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

Bureau of Competition

May 21, 2025

Elizabeth McGee
General Counsel
Novartis Pharmaceuticals Corp.
1 Health Plaza, East Hanover,
New Jersey 07936
Elizabeth.mcgee@novartis.com

Re: Improper Orange Book Patent Listings for Seebri and Utibron

Dear Ms. McGee,

I write regarding Novartis Pharmaceuticals Corp.'s ("Novartis") ongoing obligation to ensure the propriety of its 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 April 30, 2024, the FTC's Bureau of Competition (the "Bureau") sent a letter identifying a non-exhaustive list of patents that Novartis had improperly submitted for listing in the Orange Book and explained how improper Orange Book listings may harm competition.[2] Since that letter was sent, the Federal

[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* April 30, 2024 Letter from R. Rao, Deputy Director, Bureau of Competition, to Novartis Pharmaceuticals Corp., https://www.ftc.gov/system/files/ftc_gov/pdf/novartis-seebri-and-utibron-4302024.pdf.

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

The following patents included in the Bureau's prior delisting letter remain in the Orange Book as of the date of this letter:

NDA	Product(s)	Proprietary Name	Patent Number	Listing Type
207923	1	Seebri	8182838	DP
207930	1	Utibron	8182838	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 Novartis patents, it is Novartis'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 that result from this.[4] The FTC will remain 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

[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.