Exhibit 1

[redacted]

(PUBLIC VERSION)

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before The Honorable Clark S. Cheney
Administrative Law Judge

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

COMPLAINANTS' OPENING POST-HEARING BRIEF

[redacted]

- Even assuming IQOS might be meaningfully adopted in the U.S., an exclusion order is nonetheless warranted because there are thousands of substitute PRRPs—removal of one will not harm the public interest. Respondents' own experts concede that those other PRRPs have not only been successful at moving smokers away from cigarettes, but they are the most successful products at doing so. And Respondents' suggestion that some of these alternatives will not be authorized by FDA is belied by their own experts' admissions that such products will, in fact, obtain FDA market authorization.

- Respondents argue that IQOS is more successful at transitioning smokers from CC than other alternatives, but Respondents' so-called conversion "evidence" is grossly misleading and unreliable, based on nothing more than self-serving, results-oriented studies that are wholly inconsistent with independent studies showing that smokers are not interested in IQOS, abandon IQOS, or at best become dual users.

In short, the public interest is best served by protecting Reynolds's patent rights and excluding IQOS from the U.S. market.

A. Factors 1 And 4: Public Health/Welfare And U.S. Consumers

1. According To FDA, Respondents Have NOT Demonstrated That IQOS "Will Benefit The Population As A Whole"

(a) FDA Denied Respondents' Reduced-Risk MRTPA Claims

Respondents submitted an MRTPA to FDA seeking three separate marketing claims for its products: two reduced-risk claims and one reduced-exposure claim. (JX-0034.7-8.) FDA denied the two reduced-risk claims, and authorized the reduced-exposure claim. (JX-0034.8,11.) Respondents rely here on the same information they submitted to FDA. FDA reviewed this information and concluded it was insufficient to establish any significant public-health benefit:

> After conducting *a thorough scientific review* of the information contained in the MRTPAs; the recommendations from the Tobacco Products Scientific Advisory Committee; comments, data, and information submitted to FDA by interested persons; and other scientific information identified by the agency from other sources, I conclude that: With respect the risk modification order requests, *the applicant* **has not demonstrated** *that* as actually used by consumers**,** *the products sold* or distributed with the proposed modified risk information *will significantly reduce harm* and the risk of tobacco-related disease to individual tobacco users *and benefit the health of the population as a whole*, taking into account both

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impact public health and welfare or U.S. consumers, because there are many existing PRRPs in the market that are more than adequate to satisfy consumer demand.

(a) Thousands Of PRRPs Are Currently Available On The U.S. Market

Both parties' experts agree that thousands of PRRPs are currently available in the U.S. Dr. Murrelle testified that "there are literally thousands of existing PRRPs on the U.S. market that have at least the same harm reduction and transition rate, where transition rate is moving people away from combusted cigarettes, … as IQOS." (Hrg.Tr.454:8-12.) Dr. Rodu agrees: Just considering e-cigarettes, "[t]here are thousands of choices, reflecting the fact that they are the most popular—and most successful—quit-smoking aids." (Hrg.Tr.1296:1-12; *see also* Hrg.Tr.1291:15-22 (identifying "a whole host of options that are now available to smokers" including "vaping products, smokeless tobaccos like dip and chew and Snus.").) And Respondents' Mr. Magnani testified that [redacted] (JX-0093C.195:23-196:12.)

These PRRPs generally fall into 6 categories:

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(CDX-0005C.3; Hrg.Tr.455:2-459:3.) Reynolds is a leading supplier of products in all but the NRT category. (Hrg.Tr.66:1-71:20.) As Dr. Murrelle testified, removal of a single PRRP (IQOS) from the thousands available to U.S. consumers will not have a meaningful impact on the public health and welfare of U.S. consumers. (Hrg.Tr.459:4-16.)

Despite these thousands of options, Respondents overemphasize that IQOS is one of few HNB products on the market. The relevant market is not just HNB, *see* Section VII.B, *infra*, but even if it were, Reynolds's Eclipse HNB product will adequately serve the limited demand for HNB products in the United States. Indeed, Dr. Benson agreed that she doesn't "consider IQOS to be novel in view of Eclipse." (Hrg.Tr.1365:19-1366:3.)

(b) Existing PRRPs Have At Least The Same Potential To Offer Reduced Risk And Exposure Compared To IQOS

Respondents try to distinguish IQOS from other PRRPs by touting it as a product that offers reduced exposure and potentially reduced harm as compared to CCs. But there is no credible