Teva v. Amneal: Reshaping Generic Drug Rights

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Overview

In an important decision clarifying certain aspects of the Orange Book listing process, the Federal Circuit ruled that patents must claim an active ingredient to be properly listed. This decision marks a significant development in pharmaceutical patent litigation, emphasizing the limits of Orange Book listings for device-related patents and reinforcing the role of antitrust considerations in Hatch-Waxman disputes. Teva is widely expected to petition for certiorari as the case will likely shape future strategies for both innovator and generic pharmaceutical companies making decisions about listing drug/device combination patents with the FDA and how these are challenged when improper, including navigating the intersection of patent and antitrust law.

Legal and Regulatory Context

The Hatch-Waxman Act of 1984 revolutionized the generic drug industry by introducing the Abbreviated New Drug Application (ANDA) process, which allows companies pursuing follow-on small molecule pharmaceuticals (i.e., generic drugs) to bypass expensive and time-consuming clinical trials by demonstrating bioequivalence to the branded drug approved under a New Drug Application (NDA), as well as establishing a framework for resolving legal disputes between the NDA holder and generic pharmaceutical companies.

A key component of this framework is the requirement that an NDA filer must list any patents that cover its NDA product in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication. The first printed version of this FDA publication had an orange cover, resulting in it being nicknamed the "Orange Book." The NDA holder receives certain rights in exchange for listing the relevant patents in the Orange Book. When a pharmaceutical company seeks to enter the market with a generic version of an innovator company's drug, it must file an ANDA and certify the status of its proposed product against any Orange Book listed patents under one of four categories:

- **Paragraph I:** No patent information filed.
- **Paragraph II:** The patent has expired.
- **Paragraph III:** It will not commercialize until after patent expiration.
- **Paragraph IV:** The patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the drug product.

When an ANDA seeks to use an NDA reference product that includes Orange Book listed patents, the ANDA must include the relevant certification statement as to each patent and issue a Notice Letter regarding any Paragraph IV certifications to the patentee and to the NDA holder. The Hatch-Waxman Act lays out the rules of engagement under which the NDA-holding company can take legal action against the generic pharma company.

Case Facts and Procedural Posture

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Teva ceased production of its ProAir® HFA albuterol inhaler product in 2022, and yet it maintained a listing of nine patents in the Orange Book in connection with the product, thereby creating a legal/regulatory impediment to other companies attempting to market generic versions. Amneal decided to make a generic version of albuterol sulfate and filed an ANDA, which included a Paragraph IV certification of Teva's nine Orange Book listed patents. The receipt of the Notice Letter associated with the ANDA filing acceptance triggered the 45-day window for Teva to sue Amneal for patent infringement, which it did for five of the identified patents. Such a suit results in an automatic stay of 30 months, preventing the FDA from approving the ANDA unless the litigation is favorably resolved.

During the ensuing litigation, Amneal filed a counterclaim under the Federal Food, Drug And Cosmetic Act (FFDCA), asserting that the listed patents did not claim the ProAir® HFA's active ingredient, albuterol sulfate, and thus did not meet the Orange Book listing requirements. The Federal Trade Commission (FTC) filed an amicus brief supporting the position that these patents were improperly listed, potentially harming competition and increasing consumer costs. The Federal Circuit sided with Amneal and the FTC, holding that the patents in question only claimed inhaler *devices*, rather than the active ingredient, and thus did not meet the Orange Book listing requirements. The court stated that "patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the application." As a result, the court ordered Teva to delist the five patents from the Orange Book.

The Federal Circuit found Amneal's counterclaim argument persuasive, concluding that Teva's asserted patents did not claim the active ingredient. As a result, the court upheld the District Court's delisting order. The Federal Circuit's ruling clarifies that a "drug" is separate from a "device" when evaluating a drug/device combination product under the Orange Book Transparency Act (OBTA), a 2021 amendment to the FFDCA. Specifically, the court rejected Teva's argument that any component of an article that can treat disease meets the OBTA's definition of a "drug." The court also held that the touchstone of the distinction was that a device excludes an active ingredient, noting that the ProAir® HFA product clearly has drug and device subparts.

The Federal Circuit stayed the delisting order on January 22, 2025, following Teva's request for an *en banc* hearing. However, as of March 3, 2025, the court denied Teva's request. The next day, Teva filed an additional request to stay the District Court's delisting order while seeking review from the Supreme Court. Unless the Supreme Court intervenes, Teva must submit its delisting requests to the FDA by March 17.

Beyond the delisting order, Amneal has also filed five antitrust counterclaims against Teva, alleging that it knowingly misused the Orange Book listing process to maintain exclusivity and unlawfully block generic competition, which remain pending before the District Court. If ultimately successful, Amneal's claims could result in significant financial and regulatory consequences for Teva, while reinforcing judicial scrutiny over improper Orange Book listings of patents that the FTC has previously argued are improper and anti-competitive. It also remains to be seen whether this clarified "active ingredient" requirement for Orange Book listings will also be applied to the parallel field of large molecule biologics/biosimilars litigation under the Biologics Price Competition and Innovation Act (BPCIA) of 2009.

Broader Significance

This decision carries significant implications for both brand-name and generic drug companies. Supporters argue that the ruling helps eliminate improperly listed patents, enabling generic

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manufacturers to enter the market more quickly and ultimately lowering drug prices for consumers. Conversely, there is speculation that branded drugmakers may attempt to submit delisted patents for reissuance, shifting their focus to methods of treatment rather than just devices. If approved by the USPTO, these patents could then be relisted in the Orange Book. However, patentees can only request a broadening reissue within two years of the patent's original issue date, and any reissued patent cannot introduce new matter beyond what was disclosed in the original application.

As this situation evolves, both brand-name and generic drug manufacturers will need to carefully assess their strategies in response to these regulatory and legal developments.

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