


Court Orders Patents Delisted from Orange Book: Is FTC's Newly Aggressive Posture Having an Impact?

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

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Over the past year, FTC has placed two sets of Orange Book listings in its crosshairs, but, to date, FTC has not actually begun any litigation on its own. Instead, the Commission has decided to file amicus briefs supporting FTC's policy statement that it would "scrutinize improper Orange Book listings" and "use its full legal authority" to "tak[e] actions against companies and individuals that improperly list patents in the Orange Book that do not meet the statutory listing criteria."

One of the products identified by FTC as having improperly listed patents was Teva's ProAir HFA product. Amneal filed an ANDA to make and sell a generic version of ProAir HFA and was sued on various Orange Book-listed patents, including five "Inhaler Patents" that FTC had originally deemed improperly listed.

Amneal brought a motion for judgment on the pleadings that these Inhaler Patents were improperly listed, and FTC supported the motion as amicus curiae. Yesterday, Judge Chesler in the District of New Jersey agreed that these Inhaler Patents were improperly listed and needed to be corrected or deleted from the Orange Book. Judge Chesler's opinion concluded that the Inhaler Patents did not claim "the drug for which the applicant submitted the application" (albuterol sulfate), nor did the Inhaler Patents claim the "finished dosage form" that is the subject of the NDA.

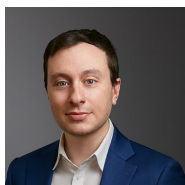
So far, FTC has managed to obtain some success with two sets of Orange Book patents delisted voluntarily, and now another set of Orange Book patents delisted due to a generic applicant's litigation efforts. Time will tell if FTC will take on a more direct role in patent delistings, but it's clear that the FTC intends to remain active in this area.

[T]he Inhaler Patents do not claim the drug for which the applicant submitted the application.

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