EXHIBIT 1
(PUBLIC)

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

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.	Civil Action No. 1:20-cv-393

AMENDED AND SUPPLEMENTED OPENING EXPERT REPORT

OF STACY EHRLICH

Stacy Ehrlich — April 26, 2021

I. SCOPE OF REPORT

1. I was retained on behalf of Plaintiffs Altria Client Services, LLC (ACS), Philip Morris USA, Inc. (PM USA), and Philip Morris Products S.A. (PMP) (collectively, Plaintiffs) to provide opinions in the above-captioned case against Defendants RAI Strategic Holdings, Inc. (RAISH) and R.J. Reynolds Vapor Company (RJRV) (collectively, Reynolds) regarding certain aspects of damages related to Reynolds' infringement of U.S. Patent Nos. 6,803,545 (the '545 Patent); 10,104,911 (the '911 Patent); 10,420,374 (the '374 Patent); 10,555,556 (the '556 Patent); and 9,814,265 (the '265 Patent), (collectively, Asserted Patents).[1] Specifically, I was asked to opine on the importance of the Asserted Patents to Reynolds in relation to its pursuit of premarket authorization via premarket tobacco applications (PMTAs) and its pursuit of modified risk authorization via modified risk tobacco product applications (MRTPAs) from the U.S. Food and Drug Administration (FDA) for its VUSE e-cigarettes.[2]

2. I submitted my initial opening expert report in this matter on February 24, 2021. I understand that, since that date, additional depositions have been taken and additional documents have been produced, including but not limited to, communications between FDA and Reynolds. Accordingly, I have prepared this amended and supplemental report ("Report") to account for the additional evidence received after February 24, 2021, and to supersede my previous submission.[3]

3. It is my opinion that, from a regulatory perspective, Reynolds derives particular benefit from its infringement of the Asserted Patents because this technology is involved in and important to FDA's PMTA review of Reynolds' VUSE e-cigarettes. Premarket authorization is

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[1] For purposes of my Report, I have assumed that Reynolds infringes the Asserted Patents. I offer no technical opinion related thereto.

[2] "E-cigarettes" also are known as "ENDS" products or "vaping" or "vape" products.

[3] I also have made corrections to certain footnote citations.

valuable and vital to Reynolds, given that, without it, its e-cigarettes will remain illegal and may be forced off the U.S. market pursuant to provisions within the Federal Food, Drug, and Cosmetic Act (FDCA).

4. It is my opinion that, from a regulatory perspective, Reynolds derives particular benefit from its infringement of the Asserted Patents because this technology is involved in and important to FDA's MRTPA review of Reynolds' VUSE e-cigarettes. [redacted].

II. CREDENTIALS AND COMPENSATION

5. I have been an attorney with Kleinfeld Kaplan and Becker LLP (KKB) in Washington, DC since 1996. KKB is a boutique law firm established in 1967 that focuses on the regulation of products under the jurisdiction of FDA and related federal and state agencies, including the U.S. Federal Trade Commission (FTC).

6. I have a B.A. in English, *magna cum laude*, from Emory University in Atlanta, Georgia, and a J.D., *cum laude*, from Harvard Law School. I am admitted to practice in the District of Columbia. I have been recognized by The Best Lawyers in America and Super Lawyers for FDA Law. My *Curriculum Vitae* is included as Exhibit 1.

7. I have been extensively involved in FDA's regulation of tobacco and nicotine products since prior to the enactment of the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009. I regularly advise clients in these industries, including serving as outside counsel to the Coalition of Independent Tobacco Manufacturers of America, with whom I worked to negotiate the small business provisions of the TCA. Over the past decade, I have counseled many

clients with respect to the development and preparation of tobacco product premarket submissions to FDA, assisting numerous companies in obtaining marketing orders for their products.

8. Additionally, I speak and write extensively on issues related to FDA regulation, including nicotine and tobacco product regulation and enforcement. I have served on the Board of Directors of the Food and Drug Law Institute (FDLI), and I am currently serving my second term on the FDLI Tobacco and Nicotine Products Committee.

9. I am being compensated at the rate of $825 per hour.

10. Neither I nor my law firm has an interest in the outcome of this matter.

III. MATERIALS REVIEWED

11. To inform my opinions in this Report, I have relied on the Initial Expert Reports[4] of and interviews with Paul Meyer (for damages), Joseph McAlexander (for the ’545 and ’374 Patents), John Abraham (for the ’911 and ’556 Patents), and Henry Walbrink (for the ’265 Patent), including, but not limited to, their descriptions of the characteristics of the Asserted Patents.

12. A list of materials I considered in preparing this Report is included as Exhibits 2 (updated) and 3. I also relied on the education, experience, and knowledge that I have gained from working in the FDA arena for over two decades.

13. The materials referenced in my Report are exemplary in nature and intended to aid understanding. I may rely at trial on these materials, as well as other documents and items produced in this case, such as deposition exhibits, deposition and trial testimony, discovery responses, and publicly available materials. I reserve the right to use visual aids, demonstratives, and physical evidence at trial, including any materials that I considered in forming the opinions described in this Report.

[4] This includes any amendments and/or supplementation to these reports.

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