UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
Bureau of Competition

November 7, 2023

Astrazeneca LP
Attn: Legal Counsel
c/o The Corporation Trust Co.
Corporation Trust Center
1209 Orange St.
Wilmington, New Castle, DE
19801

21929	1	Symbicort	7587988*PED	DP
			7587988	DP
			8387615*PED	DP
			8387615	DP
			8528545*PED	DP
			8528545	DP
			8616196*PED	DP
			8616196	DP
			8875699*PED	DP
			8875699	DP

As the Policy Statement explains, patents improperly listed in the Orange Book may delay lower-cost generic drug competition. By listing their patents in the Orange Book, brand drug companies may benefit from an automatic, 30-month stay of FDA approval of competing generic drug applications.[4] In addition to delays resulting from such a stay of approval, the costs associated with litigating improperly listed patents may disincentivize investments in developing generic drugs, which risks delaying or thwarting competitive entry. The Supreme Court recognizes that improper Orange Book listings have prevented or delayed generic drug entry since at least the 1990s.

As detailed in the Policy Statement, the FTC has several tools at its disposal to address improper Orange Book listings. One of those tools is using the FDA's process to dispute "the accuracy or relevance of patent information submitted" to the FDA for publication in the Orange Book.[9]

We have opted to use the FDA's regulatory dispute process to address the improper listings, but we retain the right to take any further action the public interest may require, which may include investigating this conduct as an unfair method of competition under Section 5 of the FTC Act, 15 U.S.C. § 45, and as described in the Policy Statement.

Sincerely,

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Rahul Rao
Deputy Director
Bureau of Competition

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturers Improper Listing of Pahe FDAurers s the