UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
Bureau of Competition

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By Federal Express and Email

David R. McAvoy
Chief Legal Officer
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generic drug applications.[4] In addition to delays resulting from such a stay of approval, the costs associated with litigating improperly listed patents may disincentivize investments in developing generic drugs, which risks delaying or thwarting competitive entry. The Supreme Court has recognized that improper Orange Book listings prevent or delay generic drug entry.[5] Even brief delays in generic competition can reduce patient access to more affordable alternatives and increase costs across the entire health care system.[6]

For decades, the FTC has sought to reduce the anticompetitive effects that result from improperly listing patents in the Orange Book, through enforcement and through amicus briefs articulating that improper listings may violate the antitrust laws.[7] The FTC's Policy Statement serves to reinforce the FTC's concerns about the anticompetitive consequences of improper Orange Book listings and provide notice that the "FTC will continue to use all its tools to halt unlawful business practices that contribute to high drug prices."[8]

As detailed in the Policy Statement, the FTC has several tools at its disposal to address improper Orange Book listings. One of those tools is using the FDA's process to dispute "the accuracy or relevance of patent information submitted" to the FDA for publication in the Orange Book.[9]

We have opted to use the FDA's regulatory dispute process to address the improper listings, but we retain the right to take any further action the public interest may require, which may include investigating this conduct as an unfair method of competition under Section 5 of the FTC Act, 15 U.S.C. § 45, and as described in the Policy Statement.

Sincerely,

/s/ Rahul Rao
Deputy Director
Bureau of Competition

Enclosure: FTC Policy Statement Concerning Brand Drug Manufacturers Improper Listing of Patents in the Orange Book

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[4] Policy Statement at 3 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).
[5] *Id.* at 3 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012)).
[6] *Id*. at 4.
[7] *Id.* at 3; *see also* Decision and Order, *In re Biovail Corp*., FTC Dkt. No. C-4060 (F.T.C. Oct. 2, 2002); Federal Trade Commission's Brief as *Amicus Curiae*, *Jazz Pharms., Inc. v, Avadel CNS Pharms*. No. 1:21-cv-00691 (D. Del. Nov. 10, 2022) (Doc. No. 22-3), https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf; *see also* Mem. of Law of *Amicus Curiae* the Federal Trade Commission In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litig.*, MDL Docket No. 1410 (S.D.N.Y. Jan. 8, 2002), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf.
[8] Policy Statement at 6.
[9] 314.53(f)(1)(i)(A).