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

(Ehrlich) 1464:3-6. For SE products, the FDA only requires them to be no more harmful than a predicate product—*i.e.*, a grandfathered product—implicating ***minimal*** FDA harm assessment, far less data, and does not "deal with that public health standard that's at the end of the PMTA." Tr. (Figlar) 149:16-150:3; Tr. (Murrelle) 514:14-16; Tr. (Clissold) 529:17-24; Tr. (Ehrlich) 1463:25-1464:25. Indeed, ***the most harmful tobacco product in existence*** could be sold legally, so long as it is grandfathered, and another product could obtain SE authorization as long as it were no more harmful than that most harmful tobacco product, resulting in ***no*** substantive FDA harm assessment for either. Tr. (Ehrlich) 1438:21-1439:7. This is how Eclipse, Complainants' commercially failed HNB product, remains on the U.S. market. Tr. (Figlar) 66:6-12, 138:20-22, 149:8-15; Tr. (Murrelle) 468:14-17; Tr. (Ehrlich) 1438:6-20. The original Eclipse was grandfathered, and subsequent versions were ***bootstrapped*** to that grandfathered product. Tr. (Figlar) 66:6-12138:20-22, 149:8-150:3; Tr. (Ehrlich) 1438:6-20. Other grandfathered or SE products include smokeless tobacco and also lack any FDA harm assessment. Tr. (Murrelle) 467:23-468:7.

3. Lack Of FDA Authorization Renders E-Cigarettes Illegal

All e-cigarettes are ***illegal*** and thus cannot be IQOS substitutes. Tr. (Ehrlich) 1414:10-21, 1477:11-13, 1478:3-14. As discussed, e-cigarettes must obtain PMTA authorization to be legally sold in the U.S., but, to date, ***none*** have achieved this. RX-0324.5; Tr. (Figlar) 68:24-69:5; Tr. (Ehrlich) 1465:3-16. Thus, no e-cigarette on the U.S. market today is legal. *Id.* FDA crafted a compliance policy for discretionary enforcement so that e-cigarettes on sale as of the date of the Deeming Rule, all of which were automatically illegal without a PMTA, could remain on the market until a specified deadline for premarket submissions. Tr. (Ehrlich) 1475:8-24. "Significantly, this policy did ***not confer lawful marketing status*** on new tobacco products being marketed without the necessary premarket authorization." RX-0324.5 (emphasis added); *see* Tr.

(Ehrlich) 1416:15-24.

Under its compliance policy, FDA delayed enforcement of the e-cigarette PMTA deadline multiple times, leaving these illegal products on the U.S. market without any FDA harm review. *See* RX-0324.5-.7; Tr. (Ehrlich) 1414:22-1415:17. Several stakeholders, including the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, the Truth Initiative, and individual physicians, were concerned about the unaddressed surge of youth use of e-cigarettes and considered the FDA's delay an APA violation, so they sued to force the agency to fulfill its legal obligations. *Id.*; RX-0324.6; *Am. Academy of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019). The judge held in the plaintiffs' favor, finding "a purposeful avoidance by the industry of complying with the premarket requirements," and vacated FDA's compliance policy. *Id.* at 485, 487; Tr. (Ehrlich) 1415:18-22.

Given the uncertainty surrounding the efficacy of e-cigarettes and the public health emergency caused by the epidemic level of youth use, the court ordered that all e-cigarette PMTAs must be submitted to FDA by September 9, 2020, to avoid further delay of statutorily mandated FDA harm review. RX-0324.6-.7; Tr. (Clissold) 530:19-21; Tr. (Ehrlich) 1415:23-1416:14; *Pediatrics*, 399 F. Supp. 3d at 486. The court allowed a product subject to a timely PMTA to remain on the market "for a period not to exceed one year ***from the date of application***." *Pediatrics*, 399 F. Supp. 3d at 487; *see* Tr. (Clissold) 571:3-12; Tr. (Ehrlich) 1416:5-14, 1469:18-1470:8.

Consequently, not only do they remain illegal, e-cigarettes with no PMTA and those with a PMTA submitted more than a year ago (thus outside of the court's grace period) are no longer exempt from FDA enforcement. *See, e.g.,* RX-0324.4, .5, .11, .12; Tr. (Clissold) 571:19:572-7;

Tr. (Ehrlich) 1419:15-20, 1470:4-9. Notably, the grace period for Complainants' Vuse Solo ***already*** expired in October 2020, and, absent highly unlikely action by FDA, the grace period for the other Vuse e-cigarettes will expire this year in April (Vibe and Ciro) and September (Alto)—all prior to the Final Determination in this Investigation. *See* JX-0112C (Figlar) at 116:3-14; Tr. (Figlar) 81:13-17, 98:17-23, 100:1-7, 134:4-16; Tr. (Clissold) 537:13-17; Tr. (Ehrlich) 1416:25-1417:17, 1471:11-22.

E-cigarette PMTA enforcement delays experienced over the last few years will not continue indefinitely. The district court judge explicitly retained jurisdiction over the case to ensure he could take further action, as needed, and both FDA experts agree that any deviations from the judge's order can only be made with leave of court. Tr. (Clissold) 571:3-18; Tr. (Ehrlich) 1417:6-9, 1422:24-1423:4, 1494:6-13; *Pediatrics*, 399 F. Supp. 3d at 487. Moreover, FDA has warned that "[m]anufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns." RX-0324.28.

4. Lack Of FDA Authorization Renders The E-Cigarette Market Highly Uncertain

Another reason e-cigarettes cannot be IQOS substitutes is that the U.S. market for such products is uncertain and unreliable. Tr. (Ehrlich) 1417:10-23. First, no one knows whether or when ***any*** or ***which*** e-cigarettes will receive PMTA-authorization. Tr. (Ehrlich) 1448:11-1449:17, 1486:13-17. To date, no e-cigarette has received such authorization. *See, e.g.,* JX-0039 at -6450. David Kessler, former FDA Commissioner and Co-Chair of President Biden's Coronavirus Taskforce, "wouldn't want to bet on" any e-cigarettes surviving the FDA review due to "the explosion in youth use" of those products and the uncertainty in the industry it has caused. RX-0325.3-.4; Tr. (Ehrlich) 1449:18-1450:10; *see* Tr. (Clissold) 572:21-573:25, 574:4-575:1. Complainants' Dr. Figlar and Mr. Clissold both conceded there is no guarantee that any e-cigarette

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.