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FTC Peeling Back the Layers of the Orange Book

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The Federal Trade Commission (FTC) is continuing to pursue pharmaceutical manufacturers for allegedly improperly listing patents in the "Orange Book," delaying the entry of generic drug competitors. On May 21, the FTC renewed its challenge to more than 200 patents listed on the Orange Book covering 17 different brand-name products, sending warning letters to several major pharmaceutical companies, including Amphastar, Mylan, Covis Pharma, and three Teva entities. The FTC claims that these companies' device patents—covering devices used in treatments for asthma, COPD, and diabetes—do not meet the statutory criteria for Orange Book listing.

Beginning with a September 2023 policy statement, the FTC has pressed the view that brand-name drug manufacturers have been improperly including patents on the list of Approved Drug Products with Therapeutic Equivalence, better known as the Orange Book. Orange Book listings that fail to meet statutory criteria laid out by the Hatch-Waxman Act and FDA regulations can delay the introduction of generic drugs by triggering a 30-month stay of FDA approval even if a court were ultimately to find the patent(s) at issue invalid or not infringed. According to the FTC, such improper listing can potentially constitute an unfair method of competition under Section 5 of the Federal Trade Commission Act (FTCA) or unlawful monopolization under Section 2 of the Sherman Act.

The FTC had previously sent warning letters to these companies (as well as several others) in both November 2023 and April 2024, but appeared to take no direct action regarding these warning letters. The new warning letters follow on the heels of the Federal Circuit's December 2024 decision in *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC.*, an important decision clarifying the scope of Orange Book patent listings. In the *Teva* case, the Federal Circuit held that several of Teva's patents, including some cited by the FTC in its prior warning letters (and in an amicus brief the FTC filed in this case), did not meet the criteria for Orange Book listing. In particular, the Federal Circuit ruled that to qualify for Orange Book listing, the patent must actually claim the active ingredient of the drug, rather than merely components of the device used to administer it. This decision prevents the listing of patents that might cover aspects of brand-name drugs like more general delivery devices rather than the drug substance or formulation itself. The FTC's warning letters have flagged several of these general delivery devices used across multiple drugs, which are agnostic to any particular drug substance or formulation. Post *Teva*, these types of patents should be delisted across all drugs.

While the FTC has not brought any formal enforcement action against a brand-name manufacturer since its September 2023 policy statement, except for a civil investigative demand to Teva reported in the Wall Street Journal in July, the FTC claims its prior warning letters led to the voluntary withdrawal of patent listings across 22 different brand-name products, though many companies have continued to list their patents. It seems that the FTC may be willing to let private parties fight these types of disputes first (as Amneal did in *Teva*), but this still requires a private party to fight the exact problem FTC has noted. But as the FTC further points out in its recent warning letters, private plaintiffs have begun pursuing antitrust cases against brand-name manufacturers for improper listings. A federal district court in Massachusetts recently allowed a private antitrust claim by the Massachusetts Laborers' Health & Welfare Fund against Boehringer Pharmaceuticals for improperly listing patents in the Orange Book to survive a motion to dismiss.

Given these developments, it is uncertain whether the FTC itself will pursue formal enforcement action or litigation, or continue to act through amicus briefs in private litigation and warning letters. No matter the FTC's approach, it is clear that brand-name drug manufacturers are facing increasing pressure to reevaluate their Orange Book listings and consider delisting patents that don't meet the Federal Circuit's interpretation of the listing criteria.

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