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Increased Scrutiny by Federal Trade Commission of Orange Book Listings

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This article examines the policy statement issued by the Federal Trade Commission (FTC) in September 2023, indicating that it would increase scrutiny of patents listed in the Orange Book, a publication regulated by the Federal, Food, Drug and Cosmetic Act (FDCA) that lists all small molecule drugs approved by the US Food and Drug Administration (FDA). The FTC's focus is on ensuring that only appropriate patents — those covering drug substances, drug products and methods of use — are listed. This scrutiny aims to prevent improper listings that could delay generic drug approvals and maintain market exclusivity for brand-name drugs longer than warranted.

The Orange Book listing process is crucial for brand manufacturers, as it provides notice to generic manufacturers about existing patents, initiating regulatory and legal processes under the Hatch-Waxman Act. If a generic manufacturer wishes to market a drug before a listed patent expires, it can file a "Paragraph IV" certification, challenging the patent's validity or enforceability. If the brand-name patent holder files an infringement suit within 45 days of receiving notice of such PIV certification, a 30-month stay to FDA approval is put in place, allowing time for the patent dispute to be resolved.

The FTC has primarily targeted device patents that do not mention any drug in their claims, arguing that such patents do not meet the statutory criteria for an Orange Book listing. The FTC has sent warning letters to several pharmaceutical companies, urging them to delist improper patents. Some companies have complied, while others argue that their patents meet statutory guidelines and do not have anticompetitive effects. The FTC's actions are part of a broader effort to address alleged patent abuses and reduce prescription drug prices as outlined in the Inflation Reduction Act Initiative.

The increased scrutiny by the FTC has led to a rise in antitrust litigation filed by private entities, alleging improper patent listings and monopolization. These lawsuits seek damages for overcharges during periods when generic competition was allegedly delayed. The FDA has stated that it will continue to work with the FTC to address potential efforts to impede competition. As a precaution,

New Drug Application (NDA) holders should ensure their Orange Book listings comply with statutory requirements to avoid FTC action and potential legal disputes. The practical impact of a patent delisting depends on various factors, including the presence of other listed patents and the specifics of each case.

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