EXHIBIT 74

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 ("TCA"). 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, 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. THE DEEMING RULE AND ITS EFFECT ON E-CIGARETTE DESIGNS

5. Congress passed the TCA in 2009, giving FDA authority to regulate cigarettes and certain other specified tobacco products.[1] The TCA further provided that FDA may promulgate regulations "deeming" other products to be subject to its tobacco product authorities under the statute.[2]

6. The Deeming Rule, which went into effect on August 8, 2016, expanded the TCA's applicability to all products meeting the statutory definition of "tobacco product," including e-cigarettes and e-liquids. This meant that all deemed "new tobacco products" – defined as tobacco or nicotine products that were not marketed in the United States as of February 15, 2007, or were modified after that date[3] – had to have premarket authorization in order to be sold legally in the United States.

7. It is generally accepted that no modern e-cigarette product was commercially marketed in the United States as of February 15, 2007, making all current e-cigarettes new tobacco products under the TCA.[4] This includes VUSE products from R.J. Reynolds Vapor Company

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[1] 21 U.S.C. § 387a(b); *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, FDA, at 3 (Apr. 2020), https://www.fda.gov/media/133880/download ("FDA E-Cigarette Guidance"); *see* Mitch Zeller, *Perspective: FDA's Preparations for the September 9 Submission Deadline*, FDA (Aug. 31, 2020), https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline ("Director Perspective").

[2] 21 U.S.C. § 321(rr); 21 U.S.C. § 387a(b).

[3] 81 Fed. Reg. 28974 at 28975-76 (May 10, 2016); FDA E-Cigarette Guidance at 3-4, 10; Director Perspective.

[4] Director Perspective.

("Reynolds")—specifically the VUSE Solo G2 and VUSE Alto cartridges that the jury in the above-captioned case found to infringe U.S. Patent Nos. 10,104,911 and 9,814.[5]

8. Thus, before e-cigarette products can be legally sold in the United States, they must earn premarket tobacco product ("PMT") authorization from FDA.[6] I have worked on approximately forty PMT applications.

9. The PMT authorization requirement triggered by the Deeming Rule rendered all e-cigarettes on sale in the United States as of August 8, 2016, instantaneously illegal.[7]

10. In order to prevent the total and immediate removal of these e-cigarettes from the U.S. market, however, FDA unveiled a compliance policy whereby e-cigarettes (and other new tobacco products in the newly deemed categories) already on the U.S. market as of the Deeming Rule's effective date could remain so until a specified deadline for submitting PMT applications.[8] FDA made clear, however, that the compliance policy did not confer lawful marketing status on new tobacco products being sold without the necessary PMT authorization.[9]

11. The protections of this compliance policy are extinguished if the design of the new tobacco product is modified from the design that existed as of the effective date of the Deeming Rule, August 8, 2016.[10] If such a modification were to occur, the new tobacco product must be removed from the U.S. market until FDA grants PMT authorization to the modified design.[11]

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[5] Dkt. 1414; *see* FDA E-Cigarette Guidance at 4; Director Perspective.

[6] 81 Fed. Reg. at 28975-76; FDA E-Cigarette Guidance at 4, 10; Director Perspective.

[7] *See* FDA E-Cigarette Guidance at 10-11.

[8] *See* FDA E-Cigarette Guidance at 4; Director Perspective.

[9] FDA E-Cigarette Guidance at 4; *see* Director Perspective.

[10] FDA E-Cigarette Guidance at 4, 10.

[11] *See id.*

III. THE DESIGN OF REYNOLDS' VUSE ALTO E-CIGARETTE CARTRIDGES

12. I understand that cartridges embodying the design of the VUSE Alto cartridges were offered for sale in the United States as of August 8, 2016, the effective date of the Deeming Rule's enactment, under the name Wabling by an entity other than Reynolds.[12]

13. I further understand that Reynolds did not develop the design for the VUSE Alto cartridges itself but instead licensed that design from Shenzhen Smoore Technology Ltd. during the second half of 2018.[13] Reynolds then relaunched that design in the U.S. market as VUSE Alto in August 2018.[14]

14. I also understand that Reynolds has only one pending PMT application for the VUSE Alto cartridges, and that application reflects the Wabling cartridge design that was on sale as of August 8, 2016.[15]

15. In order for Reynolds to continue to sell the VUSE Alto cartridges in the United States prior to FDA granting the pending VUSE Alto PMT application, Reynolds may not make any changes to the cartridges' design as it existed on August 8, 2016.[16]

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[12] Ex. 1 (Hunt Dep.) 299:2-300:4 (Apr. 14, 2021) (testifying that the Wabling cartridge is the same product as the Alto cartridge and was sold in the United States prior to August 8, 2016).

[13] Ex. 2 (Gilly Dep.) 70:24-71:15 (Dec. 3, 2020) (testifying that Reynolds "obtained a license to sell that [Alto] product in the send half of 2018" from Smoore); Ex. 3 (Figlar Hr'g Tr. 553:2-16 (June 9, 2022) (testifying that Alto "was a product that we [Reynolds] licensed from one of our suppliers"), 558:22-559:15 (testifying that Reynolds "negotiated with [its] supplier to get a license to use that [Alto] product"), 575:9-20 (testifying that a Chinese company called Smoore designed the Alto, not Reynolds).

[14] Ex. 1 (Hunt Dep.) 299:2-8 (testifying that Alto was first sold by Reynolds in August 2018).

[15] Ex. 3 (Figlar Hr'g Tr.) 566:1-11 (testifying that single Alto PMT application is still pending); Ex. 1 (Hunt Dep. 299:2-300:4) (testifying that the Wabling cartridge is the same product as the Alto).

[16] Ex. 3 (Figlar Hr'g Tr.) 553:2-16 ("[A]ny new innovations have to either be off of this [Alto] design or any new design has to go straight to the FDA before you can go into market."); *see* FDA E-Cigarette Guidance at 4, 10. Notably, even if the VUSE Alto cartridge does not change its

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