

**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



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

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I. INTRODUCTION

RJR cannot repair the unreliable premise on which Mr. Clissold's design-around opinions are based. The purported design-arounds for the '265 and '911 Patents simply would not have been "available" from a regulatory perspective for them to be reliably considered at the time of the hypothetical negotiations for those patents. None of RJR's factually incorrect and legally erroneous arguments obviate the indisputable reality—RJR's design-arounds were unavailable from a regulatory perspective and cannot be reliably considered for damages.

First, the Court should reject RJR's argument that PMI/Altria's challenge to Mr. Clissold's opinions is better suited to a summary judgment motion. PMI/Altria seeks to exclude these opinions because each is grounded in a misapplication of law, rendering all of them unreliable and unsuitable for a jury's consideration. A *Daubert* motion is precisely the procedural vehicle to review (and exclude) unreliable expert testimony based on a misunderstanding of the law, particularly when the proffered opinions are as speculative as Mr. Clissold's. Neither of the two non-binding district court cases RJR relies on suggest otherwise.

Second, the Court should reject RJR's legally erroneous argument that the redesigned products are "available" in the reasonable royalty context based on the *sheer possibility* that they could receive PMT authorization sometime "during the life of the patent." Dkt. 955 at 9. RJR cites no authority supporting this proposition and, instead, conflates cases addressing *technical feasibility* of non-infringing alternatives with the *regulatory availability of illegal products* like the redesigns at issue here. The premise of Mr. Clissold's opinions is rank speculation, making those opinions unreliable and ripe for exclusion.

Third, the Court should reject RJR's eleventh-hour re-characterization of Mr. Clissold's

opinions regarding the erroneous “options”¹ that purportedly would have allowed RJR to sell the redesigns on the U.S. market before earning PMT authorization. Even if the Court considers this dubious re-interpretation, it still would not render Mr. Clissold’s design-around opinions reliable.

In sum, nothing in RJR’s opposition rehabilitates Mr. Clissold’s fundamentally unreliable and speculative opinions regarding RJR’s alleged design-arounds for the ’265 and ’911 Patents. Accordingly, the Court should exclude any testimony from Mr. Clissold regarding those opinions.

II. ARGUMENT

RJR contends that the Court should deny PMI/Altria’s request to exclude because it is an untimely summary judgment motion that mischaracterizes the law and Mr. Clissold’s opinions. Each argument fails. In his report, Mr. Clissold describes “options” that purportedly would have allowed the redesigns to be sold in the United States before earning PMT authorization. Dkt. 922-1 (Clissold Rbt.) ¶¶ 35-38. The problem is that these so-called “options” are premised on a misapplication of law, rendering each of them unreliable and an appropriate subject for a *Daubert* motion.² Dkt. 922 at 6-12. RJR’s attempt to backtrack from Mr. Clissold’s “options” tacitly acknowledges as much.

A. PMI/Altria Appropriately Challenges Mr. Clissold’s Unreliable Design-Around Opinions At The *Daubert* Stage

RJR argues that PMI/Altria’s challenge to Mr. Clissold’s opinions is an untimely summary judgment motion that is inappropriate for *Daubert* review. Not so. Courts have excluded expert opinions at the *Daubert* stage where, as here, the expert offered “speculative” opinions based only

¹ RJR only defends Mr. Clissold’s PMTA amendment “option,” calling the safety modification and supplemental PMTA “options” “beside the point” and “immaterial.” Dkt. 955 at 12; Dkt. 922-1 (Clissold Rbt.) ¶¶ 35-38; Dkt. 922 at 8-12. Thus, the Court should consider waived any argument opposing the exclusion of Mr. Clissold’s design-around opinions based on these other “options.”

² Mr. Clissold admits that his so-called “options” are merely “a possibility.” Dkt. 922 at 8. Thus, these opinions are speculative as well as unreliable, providing yet another basis for exclusion. *Id.*

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