

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)

Appearances:

For Complainants RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company:

David M. Maiorana, Esq., Ryan B. McCrum, Esq., and Kenneth S. Luchesi, Esq. of Jones Day of Cleveland, OH

Stephanie E. Parker, Esq. of Jones Day of Atlanta, GA

Anthony M. Insogna, Esq. of Jones Day of San Diego, CA

John J. Normile, Esq. of Jones Day of New York, NY

For Respondents Altria Client Services LLC, Philip Morris USA, Inc., and Philip Morris Products S.A.:

Maximilian A. Grant, Esq., Bert C. Reiser, Esq., and Jamie D. Underwood, Esq. of Latham & Watkins LLP of Washington, DC

Brenda L. Danek, Esq. of Latham & Watkins LLP of Chicago, IL

For the Office of Unfair Import Investigations:

Margaret D. Macdonald, Esq., Anne Goalwin, Esq., and Sarah J. Sladic, Esq.

PUBLIC VERSION

Table of Contents

I. Introduction..... 2

 A. Procedural History 2

 B. The Private Parties 5

 1. Complainants 5

 2. Respondents 5

 C. The Asserted Patents..... 6

 1. U.S. Patent No. 9,901,123..... 6

 2. U.S. Patent No. 9,930,915..... 10

 3. U.S. Patent No. 9,839,238..... 11

 D. The Accused Products..... 14

 E. The Domestic Industry Products..... 14

II. Jurisdiction & Importation..... 14

 A. Subject Matter Jurisdiction 14

 B. Personal Jurisdiction 15

 C. Importation..... 15

 D. *In Rem* Jurisdiction 16

 E. Standing 16

III. Legal Principles 16

 A. Claim Construction 16

 B. Infringement..... 18

 1. Direct Infringement..... 18

 2. Induced Infringement..... 19

 3. Contributory Infringement..... 19

 C. Validity 20

 1. Anticipation..... 20

 2. Obviousness 20

 3. Written Description..... 22

 4. Indefiniteness 22

 D. Domestic Industry..... 23

 1. Economic Prong..... 23

 2. Technical Prong 24

..

PUBLIC VERSION

IV. Level of Ordinary Skill in the Art..... 24

V. The '123 Patent..... 25

 A. Claim Construction..... 25

 B. Infringement..... 25

 1. Claim 27..... 26

 2. Claims 28–30 34

 3. Indirect Infringement 34

 C. Technical Prong of the Domestic Industry Requirement..... 36

 D. Validity 37

VI. The '915 Patent..... 41

 A. Claim Construction..... 41

 B. Infringement..... 41

 1. Claim 1..... 41

 2. Claims 2, 3, and 5 54

 3. Indirect Infringement 54

 C. Technical Prong of the Domestic Industry Requirement..... 55

 D. Validity 57

 1. The Accord Devices..... 58

 2. Indefiniteness 64

VII. The '238 Patent..... 64

 A. Claim Construction..... 64

 B. Infringement..... 65

 1. “an elongated shell with an interior, a proximal end, and an opposing distal end” 66

 2. “a coupler . . . having a first end that forms a wall and that engages the proximal end of the shell” 68

 3. “configured to releasably engage a cartridge” 70

 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” 72

 5. “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler” 76

 C. Indirect Infringement 79

 D. Technical Prong of the Domestic Industry Requirement..... 79

...

PUBLIC VERSION

- 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” 80
- 2. “the first end of the pressure channel is spatially separated from the air inlet channel relative to the longitudinal axis of the coupler” 83
- 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” 83
- E. Validity 84
 - 1. Cohen 85
 - 2. Newton 88
 - 3. Lack of Written Description 90
- VIII. Economic Prong of the Domestic Industry Requirement 92
 - A. The ’238 and ’915 Patents 92
 - B. The ’123 Patent 93
 - 1. Reynolds’s Investments in Plant and Equipment..... 93
 - 2. Reynolds’s Employment of Labor and Capital..... 95
 - 3. Reynolds’s Investment in Exploitation of the ’123 Patent 96
 - C. FDA Approval of the Domestic Industry Products..... 97
- IX. Conclusions of Law 99
- X. Findings of Fact With Respect to the Public Interest 100
 - A. The Public Health and Welfare..... 102
 - 1. Tobacco use harms the public health and welfare 103
 - 2. The FDA found IQOS exposes users to carcinogens and is expected to cause them harm 104
 - 3. The FDA did not find IQOS would provide a potential benefit to the population as a whole..... 106
 - 4. Philip Morris has marketed IQOS to youth in contravention of its own policies and FDA restrictions 107
 - 5. Comments from members of the public do not support denial of a remedy..... 110
 - 6. Combustion cigarette smokers have safer options than IQOS, and those options have been proven effective in reducing harm 118
 - 7. Public Health Conclusion 118
 - B. The Production of Like Articles in the United States 119
 - C. Competitive Conditions in the United States Economy 122
 - D. United States Customers 123

PUBLIC VERSION

E. Public Interest Conclusion 123

XI. Recommended Determination on Remedy and Bond..... 123

 A. Limited Exclusion Order..... 124

 B. Cease and Desist Order 126

 C. Bond During Presidential Review 128

XII. Initial Determination on Violation..... 131

XIII. Order 132

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.