

# Exhibit 21

CONTAINS CONFIDENTIAL BUSINESS INFORMATION  
SUBJECT TO PROTECTIVE ORDER

UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, DC

Before the Honorable Clark S. Cheney  
Administrative Law Judge

In the Matter of

CERTAIN TOBACCO HEATING  
ARTICLES AND COMPONENTS THEREOF

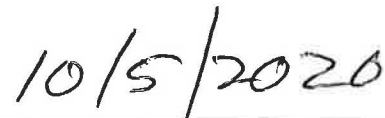
Investigation No. 337-TA-1199

EXPERT REPORT OF BRAD RODU

RELATING TO THE PUBLIC INTEREST



Brad Rodu



October 5, 2020

CONTAINS CONFIDENTIAL BUSINESS INFORMATION  
SUBJECT TO PROTECTIVE ORDER

process that gives it a different flavor than American dip, and somewhat lower levels of unwanted contaminants. Like dip, snus is marketed in many flavors and small pouches.

169. The use of STPs results in similar blood nicotine levels as cigarettes, but with slower absorption that is unsatisfying to many smokers.<sup>255</sup> These products also do not look like combustible cigarettes and to not reproduce the smoking ritual. In addition, esthetic concerns limit STPs' usefulness for women in particular and for some ethnic and racial groups.<sup>256</sup>

**D. E-cigarettes are not adequate substitutes for IQOS®**

170. Another alternative nicotine delivery system to combustible cigarettes is an e-cigarette (which also includes any product producing vapor derived from a liquid containing various levels of, or no, nicotine).

**1. Performance of e-cigarettes shows a need for other PRRPs**

171. E-cigarettes have been sold in the American market since 2007.<sup>257</sup> While e-cigarettes mimic some of the rituals of smoking, their haphazard development as consumer electronic products has produced a wide variation in quality, resulting in low satisfaction among traditional smokers and rare but serious battery malfunctions and misuse.<sup>258</sup>

172. E-cigarettes may be a good choice for certain individuals. That said, many try e-cigarettes and then abandon them.<sup>259</sup> A considerable number of people also engage in dual use of

---

<sup>255</sup> PMP\_ITC01901802-39.

<sup>256</sup> PMP\_ITC01901802-39.

<sup>257</sup> 1199\_RESP00010908.

<sup>258</sup> See 1199\_RESP00016335-46.

<sup>259</sup> See PMP\_ITC01875417; 1199\_RESP00016335-46.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION  
SUBJECT TO PROTECTIVE ORDER

e-cigarettes and combustible cigarettes, which reduces the health benefits of completely switching to a PRRP.<sup>260</sup> In fact, National Health Interview Surveys from the Centers for Disease Control and Prevention reveal that the number of current smokers using e-cigarettes has always been higher than the number of former smokers using them.<sup>261</sup>

**2. Youth use of e-cigarettes is high and remains under scrutiny**

173. There is no question that the use of e-cigarettes among high school and middle school students has increased. Accordingly, governmental officials are “taking a comprehensive aggressive approach “ to the situation.<sup>262</sup> Complainants, too, acknowledge there is a problem. For example, in February 2020, RAI’s CEO testified in a House Committee hearing about the perils of youth adoption of e-cigarettes.

174. In September 2020, the CDC reported that “19.6% of high school students (3.02 million) and 4.7% of middle school students (550,000) reported current e-cigarette use.”<sup>263</sup> Of those users, “38.9% of high school students and 20.0% of middle school students reported using e-cigarettes on 20 or more of the past 30 days; 22.5% of high school users and 9.4% of middle school users reported daily use.”<sup>264</sup>

---

<sup>260</sup> See 1199\_RESP00011888; 1199\_RESP00016335-46.

<sup>261</sup> *CDC Data: Vaping Increased in 2018, Particularly Among Former Smokers*, TOBACCO TRUTH (last visited Oct. 5, 2020), <https://rodutobaccotruth.blogspot.com/2019/07/cdc-data-vaping-increased-in-2018.html>.

<sup>262</sup> 1199\_RESP00010611; see also 1199\_RESP00010620-21; 1199\_RESP00011826-31; 1199\_RESP00014244-53; 1199\_RESP00014536-47; 1199\_RESP00010295-300; 1199\_RESP00010702-886; 1199\_RESP00010908-11; 1199\_RESP00011330-39.

<sup>263</sup> 1199\_RESP00015126.

<sup>264</sup> 1199\_RESP00015126.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION  
SUBJECT TO PROTECTIVE ORDER

175. While no measures ever taken by manufacturers and suppliers of adult substances have ever guaranteed zero use by teens, the highly restrictive sales program implemented by Respondents worldwide has minimized youth uptake of IQOS®.<sup>265</sup> The FDA-approved post-marketing surveillance plan also will ensure that IQOS® is marketed and sold only to adult smokers.<sup>266</sup> Moreover, as a product, studies have shown that IQOS® simply does not appeal to youth in the way that e-cigarettes do.<sup>267</sup>

**3. The e-cigarette market is undergoing major disruption**

176. In addition to concerns about the performance or appeal of e-cigarettes and the questions surrounding youth uptake of such products, the e-cigarette market is undergoing major disruption. For years, e-cigarettes were technically on the U.S. market illegally.

177. This issue of illegality was addressed through a deadline on September 9, 2020, whereby all e-cigarette companies had to file PMTAs with the FDA in order to remain on sale in the United States.<sup>268</sup> Applications had to be filed for each device, each flavor, and each concentration of nicotine liquids or pods, making some vape shops responsible for hundreds of PMTAs.<sup>269</sup> Each application is required to demonstrate that the products are “beneficial to the population as a whole including users and non-users . . . [taking] into account the increased or decreased likelihood that existing tobacco users will stop using such products, and the increased

---

<sup>265</sup> See 1199\_RESP00011619; PMP\_ITC05452788.

<sup>266</sup> 1199\_RESP00012398-403.

<sup>267</sup> See, e.g., PMP\_ITC01768947-55; 1199\_RESP00012388.

<sup>268</sup> 1199\_RESP00014297.

<sup>269</sup> See 1199\_RESP00014300-01; 1199\_RESP00014118-69.

# 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.