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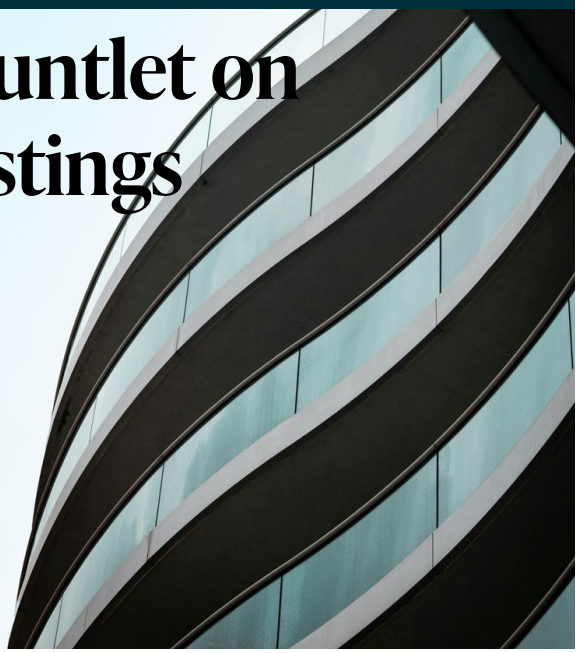
FTC Throws Down the Gauntlet on Improper Orange Book Listings



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By: Rebecca L. Clegg

The FTC recently issued a policy statement warning drug manufacturers that it "intends to 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."

The Hatch-Waxman Act requires brand drug manufacturers to list in FDA's Orange Book all patents directed to the drug substance, the drug product (i.e., formulation or composition), or a method of using the drug (i.e., indication). *See* 21 U.S.C. § 355. Any company seeking approval from FDA to market a generic version of that product is required to certify that each non-expired Orange Book listed patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* This Paragraph IV notice permits the brand drug manufacturer to sue the generic applicant for infringement, which triggers a 30-month stay of approval of the generic product by the FDA if the lawsuit is timely filed.

In justifying its position, the FTC explains that improper listing of patents in the Orange Book is a "method of competition" and "can be unfair because it is not competition on the merits of drug quality or price, and it tends to negatively affect competitive conditions by impeding opportunities for generic rivals to compete, thus limiting consumer choice." The policy statement also suggests that the FTC may refer false Orange Book certifications to the U.S.

Department of Justice for potential criminal penalties. In addition, the FTC may consider a company's history of improperly listing patents during review of a potential merger.

The FTC's policy stands in stark contrast with FDA's purely administrative role in maintaining the Orange Book listings. FDA does not unilaterally undertake any review of the patents that a drug company submits for listing in the Orange Book. FDA nevertheless supported the FTC's policy statement, and the FTC states that it may also utilize FDA's process for disputing Orange Book patent listings (as set out in 21 C.F.R. 314.53(f)(1)) as part of its crackdown. The FTC also reiterates that all currently Orange Book listed patents must comply with the law and advises that "NDA holders… should immediately remove any patents that fail to meet listing requirements."

With its latest policy statement, the FTC provided notice of its increased interest in exercising its enforcement scrutiny in the pharmaceutical industry. Accordingly, both brand and generic drug manufacturers should monitor the FTC's efforts to police the Orange Book, as the increased attention may change the risks associated with listing patents in the Orange Book and deciding whether to pursue development of a generic drug product.

> **"Improper patent listings in the Orange Book illegitimately delay or lock out generic manufacturers from entering the market, depriving Americans of access to lower-cost medicines and drug products," said FTC Chair Lina M. Khan. "The FTC is making clear that improper Orange Book listings may be an unfair method of competition in violation of the FTC Act. We won't hesitate to use all our tools to combat illegal practices that are inflating the price of health care, including medicines."**
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> FTC www.ftc.gov/...

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