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A Change In Big Pharma Response To FTC Delisting Warnings

By **Ratib Ali and Celia Lu** (September 2, 2025, 5:59 PM EDT)

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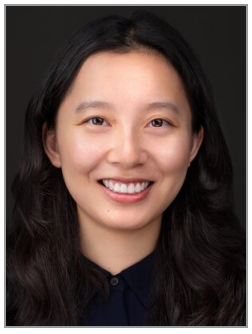

Celia Lu

The Federal Trade Commission continues to be concerned about improper patent listings in the U.S. Food and Drug Administration's Orange Book, their deterrence of generic entry, and their consequent impact on prescription drug prices.

In response, the FTC has identified allegedly improperly listed patents in three waves.

First, in November 2023, the FTC sent notices to pharmaceutical companies regarding hundreds of entries on the Orange Book, which involved 62 unique patents held by 10 firms.[1]

Then, in April 2024, the FTC challenged "more than 300 junk listings," some of which were also included in the first wave.[2]

In a third wave of letters, sent in May of this year, the FTC reinforced most of its previous warnings to pharmaceutical companies that had not yet complied.

Last month, we **investigated** the companies' different reactions to the first and second waves of FTC notices until the end of 2024 using the Orange Book data files, finding that the effect of the FTC notices has been de minimis. Now, we look at July data following the May letters.[3]

While none of the second-wave warnings resulted in delisting during 2024, we find that 41 unique patents were delisted in 2025, affecting 11 drugs.

A majority of the delistings involved GLP-1 drugs (like Novo Nordisk's Saxenda and Ozempic, and AstraZeneca's Bydureon) and COPD inhaler products (AstraZeneca's Symbicort, GSK's Anoro Ellipta and Incruse Ellipta, and Boehringer Ingelheim's Striverdi Respimat, among others).

	First wave November 2023	Second wave April 2024	Third wave May 2025	Total[4]
Unique patents challenged	62	60	29[5]	96
Unique patents challenged not involved in earlier waves	*62*	*34*	*0*	*96*
Responses				
Patents delisted 2023-24	11[6]	0	N/A	11
Patents delisted 2025	7[7]	35	1	41
Total	18	35	1	50
% delisted	*29%*	*58%*	*3%*	*52%*

The results show the significant recent improvement in the effectiveness of the FTC's warnings since

the new administration took office, with the FTC's success rate increasing from 11 to 50 delisted patents. By comparison, from November 2023, when the FTC first sent warning letters, to the end of 2024, only three pharmaceutical companies complied (Glaxo Group Ltd., Impax Labs, Kaleo Inc.).[8]

Viewed in terms of Orange Book entries, by July of this year, the absolute number of delistings nearly doubled from the first to the second wave, though the FTC's success rate fell from 29% to 17%.

	First wave	Second wave	Third wave	Total
OB entries challenged	110	334	249	693
OB entries delisted	32	56	1	89
% delisted	*29%*	*17%*	*1%*	*13%*

The result is consistent with either or both of the following hypotheses.

First, on Dec. 20, 2024, the U.S. Court of Appeals for the Federal Circuit **held** that the inhaler products involved in Teva Branded Pharmaceutical Products R&D Inc. v. Amneal Pharmaceuticals of New York LLC must be delisted from the Orange Book since they do not recite an active ingredient;[9] the decision and Teva's delistings may have prompted other pharmaceutical companies to delist similarly situated patents.

Alternatively, there may have been a behavioral aspect: The new FTC administration's pursuit of improperly listed patents may have signaled enforcement continuity that transcended political allegiances, prompting some companies to fold.

While the FTC's delisting efforts appear to have substantial impact, that impact has been limited to GLP-1s and inhalers. This leaves some drugs with no patents listed in the Orange Book (for instance, GSK's Arnuity Ellipta), but most drugs continue to enjoy exclusivity protections through the Orange Book.

It will be interesting to see whether FTC Chair Andrew Ferguson escalates the crackdown on junk patent listings and, crucially, whether FTC action results in more generic entry in these drug markets.

Ratib Ali is an economist and Celia Lu is an economic analyst at Competition Dynamics.

[1] A patent appears as a separate Orange Book (or "Approved Drug Products with Therapeutic Equivalence Evaluations") entry for each formulation and dosage that practices it.

[2] FTC, "FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs." Available at: https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma. Last accessed on April 10, 2025.

[3] We thank the Federal Trade Commission for pointing us to more recent data.

[4] Total is not the sum of first, second, and third waves because some of the same patents (delisted or otherwise) were warned in multiple waves. Total is not the sum of patents delisted prior to 2025 and in 2025, because some of the same patents were delisted in both time periods in response to warnings in different waves.

[5] One patent owned by Covis Pharma GMBH was delisted before the FTC sent the third wave; the FTC withdrew the corresponding challenge later. See FTC, "Warning Letter to Azurity Pharmaceuticals, Inc." Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/warning-letter-azurity.pdf. Last accessed on August 24, 2025.

[6] An additional five patents expired (removing them from the Orange Book) before or during January 2025. We assume their delisting from the Orange Book is due to their expiration, and exclude patents delisted due to patent expiration from our analysis.

[7] An additional five Teva patents were delisted following the Teva v. Amneal litigation under court order. We do not deem these delisting as a response to FTC warning letters. See Teva Branded Pharm. Prods. R&D v. Amneal Pharm. of N.Y., No. 2024-1936 (Dec 20, 2024) ("Teva v. Amneal litigation").

[8] FTC issued separate warning letters to Glaxo Group Limited and Glaxo Smith Kline, but Glaxo Group is subsidiary of Glaxo Smith Kline. See GSK Annual Report 2022. Available at: https://www.gsk.com/media/6803/gsk-group-company-names-and-addresses.pdf.

[9] Teva v. Amneal litigation.
