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

Office of the Director
Bureau of Competition

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**By Federal Express and Email**

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Dear Counsel,

On September 14, 2023, the Federal Trade Commission ("FTC") issued a Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book.[1] The Policy Statement, a copy of which is appended to this letter, highlights the negative impacts that improper Orange Book patent listings may have on drug competition and notifies market participants "that the FTC intends to scrutinize [such] improper listings as unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act."[2]

This letter is to inform you that we believe certain patents have been improperly or inaccurately listed in the Orange Book with regard to Covis Pharma's Tudorza and Duaklir Pressair products and that we have availed ourselves of the FDA's regulatory process and submitted patent listing dispute communications to the FDA regarding the listings identified below:[3]

[1] Federal Trade Commission, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023), FTC Policy Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in Orange Book (hereinafter "Policy Statement").
[2] Policy Statement at 1.
[3] The Orange Book listings identified as improper in this chart should not be read as an exhaustive list of every patent that your company may have improperly submitted. Indeed, your firm bears the burden of listing patents in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements.

| NDA | Product(s) | Proprietary Name | Patent Number | Listing Type |
|---|---|---|---|---|
| 202450 | 1 | Tudorza Pressair | 8051851 | DP |
| 210595 | 1 | Duaklir Pressair | 8051851 | 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.[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 listing patents in the Orange Book, through enforcement and through amicus briefs articulating that improper listings may violate the antitrust laws.

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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