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FTC Issues Policy Statement Confirming Its Position That Improperly Listing Patents in the Orange Book May Be Considered a Violation of the FTC Act

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The Federal Trade Commission (FTC) has released a new Policy Statement addressing one of its long-standing concerns in the pharmaceutical industry: the improper listing of patents in the Orange Book. In an open meeting of the commissioners in September, the FTC voted unanimously to approve the issuance of the new statement, which directly addresses the improper listing of patents in the Food and Drug Administration's (FDA) publication of *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book" (Policy Statement). The Policy Statement is a forceful warning to companies and individuals that may thwart competition in pharmaceutical markets through improperly listed patents.

The Hatch-Waxman Act sets forth the criteria for publication of patents in the Orange Book. The act was intended to encourage new pharmaceutical development and greater public access to generic drugs and established the approval pathway for generic drugs. The Hatch-Waxman Act identifies two requirements for a patent to be eligible for listing in the Orange Book. First, the patent must be one for which "infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug."[1] Second, the patent must claim one of three categories of subject matter — "a drug substance (active ingredient)," "a drug product (formulation or composition)," or "a method of using such drug for which approval is sought or has been granted in the [patent holder's New Drug Application]."[2]

Although these requirements exist, the FDA does not itself investigate whether a listing is appropriate. Generally, this leaves a company with a potentially competing generic product that suspects a patent is improperly listed in the Orange Book with no path other than patent litigation and a delay in the FDA approval process. The FTC's Policy Statement addresses how this framework may have played a role in distorting pharmaceutical markets "for decades," and specifically notes that incorrectly listing a patent in the Orange Book "may disincentivize investments in developing a competing product and increase the risk of delayed generic and follow-on product entry, reducing patient access to more affordable prescription drugs and increasing costs to the healthcare system."

The Policy Statement is not the first time the FTC has directly addressed this subject. The FTC previously made its opposition to improper Orange Book listings clear in 2002, when it filed administrative litigation claiming, among other things, that the wrongful listing of a patent in the Orange Book for the purpose of blocking generic competition constituted a violation of the FTC Act.[3] Similarly, in late 2022, the FTC, by a 4-0 vote, filed an amicus brief in a patent infringement action, explaining that when patents are listed that do not meet the statutory listing criteria, the purpose of the Hatch-Waxman Act's 30-month stay on approval of competing drugs is frustrated,

leading instead to the blocking of consumer access to a competing product that might reduce prices, improve quality, or both without any countervailing benefit.[4] The FTC further argued in the amicus brief that the 30-month stay actually incentivizes companies to wrongfully list patents in the Orange Book.

The Policy Statement affirms these views, and makes clear that the FTC will not hesitate to use its enforcement powers in this area. The Policy Statement is not critical of the Hatch-Waxman Act, but instead focuses on the distortion of pharmaceutical markets, the delay of generic product launches, and the possibility of higher drug prices resulting from improperly listed patents. In addition to Section 5 of the FTC Act, the Policy Statement notes that improper listing in the Orange Book may be actionable under Sherman Act Section 2's prohibition of monopolization and that failure to remove an improperly listed patent may be deemed unfair competition. The statement is unsurprising in that it further implements this administration's stated goals to promote competition in the pharmaceutical industry, including through support of the generic drug patent framework.

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[1] 21 U.S.C. § 355(b)(1)(A)(viii).

[2] *Id.*

[3] *See Biovail Corporation*, FTC File No. 011-0094 (Oct. 4, 2002), https://www.ftc.gov/sites/default/files/documents/cases/2002/10/biovailcmp.pdf.

[4] *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, Inc.*, No. 21-CV-00691 (Nov. 10, 2022), https://www.ftc.gov/legal-library/browse/amicus-briefs/jazz-pharmaceuticals-inc-v-avadel-cns-pharmaceuticals-llc.

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