



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

Office of the Director
Bureau of Competition

November 7, 2023

By Federal Express

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-Listed Patents for EPIPEN and EPIPEN JR

Dear Mr. Roman:

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 Mylan Specialty LP’s EPIPEN and EPIPEN JR. 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
patent that your company may indeed, have firm bears the burden of listing submitted in the Orange Book accurately and in accordance with all relevant statutory and regulatory requirements.

