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LATHAM & WATKINS LLP

April 23, 2020

BY EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, DC 20436

Re: *Certain Tobacco Heating Articles and Components Thereof,*
ITC Docket No. 337-TA-3447

Dear Secretary Barton:

Enclosed please find as a courtesy filing the Public Interest Comments of the Consumer Advocates for Smoke-free Alternatives Association.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

The Consumer Advocates for Smoke-free Alternatives Association

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April 22, 2020

VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

Re: Certain Tobacco Heating Articles and Components Thereof, Investigation No. 337-TA-3447

Dear Secretary Barton:

The Consumer Advocates for Smoke-free Alternatives Association (CASAA) submits the following comments to the U.S. International Trade Commission ("ITC") in response to the Public Interest Statement filed on April 9, 2020 in the above-referenced case. Complainants ask the ITC to exclude from the U.S. market all IQOS heat not burn ("HnB") systems. CASAA believes that such severe measures are inappropriate, would remove choices for consumers seeking a low-risk alternative to smoking, and would give a competitive advantage to high-risk traditional cigarettes, all of which work against the public interest and genuine public health.

By way of background, CASAA is a non-profit 501(c)(4) organization with an all-volunteer board and a grassroots membership of more than a quarter of a million individuals from all walks of life. CASAA is a consumer organization, not a trade association or industry representative. CASAA is dedicated to ensuring the availability of reduced harm alternatives to

smoking and to providing smokers and non-smokers alike with honest information about those alternatives so that they can make informed choices.

CASAA specifically has no comment in connection with the underlying issue of whether or not there has been patent infringement. CASAA speaks only on the issue of the necessity of ensuring that IQOS remains available for consumer purchase and use in the United States.

1. IQOS is used in the U.S. as a reduced risk alternative to smoking.

Complainants describe the physical use of IQOS in their complaint, but they give short shrift to discussing the promise that HnB technology holds for people who smoke, and particularly for those who have tried approved smoking cessation products and/or e-cigarettes (sometimes referred to as vapor products) and found them to be an unacceptable low-risk substitute for smoking. IQOS is the only HnB product that has successfully navigated the complicated, expensive, and uncertain premarket tobacco product application (PMTA) process, receiving Food and Drug Administration (FDA) approval to be sold in the U.S. As part of the PMTA process, FDA concluded that marketing IQOS is "appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes."[1]

IQOS is not simply another tobacco product. IQOS allows consumers to replace their smoking habit with HnB technology, thereby lowering their exposure and risk as compared to smoking.

[1] "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway," Food and Drug Administration News Release, April 30, 2019, https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

2. Removing IQOS from the marketplace will reduce choices for consumers seeking reduced-risk alternatives to smoking, which is against the public interest.

Complainants refer to a broad category of "potentially reduced risk products" they define as "electronic nicotine delivery systems" (ENDS), which they assert includes both HnB (specifically, IQOS, since it is the only HnB product currently available in the U.S.) and e-cigarettes. Complainants assert that the existence of other products in the ENDS category means that if IQOS is removed from the market, consumers will still have choices. This is, at best, disingenuous.

While it is sometimes convenient to talk about e-cigarettes and HnB, both of which are lower risk than smoking, as a cohesive ENDS product class, there are substantial differences between these types of products (and, in fact, substantial differences even within the e-cigarette product category). These differences in form factor, design, and patterns of use are important because they allow consumers to find products that work for them as an acceptable and effective reduced-risk alternative to smoking. Specifically, IQOS heats tobacco, while e-cigarettes heat a liquid. For the consumer, e-cigarettes and HnB provide very different experiences in terms of, among other things, the nicotine delivery, taste and aroma. These differences are substantial enough such that for some people who smoke, e-cigarettes will not be an effective alternative, and HnB technology may be the only product that enables them to make the switch from smoking and to reduce their health risk.

Complainants' assertion also ignores the fact that as a practical matter, the biggest competition for all products in the reduced-risk category are traditional combustible cigarettes. Consumers who cannot find an acceptable low-risk alternative to smoking will likely continue or return to smoking. Consequently, anything that serves to reduce choices will necessarily cause

fewer consumers to make the switch and more consumers to keep smoking. In effect, reducing choices for consumers in the ENDS category protects the competitive advantage that combustible tobacco products currently enjoy over low-risk nicotine products, which is a huge loss in terms of genuine public health.

As noted previously, among the ENDS category that Complainants refer to, IQOS is the only product that has successfully navigated the complicated, expensive, and uncertain PMTA process allowing it to be sold in the U.S. once FDA begins stricter enforcement of the PMTA requirement, which is anticipated to occur sometime later this year. Once FDA begins enforcement, consumer choice in the ENDS category will be dramatically reduced to perhaps only a handful of products that will gain a temporary delay in enforcement due to filing an acceptable PMTA. Moreover, it will likely be years before another product using HnB technology is available in the U.S. due to the FDA's lengthy and uncertain PMTA process.

Removing IQOS from the market under these circumstances would be unconscionable.

3. Removal of IQOS from the U.S. marketplace will discourage diversity in the harm reduction arena, which is against the public interest.

As mentioned previously, IQOS is the only product in the ENDS category (as defined by Complainants) that is being marketed under a PMTA. The PMTA process requires a substantial commitment of time, money, and expertise, and there is little certainty in the process. The current PMTA process is daunting, and CASAA is concerned that removal of the only ENDS product with a PMTA will discourage other businesses with ENDS products from filing for PMTAs. From a consumer perspective, it is vitally important that a diversity of products remain on the market, and that cannot happen if businesses are deterred from filing PMTAs.

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