Exhibit 4
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CONFIDENTIAL VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN TOBACCO HEATING ARTICLES AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1199**

COMMISSION OPINION

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healthier than any other PRRPs. Hrg. Tr. 1434:2-5. Ms. Ehrlich further testified that it was "possible that other potentially risk-reducing products offer similar exposure risk benefits to the IQOS product, but the FDA has simply not made that determination." Hrg. Tr. 1460:16-25. In addition, both parties' experts testified that there are thousands of alternatives currently available in the United States for combustible cigarette smokers looking for potentially less harmful alternatives to smoking cigarettes. Hrg. Tr. 454:8-12, 458:4-459:3, 1291:15-22, 1295:17-1296:12; CX-528; CPX-211.

While Philip Morris touts the IQOS PMTA authorizations, it does not address the FDA's statements that any alleged benefit of IQOS is premised on robust adoption of IQOS combined with the users' complete cessation of combustible cigarette use, neither of which has been shown to have occurred. FID at 106-107 (citing JX-0034 at 13 ("the benefits of reducing exposure to harmful and potentially harmful chemicals require complete cessation of combusted cigarette smoking"); Hrg. Tr. 1306:22-1308:3 (Philip Morris's expert testifying that "if IQOS does not receive robust adoption in the United States, the public health benefits of it cannot be realized"). Philip Morris does not dispute that IQOS has not been robustly adopted. It simply argues that IQOS will be robustly adopted in the United States in the future, however, this argument is speculative and unsupported. PMIR at 69-75. In addition, Philip Morris's own expert, Dr. Rodu, testified that "no substantially safer product has had robust adoption in the United States" and that "smokeless tobacco products, Snus products, e-cigarettes, none of them have had robust enough adoption to allow enough smokers to live longer and healthier lives." Hrg. Tr. 1308:4-20.

In particular, IQOS has not been robustly adopted in the United States. At the time of the evidentiary hearing, with just over a year of sales in the U.S. market, "IQOS devices sold have

been [redacted] . . . [a]nd the net sales . . . on those units sold have been [redacted]." Hrg. Tr. 655:24-655:2. Similarly, [redacted]. Hrg. Tr. 656:8-12; CDX-0004C at 56. Based on these numbers, "[redacted] Hrg. Tr. 656:19-24. Even if the focus is narrowed to the regions where IQOS was being sold at the time of the evidentiary hearing, only [redacted] of smokers have purchased an IQOS device, and "the vast majority of those have either abandoned IQOS or are dual users." Hrg. Tr. 656:25-657:7; CDX-0004C.59. The Commission finds that the minimal adoption of IQOS in the United States combined with the FDA's premise that robust adoption is needed to realize any benefit of IQOS supports the conclusion that the exclusion of IQOS will not adversely affect the public health and welfare. [45]

Based on all of the evidence regarding IQOS, especially statements by the FDA and expert testimony of record including that there are thousands of alternative products available, the Commission finds that the public health and welfare factor does not weigh against issuing a remedy in this investigation.[46]

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[45] The Commission is not precluded from issuing a remedy simply because an infringing product is regulated by the FDA and there may be some benefit for certain individuals. *See Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Notice at 2 (Jan. 10, 1990) (determining that the public-interest factors did not preclude excluding the infringing antibiotics and that LEO and CDOs were the appropriate remedy).

[46] Philip Morris contends that any ITC remedy would usurp the exclusive authority of the FDA to regulate tobacco products in the United States under the TCA and FDCA. PMIR at 47. Moreover, it contends that the Commission's public interest analysis as to the public health and welfare amounts to "second-guessing" the FDA's "exclusive jurisdiction over tobacco product harm assessment" and expertise in evaluating IQOS. *Id.* at 50-56. Philip Morris's arguments, however, mistakenly view the FDA's authority as mandating that its IQOS tobacco products must be made available for sale in the United States, notwithstanding the Commission's findings

appropriate. *See* 19 C.F.R. § 210.76(a)(1) (stating that "the public interest" may serve as a basis for modification of remedial orders); *see also Personal Data and Mobile Commc'ns Devices* Comm. Op. at 68 (finding "the Commission has established procedures that permit modification or rescission of an exclusion order, as appropriate based on a reassessment of the changed facts or public interest at such time. 19 C.F.R. § 210.76(a)(1).").

Philip Morris also challenges the ALJ's finding that IQOS adoption is not widespread among U.S. consumers, [redacted]. We agree with the ALJ that the evidence shows that the U.S. market for IQOS is not robust, and Philip Morris exaggerates the level of adoption of IQOS. *See* PMIR at 69-75; FID at 123. Philip Morris repeatedly relies on global evidence as to IQOS adoption and use instead of evidence regarding U.S. consumers. *Id.* Philip Morris also relies on new evidence – that HeatSticks are now available in retail stores in Georgia, North Carolina, South Carolina, and Virginia – and sales data for the second quarter of 2021 that was not presented at the evidentiary hearing. *Id.* at 72-74 (citing various webpages). The evidence presented to the ALJ showed approximately [redacted] in the United States, which is a small percentage of U.S. consumers, even if compared to U.S. combustible cigarette smokers. FID at 123, 107; JX-0034 at 60, 62. Philip Morris's new evidence allegedly shows a [redacted], but Philip Morris fails to provide any actual numbers, underlying analysis, or context as to whether the IQOS users switched completely from combustible cigarettes. PMIR at 72-73. This new evidence was also never subject to expert review or cross-examination. Even if the [redacted] is considered, such an increase would result in an additional [redacted], which is still a very small percentage of U.S. consumers.

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