Insight

Primer: FTC Scrutinizes Orange Book Listings

FRED ASHTON | MAY 15, 2024

Executive Summary

- In September 2023, the Federal Trade Commission (FTC) issued a policy statement warning pharmaceutical companies of potential legal action if patents listed in the Food and Drug Administration's (FDA) *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, are found to be improper or inaccurate.
- The FTC sent notice letters – the first tranche in November 2023 and the second in April 2024 – to drug manufacturers challenging more than 400 patents and filed patent listing dispute notifications with the FDA.
- The FTC asserted that improper or inaccurate listings block or delay competition from generic alternatives and that such activity could be considered an unfair method of competition in violation of Section 5 of the FTC Act.

Introduction

In September 2023, the Federal Trade Commission (FTC), with support from the U.S. Food and Drug Administration (FDA), issued a policy statement warning pharmaceutical companies of its intent to "scrutinize improper Orange Book patent listings as potential unfair methods of competition in violation of Section 5 of the FTC Act." The FTC asserted that improper listings may harm competition from generic alternatives.

The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, more commonly referred to as the Orange Book, "lists all of the nonbiologic drugs approved by the FDA…[and] includes information on patents and regulatory exclusivities that may protect a brand-name drug from generic competition," according to a May 2024 Congressional Research Service report.

In a warning shot, the FTC issued its first round of notice letters to 10 pharmaceutical manufacturers in November 2023, alleging more than 100 patents were "improperly or inaccurately" listed in the Orange Book. Many of these patents involved asthma inhalers and epinephrine autoinjectors. The FTC expanded its inquiry in April 2024 to include more than 300 additional patents covering drugs for diabetes, weight loss, asthma, and COPD. To seek redress, the FTC filed patent listing dispute notifications with the FDA over the accuracy or relevance of the listed patent information.

Many questions remain unanswered as the FTC failed to provide a basis for which it believed the patents were improperly or inaccurately listed in the Orange Book. Moreover, it is unclear whether the FTC will pursue antitrust litigation against firms that choose to leave listing information unchanged.

The Orange Book, the FDA, and Competitive Concerns

The Federal Food, Drug, and Cosmetic Act requires companies seeking the approval of a new drug to include patent information in their new drug applications. If the drug is approved, the patent and exclusivity information will be housed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the Orange Book (for the color of its print cover). While the FDA maintains the Orange Book, it does not police the information included, describing its role in patent listings as "ministerial," relying on pharmaceutical companies to submit accurate information.

Drug patents and regulatory exclusivities statutes seek to balance trade-offs between incentivizing innovation with competition from lower-priced generic drugs. Patents and regulatory exclusivities concerning new drug applications foster innovation by affording drug manufacturers a period in which they can charge supracompetitive prices to recoup their investments.

Yet some members of Congress and the FTC believe drug manufacturers may be abusing these patents and exclusivity protections to block or delay generic drug entry to prolong their monopoly status.

On September 13, 2023, Senator Elizabeth Warren (D-MA) and Representative Pramila Jayapal (D-WA) sent a letter to FTC Chair Lina Khan urging the agency to issue a policy statement concerning improper Orange Book listings. Warren and Jayapal alleged that "Big Pharma regularly lists patents…outside the scope of the Orange Book" and do so to block "competitors from introducing lower-cost generic drugs."

The following day, on September 14, 2023, the FTC issued a policy statement warning pharmaceutical manufacturers of its intent to scrutinize alleged improper or inaccurate Orange Book listings to determine whether the practice constitutes as an unfair method of competition in violation of Section 5 of the FTC Act. The FTC added that certain improper listings of patents may even be considered "illegal monopolization," which would violate Section 2 of the Sherman Act. The agency also threatened to use a "firm's history of improperly listing patents during merger review," suggesting prior bads act would negatively affect chances of approval.

The FTC argued that improper listings could "disincentivize investments in developing a competing product and increase the risk of delayed generic and follow-on product entry." The agency cited a 2002 FTC study in which it found several instances of companies abusing various statutes to block or significantly delay competition from generic drugs.

Notice Letters

On November 7, 2023, the FTC delivered its first round of notice letters. Letters were sent to 10 companies that claimed more than 100 patents were allegedly improperly or inaccurately listed in the Orange Book.

The FTC also informed the companies that it "opted to use the FDA's regulatory dispute process to address the improper listings," but reserved the right to investigate the conduct as an unfair method of competition in violation of Section 5 of the FTC Act.

On April 30, 2024, the FTC expanded its investigation, disputing more than 300 Orange Book listings. The letters were similar to those sent in November.

The press announcement and the contents of the letters left many questions unanswered. Most notable was the absence of the basis on which the agency believed the patents were improperly or inaccurately listed. The letters

only provide a list of patents. More detailed information was presumably sent to the FDA, as statute dictates a patent listing dispute "must include a statement…that describes the specific grounds for disagreement regarding the accuracy or relevance of patent information."

Moreover, unlike the policy statement that garnered a 3-0 vote by the FTC, it appears the decision to issue the notice letters received no such vote. While the FTC does not typically vote on whether to issue notice letters, failing to do so makes it difficult to discern which member(s) of the Commission supported it. This is particularly relevant to the second round of notice letters. Republican Commissioners Melissa Holyoak and Andrew Ferguson were sworn in after the FTC issued the policy statement and first set of notice letters, but arrived just weeks before the second tranche of notice letters was sent. It is unclear if the policy statement or the approach of using the FDA's regulatory dispute process was supported by the two new members of the Commission.

Changes to the Orange Book

The FDA's *Orange Book Patent Listing Dispute List*, last updated on April 12, 2024, reflects the patents identified by the FTC in the first set of notice letters. In response, four drug companies with six new drug applications and 17 associated patents updated their Orange Book listings. The rest remained unchanged. The more than 300 patents included in the second batch of notice letters have not yet been added to the list.

Going forward, it would seem that Section 5 claims against firms that did not opt to update their Orange Book filings would be pending from the FTC unless the companies subject to the inquiry have been able to convince the Commission that the patents listed are indeed proper.

Conclusion

The FTC's Orange Book policy statement put drug manufacturers on notice that it will investigate improperly or inaccurately listed patents to deem whether they constitute unfair methods of competition in violation of Section 5 of the FTC Act.

Following up on its promise, the FTC issued notice letters alerting several firms that it had filed with the FDA patent dispute notifications over more than 400 patents it claimed were inaccurately or improperly listed in the Orange Book.

The basis for these claims remains unclear. It is also uncertain whether the FTC will follow up on its promise to file antitrust claims against firms that opted to leave their patent listings unchanged.