market. Hrg. Tr. 505:13–506:10; CDX-0005.15. In the snus category, Swedish Match obtained similar marketing authorization from FDA as was provided for IQOS, allowing its General Snus products to be marketed as reduced risk. CX-1280 at 1. Dr. Murrelle testified that Copenhagen Snus is also available in this category. Hrg. Tr. 506:11–20; CDX-0005.15.

In the oral tobacco products category, Dr. Murrelle identified Velo, ZYN, and on! as examples of available products. Hrg. Tr. 504:21–505:12; CDX-0005.15.

Numerous nicotine replacement therapies are also marketed in the United States, including Commit, Nicorette, and NicoDerm. Hrg. Tr. 504:13–20; CDX-0005.15. Dr. Murrelle testified that each of the Commit, Nicorette, and NicoDerm products are FDA-approved smoking cessation products. *Id.*

Reynolds’s expert Dr. Murrelle testified that thousands of e-cigarette or vaping options are currently available in the United States for smokers looking for an alternative to combustion cigarettes. Hrg. Tr. 454:8–12, 458:4–459:3. Dr. Murrelle identified Juul, Blu, and Naked as examples. Hrg. Tr. 503:14–504:5; CDX-0005.15. Philip Morris’s expert Dr. Rodu also testified that, just considering e-cigarettes, “[t]here are thousands of choices.” CX-0528.2. Dr. Rodu further testified that e-cigarettes have proven to be more successful at transitioning smokers off of

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combustion cigarettes than IQOS. Hrg. Tr. 1300:21–1301:7. Dr. Rodu came to this opinion about e-cigarettes after he submitted a lengthy paper in 2017 evaluating IQOS. JX-0026; Hrg. Tr. 1293:7–1294:15. He was thus well-aware of IQOS when he declared e-cigarettes to be the “best” and “most popular—and most successful—quit smoking aids.” CX-0528.2. Philip Morris admitted that its products are properly classified under subheadings 8543.70.9930 and 8543.90.8850 of the Harmonized Tariff Schedule of the United States, which are classifications for vaping articles. *See* Philip Morris Resp. to Compl. ¶ 111 (EDIS Doc. ID 717980); Response of Respondents Philip Morris International Inc. and Philip Morris Products S.A. to the Amended Complaint and Notice of Investigation ¶ 111 (EDIS Doc. ID 717975) (Aug. 24, 2020). Thus, Philip Morris has effectively conceded that the thousands of e-cigarettes and vaping devices on the U.S. market are like products to the IQOS in the trade context.

Philip Morris argues that the FDA has not authorized the sale of e-cigarettes and therefore they are “illegal” and cannot be considered like products to the IQOS. *See* RIB at 71, 75–77. But Philip Morris cites no authority supporting the proposition that the regulatory status of an article can preclude it from being a like article. I conclude, and no party disputes, that the FDA has jurisdiction over the regulation of e-cigarettes and vaping products. *See* 81 Fed. Reg. 28973 (May 10, 2016) (“The Deeming Rule”). I therefore decline to make a determination on the legality of e-cigarettes in the context of this investigation. *See Amarin Pharma, Inc. v. Int’l Trade Comm’n*, 923 F.3d 959, 965 (Fed. Cir. 2019) (affirming the Commission’s restraint when the FDA “has not yet provided guidance” on an issue within the FDA’s authority). For the purposes of weighing this public interest factor, it is sufficient to find that thousands of e-cigarettes and vaping products remain on the market in the United States without the FDA taking enforcement action against them. They are like products to the IQOS.

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Finally, Philip Morris's witness, Pierpaolo Magnani, who is Global Head of Behavioral and Regulatory Insights, Philip Morris Products SA, admitted the breadth of the market of like products in the United States: "[T]here are e-cigarettes, there are oral tobacco cigarettes, heated tobacco products, which is only an advantage if you think from a harm reduction perspective. It means that, you know, those 37 million adult smokers, they have more alternatives in front of them, and they can choose one of the many alternatives." JX-0093C at 195:23–196:12.

In sum, the effect of an exclusion order or cease and desist order will not diminish the production of like articles in the United States. This factor does not weigh against entry of a remedy.

C. Competitive Conditions in the United States Economy

The private parties and Staff submitted no evidence specifically directed to competitive conditions in the United States economy.

A submission from Congressman George Holding stated that the exclusion of IQOS threatens American agriculture and jobs. EDIS Doc. ID 709114. He submits that tobacco growers rely on products like IQOS to support their families and communities, especially as the new industry evolves. *Id.* Congressman Holding urged the Commission to carefully evaluate the economic implications of an exclusion order in North Carolina. *Id.*

The record indicates that there are currently [REDACTED] IQOS users in the United States, and [REDACTED]. CPX-0235C; CX-0127C; JX-0094C at 106:24–107:4; JX-0034 at 60, 62. Thus, even if the IQOS devices were excluded, most IQOS users would continue to smoke tobacco grown in North Carolina and elsewhere. In addition to IQOS users, there are 34 million combustion smokers of tobacco. RX-0315.2. The demand for tobacco in North Carolina from those smokers will remain high even

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if an exclusion order is entered. I do not find that this factor weighs against entry of an exclusion order.

D. United States Customers

As noted above, IQOS adoption is not widespread among U.S. consumers, with currently [REDACTED] [REDACTED]. CPX-0235C; CX-0127C; JX-0094C at 106:24–107:4. As compared to the population as a whole, or even the population of 34 million smokers specifically, the effect of a remedy in this investigation on consumers would be minimal. For the small number of affected IQOS consumers, there are thousands of other tobacco choices and cessation products available. Hrg. Tr. 459:4–16. Moreover, as noted above, there may be health and economic benefits to U.S. consumers if IQOS is excluded, particularly if young people targeted by Philip Morris have no access to IQOS to begin a harmful tobacco addiction that will be costly to them and to society as a whole.

The effect of a remedy on U.S. consumers does not weigh against entry of a remedy.

E. Public Interest Conclusion

In sum, the public interest evidence of record does not weigh against entry of a remedy.

XI. RECOMMENDED DETERMINATION ON REMEDY AND BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(1)(ii).

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A. Limited Exclusion Order

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). A limited exclusion order directed to a respondent's infringing products is among the remedies that the Commission may impose. *See* 19 U.S.C. § 1337(d).

Reynolds contends it is “entitled to a permanent limited exclusion order, pursuant to 19 U.S.C. § 1337(d), barring from entry into the U.S. any Accused Products that infringe one or more of the Asserted Claims of the Asserted Patents.” CIB at 101. Although Philip Morris does not dispute that a limited exclusion order would be an appropriate remedy for a violation of section 337, *see* RIB at 87–92, it argues that any remedial order “should include an exemption for service, warranty, repair, or replacement of any products sold before the issuance of any exclusion order” and “should contain the standard provision.” RIB at 87–89. Staff takes the position that “an exception to any limited exclusion order for service, warranty, repair, and replacement products, but not for non-commercial consumption, is appropriate” because the record evidence shows that Philip Morris's IQOS products are subject to contractual warranty and repair obligations. SIB at 139 (citing CX-0450 (IQOS User Guide) at 17 (outlining “IQOS Limited Warranty” and directing users where and how to make a warranty claim under that warranty)).

Staff also “believes that a standard certification provision is appropriate, particularly if the exclusion order includes the requested service, warranty, repair, and replacement products exception.” SIB at 139 (citing *Certain Digital Televisions & Certain Prods. Containing Same & Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op. at 11–12 (Apr. 23, 2009)). Staff asserts that “the Commission now generally includes a certification provision in every exclusion order because it is something that ‘[U.S. Customs and Border Protection] typically requests.’” *Id.*

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(citing *Certain Road Construction Machines & Components Thereof*, Inv. No. 337-TA-1088, Comm’n Op. at 50 (July 15, 2019); *Certain Composite Aerogel Insulation Materials and Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm’n Op. at 62 (Feb. 22, 2018) (explaining that complainant’s request to depart from standard certification provision was “contrary to the Commission’s standard practice for the past several years to include certification provisions in exclusion orders to aid [U.S. Customs and Border Protection]”)). Philip Morris agrees that any limited exclusion order “should contain the standard provision allowing Respondents to certify, pursuant to procedures to be specified by U.S. Customs and Border Protection, that it is familiar with the terms of the order, that it has made appropriate inquiry, and that, to the best of its knowledge and belief, the products being imported are not excluded from entry under the order.” RIB at 89. Reynolds, on the other hand, argues that

No certification procedure is needed in this Investigation because a visual inspection of the Accused Products by Customs would readily resolve whether they should be excluded based on the product packaging that identifies the model of the device. There are no non-infringing models of the Accused Products authorized for sale in the United States. Also, due to FDA regulations, Respondents are unable to modify the Accused Products to avoid infringement while still retaining their authorization to market the products in the U.S.

CIB at 103.⁶

If the Commission determines that a violation of section 337 has occurred and if consideration of the statutory public interest factors does not require that remedies be set aside or modified, I recommend that the Commission issue a limited exclusion order barring entry of

⁶ In its responsive post-hearing brief, Philip Morris asserts for the first time contentions as to why HeatSticks should not be included within the scope of remedial orders. RRB at 84–86. These contentions were not presented in Philip Morris’s pre-hearing brief and are therefore waived. *See* Order No. 8 at Ground Rule 11.2.

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products that infringe the Asserted Patents. I do not recommend a warranty and repair exception to the limited exclusion order. Such exceptions may be made if a respondent establishes that its customers expect or require exact replacement parts or will be detrimentally affected by using non-infringing alternatives. *Certain Optoelectronic Devices for Fiber Optic Commc'ns, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-860, Comm'n Op. at 31–33 (Apr. 17, 2014). Here, Philip Morris has not provided any such evidence from its customers or demonstrated that a repair industry exists in the United States. *See Certain Magnetic Data Storage and Tapes and Cartridges Containing the Same (II)*, Inv. No. 337-TA-1076, Initial Determination at 174, *aff'd*, Comm'n Op. at 61–62 (denying exception because respondent failed to provide sufficient evidence).

I also do not recommend the inclusion of a certification provision in the limited exclusion order. A certification procedure is used when U.S. Customs and Border Protection may not be able to identify infringing goods through a visual inspection. Here, however, such a procedure is not warranted because the adjudicated models of IQOS infringe without exception. U.S. Customs and Border Production would be able to identify what products should be excluded by a simply visual inspection.

B. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for a violation of section 337. 19 U.S.C. § 1337(f)(1). The Commission may issue a cease and desist order when it has personal jurisdiction over the party against whom the order is directed. *Gamut Trading Co. v. U.S. Int'l Trade Comm'n*, 200 F.3d 775, 784 (Fed. Cir. 1999).

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Under Commission precedent, “[c]ease and desist orders are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.” *Certain Air Mattress Systems, Components Thereof, and Methods of Using the Same*, Inv. No. 337-TA-971, Comm’n Op. at 49 (May 17, 2017) (citations and footnote omitted).

Reynolds argues it is entitled to cease and desist orders “directed to Respondents in view of the commercially significant inventories of Accused Products that Respondents have stipulated they hold in the U.S.” CIB at 101 (citing Stip. ¶¶ 119–29). Although Philip Morris does not dispute that a cease and desist order would be an appropriate remedy if the Commission found a violation of section 337, it argues that cease and desist orders should not issue as to respondents Altria Client Services LLC or Philip Morris Products S.A. because those entities “do not keep, store, hold, warehouse, maintain, or control a commercially significant inventory of the Accused Products in the U.S.” RRB at 86–88. *See* RIB at 87–92; RRB at 86–88. Staff takes the position that cease and desist orders directed to all Philip Morris entities are appropriate. SIB at 140.

Philip Morris has stipulated that as of at least August 31, 2020, Altria Group Distribution Company, [REDACTED], and Philip Morris USA all keep, hold, warehouse, or maintain within the United States certain products for and on behalf of Philip Morris USA as identified in exhibits CX-0321C and CX-322C, *i.e.*, the Accused Products. Stip. ¶¶ 119–24. Philip Morris has further stipulated that Philip Morris USA maintains control over the inventories of these Accused Products that are kept, stored, held, warehoused, maintained, or controlled for and on behalf of Philip Morris USA. *Id.* ¶ 125. Moreover, Philip Morris has stipulated that these physical locations where Philip Morris USA

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keeps, stores, holds, warehouses, maintains, or controls inventories of the Accused Products constitute a “commercially significant inventory” of the Accused Products as identified in exhibits CX-0321C and CX-322C. *Id.* ¶¶ 124, 126. I find, based on these undisputed facts, that Philip Morris has a commercially significant domestic inventory of products that infringe the Asserted Patents.

I next consider whether the mere existence of commercially significant domestic inventories automatically entitles Reynolds to cease and desist orders against Philip Morris. This was up for some debate in *Certain Dental Implants*, Inv. No. 337-TA-934, USITC Pub. No. 4905 (June 1, 2019), where the Commission was divided on the issue. However, the Commission has now settled the point and clarified that a complainant has an affirmative burden to show that a cease and desist order “is *necessary* to address the violation found in the investigation.” *Certain Air Mattress Systems*, Comm’n Op. at 49–50 (emphasis added).

Reynolds’s scant briefing failed to show that cease and desist orders are necessary to prevent Philip Morris from undercutting the remedy provided by a limited exclusion order. On the facts of this record, it is my recommendation that no cease and desist orders issue if the Commission determines that a violation of section 337 has occurred and if consideration of the statutory public interest factors does not require that remedies be set aside or modified.

C. Bond During Presidential Review

Pursuant to section 337(j)(3), the administrative law judge and the Commission must determine the amount of bond to be required of a respondent, during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

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When reliable price information is available, the Commission has often set the bond by eliminating the differential in sales prices between the domestic product and the imported, infringing product. *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 24, USITC Pub. No. 2949 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm’n Op. at 41–43, USITC Pub. No. 2670 (1995). A 100% bond has been required when no effective alternative existed. *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm’n Op. at 26–27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

With respect to bond, Reynolds argues that a bond of 100% is appropriate. *See* CIB at 103–04. Reynolds argues that a direct comparison of product pricing in this investigation is not meaningful here and fails to take into account that one VUSE Solo cartridge provides more than ten times the number of puffs as one accused HeatStick. *Id.* Reynolds’s expert Dr. Mody testified that evaluating pricing on a “per-puff basis” is more appropriate under the circumstances of this investigation than a straight comparison of retail pricing and concluded that a 100% bond would be appropriate under a per-puff-basis analysis. *See id.*

As an initial matter, Reynolds has not demonstrated that a bond is needed to protect its domestic industry from unfair importation during the Presidential review period in the event the Commission finds a violation of section 337 and imposes a remedy. *See Certain Mobile*

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Telephones and Wireless Commc'n Devices Featuring Digital Cameras, and Components Thereof, Inv. No. 337-TA-703, Recommended Determination at 148 (Jan. 24, 2011) (complainant failed to provide evidence on the necessity of a bond); *Certain Digital Video Receivers and Related Hardware and Software Components*, Inv. No. 337-TA-1103, Initial Determination at 320 (July 21, 2006) (recommending 0% bond where complainant “has not satisfied its burden of establishing a need for a bond”). Here, the record contains reliable price information regarding the Accused Products and the domestic industry products. For example, Philip Morris’s expert Dr. Arnold testified that the retail prices for the accused IQOS systems in the United States exceed the prices of the domestic industry VUSE products. RX-0747C at Q9. The table below illustrates that point:⁷

IQOS Kits and VUSE Power Units – Price Differential

	IQOS Kit	VUSE Solo		VUSE Vibe	
	Price	Price	Price Differential	Price	Price Differential
Retail Price	\$100.00	\$11.99	–\$88.01	\$11.99	–\$88.01
Average Retail Price					
Average Import Price					

Id. at Q12, Q13 (citing CX-0147C; RPX-0024C; <https://vusevapor.com/devices/solo>; <https://vusevapor.com/devices/vibe>). Each of these comparisons demonstrates that the IQOS systems are not being imported or sold at prices that undercut Reynolds’s domestic industry products. Additionally, Reynolds’s “per-puff” price theory has no basis fact. Reynolds has shown

⁷ The “Retail Price” row in the table is only a suggested list price. The record evidence shows that the products are offered at different prices, so averages are informative also. *See, e.g.*, Hrg. Tr. 655:24–656:4.

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no evidence that the relevant market moves on a “per-puff basis” making a bond set on those terms necessary “to protect the complainant from any injury.” *See* 19 U.S.C. § 1337(j)(3).

Therefore, because Reynolds has failed to demonstrate the necessity of a bond, and because a price differential analysis shows that the Accused Products are not imported or sold at prices that would undercut Reynolds’s VUSE products, it is my recommendation that the Commission, in the event it finds a violation of section 337 has occurred, set a 0% bond for any importations of infringing products during the Presidential review period.

XII. INITIAL DETERMINATION ON VIOLATION

For the reasons set forth above, it is my initial determination that a violation of section 337 of the Tariff Act, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain tobacco heating articles and components thereof based on infringement of U.S. Patent No. 9,901,123 and U.S. Patent No. 9,930,915.

I hereby certify to the Commission this Initial Determination and the Recommended Determination.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

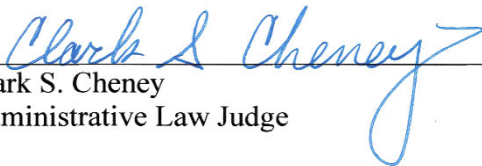
Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

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XIII. ORDER

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). To the extent possible, the proposed redactions should be made electronically, in a single PDF file using the “Redact Tool” within Adobe Acrobat. The proposed redactions should be submitted as “marked” but not yet “applied.” The proposed redactions should be submitted via email to Cheney337@usitc.gov and not filed on EDIS.

SO ORDERED.


Clark S. Cheney
Administrative Law Judge

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served via EDIS upon the Commission Investigative Attorney, **Sarah Sladic, Esq.**, and the following parties as indicated, on **June 3, 2021**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

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