

EXHIBIT E

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.

Date: February 1, 2021

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1 UNITED STATES INTERNATIONAL TRADE COMMISSION
2 Washington, D.C.
3 Before the Honorable Clark S. Cheney
4 Administrative Law Judge

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7 In the Matter of Investigation No.
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9 CERTAIN TOBACCO HEATING ARTICLES 337-TA-1199
10 AND COMPONENTS THEREOF
11 -----x

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16 Monday, February 1, 2021

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21 The parties met, via remote videoconferencing, pursuant to
22 notice of the Administrative Law Judge, at 9:00 a.m.
23 Eastern.

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25 Reported by: Karen Brynteson, RMR, CRR, FAPR

1 JUDGE CHENEY: Please proceed, Mr. Grant.

2 MR. GRANT: Thank you, Judge.

3 DIRECT EXAMINATION

4 BY MR. GRANT:

5 Q. Can you please introduce yourself to the Judge
6 and tell him what you do?

7 A. Yes. Good morning, Judge Cheney. My name is
8 Stacy Ehrlich. I'm a partner at the law firm of
9 Kleinfield, Kaplan & Becker in Washington, D.C., where I've
10 practiced for the last 25 years.

11 Q. And where did you go to law school?

12 A. I went to Harvard Law School.

13 Q. Can you tell the Judge what sort of law you
14 practice?

15 A. Sure. My expertise and -- and that of my firm
16 is -- is FDA regulatory law for the most part. I also do
17 some Federal Trade Commission advertising law, and for the
18 last decade or so, a large percentage of my practice has
19 focused on tobacco and nicotine products.

20 Q. Okay. Now, have you worked on any of these
21 tobacco substantial equivalence applications that we've
22 heard a lot about?

23 A. Yes. Since 2011, I've worked on at least 100
24 substantial equivalence reports, at least dozens of which
25 have been authorized by FDA.

1 Q. Okay. And we've heard a lot of talk about
2 PMTAs. Have you advised on any of those?

3 A. Yeah, I would say I've advised on at least 15
4 PMTAs, and one -- one of -- most are still pending, but one
5 has been authorized.

6 Q. Okay. And I think we heard that -- from
7 Mr. Clissold that he hadn't worked on any MRTPAs, and from
8 Ms. Gilchrist, they're fairly rare. Have you worked on any
9 of those?

10 A. Yes. In fact, I have worked on one MRTP that
11 has been authorized by FDA.

12 Q. Okay. Have you been recognized by any outside
13 organizations for your work in FDA law?

14 A. Yes, for example, I routinely am recognized in
15 the Best Lawyers of America and Super Lawyers for FDA law.

16 Q. Okay. And outside of your practice and your
17 client work, can you describe your professional involvement
18 in FDA regulatory issues relating to tobacco products?

19 A. Sure, I speak and write very frequently on these
20 issues. I also served a term on the Board of Directors of
21 the Food & Drug Law Institute, and I'm currently serving my
22 second term on the FDL I Tobacco and Nicotine Products
23 Committee.

24 MR. GRANT: Your Honor, at this time, we would
25 tender Ms. Ehrlich as an expert in the field of FDA law and

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