EXHIBIT 3
(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 No. 1:20-cv-00393-LO-TCB

EXPERT REPORT OF DAVID B. CLISSOLD, ESQ. IN RESPONSE TO AMENDED AND SUPPLEMENTED OPENING REPORT OF STACY EHRLICH

Dated 05/06/2021

David B Clissold

David B. Clissold, Esq.

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[redacted]

[redacted]

9. As discussed in more detail in my report, I understand that the Asserted Patents have no relevance to PMTA review if Reynolds does not infringe, or if the patents are found invalid. Ms. Ehrlich's report contains no analysis establishing that the alleged benefits are, in fact, a result of using a particular patent claim. Whether the particular benefits relied on by Ms. Ehrlich are actually fairly attributable to the particular patent claims asserted against Reynolds is a subject for the technical experts. Moreover, there is nothing in any FDA regulation or guidance to suggest that the technology embodied in an Asserted Patent, and only that technology, is required, or even preferable. I also understand that Reynolds's technical experts are providing design-around options for the '374, the '911, and the '265 Patents. Relative to the hypothetical negotiation dates, I conclude that the design-arounds could have been implemented into the original PMTAs for Reynolds' products prior to the submission of their PMTAs, and that the timing of the review or the probability of authorization would not have been affected. The hypothetical negotiating date for the '545 patent is March 2013. This is more than a year before FDA even proposed to regulate e-cigarettes, and thus e-cigarettes could incorporate this technology or not, or change a product to include or replace the technology, with no FDA regulatory consequence at that time.

V. ANALYSIS

10. The "Family Smoking Prevention and Tobacco Control Act" ("Tobacco Control Act," or "TCA") amended the Federal Food, Drug, and Cosmetic Act ("FDC Act"), giving FDA the authority to regulate tobacco products. "Tobacco product" is defined broadly to mean "any product made or derived from tobacco that is intended for human consumption, including any

despite the dire consequences that Ms. Ehrlich envisioned for FDA enforcement post- *American Pediatrics* (Ehrlich at ¶¶ 33-40), products covered by a PMTA submitted before September 9, 2020 are at no imminent risk of FDA enforcement, be that by Warning Letter, import detention, or tweet, and retailers may continue to sell such products freely.

35. Ms. Ehrlich asserts that if a product is "modified or redesigned" after August 8, 2016, it is treated by FDA as a new tobacco product and cannot be marketed without a PMTA authorization. Ehrlich at ¶ 29. However, that does not necessarily mean that an applicant must submit a new PMTA for any modification. To the contrary, an applicant seeking to modify a product for which a PMTA has been submitted may seek to have changes authorized either by filing an amendment to the original application or by submitting a supplemental PMTA.

36. FDA has recognized that it may be appropriate to submit an amendment to a pending PMTA to account for product modifications. For example, in 2019 FDA issued a compliance policy guide stating that manufacturers could make certain modifications to their tobacco products to address a voluntary industry battery standard and to comply with requirements related to safe packaging of liquid nicotine products. *Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products* (Nov. 2019) https://www.fda.gov/media/133009/download. FDA said it would not consider those changes to create a "new" tobacco product and emphasized that it "does not intend to initiate enforcement action against such modified products on the basis of these modifications." *Id.* at 3, 8. The agency advised that "[f]or such products modified after the submission of a marketing application for the non-modified product, FDA recommends that manufacturers submit an amendment to the original application that describes the modifications." *Id.* at 5. Additionally,

under the draft PMTA regulations, an applicant may amend a PMTA after it has been submitted but before it has been authorized.[4]

37. In addition to the possibility of amending a PMTA, in proposed regulations FDA explained that an applicant who modifies or redesigns a product with a PMTA "may, as an alternative format of submitting" a full PMTA, "submit a supplemental PMTA to seek marketing authorization for modifications to such product, which result in a new tobacco product under 910(a)(1) of the Federal Food, Drug, and Cosmetic Act." 84 Fed. Reg. at 50612 (proposed 21 C.F.R. § 1114.15). A supplemental PMTA must include new information concerning the modifications that create the new tobacco product, but the applicant can cross-reference the previously submitted PMTA for the original tobacco product. *Id*. at 50566 (discussing proposed 21 C.F.R. § 1114.15). Because of the greatly reduced amount of information submitted in a supplemental PMTA, FDA review of a supplemental PMTA can be expected to be much faster than review of a full PMTA. As FDA explained, a supplemental PMTA "would reduce the burden of submitting and reviewing an application." *Id.* at 50568. Thus, an applicant with a pending PMTA may be able to wait for the PMTA to be authorized and then submit the "modification or redesign" as a supplemental PMTA. Among the changes or modification that FDA indicated it would accept as a supplemental PMTA are "[c]hanges to coil configuration if number of coils, coil gauge, material, and overall coil resistance remain unchanged" as well as

[4] "FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. An amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA's request, the reason for submitting the amendment." Proposed 21 C.F.R. § 1114.9(a)(1), 84 Fed. Reg. 50566 (Sep. 25, 2019).

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