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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Teva Branded Pharmaceutical
Products R&D, Inc.
Attn: Legal Counsel
c/o Corporate Creations Network Inc.
3411 Silverside Road
Tatnall Building, Ste. 104
Wilmington, New Castle, DE 19810

Re: Improper Orange Book-Listed Patents for QVAR 40, ProAir HFA, ProAir DigiHaler

Dear Teva 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 Teva Branded Pharmaceutical Products R&D, Inc'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]

[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 Number	Product	Patent Number	Listing Type
21457	1	ProAir HFA	8132712	DP
			9463289	DP
			9808587	DP
			10022509	DP
			10022510	DP
			10086156	DP
			10561808	DP
			10695512	DP
			11395889	DP
205636	2	ProAir DigiHaler	8651103	DP
			8978966	DP
			9216260	DP
			9463288	DP
			9731087	DP
			9782550	DP
			9782551	DP
			10022510	DP
			10124131	DP
			10561808	DP
			10569034	DP
			10765820	DP
			11000653	DP
			11266796	DP
			11351317	DP
			11357935	DP
			11439777	DP
			11464923	DP

20911	2	QVAR 40	9463289	DP
			9808587	DP
			10022509	DP
			10022510	DP
			10086156	DP
			10561808	DP
			10695512	DP
			11395889	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.[7] The FTC's Policy Statement serves to reinforce the FTC's concerns about the anticompetitive consequences of improper 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]

[4] Policy Statement at 3 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).
[5] Policy Statement at 3 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012)).
[6] Policy Statement at 4.
[7] Policy Statement at 3; *see also* Decision and Order, *In re Biovail Corp*., FTC Dkt. No. C-4060 (F.T.C. Oct. 2, 2002); Federal Trade Commission's Brief as *Amicus Curiae*, *Jazz Pharms., Inc. v, Avadel CNS Pharms*. No. 1:21-cv-00691 (D. Del. Nov. 10, 2022) (Doc. No. 22-3), https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf; *see also* Mem. of Law of *Amicus Curiae* the Federal Trade Commission In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litig.*, MDL Docket No. 1410 (S.D.N.Y. Jan. 8, 2002), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf.
[8] Policy Statement at 6.
[9] Policy Statement at 6 (citing 21 C.F.R. § 314.53(f)(1)).

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 07:40:38 -05'00'

Rahul Rao
Deputy Director
Bureau of Competition

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