EXHIBIT 4

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UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN TOBACCO HEATING ARTICLES 337-TA-1199

AND COMPONENTS THEREOF

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Pages: 1396 through 1603

Place: Washington, D.C.

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regulation of tobacco and nicotine products.

JUDGE CHENEY: Any objection?

MR. BAYUK: No objection from Complainants, Your Honor.

MS. SLADIC: No objection from the Staff.

JUDGE CHENEY: Hearing no objection, Ms. Ehrlich will be recognized as an expert in the field of FDA law and regulation of tobacco and nicotine products.

Please proceed, Mr. Grant.

MR. GRANT: Thank you very much, Your Honor.

BY MR. GRANT:

Q. Now, have you ever testified as an expert in any kind of a court case before?

A. No, I have not, although I have been approached a few times in the past.

Q. Okay. Well, if you've been approached in the past and you haven't testified, I can only surmise that you said no. If that's true, why did you say yes in this case?

A. Yeah, I -- I decided to participate in this case because I do believe it's essential to public health for smokers to have access to a wide variety of potentially reduced risk products that have been evaluated and authorized by FDA. IQOS is -- is one of only two products that has been both PMTA and MRPT authorizations from FDA, and, as a result, I think it is important to public health

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to maintain access to IQOS.

Q. Okay. Well, let's talk about MRTPs. What is the purpose of an MRTP?

A. An MRTP application is intended to obtain a modified risk tobacco product authorization from FDA.

Q. And what are the two types of MRTPs?

A. So there's only one MRTP, a modified risk tobacco product. All products authorized under that pathway are considered modified risk tobacco products. However, there are two kinds of orders that you can get under the MRTP provision.

You can get a risk modification order or an exposure modification order.

Q. Okay. And just so we're clear for the Court, what type of MRTP order did the FDA grant IQOS?

A. IQOS has an exposure modification order.

Q. Okay. Now, last week when court was ongoing, did you have the opportunity to listen to the testimony of Reynolds' experts, Dr. Murrelle and Mr. Clissold?

A. I did.

Q. Okay. And what's your reaction to Dr. Murrelle's characterization that shoe polish could get a reduced exposure MRTP?

A. I think that's preposterous. And I think Mr. Clissold would agree with that. Obviously, the MRTP

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Q. Okay. Why does it take so long to obtain a PMTA?

A. It's just -- there's a -- there's a lot of data, a lot of, you know, information in there and it has to be reviewed by many different disciplines at FDA. So it's a very, very rigorous review that -- you know, it just -- it takes a very long time.

Q. Okay. We can take down the FDA authorization of IQOS.

I'd like to turn to e-cigarettes now. So that the Judge has it clear in his mind, have any e-cigarettes whatsoever received a PMTA authorization?

A. No, none.

Q. Okay. Now, from a regulatory perspective, are e-cigarettes IQOS substitutes?

A. I don't believe so. In fact, they're all illegal currently. There are no legally marketed e-cigarettes right now. Some are covered by FDA's enforcement discretion policy under the Maryland District Court order in the American Academy of Pediatrics case, but none are legally marketed.

Q. Okay. So we've talked a little bit about this American Academy of Pediatrics. Can you give the Judge a little bit more background on the case and what led to its filing?

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