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Office of the Chair

Statement of Chair Lina M. Khan at the
September Open Commission Meeting on
Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book
Commission File No. P233900

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Drug prices are sky high. Americans pay more for medicines that any other country in the world. A striking number of people now report having to ration their medicines or skip them altogether because they are too expensive.[1] Many factors contribute to this unaffordability crisis—including unlawful business practices. We at the FTC are committed to using all of our tools to combat corporate conduct that unlawfully inflates drug prices.

That is why the Commission today is considering a policy statement on how the FTC will scrutinize improper "Orange Book" patent listings. The Orange Book is where brand manufacturers list their patents for FDA-approved drug products. A brand pharmaceutical company can obtain a presumptive 30-month stay of the FDA approving competitors merely by listing a patent in the Orange Book and filing a lawsuit against a generic manufacturer, regardless of whether the patent it listed is actually valid or infringed by the competing generic product. In this way, a pharmaceutical company can weaponize the Orange Book to protect monopoly rights to a medical product—even if those monopoly rights are invalid. This practice can delay or block generic and innovative drugs from entering the market, keeping prices higher for American patients.

Experience shows that we have good reason to be concerned about improperly listed patents in the Orange Book. Last year the FTC filed an amicus brief in a lawsuit that highlighted the stakes.[2] Avadel, a specialty pharmaceutical company, had developed an extended-release version of a narcolepsy drug that allowed patients to avoid having to wake up in the middle of the night to take a second dose. The FDA tentatively approved Avadel's extended-release version in 2022, but by that time, Jazz, another pharma company, had sued Avadel for infringing

[1] MUNIRA Z. GUNJA, ET AL., U.S. HEALTH CARE FROM A GLOBAL PERSPECTIVE, 2022: ACCELERATING SPENDING, WORSENING OUTCOMES, THE COMMONWEALTH FUND (2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022; Katie Adams, *Rising Costs Force 39% of Americans to Skip Ration Meds, Survey Says*, BECKER'S HOSP. REV. (Mar. 22, 2021), https://www.beckershospitalreview.com/pharmacy/rising-costs-force-39-of-americans-to-skip-ration-meds-survey-says.html; Dan Witters, *In U.S., An Estimated 18 Million Can't Pay for Needed Drugs*, GALLUP (Sept. 21, 2021), https://news.gallup.com/poll/ 354833/estimated-million-pay-needed-drugs.aspx; Ken Alltucker, *More than 1.3M Americans Ration Life-Saving Insulin Due to Cost. That's 'Very Worrisome' to Doctors.*, USA TODAY (Oct. 17, 2022), https://www.usatoday.com/story/news/health/2022/10/17/high-cost-insulin-prompts-1-3- million-americans-ration-drug/10498626002/.

[2] Fed. Trade Comm'n's Brief as Amicus Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 21-691-GBW (D. Del. Nov. 10, 2022).

Jazz's "Risk Evaluation and Mitigation Strategies" ("REMS") patent—a patent that had nothing to do with the drug itself or an approved method of using the drug. Jazz cited the Orange Book to automatically trigger the 30-month stay, blocking Avadel from the market. The Federal Circuit court eventually held that the patent was improperly listed in the Orange Book and ordered it to be delisted.[3] Following this order, the FDA granted final approval of Avadel's new drug—nearly ten months after the original tentative approval. In that intervening period, Jazz continued to rake in monopoly profits and patients were deprived of a potentially superior formulation of a critical narcolepsy drug.[4]

Concerns over improper Orange Book listings have also been raised in the context of device patents. For example, in late 2016 direct purchasers of the insulin Lantus brought an antitrust lawsuit claiming that certain device patents were improperly listed in the Orange Book, resulting in delay of entry of competing insulin products. That case made its way to the First Circuit, which agreed with the plaintiffs that device patents that do not claim the drug itself are not properly listed in the Orange Book as a matter of law.[5] The same concern has been raised with regard to brand inhalers for asthma and chronic obstructive pulmonary disease. Even though inhalers have been on the market for decades, they have faced relatively limited generic competition in recent years.[6]

Our laws—and even the Constitution[7]—enshrine an important role for patents in promoting innovation and creativity. But abuse of patent rights can deprive Americans of access to more affordable drugs and medical products, and the FTC has a long history of challenging these practices when they violate the antitrust laws.[8]

The policy statement we're considering today builds on this important work. This statement explains that patents that are improperly listed in the Orange Book can unlawfully harm patients, competition, and innovation, and notes that these practices may be an unfair method of competition and violate the FTC Act.

The soaring price of drugs, including essential life-saving medicines, is a real crisis in our country, and we at the FTC have an obligation to use all our tools and authorities to combat any illegal business practices that may be contributing to the crisis.

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[3] *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1380 (Fed. Cir. 2023).
[4] *See* Rebecca Robbins, *A Drug Company Exploited a Safety Requirement to Make Money*, N.Y. TIMES (Feb. 28, 2023), https://www.nytimes.com/2023/02/28/business/jazz-narcolepsy-avadel-patents.html (noting that Jazz's narcolepsy drug "generat[ed] more than $13 billion in revenue since Jazz acquired it in 2005").
[5] *In re Lantus Direct Purchaser Antitrust Litig*., 950 F.3d 1 (1st Cir. 2020).
[6] *See* Brandon J. Demkowicz, et al., *Patenting Strategies on Inhaler Delivery Devices*, 164 CHEST 450 (2023); William B. Feldman, et al., *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, 329 JAMA 87 (2023).
[7] U.S. CONST. art. I, § 8, cl. 8.
[8] *See, e.g.*, FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (2022); *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (holding that pay-for-delay settlements can violate antitrust laws); *FTC v. Shkreli*, 581 F. Supp. 3d 579, 590 (S.D.N.Y. 2022) (banning Martin Shkreli from the pharmaceutical industry); *In re Bristol-Myers Squibb Co.*, FTC File No. 0110046 (May 25, 2004) (settling charges that, among other things, respondent purposely made wrongful listings in the Orange Book); *Biovail Corp.*, FTC File No. 0110094 (Oct. 2, 2002) (same).

I am eager for us to continue approaching this work with the enormous urgency that it deserves, and I am grateful to the FTC teams whose talent and commitment will allow us to do so. Many thanks to the Office of Policy Planning for giving us the opportunity to consider this policy statement, including Hillary Green, Sarah Mackey, Anu Sawkar, Marc Lanoue, David Barclay, and Brad Vettraino.

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