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

Norton (Waterford) Limited
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Re: Improper Orange Book Patent Listings for QVAR Redihaler

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 Norton (Waterford) Limited's QVAR RediHaler product 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
207921	1, 2	QVAR Redihaler	11865247	DP
			11896759	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 has recognized that improper Orange Book listings prevent or delay generic drug entry.[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]

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.

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[4] Policy Statement at 3 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).
[5] *Id.* at 3 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012)).
[6] *Id*. at 4.
[7] *Id.* 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] 314.53(f)(1)(i)(A).

Sincerely,

/s/ Rahul Rao
Deputy Director
Bureau of Competition

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