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

ORAL ARGUMENT REQUESTED

BRIEF IN SUPPORT OF PMI/ALTRIA'S *DAUBERT* MOTION TO EXCLUDE DESIGN-AROUND TESTIMONY OF RJR'S EXPERT, DAVID CLISSOLD



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I. INTRODUCTION

The Court should exclude RJR's expert, David Clissold, from testifying that RJR's alleged design-arounds to the technology claimed in U.S. Patent Nos. 9,814,265 ("the '265 Patent") and 10,104,911 ("the '911 Patent") would have been "available" to RJR from a regulatory perspective at the time of the hypothetical negotiations for those patents

These opinions are unreliable, untethered to basic laws governing tobacco products, and speculative. Mr. Clissold's own report and deposition testimony contravene his design-around conclusions. In fact, Mr. Clissold admits that e-cigarette

Ex. 1 (Clissold Rbt.) ¶ 18; see Ex. 2 (Clissold Dep.) 45:20-46:4, 47:5-48:18, 53:12-58:10. As such, it is undisputed that, as of the hypothetical negotiations , RJR was barred from selling modified versions of e-cigarettes that were on the market on August 8, 2016 (i.e., Accused Products incorporating the alleged design-arounds), unless and until the U.S. Food and Drug Administration ("FDA") granted premarket tobacco ("PMT") authorization to those products.

In an attempt to circumvent applicable law and FDA's enforcement discretion policy, Mr. Clissold speculates that RJR had multiple "options" that would have allowed the sale of RJR's unauthorized, redesigned products *prior to* PMT authorization. Each of Mr. Clissold's alleged "options," however, lacks any factual or legal support. They are pure speculation based on an unsound and unacceptable (indeed, unidentifiable) methodology. Accordingly, the Court should exclude Mr. Clissold's opinions.

II. FACTUAL BACKGROUND

A. RJR's Design-Arounds

PMI/Altria assert five patents against RJR's VUSE Solo, Vibe, Ciro, and Alto e-cigarettes ("Accused Products"), including the '265 Patent against the Alto and the '911 Patent against all



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