

FTC Spoke, Kaleo and Impax Listened: Orange Book Patent Delistings Begin

A photograph of a modern building with a curved glass facade, showing multiple floors and windows, set against a light blue sky.

1 MIN READ

December 14, 2023, 1:06 PM

By: Ross E. Blau

As discussed [last month](#), the FTC sent letters to 10 pharmaceutical companies, asserting that their listing of over 100 patents in FDA's Orange Book for a variety of products was improper. Shortly thereafter, the FTC began using the administrative process with FDA to challenge these patent listings, and all of the companies had until [December 16, 2023](#) to respond.

It appears that prior to this deadline at least two companies – Impax Labs and Kaleo, Inc. – may have felt pressure to reconsider their patent listings.

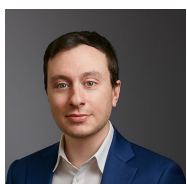
Specifically, Impax [delisted](#) both of its patents directed to Adrenaclick, the same patents that the FTC had noticed in its [November 7, 2023 letter](#). There are currently no approved generic applicants for Adrenaclick, and no additional patents directed to Adrenaclick in the Orange Book. Similarly, Kaleo [delisted](#) eight patents directed to AUVI-Q, the same patents that the FTC had noticed in [its letter to Kaleo](#). Given that the Orange Book lists more than twenty patents for AUVI-Q, it seems that any potential generic applicant still has quite the battle ahead.

It will be interesting to continue to monitor for any further patent delistings, particularly with the December 16, 2023 deadline coming up. Time will tell whether the FTC will take any further action against those companies that don't follow Kaleo and Impax's paths. And, it remains to be

seen whether we can expect further fallout in private litigation from FTC's recent, more aggressive actions in this area.



Related People



Ross E. Blau

To subscribe to our publications, [click here](#).

TAGS

pharma

News & Insights

- GCR Live: Law Leaders Global 2025
SPEAKING ENGAGEMENT ANTITRUST
- Evidence for Trial Lawyers: Motions, Introducing Evidence, and Objections
SPEAKING ENGAGEMENT INTELLECTUAL PROPERTY
- NYC Bar Trade Secrets Symposium 2024: Navigating the Law of Trade Secrets and Restrictive Covenants
SPEAKING ENGAGEMENT INTELLECTUAL PROPERTY
- Stakeholders 24th Annual CYOC Career Development Conference
SPONSORSHIP
- IAM Connect Patent Policy and Litigation Conference 2024
SPEAKING ENGAGEMENT INTELLECTUAL PROPERTY
- CompLaw 33rd Annual Advanced EU Brussels Conference
SPEAKING ENGAGEMENT ANTITRUST
- Jason Murata Named a Profiles in Diversity Journal Diverse Lawyers Making a Difference Award Winner
AWARDS & RECOGNITIONS INTELLECTUAL PROPERTY
- AIC General Counsel Day 2024
SPEAKING ENGAGEMENT ANTITRUST
- ALM General Counsel Conference East 2024
SPEAKING ENGAGEMENT ANTITRUST
- Global M&A Antitrust Outlook: Trends Shaping Enforcement Strategies
SPEAKING ENGAGEMENT ANTITRUST