Exhibit 15

PUBLIC VERSION

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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

[redacted]

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

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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) "dragging" these third parties "through the mud" (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.

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1279:17-1283:2. HeatStick sales reflect this strong IQOS adoption. JX-0035 at -3417, -3432, -3442, -3444-46, -3450, -3464. Tobacco control experts, including Dr. Rodu and the American Cancer Society, have found that IQOS has reduced CC smoking and improved public health. JX-0021 at -0652-53; JX-0026 at -1610-12; JX-0030 at -1844; JX-0031 at -1868; RX-0312.5; Tr. (Rodu) 1280:3-1284:12; *compare* JX-0026 at -1600-01 *with* Tr. (Rodu) 1278:15-23.

There can be no doubt that some significant number of the 34 million U.S. CC smokers need and will adopt the IQOS alternative as it is introduced beyond the current limited test markets. According to the CDC, smoking is the leading cause of preventable death and disease. RX-0315.1, .5; Tr. (Rodu) 1275:3-10; *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 371 (D.D.C. 2017) ("*Nicopure I*"). According to public health authorities: (1) ***on an annual basis***, more Americans die of smoking-related diseases (480,000) than have perished in the COVID-19 pandemic, RX-0315.5; Tr. (Rodu) 1275:3-19; (2) without intervention, in 10 years, ***5 million*** Americans will die from CC smoking, Tr. (Rodu) 1275:21-23; *see* Tr. (Arnold) 1140:8-1141:9; and (3) ***16 million*** Americans live with a serious smoking-related disease, costing ***$300 billion*** in annual healthcare costs, RX-0315.5.

According to the CDC, most CC smokers want to quit, 50% attempt to quit each year, but only 10% succeed. RX-0315.4, .6-.7; CX-1284 at -2082; Tr. (Rodu) 1275:24-1276:8, 1286:2-7. The existing alternatives are neither sufficient solutions nor IQOS substitutes. Tr. (Rodu) 1276:9-16, 1284:13-23. In its "Strategic Policy Roadmap," FDA pledged to "take a fresh look at products that can deliver satisfying levels of nicotine to adults who want access to it without burning tobacco" but that also have undergone "an appropriate series of regulatory checkpoints"—a revolutionary policy shift that "could truly make a positive public health impact." JX-0024 at -0892; Tr. (Rodu) 1277:1-1278:3. IQOS exemplifies the type of product FDA needs to fulfill its

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