

# Exhibit 10

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

PHILIP MORRIS PRODUCTS S.A.,

Plaintiff,

v.

R.J. REYNOLDS VAPOR COMPANY,

Defendant.

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

**DECLARATION OF STACY EHRlich**

I, Stacy Ehrlich, declare as follows:

**I. PROFESSIONAL BACKGROUND AND EXPERTISE**

1. I am a partner at the law firm of Kleinfeld, Kaplan & Becker, LLP in Washington, DC. I received my law degree, *cum laude*, from Harvard Law School, am admitted to practice in the District of Columbia, and have been specializing in regulatory law for over twenty-five years.

2. A significant part of my regulatory experience involves laws and regulations related to the U.S. Food and Drug Administration (“FDA”). At least half of my current practice deals with FDA regulation of tobacco and nicotine products under the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. This specialization requires me to keep abreast of FDA’s policies, statements, decisions, and actions related to those products.

3. Types of FDA tobacco and nicotine regulatory work I assist clients with include consulting on and shepherding through important FDA authorization applications.

4. I also have served as an FDA expert twice—once in the above-captioned matter and once in the related investigation before the U.S. International Trade Commission (“ITC”), Inv.

No. 337-TA-1199. Both were on behalf of Philip Morris Products, S.A. (“Philip Morris”), and I am generally familiar with the FDA-related aspects of both actions.

## II. FDA’S AUTHORIZATIONS FOR TOBACCO AND NICOTINE PRODUCTS

5. “New tobacco products” are tobacco or nicotine products that were either introduced for the first time in the United States after February 15, 2007, or were modified after that date. Companies must seek permission from FDA before they can legally offer and sell “new tobacco products” on the U.S. market. The market-entry permission that e-cigarettes, like VUSE products from R.J. Reynolds Vapor Company (“Reynolds”), must earn is called a premarket tobacco product (“PMT”) authorization. In order to obtain PMT authorization, an applicant must demonstrate to FDA that the product in question is appropriate for the protection of public health—a stringent standard. I have worked on approximately forty PMT applications.

6. As of the date of this declaration, FDA has granted PMT authorization to multiple e-cigarettes, including products from NJOY LLC, Logic Technology Development LLC, and Reynolds. With regard to Reynolds, FDA has granted PMT authorization to its VUSE Solo (both the G1 and G2 versions), VUSE Vibe, and VUSE Ciro. The PMT application for Reynolds’ VUSE Alto is still pending.

7. In addition to the e-cigarette PMT authorizations listed above, FDA also has granted PMT authorization to other types of tobacco and nicotine products.

8. One of the PMT-authorized non-combustibles outside of the e-cigarette category is the IQOS heat-not-burn product (“HNB”) developed and commercialized by Philip Morris.

9. Besides the IQOS HNB, no other HNB has earned PMT authorization.

10. The IQOS HNB also has earned modified risk tobacco product (“MRTP”) authorization. In order to obtain MRTP authorization, an applicant must demonstrate to FDA,

among other things, that the product under review benefits or is expected to benefit the health of the population as a whole. This standard is even more stringent than the standard for PMT authorization.

11. No Reynolds product has earned MRTP authorization.

12. No e-cigarette has earned MRTP authorization.

13. Besides the IQOS HNB, no other inhalable smoke-free alternative (*i.e.*, in either the HNB or e-cigarette category) has earned both PMT- and MRTP authorizations. Because of these distinctions, removing the IQOS HNB from the U.S. market would deprive U.S. adult smokers of a product for which there is no substitute, from a regulatory perspective.

### **III. NO PUBLIC INTEREST HARM FROM LIMITED VUSE REMOVAL**

14. My understanding is that, in the above-captioned matter, cartridges for Reynolds' VUSE Alto and VUSE Solo G2 were found to infringe two patents owned by Philip Morris. I also understand that Philip Morris now seeks to permanently enjoin Reynolds from manufacturing, offering for sale, and selling those cartridges in the United States. It is my opinion that such an injunction does not pose any harm to the public interest.

15. Even if the VUSE Alto and VUSE Solo G2 cartridges were removed from the U.S. market, multiple PMT-authorized e-cigarettes would still be available from Reynolds and other manufacturers. Consequently, American adult smokers would still have access to devices from the same product category with the same FDA authorizations (or more in the case of VUSE Alto, which currently has no FDA authorizations). This means there would be no meaningful negative impact on the public interest from issuing the injunction that Philip Morris seeks.

16. In addition to other PMT-authorized e-cigarettes, U.S. adult smokers would continue to have access to PMT-authorized non-combustibles from other product categories.

Although I do not consider all PMT-authorized products to be substitutes for one another, I am aware that Reynolds took such a position in the related ITC investigation. Specifically, I am aware that Reynolds argued on multiple occasions that there are thousands of potentially reduced risk products available on the U.S. market, and therefore removing any one product would not harm the public interest. Reynolds' arguments to the ITC further support that there would be no meaningful negative impact on the public interest from issuing the injunction that Philip Morris seeks.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on August 11, 2022

A handwritten signature in black ink, appearing to read 'SE', is written over a horizontal line.

Stacy Ehrlich