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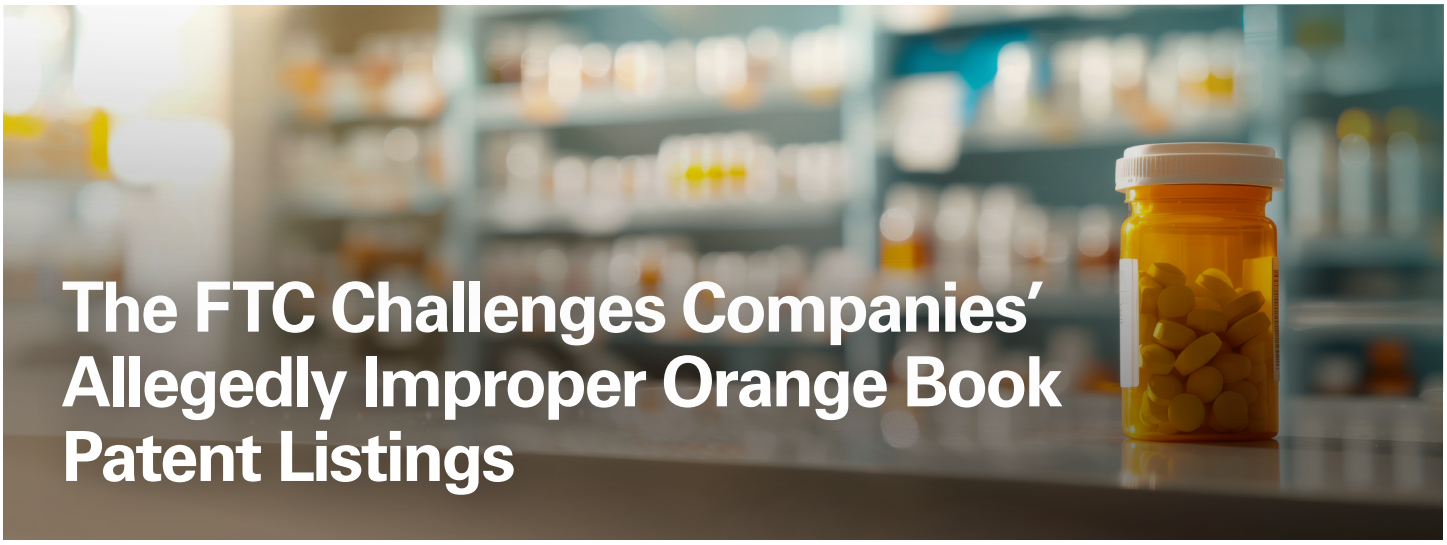

The FTC Challenges Companies' Allegedly Improper Orange Book Patent Listings

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If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

Douglas R. Nemec
Partner / New York
212.735.2419
douglas.nemec@skadden.com

Larry F. Taylor
Law Clerk / New York
212.735.2799
larry.taylor@skadden.com

Key Points

- The FTC is stepping up its initiative to challenge what it views as improper patent listings in the Orange Book, applying pressure on branded pharmaceutical companies.
- While the majority of companies whose patents have been challenged have not delisted them, believing they are properly listed, some have complied with the FTC's requests.
- In response to the FTC campaign, FDA has promised to provide updated guidelines on complying with the Orange Book, something it has not done for four years.
- FTC officials hope that the removal of purportedly improper listings will make it easier for generic competitors to enter the market.

The Federal Trade Commission (FTC) has called attention in the past year to its perception of the influence that branded pharmaceutical companies have over the price of beneficial drugs. Most recently, the agency has asserted that drugmakers may be utilizing a patent tactic to delay generic competition.

By challenging patents the FTC claims are needlessly listed, the agency hopes to disrupt a practice it contends is keeping drug prices artificially high.

In light of this additional pressure from the FTC, companies should take into account how they go about listing their patents in the Food and Drug Administration's (FDA's) Orange Book and consider delisting inapplicable patents before they are challenged.

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Regulation of the Pharmaceutical Market

The online Orange Book, colloquially named for the color of its cover when it was first completed as a hard copy publication on Halloween in 1980, is a core component of the FDA-regulated generic drug development and approval process. The publication operates as a database of pharmaceutical products approved on the basis of safety and effectiveness (*i.e.*, branded drugs), and includes listings of patents identified as covering those drugs.

Much of the information in the Orange Book is supplied by new drug application (NDA) holders. However, FDA has not offered any updated guidance on how and which patents should be listed in the Orange Book since 2020. This lack of guidance has caught the FTC's attention.

In 2022, the FTC filed an amicus brief with the U.S. District Court for the District of Delaware in the case of *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*, arguing that the 30-month stay of generic approval provided for in the Food, Drug and Cosmetic Act operates as an incentive for brand companies to overlist patents in the Orange Book. As examples, FTC asserted that companies sometimes list patents for devices such as inhalers and other methods of delivering a drug that do not apply to the drug itself and therefore should not be listed.

Branded Pharmaceutical Companies Beware

Following on its amicus filing in the *Jazz Pharmaceuticals* case, FTC put the market on notice of its concern in a September 2023 policy statement, announced jointly with FDA. The policy statement said the FTC "intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act."

The notice further explained that FTC believes listing nonlistable patents blocks consumer access to competing products that might reduce prices, improve quality or both.

"By filing bogus patent listings, pharma companies block competition and inflate the cost of prescription drugs, forcing Americans to pay sky-high prices for medicines they rely on," FTC Chair Lina Khan said in April 2024.

In response to the FTC's push, FDA promised to issue updated guidance to companies about which patents to list in the Orange Book.

FTC Goes on the Offensive

In November 2023, the FTC followed through on the policy statement by challenging more than 100 patent listings. Using FDA's regulatory dispute process, the FTC asserted that patents listed by the branded companies were improper.

The majority of companies that received a challenge have not delisted their patents, largely asserting that they believe they are acting lawfully and that federal authorities have not notified them that their actions are improper. For example, in a January 15, 2024, letter to lawmakers, drug manufacturer Teva stated that "[a]t no time did Teva use these patent listings to stifle competition, prolong a monopoly, or price gouge patients." It said it believes robust patent listings are pro-competitive.

But some companies have been receptive to the FTC's challenge and have taken measures to delist their patents with FDA.

In March 2024, the FTC also filed an amicus brief in *Teva v. Amneal* in the U.S. District Court for the District of New Jersey, in which it took the position that the Hatch-Waxman Act limits drug products to "a finished dosage form, *e.g.*, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily in association with one or more other ingredients." According to the FTC, patents claiming devices or device components therefore are not listable.

In April 2024, the FTC challenged over 300 patent listings in the Orange Book as improper or inaccurate. According to the FTC, these challenges were in part aimed at trying to facilitate the development of affordable alternatives to brand name drugs like Ozempic and Victoza.

FDA has found that having at least one generic competitor for a brand name drug cuts prices by almost 40%. The FTC hopes that its efforts will lead to more companies delisting patents and, in turn, generic manufacturers developing more generic (presumably cheaper) versions of a branded drug in the coming years.

Stimulating Price Competition

The FTC's recent effort to challenge purportedly improper patent listings in the Orange Book is only one of the many initiatives taken under Chair Khan's leadership with the asserted purpose of attempting to stimulate price competition in the pharmaceutical market. These initiatives come amid, and perhaps because of, the slow progress of various patent reform proposals pending in Congress.

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In addition to challenging patent listings, the FTC has:

- Challenged two major pharmaceutical mergers.
- Launched probes of pharmacy benefit managers (PBMs), which serve as "middlemen" between drug manufacturers and insurers, focused on the PBMs' perceived impact on pricing and competition in the pharmaceutical market.

Despite the FTC's obvious commitment to the cause, questions persist regarding when and how the FTC will follow through on its threats to crack down on allegedly improper Orange Book patent listings.

As a threshold matter, the lack of FDA guidance on Orange Book practices creates murkiness around what patents may properly be listed. Moreover, there is scant precedent for whether improper Orange Book listings actually stifle competition in a way that would support claims of unfair competition or violation of the antitrust laws.

FDA could ease some of these hurdles with the guidance it has promised to provide. Congress also appears poised to act, as senators expressed concerns over device patent listings in a May 2024 hearing, and a Congressional Research Service report the same month flagged Orange Book patent listings and the 30-month stay as topics of interest.

With momentum building on all these fronts it appears to be a question of when, not if, further enforcement actions will occur.

One Manhattan West / New York, NY 10001 / 212.735.3000