



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

Bureau of Competition

May 21, 2025

Mylan Specialty LP  
Attn: Legal Counsel  
Corporation Service Co.  
251 Little Falls Dr.  
Wilmington, New Castle, DE  
19808

Brian Roman  
Global General Counsel  
Viatris Inc.  
1000 Mylan Blvd.  
Canonsburg, PA 15322  
Brian.Roman@viatris.com

*Re: Improper Orange Book Patent Listings for EPIPEN and EPIPEN Jr.*

Dear Mr. Roman:

I write regarding Mylan Specialty LP's ("Mylan") 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.<sup>1</sup> On November 7, 2023, the FTC's Bureau of Competition (the "Bureau") sent a letter identifying a non-exhaustive list of patents that Mylan had improperly submitted for listing in the Orange Book and explained how improper Orange Book listings may harm competition.<sup>2</sup> Since that letter was sent, the

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<sup>1</sup> 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](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](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))).

<sup>2</sup> See November 7, 2023 Letter from R. Rao, Deputy Director, Bureau of Competition, to Mylan Specialty LP, [https://www.ftc.gov/system/files/ftc\\_gov/pdf/mylan-specialty-orange-book.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/mylan-specialty-orange-book.pdf).

Federal Circuit’s ruling in the *Teva v. Amneal* case has confirmed that the identified patents do not meet applicable Orange Book listing criteria.<sup>3</sup>

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
19430	1	EPIPEN	7449012	DP
			7794432	DP
			8048035	DP
			9586010	DP
19430	2	EPIPEN JR	7449012	DP
			7794432	DP
			8048035	DP
			9586010	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 Mylan patents, it is Mylan’s responsibility to ensure that all of its patent listings comply with the statutory listing requirements, as clarified by *Teva v. Amneal*.

Combating 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.<sup>4</sup> 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.

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<sup>3</sup> *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.”).

<sup>4</sup> 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](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](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_pharmaceutical_products_and_distribution.pdf).

Sincerely,

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