#### **PUBLIC VERSION**

## UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

In the Matter of

CERTAIN TOBACCO HEATING ARTICLES AND COMPONENTS THEREOF

Investigation No. 337-TA-1199

RESPONDENTS' REPLY SUBMISSION TO COMMISSION'S NOTICE



Philip Morris Products, S.A.

### **TABLE OF CONTENTS**

I.	INTR	CODUC	TION	1		
II.	CONSTRUCTION OF "ELECTRICAL ENERGY SOURCE"					
	A.	An "electrical energy source" Is Not Equivalent To A "receptacle"				
		1.	A "receptacle" Can Be Housed In The "electrical energy source"	4		
		2.	An "electrical energy source" Need Not Be or Have A "receptacle"	6		
		3.	Exemplary Passages Are Legally Insufficient To Limit "electrical energy source" To A "receptacle"	8		
	B.	A "re	eceptacle" Requires "inserting"	9		
	C.	The l	Proposed Construction Will Affect The FID's Findings	12		
III.	REM	REMEDY AND BONDING				
	A.	Any Remedial Order Should Include Certain Exceptions And A Reporting Requirement				
		1.	Respondents' Undisputed Warranty Contracts With Existing Customers Compel A Service, Warranty, Repair, Or Replacement Exception In Any Remedial Order	15		
		2.	Any Remedial Order Should Include A Certification Provision	15		
		3.	Any Remedial Order Should Include A Reporting Requirement To Address Complainants' Failure to Obtain FDA Authorization For Their DI Products	16		
		4.	Any Remedial Orders Should Not Extend To HeatSticks	18		
	B.	The Commission Should Not Issues CDOs In This Investigation				
		1.	Commission Law Requires Proof Of Necessity To Issue A CDO	21		
		2.	Commission Precedent Confirms That Evidence Of A Commercially Significant Inventory Alone Does Not Automatically Demonstrate "Necessity" For Issuance Of A CDO	23		
		3.	Complainants Failed To Prove Or Argue Why CDOs Are Necessary For Any Respondent	26		
		4.	At A Minimum, No CDO Should Issue To ACS And PMP	26		



	C.	No Bond Is Necessary During The Presidential Review Period28	
IV.	V. IT IS VITAL TO PUBLIC INTEREST TO KEEP IQOS ON THE U.S		
	A.	The Public Interest Standard Is Not Meant To Be Insurmountable29	
	B.	FDA Already Found IQOS Aids And Is Expected to Aid Public Health33	
		I. IQOS PMTA Authorizations Show Positive Public Health Benefits34	
		2. IQOS MRTP Authorizations Show Positive Public Health Benefits35	
		B. PMTA and MRTP Authorizations Are Difficult To Achieve	
	C.	There Is No Substitute For IQOS	
		Safer <i>And</i> Equally Effective IQOS Substitutes Are <i>Not</i> Available42	
		2. "Like Articles" Must Be Viable, Legal, Available Substitutes47	
	D.	QOS Is And Will Continue To Be Successful	
	E.	A Hearing on the PI Issues Core to ITC Investigations Is Warranted60	

## **TABLE OF AUTHORITIES**

#### **CASES**

Am. Med. Sys., Inc. v. Biolitec, Inc., 618 F.3d 1354 (Fed. Cir. 2010)
Amarin Pharma, Inc. v. ITC, 923 F.3d 959 (Fed. Cir. 2019)
Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801(Fed. Cir. 2002)
Certain Air Mattress Systems, Components Thereof, and Methods of Using the Same, Inv. No. 337-TA-971, Comm'n Op. (May 17, 2017)
Certain Automatic Crankpin Grinders, Inv. No. 337-TA-60, USITC Pub. 1022, Comm'n Op. (Dec. 1979)
Certain Baseband Processor Chips & Chipsets, Transmitter & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets, Inv. No. 337-TA-543, Comm'n Op. (June 7, 2007)
Certain Baseband Processor Chips & Chipsets, Transmitter & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets, Inv. No. 337-TA-543, Notice (Feb. 9, 2007)
Certain Composite Aerogel Insulation Materials and Methods for Manufacturing the Same, Inv. No. 337-TA-1003, Comm. Op. (Feb. 22, 2018)
Certain Dental Implants, Inv. No. 337-TA-934, Comm'n Op. (May 11, 2016)
Certain Digital Video Receivers, Inv. No. 337-TA 1103, Initial and Recommended Determination (June 4, 2019)
Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same, Inv. No. 337-TA-959, Comm'n Op., Additional Views of Commissioner Kieff (Feb. 13, 2017)
Certain Electronic Nicotine Delivery Systems and Components Thereof, Inv. No. 337-TA-1139, Comm'n Op. (May 5, 2020)
Certain Fluidized Supporting Apparatus and Components Thereof, Inv. Nos. 337-TA-182, 337-TA-188, Comm'n Op. (Oct. 1984)



Certain Inclined Field Acceleration Tubes, Inv. No. 337-TA-67, USITC Pub. 1119, Comm'n Op. (Dec. 1980)
Certain Inclined-Field Acceleration Tubes and Components Thereof, Inv. No. 337-TA- 67, USITC Pub. No. 1119, Comm'n Op. (Dec. 1980)
Certain Indomethacin, Inv. No. 337-TA-183, Initial Determination, 1986 WL 379338 (Aug. 13, 1986)
Certain Infotainment Systems, Components Thereof, and Automobiles Containing the Same, Inv. No. 337-TA-1119, Comm'n Op. (May 28, 2020)
Certain Lithium Metal Oxide Cathode Materials, Lithium-Ion Batteries for Power Tool Prods.  Containing Same, and Power Tool Prods. with Lithium-Ion Batteries Containing Same, Inv. No. 337-TA-951, Notice (Oct. 11, 2016)
Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (I), Inv. No. 337-TA-1012, Comm'n Op. (Apr. 2, 2018)
Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II), Inv. No. 337-TA-1076, Comm'n Op. (June 20, 2019)
Certain Microfluidic Devices, Inv. No. 337-TA-1068, Comm'n Op. (Jan. 10, 2020)
Certain Neodymium-Iran-Boron Magnets, Magnet Alloys, and Articles Containing Same, Inv. No. 337-TA-372, Comm. Op. (Oct. 28, 1997)
Certain Road Construction Machines & Components Thereof, Inv. No. 337-TA-1088, Comm. Op.(July 15, 2019)
Certain Robotic Vacuum Cleaning Devices and Components Thereof Such As Spare Parts, Inv. No. 337-TA-1057, Comm'n Op. (Feb. 1, 2019)
Certain Sleep-Disordered Breathing Treatment Sys., Inv. No. 337-TA-890, Comm'n Op. (Jan. 16, 2015)
Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators, Inv. No. 337-TA-1110, Initial and Recommended Determination (Aug. 1, 2019) 16, 18
Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof, Inv. No. 337-TA-965, Comm'n Op. (Feb. 1, 2017)
Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof, Inv. No. 337-TA-910, Comm'n Op.(Oct. 30, 2015)



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