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

Bureau of Competition

May 21, 2025

Norton (Waterford) Limited
Attn: Legal Counsel
Waterford Industrial Park
Unit 301, Cork Rd
Waterford, X91 WK68, Ireland

Brian Savage, SVP and General Counsel
Global Litigation, Teva Pharmaceuticals
USA, Inc. 400 Interpace Pkwy, Suite 3
Parsippany, NJ 07054
brian.savage@tevapharm.com

Re: Improper Orange Book Patent Listings for QVAR RediHaler

Dear Mr. Savage,

I write regarding Norton (Waterford) Limited's and Teva Pharmaceuticals' ("Teva") ongoing obligation to ensure the propriety of patent listings in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), particularly in light of the U.S. Court of Appeals for the Federal Circuit's decision in *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, 124 F.4th 898 (Fed. Cir. 2024) (hereinafter "*Teva v. Amneal*").

The FTC has previously explained that patents improperly listed in the Orange Book may harm competition and delay generic drug entry, as courts have recognized.[1] On November 7, 2023, and April 30, 2024, the FTC's Bureau of Competition (the "Bureau") sent Teva letters identifying non-exhaustive lists of patents that had been improperly submitted for listing in the Orange Book and explained how improper Orange Book listings may harm competition.[2] Since

[1] Fed. Trade Comm'n, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Brief for Fed. Trade Comm'n as Amicus Curiae, *SmithKline Beecham Corp. v. Apotex Corp.*, No. 99-CV-4304 (E.D. Pa. Jan. 28, 2003), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/smithkline-beecham-corp.v.apotex-corp./smithklineamicus.pdf; *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012); *see also Massachusetts Laborers' Health & Welfare Fund v. Boehringer Ingelheim Pharms., Inc.*, No. 24-CV-10565-DJC, 2025 WL 928747, at *20 (D. Mass. Mar. 27, 2025) ("[Plaintiff's] alleged injury, having to pay higher prices for drugs it otherwise would not need to but for [Defendants'] allegedly wrongful listing, is the precisely the kind of '[t]hreaten[ed] economic harm to consumers [that] is plainly sufficient to authorize injunctive relief.'" (quoting *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 661 (2d Cir. 2015) (cleaned up)).

[2] *See* Nov. 7, 2023 Letter from R. Rao, Deputy Director, Bureau of Competition, to Norton (Waterford) Ltd., https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf; Apr. 30, 2024 Letter from R. Rao, Deputy Director Bureau of Competition, to Norton (Waterford) Ltd., https://www.ftc.gov/system/files/ftc_gov/pdf/teva-norton-qvar-redihaler-4302024.pdf.

those letters were sent, the Federal Circuit's ruling in the *Teva v. Amneal* case has confirmed that the identified patents do not meet applicable Orange Book listing criteria.[3]

While Teva has requested the delisting of patents specifically at issue in the Federal Circuit's *Teva v. Amneal* decision, a number of other patents included in the Bureau's prior delisting letters remain in the Orange Book as of the date of this letter, including the following:

NDA	Product(s)	Proprietary Name	Patent Number	Listing Type
207921	1,2	QVAR RediHaler	10022509	DP
			10022510	DP
			10086156	DP
			10695512	DP
			11865247	DP
			11896759	DP

With the above patents still in the Orange Book, we are, contemporaneously with this letter, submitting patent listing dispute communications to the FDA regarding these patents. Although we have not, at this time, disputed the listing of any other Teva patents, it is Teva's responsibility to ensure that all of its patent listings comply with the statutory listing requirements, as clarified by *Teva v. Amneal*.

Combatting improper Orange Book patent listings has been a part of the FTC's long-standing enforcement and advocacy work to challenge anticompetitive conduct that stymies generic drug entry and the resulting substantial cost savings.[4] The FTC will remain

[3] *Teva v. Amneal*, 124 F.4th at 911 (explaining that a patent claims the drug as required for listing in the Orange Book "when it particularly points out and distinctly claims the drug as the invention.").

[4] *See, e.g., Biovail Corp*., 134 F.T.C. 407 (2002), https://www.ftc.gov/sites/default/files/documents/cases/2002/10/biovaildo.pdf; Brief for Fed. Trade *Comm'n* as Amicus Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms*. No. 1:21-cv-00691 (D. Del. Nov. 10, 2022), ECF No. 222-3; Brief for Fed. Trade Comm'n as Amicus Curiae*, Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC,* No. 24-1936 (Fed. Cir. Sept. 6, 2024), ECF No. 62; *see also* Mem. of Law of *Amicus Curiae* the Federal Trade Commission in Opp'n to Defs.' Mot. 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; *see also* Fed. Trade Comm'n, Overview of FTC Actions in Pharmaceutical Products and Distribution (Sept. 2021), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_pharmaceutical_products_and_distribution.pdf.

vigilant to promote competition and protect the American public from the harms that flow from anticompetitive practices in the pharmaceutical industry.

Sincerely,

/s/ Kelse Moen
Kelse Moen
Deputy Director
Bureau of Competition