



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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

Boehringer Ingelheim
Pharmaceuticals, Inc.
Attn: General Counsel
c/o: The Corporation Trust Co.
Corporation Trust Center
1208 Orange St.
Wilmington, New Castle, DE,
19801

Re: Improper Orange Book-Listed Patents for Atrovent HFA, Combivent Respimat,
Spiriva, and Spiriva Respimat

To whom it may concern:

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 Boehringer Ingelheim Pharmaceuticals, Inc. 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
21527	1	Atrovent HFA	8474447	DP
21747	1	Combivent Respimat	7284474	DP
			7396341	DP
			7837235	DP
			7896264	DP
			8733341	DP
			9027967	DP
21395	1	Spiriva	7694676*PED	DP
			7694676	DP
			9010323	DP
21936	2	Spiriva Respimat	7284474*PED	DP
			7284474	DP
			7396341*PED	DP
			7396341	DP
			7837235*PED	DP
			7837235	DP
			7896264*PED	DP
			7896264	DP
			8733341*PED	DP
			8733341	DP
			9027967*PED	DP
9027967	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

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.

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

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
Deputy Director
Bureau of Competition

cc: Kathleen Collins
kathleen.collins@boehringer-ingenheim.com

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

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)).