

Exhibit 9

CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

RAI STRATEGIC HOLDINGS, INC. and
R.J. REYNOLDS VAPOR COMPANY

Plaintiffs and Counterclaim
Defendants,

v.

ALTRIA CLIENT SERVICES LLC; PHILIP
MORRIS USA INC.; and PHILIP MORRIS
PRODUCTS S.A.

Defendants and Counterclaim
Plaintiffs.

Case No. 1:20-cv-00393-LO-TCB

**PHILIP MORRIS PRODUCTS S.A.'S SUPPLEMENTAL RESPONSE TO
REYNOLDS' SIXTH SET OF INTERROGATORIES (NO. 23)**

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DEF_PUB_EDVA000057941; DEF_PUB_EDVA000057944; DEF_PUB_EDVA000057947;
DEF_PUB_EDVA000057956; DEF_PUB_EDVA000057960; DEF_PUB_EDVA000057964;
DEF_PUB_EDVA000057968; DEF_PUB_EDVA000057971 DEF_PUB_EDVA000058177;
DEF_PUB_EDVA000058180; DEF_PUB_EDVA000058183; DEF_PUB_EDVA000058186;
DEF_PUB_EDVA000058190; DEF_PUB_EDVA000058193; DEF_PUB_EDVA000058196;
DEF_PUB_EDVA000058199; DEF_PUB_EDVA000058202; DEF_PUB_EDVA000058205;
DEF_PUB_EDVA000058208; DEF_PUB_EDVA000058211; DEF_PUB_EDVA000058214;
DEF_PUB_EDVA000058217; DEF_PUB_EDVA000058220, DEF_PUB_EDVA000057709;
DEF_PUB_EDVA000057706; DEF_PUB_EDVA000057703; DEF_PUB_EDVA000057700;
DEF_PUB_EDVA000057697; DEF_PUB_EDVA000057694; DEF_PUB_EDVA000057691;
DEF_PUB_EDVA000057688; DEF_PUB_EDVA000057685; DEF_PUB_EDVA000057682;
DEF_PUB_EDVA000057679; DEF_PUB_EDVA000057589. It also has issued import alerts,
which blocked entry of over 33,000 illegal e-cigarettes in December 2020 alone. ITC Hr’g Tr.
1419:9-1420:4, 1451:4-22, 1452:14-1453:2, 1480:3-1481:16 (Ehrlich);
DEF_PUB_EDVA000057656; DEF_PUB_EDVA000057649. State and local authorities have
independently acted against illegal e-cigarettes as well. ITC Hr’g Tr. 1451:4-22 (Ehrlich);
DEF_PUB_EDVA000057974.

D. FDA Authorizations For E-Cigarettes, Like VUSE, Cannot Be Assumed

The illegal status of the VUSE e-cigarettes may never be cured, as there is no guarantee
FDA will grant PMTA authorizations for these products. Earning PMTA authorization is a
difficult and time-consuming endeavor. To do so, a product must show it is appropriate for the
protection of public health – a level of harm assessment requiring voluminous data that takes years
to collect and that must undergo technical review by FDA specialists from a variety of scientific
disciplines. 1199_RESP00010615; 1199_RESP00011697 at 1199_RESP00011707-708;

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1199_RESP00010958. And just last month, in March 2021, more than forty Members of Congress sent a letter to FDA demanding that it “deny issuing a marketing order for any e-cigarette that poses an increased risk of youth initiation or addiction.” DEF_PUB_EDVA000056125.

Given the concerns over youth use of e-cigarettes, leaders in tobacco control and the tobacco industry have expressed doubts about the viability of *any* e-cigarette PMTA being authorized. For example, 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. 1199_RESP00014222 at 1199_RESP00014224-25; ITC Hr’g. Tr. 1449:18-1450:10 (Ehrlich); *see* ITC Hr’g Tr. 572:21-573:25, 574:4-575:1 (Clissold). Reynolds’ Dr. Figlar and Mr. Clissold both concede there is no guarantee that any e-cigarette will receive PMTA authorization. ITC Hr’g Tr. 99:20-25 (Figlar); ITC Hr’g Tr. 564:10-16 (Clissold).

PMTAs for flavored e-cigarettes, like many submitted by Reynolds, face even greater scrutiny. ITC Hr’g Tr. 1450:17-24, 1487:1-19 (Ehrlich); Figlar ITC Dep. 51:8-17, 87:4-14; 1199_RESP00012998; 1199_RESP00016076. In its Guidance on Enforcement Priorities for ENDS, FDA stated that it is “concerned about the extraordinary popularity of flavored ENDS products with youth,” particularly flavored cartridge-based e-cigarettes. 1199_RESP00014118 at 1199_RESP00014131; *see* DEF_PUB_EDVA000057623 at DEF_PUB_EDVA000057625 (describing flavors as the “core” of the epidemic rise in youth use of ENDS). Accordingly, FDA has instructed that “[b]ecause of the potential impact of flavors on product toxicity and appeal to youth and young adults, scientific reviews of flavors (*e.g.*, toxicological analyses of flavor additives, chemistry analyses, clinical studies, literature reviews) should be included in a PMTA for an e-liquid.” 1199_RESP50000280 at 1199_RESP50000323.

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of June, 2021, I caused the foregoing to be served on the following Plaintiffs/Counterclaim Defendants using the designated email address: RJREDVA@jonesday.com.

/s/ Maximilian A. Grant

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