

# United States Senate

WASHINGTON, DC 20510

COMMITTEES:  
APPROPRIATIONS  
COMMERCE  
HEALTH, EDUCATION,  
LABOR, AND PENSIONS

January 29, 2024

Emma Walmsley  
Chief Executive Officer  
GSK  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom

Dear Ms. Walmsley:

I write to urge GSK to remove from its Food and Drug Administration Orange Book listings all remaining patents identified in the Federal Trade Commission's (FTC) November 7, 2023 warning letters regarding Advair HFA, Flovent HFA, Arnuity Ellipta, and Ventolin HFA.<sup>1</sup> Removal of these patents recognizes the FTC's finding that certain patents associated with these inhaler products have been improperly or inaccurately listed, which may amount to an unfair method of competition violating Section 5 of the Federal Trade Commission Act. Improper patent listing in the Orange Book can hinder competition and drive up the cost of these inhalers. I am calling on you to act now and remove all patents identified by FTC.

In Wisconsin, more than 500,000 people have asthma and nearly 6 percent of the population is estimated to suffer from Chronic Obstructive Pulmonary Disease.<sup>2</sup> These conditions frequently require management through inhaler products, including those marketed by GSK. In part due to a lack of competition, brand-name inhalers can cost up to \$600 per month – a price that is unaffordable for most families, but particularly low-income individuals who are more likely to suffer from asthma and COPD. Innovative products deserve protection but, for too long, large corporations have bent the rules to unfairly protect themselves from competition and Wisconsinites have paid the price. While drug companies are required to list certain patents in the Orange Book, bad actors can exploit this process to inappropriately deter competition and generic drug development, leading to fewer treatment options and higher prices for consumers. In recognition of this longstanding market manipulation tactic, on September 14, 2023, the FTC issued a policy statement making clear that inappropriate patent listing can be an unfair method of competition that violates Section 5 of the FTC Act.<sup>3</sup> While the Commission's policy statement is new,

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<sup>1</sup> Letter from FTC to GSK [https://www.ftc.gov/system/files/ftc\\_gov/pdf/glaxosmithkline-orange-book.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf); Letter from FTC to Glaxo Group Limited, at: [https://www.ftc.gov/system/files/ftc\\_gov/pdf/glaxo-group-orange-book.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf).

<sup>2</sup> Wisconsin Department of Health Services, Asthma: Wisconsin Asthma Statistics, at: <https://www.dhs.wisconsin.gov/asthma/facts.htm>; Centers for Disease Control and Prevention, Chronic Obstructive Pulmonary Disease (COPD) State-level Estimates, at: <https://www.cdc.gov/copd/data-and-statistics/state-estimates.html>.

<sup>3</sup> FTC Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at [https://www.ftc.gov/system/files/ftc\\_gov/pdf/p239900orangebookpolicystatement092023.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf) (hereinafter "Policy Statement").

abuse of our country's protections for intellectual property is longstanding.<sup>4</sup> The price of anticompetitive behavior is ultimately paid by Wisconsinites, through higher costs, fewer treatments, and worse health. It must stop.

GSK has had ample notice to remove improperly listed patents from the Orange Book, including from the Commission's September 14 policy statement and subsequent warning letter sent on November 7. By February 12, 2024, please confirm that you have removed all remaining patents identified in the FTC's November 7 warning letter or provide me with an explanation as to GSK's justification for its ongoing Orange Book inhaler patent listings. Thank you for your prompt attention to this matter.

Sincerely,

A handwritten signature in blue ink that reads "Tammy Baldwin". The signature is written in a cursive, flowing style.

Tammy Baldwin  
United States Senator

CC: Robert MacRae

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<sup>4</sup> See Policy Statement. See also, Decision and Order, In re Biovail Corp., FTC Dkt. No. C-4060; FTC's Brief as Amicus Curiae, Jazz Pharms., Inc. v, Avadel CNS Pharms.; and Mem. of Law of Amicus Curiae the FTC In Opposition to Defendant's Motion to Dismiss, In re: Buspirone.