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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

GlaxoSmithKline Intellectual
Property Development Limited
Attn: General Counsel
Gsk Medicines Research Centre
Gunnels Wood Road
Stevenage, Great Britain
SG1 2NY
United Kingdom

Development Limited's products and that we have availed ourselves of the FDA's regulatory process and submitted patent listing dispute communications to the FDA regarding the patents listed below:[3]

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.[5] Even brief delays in generic competition can reduce patient access to more affordable alternatives and increase costs across the entire health care system.[6]

For decades, the FTC has sought to reduce the anticompetitive effects that result from improperly listingsurope t.v42 (e.EMC /P <7MC /P <2 /P <2 7 [(th)2 C /P <MCTj[(s)-14 (r)3r)-11 (easarn<7MC e)<

Orange Book listings and provide notice that the "FTC will continue to use all its tools to halt unlawful business practices that contribute to high drug prices."[8]

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,

RAHUL RAO Digitally signed by RAHUL RAO Date: 2023.11.07 07:30:40 -05'00'

Rahul Rao
Deputy Director
Bureau of Competition

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturers Improper Listing of Patents in the Orange Book

[8] Policy Statement at 6.
[9] Policy Statement at 6 (citing 21 C.F.R. § 314.53(f)(1)).