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*.

The notice of investigation instructed the presiding administrative law judge ("ALJ") to make findings regarding the public interest. 85 Fed. Reg. at 29482-83. The Commission later added claim 3 of the '915 patent. *See* Order No. 9 (July 29, 2020), *unreviewed by* Notice (Aug. 18, 2020). The Commission also terminated respondents AGI and PMI from the investigation based on Reynolds's partial withdrawal of the complaint. *See* 85 Fed. Reg. 52152 (Aug. 4, 2020); Order No. 24 (Dec. 14, 2020), *unreviewed by* Notice (Jan. 5, 2021).

On September 29, 2021, the Commission found a violation of section 337 based on infringement of the asserted claims of the '123 and '915 patents and issued a limited exclusion order ("LEO") and cease and desist orders ("CDOs") against ACS and Philip Morris USA. 86 Fed. Reg. 54998-99 (Oct. 5, 2021) (issuing orders and terminating investigation); *see also* Comm'n Op. (Sept. 29, 2021); *see also* Final Initial Determination ("FID") (May 14, 2021). The Commission found no violation with respect to the '238 patent. *Id.* The Commission found that the statutory public interest factors did not preclude issuance of a remedy. *See* Comm'n Op. On November 29, 2021, the period of Presidential review ended without disapproval of the Commission's action by the President, *see* 19 U.S.C. § 1337(j)(2).

On December 1, 2021, Philip Morris filed an appeal with the U.S. Court of Appeals for the Federal Circuit, seeking review of issues the Commission decided against it in the Commission's final determination. *Philip Morris Products S.A., et al. v. Int'l Trade Comm'n*, Case No. 22-1227. The appeal is currently pending before the Federal Circuit.

On December 3, 2021, Philip Morris filed a motion before the Commission requesting a stay of the remedial orders pending appeal to the Federal Circuit. *See* Respondents' Motion to Stay Limited Exclusion Order and Cease and Desist Orders Pending Appeal (Dec. 3, 2021) ("PM Mot."). On December 13, 2021, Reynolds filed an opposition to Philip Morris's stay motion

before the Commission. *See* Complainants' Response to Respondents' Motion to Stay Limited Exclusion Order and Cease and Desist Orders Pending Appeal (Dec. 13, 2021) ("Reynolds Opp."). OUII did not file a response.

On December 6, 2021, Philip Morris filed an emergency motion to stay the remedial orders before the Federal Circuit. *Philip Morris*, Case No. 22-1227, ECF No. 6 (Dec. 6, 2021). On December 8, 2021, the Federal Circuit denied Philip Morris's request for relief during consideration of its Federal Circuit stay motion. *Id.*, Order, ECF No. 12 (Dec. 8, 2021). On December 16, 2021, the Commission and Reynold each filed an opposition to Philip Morris's Federal Circuit stay motion. *Id.*, ECF Nos. 13, 15 (Dec. 13, 2021). On December 21, 2021, Philip Morris filed a reply in support of its motion. *Id.*, Case No. 22-1227, ECF No. 18 (Dec. 21, 2021). On December 30, 2021, the Federal Circuit issued an order that Philip Morris's Federal Circuit stay motion is held in abeyance, and requested that the parties notify the Court upon the Commission's determination on the stay motion pending before the Commission. *Id.*, ECF No. 21 (Dec. 30, 2021).

On January 12, 2022, Philip Morris filed a Notice of Supplemental Authority concerning proceedings at the Patent Trial and Appeal Board ("PTAB"). On January 13, 2022, Reynolds filed a response that the PTAB proceedings are irrelevant to the pending motion to stay.

II. LEGAL STANDARD

The Administrative Procedure Act provides an agency with the authority to "postpone the effective date of action taken by it, pending judicial review" if the "agency finds that justice so requires." 5 U.S.C. § 705. The Federal Circuit has set forth the following four-part test to assess whether to stay a lower court's remedy pending appeal:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent

> a stay; (3) whether the issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Standard Havens Prods, Inc. v. Gencor Indus, Inc., 897 F.2d 511, 512 (Fed. Cir. 1990) (quotation omitted).

The Commission evaluates motions for stay under the *Standard Havens* test with one exception. At the agency level the movant need not demonstrate a likelihood of success on appeal. The Commission has recognized the futility of establishing a likelihood-of-success in this context given that it would be difficult to ask an agency to find that its own decision is likely to be overturned on appeal. *Certain Agricultural Tractors Under 50 Power Take-Off Horsepower*, Inv. No. 337-TA-380 ("*Agricultural Tractors*"), Comm'n Op. Denying Resp'ts' Pet. for Reconsideration and Mot. for Relief Pending Appeal at 10 (Apr. 25, 1997); *see also Washington Metro. Area Transit Comm. v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977) ("Prior recourse to the initial decisionmaker would hardly be required as a general matter if it could properly grant interim relief only on a prediction that it has rendered an erroneous decision"). Accordingly, in lieu of the likelihood-of-success prong, the Commission considers whether it has "ruled on an admittedly difficult legal question." *Holiday Tours*, 559 F.3d at 844-45 ("What is fairly contemplated is that tribunals may properly stay their own orders when they have ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained"); *see also Agricultural Tractors*, Comm'n Op. at 10. The Commission has repeatedly recited and applied this "admittedly difficult question" test in previous investigations in which stays of its remedial orders were sought pending appeal.[1]

[1] *Certain EPROM, EEPROM, Flash Memory, and Flash Microcontroller Semiconductor Devices, and Products Containing Same*, Inv. No. 337-TA-395, Comm'n Op., 2001 WL 242553,

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

determinations despite Philip Morris's actual knowledge of all proceedings before the ALJ.[2] *See* Respondents' Petition and Contingent Review of the Final Initial Determination (May 28, 2021). In view of the fact, as discussed above, that the Commission authorized the ALJ in this investigation to take evidence on the public interest, Philip Morris's contention that a public-interest determination mandated further consultation with the Department of Health and Human Services should have been raised as a ground of error in Philip Morris's petition for Commission review of the ALJ's determinations. Because it was not raised, it has been deemed abandoned by Commission rule. 19 C.F.R. § 210.43(b)(2) ("Any issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination . . . , and any argument not relied on in a petition for review will be deemed to have been abandoned and may be disregarded by the Commission.")

Moreover, none of Philip Morris's other Commission-directed submissions sought excusal of any abandonment, or otherwise raised or preserved the issue of the Department of Health and Human Service's participation in this investigation. On June 15, 2021, Philip Morris filed a statement on public interest pursuant to 19 C.F.R. § 210.50(a)(4)(i). *See* Respondents' Submission on the Public Interest (June 15, 2021). Philip Morris argued the FID fails to consider key FDA findings that were already of record in the investigation, but did not argue that the Commission must "consult with" HHS or the FDA. *Id.* On August 10, 2021, Philip Morris filed its response to the Commission's July 27, 2021 notice of review and schedule for submissions on

[2] Commission proceedings are conducted on a public record that appears on the Commission's EDIS electronic filing and recordkeeping system. Accordingly, whether HHS or FDA or any other government party participated—or did not participate—was known to Philip Morris in real-time in the Commission investigation.

certain issues under review and remedy, public interest, and bonding. *See* Respondents' Opening Brief in Response to Commission's Notice of Review (Aug. 10, 2021). Philip Morris did not argue in its response that the Commission was required and failed to "consult with" HHS or the FDA. *Id.*[3] Philip Morris requested that the Commission hold a second hearing on the public interest issues, even though the ALJ previously held a hearing on public interest issues. *Id.* at 85; Comm'n Op. at 75-76. However, even if a second hearing was held on public interest, Philip Morris never requested, much less requested the Commission to order, that HHS or the FDA be compelled to participate in such a hearing. *Id.* On August 17, 2021, Philip Morris filed a reply submission in response to the other parties' initial responses. Respondents' Reply Submission to Commission's Notice (Aug. 17, 2021). There, Philip Morris noted that "[t]he Commission may find it enlightening to discuss these matters directly with various party and third-party experts in this field and perhaps even representatives of FDA itself." *Id.* at 62. Philip Morris's position in its reply that the Commission "may find it enlightening" is at odds with its present contention that a specific, in-depth consultation with HHS is required as a matter of law.

The Commission is aware that Philip Morris has urged the Federal Circuit to decide the consultation issue as being ostensibly a legal question. *Philip Morris*, Case No. 22-1227, ECF No. 18 (Dec. 21, 2021). But there is no basis in law or reason for any tribunal—the Federal Circuit in its proceedings, or the Commission in connection with this motion to stay—to excuse

[3] Philip Morris states: "Several of the third parties that filed public interest comments in support of IQOS prior to institution of this Investigation took time again to file additional views on their own at the Commission phase, including PPI, AVA, and former Congressman George Holding," and cites a letter from former Congressman George Holding. *Id.* at 79. The letter stated, "I urge a careful review of the FDA's authorizations of the IQOS and encourage direct consultations with the agency . . . ." *Id.* Neither the letter, however, nor *any* submission by Philip Morris argued that the absence of "direct consultations" (whatever that may be) would constitute legal error.

Philip Morris's abandonment. Unlike the one case that Philip Morris has cited to the Federal Circuit, *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1322-23 (Fed. Cir. 2020), the issues here were never raised, much less briefed and preserved in Commission proceedings. Issues about the ALJ's obligations or the Commission's obligations in connection with the merits or the public interest inquiry must be raised at such a time as it matters. The "consult with" argument raised now by Philip Morris comes far too late, and the Commission deems it abandoned.

2. Philip Morris's Motion Ignores the Commission's Consistent and Longstanding Practices

As discussed above, Philip Morris's argument has been abandoned, and an opinion on a motion to stay presents an inappropriate opportunity for the Commission to opine at length on the issue as though Philip Morris preserved it. For the benefit of the parties, the public, and the Commission's reviewing court, however, the Commission notes that the Commission's practices and procedures in this case reflect the Commission's longstanding and consistent interpretation of section 337 and Commission rules.

Pursuant to its longstanding rules, the Commission serves copies of the notice of investigation upon various government agencies, including HHS.[4] *See* 19 C.F.R. § 210.11(a)(4).

[4] The Commission's practices, in relevant part, trace at least to the mid-1990s. In 1994, the Commission's Inspector General ("IG") investigated the Commission's practices with respect to other agencies. ITC Office of Inspector General Audit Report No. IG-03-94 (Aug. 1994) at 4; *see also* PM Mot. at 6-7, n.7; Reynolds Opp. at 9-10. The IG "contacted representatives from HHS, Justice, FTC and the Customs Service, who all similarly" commented that "resource constraints had severely limited their ability to review the 337 documents; two said that the documents were immediately discarded." *Id*. at 5. The IG recommended revising the Commission's rules to address these concerns. *Id*. The Commission agreed that the system needed "improvement." ITC Proposed Rules, 60 Fed. Reg. 16,082, 16,083 (proposed Mar. 29, 1995) (to be codified at 19 C.F.R. § 210). After the IG's 1994 report, the Commission engaged in notice-and-comment rulemaking that resulted in the amended regulations at issue here.

The Commission actually served the Notice of Investigation on the HHS attorney who has been delegated by HHS to monitor Commission investigations. *See* Notice of Institution at 8, 22; 19 U.S.C. § 1337(b)(2); 19 C.F.R. § 210.11(a)(4). Neither that attorney nor anyone else at HHS thereafter requested any unusual treatment for this investigation (such as paper copies) of future notices. Commission notices seeking briefing or comments from the public, including from interested government agencies, are published in the *Federal Register*, constituting notice, as a matter of law, under the Federal Register Act, 44 U.S.C. § 1501 *et seq.* *See id.* §§ 1507-1508. Here, the Commission published the notice of investigation and two additional notices in the *Federal Register* soliciting comments from the public, including government agencies. *See* 85 Fed. Reg. 29482-83 (May 15, 2020) (notice of investigation); 86 Fed. Reg. 28382 (May 26, 2021); 86 Fed. Reg. 41509-11 (Aug. 2, 2021).

The present investigation was conducted in conformity with these rules. If Philip Morris was aggrieved by the application of the Commission's duly-promulgated rules to this investigation, the time for objection was before the ALJ in the Commission investigation, and not in a collateral motion to stay, or in an appeal to the Commission's reviewing court. Likewise, if Philip Morris desired more engagement with other government agencies than the Commission rules provide for, and which may be within the Commission's discretion to exercise, it was incumbent upon Philip Morris to seek such engagement before the Commission, and to object during the proceeding itself if Philip Morris did not receive what it sought, rather than after the investigation has concluded and on appeal before the Federal Circuit.

Philip Morris offers dictionary definitions for "consult" that it never presented to the Commission in the underlying investigation. To Philip Morris, "to consult" means "to seek information or advice from," or to "to have regard to." PM Mot., Ex. A (New Oxford American

Dictionary (3d ed. 2010); *id.*, Ex. B (Merriam-Webster's Collegiate Dictionary (10th ed. 1999). It is difficult to decipher Philip Morris's arguments because the Commission appears to have satisfied each definition. The first definition is met because the Commission sought information from the listed agencies in the *Federal Register* notices and by actual service of the notice of investigation. The second definition is met because the FDA's views were part of the record here and were considered by both the ALJ and the Commission. Both the ALJ and the Commission extensively considered the FDA's statements regarding IQOS when considering the public interest factors. Comm'n Op. at 56-72; FID at 103-118. Such arguments could have been explored in more detail in the underlying investigation if Philip Morris had timely raised the issue.

Reynolds argues that the Commission's statutory obligation to consult with government agencies is discretionary under section 337, but in all events, was satisfied here. Reynolds Opp. at 4-10. The Commission finds it unnecessary to reach those arguments here, where Philip Morris fails to show an admittedly difficult legal question, even under its preferred definitions, and ignores its dispositive abandonment.

3. Philip Morris Fails to Raise an Admittedly Difficult Legal Issue Regarding Reynolds's Domestic Industry

Philip Morris also argues that the Commission erred in finding that Reynolds satisfies the domestic industry requirement. PM Mot. at 8-10. In particular, Philip Morris takes issue with the Commission's crediting of Reynolds' investments in its VUSE Solo and Vibe e-cigarette products. *Id.* at 9-10. The Federal Circuit has recognized that "the domestic industry requirement generally involves questions of both law and fact." *Motorola Mobility, LLC v. ITC*, 737 F.3d 1345, 1348 (Fed. Cir. 2013). In the present case, the issue is the substantiality or significance of Reynolds' investments, a question of fact. Accordingly, the Commission finds

that Philip Morris raises no legal question, much less an admittedly difficult one, for purposes of a stay. Even if the question were viewed as legal, the Commission has addressed the issues raised by Philip Morris below, and, upon further consideration has determined that none of the issues are admittedly difficult. FID at 97-99. In addition to the reasons set forth in the FID, Philip Morris itself notes that the FDA recently issued marketing orders for the VUSE Solo. PM Mot. at 8, n.8. Philip Morris can hardly argue that a product with the same PMTA marketing authorization as its own IQOS is illegal. Moreover, Philip Morris points to no authority that FDA approval is a condition precedent to the establishment of a domestic industry, nor is the Commission aware of any such authority.

Philip Morris has not shown an admittedly difficult legal issue regarding Reynolds's domestic industry products.

4. Philip Morris's Conclusory Arguments Regarding Infringement and Invalidity Do Not Support a Stay

Philip Morris argues without support or explanation that it will "likely succeed in challenging the Commission's findings that the asserted claims of [the '123 patent] and [the '915 patent] are valid and infringed. PM Mot. at 11. Philip Morris cites the Commission's Opinion but none of its own experts' testimony or evidence. *Id.* Accordingly, Philip Morris's subsequent notice to the Commission concerning the PTAB Final Written Decision is irrelevant to the issues actually presented in the motion to stay.[5] Philip Morris's conclusory statement in

[5] Moreover, the notice fails to identify any admittedly difficult legal issue arising from the Commission's invalidity determinations on the Commission's administrative record. *Cf. Certain Network Devices, Related Software and Components Thereof (II)* ("*Network Devices*"), Inv. No. 337-TA-945, Comm'n Op., 2017 WL 10954555, at *8 (Aug. 16, 2017) (finding that PTAB decisions that occurred after the issuance of the Commission's remedial orders failed to demonstrate a changed circumstance warranting suspension of the Commission's orders); *Cisco*

its motion, even as supplemented by its notice of supplemental authority, fails to demonstrate any admittedly difficult legal questions with respect to infringement or validity.

B. Irreparable Harm

Philip Morris argues that, unless the LEO and CDOs are stayed, it will be irreparably harmed due to lost IQOS revenues, loss of talent, business opportunities, and goodwill in the industry. PM Mot. at 11-13. Philip Morris mainly relies on loss of revenue to Philip Morris USA and to PMI, but the Commission finds such economic harm insufficient to warrant a stay. *Id.* at 11-12; *Celsis*, 664 F.3d at 930. The Commission has repeatedly considered and rejected the argument that lost sales and lost market position constitute "irreparable injury." *See Certain High-Brightness Light Emitting Diodes, and Products Containing Same*, Inv. No. 337-TA-556, Comm'n Op. at 10-12 (Aug. 20, 2007) ("*High-Brightness LEDs*"); *Certain Lens-Fitted Film Packages*, Inv. No. 337-TA-406, Comm'n Op. at 15 (June 28, 1999)) ("*LFFPs*"); *see also Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (internal citations omitted).

The Commission has considered Philip Morris's remaining arguments and has determined that Philip Morris has not demonstrated irreparable harm. As Philip Morris notes, IQOS' release was limited and it was available in only four states with only 20,000 users in the United States prior to the Commission's final determination. PM Mot. at 12, 16. Moreover, in its motion, Philip Morris offers vague and unsupported declarations with generalizations, such as alleged loss of goodwill for IQOS and HeatSticks that are sold in only four states and "projected" revenue losses without supporting calculations or substantiation of underlying assumptions. *Id*. at 11-13. Philip Morris's motion is therefore speculative and unsupported.

Sys., Inc. v. Int'l Trade Comm'n, No. 17-2289, Order at 3 (Fed. Cir. Sep. 22, 2017) (ECF 57) (denying a stay of the Commission's remedial orders where the movant sought a stay on the basis of subsequent PTAB determinations).

The Commission also notes inconsistencies between different stay factors in Philip Morris's motion. Compare, for example, Philip Morris's "increasing momentum of sales" and similar allegations for irreparable harm, PM Mot. at 12, with Philip Morris's allegations in that a stay will not substantially harm Reynolds, *id.* at 13-14. For lack of harm to Reynolds, Philip Morris adopts and relies on Reynolds's contention that "IQOS has come nowhere close to being robustly adopted . . . and is unlikely to ever be robustly adopted in the U.S." *Id*. If that is true for the lack of harm to Reynolds, then it is true for irreparable harm; and it is consistent with Philip Morris's statements to investors. *See* Reynolds Opp. at 1-2, 17-19.

Philip Morris has failed to show that it will suffer irreparable harm absent a stay.

C. Balance of Hardships

Philip Morris argues that a stay of the LEO and CDOs will not cause substantial or irreparable harm to Reynolds. *Id.* at 13-14. Philip Morris further argues that any potential harm to Reynolds would be recoverable in the form of money damages in the pending district court action in the U.S. District Court for the Eastern District of Virginia, in which Reynolds's infringement counts based on the '915 and '123 patents are stayed. *Id.* (citing *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same*, Inv. No. 337-TA-833 ("*Digital Models*"), Comm'n Op. at 8 (June 11, 2014)).

Digital Models does not support Philip Morris's argument that the balance of harms tilts in its favor. In *Digital Models*, the Commission specifically noted that:

> Commission relief is "in addition to" relief provided by the district courts. 19 U.S.C. § 1337(a)(1). Accordingly, the mere availability of a district court proceeding is not enough to tilt the harms factors in favor of a stay.

Id. at 8, n.8; *see also Semiconductor Chips*, Comm'n Op., 2008 WL 2223426, *2 n. 2 (citing 19 U.S.C. § 1337(a)(1)) ("Because section 337 remedies are in addition to, and not instead of, other

remedies at law . . . remedies potentially available in the courts are irrelevant to our analysis of whether to stay [] proceeding[s].”). In considering the balance of harms in *Digital Models*, the Commission noted that the balance of harms tipped to the respondents, where one of the respondents asserted, unlike here, that it faced “immediate irreparable ruin” from the Commission’s remedial orders. *Compare Digital Models*, Comm’n Op. at 7 *with* PM Mot. at 13-14. Moreover, the Commission has explained that a complainant “will be irreparably injured by a stay that denies its patents the full term to which they are entitled.” *LFFPs*, Comm’n Op. at 17; *High-Brightness LEDS*, Comm’n Op. at 12; *Agricultural Tractors*, Comm’n Op. at 16.

The Commission has considered Philip Morris’s arguments and has determined that Philip Morris fails to demonstrate that the balance of harms tilts in its favor.

D. Public Interest

Philip Morris repeats the same public interest arguments it previously made before the ALJ and the Commission—that there is allegedly no substitute for IQOS based on its FDA authorizations and the public interest weighs in favor of keeping IQOS on the market. PM Mot. at 14-21. The ALJ and the Commission each extensively analyzed the public interest. Comm’n Op. at 53-76; FID at 100-123. The Commission previously determined that the statutory public interest factors—including “the public health and welfare,” *see* 19 U.S.C. § 1337(d)(1), (f)(1)—do not preclude the issuance of the remedial orders in this investigation. Comm’n Op. at 53-76. Philip Morris neither directly addresses the Commission’s findings nor provides any evidence demonstrating that the Commission’s findings are incorrect. Whether viewed within the context of the public interest factors of section 337, or the public interest more generally for the equitable relief Philip Morris now seeks, the Commission finds that Philip Morris has failed to show that the public interest supports a stay. In addition to all of the public interest discussion in the Commission opinion, the Commission also notes that the “public interest favors the protection of

intellectual property rights by excluding infringing products." *Certain X-Ray Breast Imaging Devices & Components Thereof*, Inv. No. 337-TA-1063, Initial Determination at 281 (July 26, 2018); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012) (noting "[p]ublic policy favors the innovator, not the copier"); *Douglas Dynamics, LLC v. Buyers Prods. Co*., 717 F.3d 1336, 1345 (Fed. Cir. 2013).

The Commission finds that the public interest does not warrant a stay.

IV. CONCLUSION

Philip Morris's motion to stay enforcement of the LEO and CDOs is denied.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 20, 2022