EXHIBIT 5

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Clark S. Cheney
Administrative Law Judge

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

RESPONDENTS' POST-HEARING INITIAL BRIEF

The '123 and '915 patents reflect Complainants' belated and unsuccessful attempts to develop HNB technology—the asserted claims are invalid over Philip Morris's own prior art patents and devices.

For the '123 patent, Complainants stipulated that Morgan, a Philip Morris patent that predates the '123 patent by a decade, discloses every limitation of the asserted claims other than a centered heater. But it is ***undisputed*** that centered heaters were well-known in the art. A POSA understood that a centered heater was merely a design choice among just three options and would have solved the known disadvantages of Morgan's heater.

For the '915 patent, Philip Morris's prior art Accord devices render the asserted claims invalid. Complainants' expert did not even touch, much less refute, Respondents' evidence. The ***unrebutted*** evidence shows each device anticipates claims 1-3 and renders obvious claim 5.

Second, should the ALJ find a violation of Section 337 (there is none), the serious impact that any remedial orders would have on the public interest—specifically, public health and welfare—requires that the Commission take the rare step of forgoing issuance of such remedies. The evidence shows that, despite the longtime and ready availability of a host of alternative nicotine delivery products, some thirty-four million Americans continue to smoke CCs. CC smoking is associated with innumerable illnesses and, according to public health authorities, is a root cause in 500,000 deaths in the U.S. annually. The available alternatives simply have failed to help enough Americans quit CC smoking.

Enter IQOS. The evidence shows that IQOS is a unique product that ***heats*** tobacco to release nicotine, tobacco flavor, and aroma, but without combusting the tobacco and exposing the consumer to the dangerous carcinogens and harmful chemicals created by combustion. The evidence shows that, unlike other PRRPs, IQOS closely approximates the CC smoking experience,

including the (i) cigarette-like experience of the HEET Stick in a user's mouth, (ii) ritual of preparing the IQOS for use, and (iii) IQOS's cigarette-like shape and feel in hand. Collectively, these characteristics provide a sense of enjoyment and familiarity for certain smokers that no other product, including e-cigarettes, provides.

The evidence establishes that, because of these unique sensory attributes, IQOS helps some committed smokers to move away from CC smoking and reduces their exposure to harmful chemicals. Third party witness Lindsey Lewis, a thirty-year CC smoker, testified that he tried but rejected e-cigarettes and embraces IQOS precisely because it is "extremely similar to actually smoking a cigarette." Tr. (Lewis) 1260:14-18, 1263:14-20. He testified that IQOS "dramatically improved [his] personal health beyond what [he] ever thought a product could do." Tr. (Lewis) 1243:3-7, 1262:6-14. Other American smokers deserve the choice Mr. Lewis made and the opportunity to enjoy similar health benefits.

Complainants argue that the available alternatives (which have not been accepted by thirty-four million American users of CCs) are adequate substitutes for IQOS. They are wrong. There are ***no*** *substitutes* for IQOS on the market today—***none***. The evidence shows that oral tobacco, snus, nicotine patches and other cessation products are all niche products, providing distinct experiences from CC smoking, and having limited appeal. None can fairly be considered an IQOS substitute. Meanwhile e-cigarettes, Complainants' purported champion,: (i) are currently illegal in the U.S.; (ii) do not appeal to a wide swath of consumers who genuinely enjoy the combustible smoking experience; ***and*** (iii) face, at best, a highly uncertain regulatory future.

The record and applicable case law demonstrate that no e-cigarette has FDA authorization and that, in the absence of authorization, the sale of e-cigarettes is illegal in the U.S. today. While many e-cigarette manufactures have applied for authorization, the evidence also shows that there

are many open questions surrounding e-cigarettes, ranging from epidemic youth use to unknown chemistry and their unknown long-term effects on users. Because tens of thousands of e-cigarette products are under consideration, FDA's analysis is complicated by the practical impossibility of timely considering that volume. Thus, the record undisputedly establishes that no one can predict ***if*** or when any e-cigarette products will earn FDA authorization. In contrast, IQOS is the ***only*** aerosolized PRRP with PMTA and MRTP authorizations from the FDA. E-cigarettes cannot fairly be considered as substitutes for IQOS, either as a factual matter or as a matter of regulatory law.

Tellingly, the ALJ heard testimony from three disinterested witnesses who were not paid by a party for their time: Dr. Julie Gunther (private family physician); Lindsey Lewis (PPI); and Dr. Brad Rodu (University of Louisville, endowed chair for harm reduction). All were presented by Respondents. All passionately testified that American smokers need more choices and that IQOS is an exceptional product without substitutes that uniquely appeals to CC smokers. After (i) months of questioning the integrity of third parties who spoke up for IQOS with demonstrably false claims of "tainted" testimony; (ii) issuing ten subpoenas on third-party submitters and taking seven depositions; and (iii) [redacted] (per Dr. Gunther), Complainants failed to call a single third-party witness to testify. Third parties who take the Commission's role in protecting the public interest seriously deserve better.

Respondents respectfully request that the ALJ recommend to the Commission that there has been no infringement of a valid patent claim and no violation of Section 337. But if the ALJ finds a violation, IQOS should be exempted from remedial measures because removing IQOS from the market will cost lives and badly disserve the public interest.

DOCKET ALARM

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.