Exhibit 7

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN TOBACCO HEATING ARTICLES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1199**

COMMISSION OPINION DENYING RESPONDENTS' MOTION TO STAY LIMITED EXCLUSION ORDER AND CEASE AND DESIST ORDERS PENDING APPEAL

I. BACKGROUND

On May 15, 2020, the Commission instituted this investigation based on a complaint filed by RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company, all of Winston-Salem, North Carolina (collectively, "Reynolds"). 85 Fed. Reg. 29482-83 (May 15, 2020). The complaint, as supplemented, alleges a violation of section 337 based upon the importation and sale of certain tobacco heating articles and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 9,901,123 ("the '123 patent"), 9,930,915 ("the '915 patent"), and 9,839,238 ("the '238 patent") (collectively, "the Asserted Patents"). *Id.* The complaint also alleges the existence of a domestic industry. The notice of investigation names the following respondents: Altria Client Services LLC ("ACS"), Altria Group, Inc. ("AGI"), and Philip Morris USA, Inc. ("Philip Morris USA"), all of Richmond, Virginia; Philip Morris International Inc. ("PMI") of New York, New York; and Philip Morris Products S.A. ("PMP") of Neuchatel, Switzerland (collectively, "Philip Morris" or "Respondents"). *See id*. The Office of Unfair Import Investigations ("OUII") was also a party to the investigation. *See id*.

III. ANALYSIS

A. Philip Morris's Motion Does Not Raise Any Admittedly Difficult Legal Questions

Philip Morris argues that it is entitled to a stay because: 1) the Commission failed to "consult with" the Department of Health and Human Services ("HHS") as required under section 337; 2) the Commission erred in finding a domestic industry based on allegedly unlawful products; and 3) the Commission further erred in finding infringement and validity of the '123 patent and the '915 patent. PM Mot. at 4-11. Inasmuch as Philip Morris's stay motion did not argue error as to the Commission's validity determination as to the asserted claims of the '915 patent, Philip Morris's subsequent notice to the Commission concerning the PTAB's Final Written Decision as to these claims is irrelevant to the issues actually presented in the motion to stay. Moreover, the notice fails to identify any admittedly difficult legal issue arising from the Commission's invalidity determinations as to the '915 patent on the Commission's administrative record. Philip Morris's arguments are not persuasive.

1. Philip Morris's New "Consult With" Argument is Abandoned Because It Was Neither Raised nor Preserved Before the ALJ and Before the Commission

Philip Morris argues that the Commission legally erred in failing to "consult with" HHS under section 337, which mandates that "[d]uring the course of each investigation under this

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at *80 (July 9, 1998); *Certain Baseband Processor Chips & Chipsets, Transmitter & Receiver (Radio) Chips, Power Control Chips &Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543 ("*Baseband Processors*"), Comm'n Op. Denying Mots. for Stay at 5-6 (June 21, 2007); *Certain High-Brightness Light Emitting Diodes, and Products Containing Same*, Inv. No., 337-TA-556, Comm'n Op., 2008 WL 2556199, at *4-*5 (Sept. 11, 2007); *Certain Semiconductor Chips with Minimized Chip Packages*, Inv. No. 337-TA-605 ("*Semiconductor Chips*"), Comm'n Op., 2009 WL 2350644, at *2-*4 (July 29, 2009); *Certain Digital Television Products and Certain Products Containing Same and Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op., 2009 WL 2598777, at *2-*3 (Aug. 21, 2009).

section, the Commission shall consult with, and seek advice and information from, the Department of Health and Human Services, . . . and such other departments and agencies as it considers appropriate." PM Mot. at 4-8 (citing 19 U.S.C. § 1337(b)(2)). However, Philip Morris's motion to stay is the first time that Philip Morris made such an argument before the Commission.

The Commission finds that there is no admittedly difficult legal question, much less a likelihood of success as to the "consult with" argument. The Commission has rules governing when issues must be raised in Commission investigations and how they must be preserved. As set forth below, Philip Morris did not adequately raise or preserve the argument that it now seeks to raise.

Philip Morris's argument is forfeited because it was not raised and preserved before the ALJ in conformance with the ALJ's Ground Rules for the investigation. *See, e.g.*, Order No. 2 (May 15, 2020) at Ground Rule 14.1 ("Any contentions for which a party has the burden of proof that are not set forth in detail in the post-hearing initial brief shall be deemed abandoned or withdrawn."); *see also id.* Rule 11.2 (pre-hearing brief).

When the Commission instituted the investigation, it ordered the ALJ to take evidence on the public interest and to make findings of fact on the public interest. Notice, 85 Fed. Reg. 29482, 29482 (May 15, 2020); *see* 19 C.F.R. § 210.50(b)(1) (allowing the Commission to authorize the ALJ to take evidence and engage in factfinding concerning the public interest). Thus, the appropriate time for the parties to present and preserve public-interest arguments in this investigation began at the time the proceeding commenced before the ALJ. During the evidentiary hearing before the ALJ on February 21, 2021, the ALJ inquired whether section 337 allowed the Commission to consult with HHS. *See* Hrg. Tr. at 1524:17-21 (Feb. 21, 2021).

Specifically, the ALJ stated, "I am interested in your views about my authority under 19 U.S.C. 1337(b)(2), which instructs that the Commission may consult with the Department of Health and Human Services, and, by implication, the Food and Drug Administration." *Id*. at 1524:17-21. Counsel for Philip Morris responded that "[w]e have absolutely no objection whatsoever to any of that," meaning apparently, that Philip Morris had no objection to the Commission's authority to consult with the Department of Health and Human Services. *Id*. at 1571:7-8. But Philip Morris never identified a specific consultation with the Department of Health and Human Services that was required (as opposed to being merely unobjectionable) or what form that coordination must take. Nor did Philip Morris ever tell the ALJ that failure to engage in Philip Morris's unspecified consultation would be an error of law.

That Philip Morris lay in the weeds is not a procedural wrinkle that can be brushed aside; it strikes at the bedrock of the requirement of administrative exhaustion. The Administrative Procedure Act, for example, generally limits the ALJ's and the Commission's authority to engage in *ex parte* communications relevant to the merits of the investigation. 5 U.S.C. § 557(d)(1). Philip Morris did not subpoena the Secretary of Health and Human Services or urge the ALJ to do so. Such questions concerning the relationship between coordinate government entities must be raised and preserved in the investigation so that the agency can address these concerns adequately and in a timely manner. Consequently, and pursuant to the ALJ's Ground Rules for the investigation, the issue is abandoned.

In the underlying investigation, the Commission had the authority, as tribunals do, to excuse waiver in exceptional circumstances, including, for example, in instances of self-initiated Commission review of an ALJ's determinations. *E.g.*, 19 C.F.R. § 210.44. But Philip Morris never raised the "consult with" argument in its petition for Commission review of the ALJ's

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