

# Congress of the United States

Washington, DC 20515

September 13, 2023

The Honorable Lina M. Khan  
Chair  
U.S. Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Dear Chair Khan:

We are writing ahead of the Federal Trade Commission's (FTC's) open meeting tomorrow, on September 14, 2023, to strongly urge the Commission to issue a policy statement concerning the improper listing of drug-related patents in the Food and Drug Administration's (FDA's) Orange Book.<sup>1</sup> Brand-name pharmaceutical companies have routinely abused the U.S. patent system, violated antitrust law, and hiked the prices of prescription drugs to widen their own profit margins.<sup>2</sup> We urge the FTC to take steps to end Big Pharma's routine exploitation of the Orange Book and hold drug companies accountable for their anti-competitive business practices that are "imposing costs on individuals and society alike."<sup>3</sup>

The FDA's Orange Book contains a list of FDA-approved drugs and their related patent and exclusivity information, which are considered some of the "most valuable patents in the world."<sup>4</sup> Brand-name drug companies are required to list patent information in the Orange Book that cover drug substances, drug products, and method of use.<sup>5</sup> But Big Pharma regularly lists patents outside of these categories, even when courts have ruled that they are outside the scope of the Orange Book. For example, pharmaceutical companies have intentionally submitted patents for

---

<sup>1</sup> U.S. Federal Trade Commission, "FTC Announces Tentative Agenda for September 14 Open Meeting," press release, September 7, 2023, <https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-announces-tentative-agenda-september-14-open-meeting>

<sup>2</sup> American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), "The Costs of Pharma Cheating," May 2023, [https://www.economicliberties.us/wp-content/uploads/2023/05/AELP\\_052023\\_PharmaCheats\\_Report\\_FINAL.pdf](https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf); Center for American Progress, "How Big Pharma Reaps Profits While Hurting Everyday Americans," Abbey Meller and Hauwa Ahmed, August 30, 2019, <https://www.americanprogress.org/article/big-pharma-reaps-profits-hurting-everyday-americans/>

<sup>3</sup> U.S. Federal Trade Commission, "FTC Announces Tentative Agenda for September 14 Open Meeting," press release, September 7, 2023, <https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-announces-tentative-agenda-september-14-open-meeting>

<sup>4</sup> U.S. Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book," June 9, 2023, <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>; Washington Law Review, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," S. Sean Tu and Mark A. Lemley, August 5, 2022, p. 1673, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3903513](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513)

<sup>5</sup> U.S. Government Accountability Office, "Generic Drugs," March 2023, p. 6, <https://www.gao.gov/products/gao-23-105477>

devices without an active ingredient, such as inhalers,<sup>6</sup> and for distribution methods, such as the Risk Evaluation and Mitigation Strategies (REMS) for Jazz Pharmaceutical’s narcolepsy drug.<sup>7</sup>

Improper ‘sham’ patents serve the primary purpose of blocking competitors from introducing lower-costs generic drugs.<sup>8</sup> That’s because FDA is automatically barred from approving a generic drug for 30 months if a brand-name drug company sues a generic competitor for infringing on an Orange Book-listed patent.<sup>9</sup> Pharmaceutical companies are therefore incentivized to list more patents in the Orange Book, whether they’re valid or not, to hold off generic competition for multiple years and extend their own monopolies regardless of the outcome of any litigation. FTC has previously raised concerns about these activities, filing an amicus brief “highlight[ing] the significant harm to consumers when a brand company improperly lists a patent on a distribution system in the Food and Drug Administration’s ‘Orange Book’ of approved drugs and thereby blocks generic or follow-on competition.”<sup>10</sup>

The median price for a year’s supply of prescription drugs went from \$2,000 in 2008 to \$180,000 last year.<sup>11</sup> Meanwhile, three in ten patients were forced to forgo their medications due to cost.<sup>12</sup> U.S. patients spent an estimated additional amount of \$40.7 billion on pharmaceuticals in 2019 “as a result of antitrust violations by the pharmaceutical industry.”<sup>13</sup> Without competition – which Big Pharma is strategically blocking – to lower drug costs, more and more patients will be forced to choose between taking care of their financial health and their physical health. One FDA study found that the introduction of even a single generic drug can lower a drug’s price by almost 40 percent. With two generic options available, prices drop by over half.<sup>14</sup> Unjustified delays in generic competition are costing patients and taxpayers billions of dollars, just to pad Big Pharma’s profits.

---

<sup>6</sup> Health Affairs, “From Health Affairs: Inhaler Patents Focus On Devices, Not Ingredients,” May 17, 2022, <https://www.healthaffairs.org/content/forefront/i-health-affairs-i-inhaler-patents-focus-devices-not-ingredients>

<sup>7</sup> U.S. Federal Trade Commission, “FTC Amicus Brief Challenges Abuse of FDA ‘Orange Book’ Listing Procedures to Block Drug Competition,” press release, November 10, 2022, <https://www.ftc.gov/news-events/news/press-releases/2022/11/ftc-amicus-brief-challenges-abuse-fda-orange-book-listing-procedures-block-drug-competition>; New York Times, “A Drug Company Exploited a Safety Requirement to Make Money,” Rebecca Robbins, February 28, 2023, <https://www.nytimes.com/2023/02/28/business/jazz-narcolepsy-avadel-patents.html>

<sup>8</sup> American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), “The Costs of Pharma Cheating,” May 2023, p. 9, [https://www.economicliberties.us/wp-content/uploads/2023/05/AELP\\_052023\\_PharmaCheats\\_Report\\_FINAL.pdf](https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf)

<sup>9</sup> U.S. Food and Drug Administration, “Patent Certifications and Suitability Petitions,” September 8, 2023, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions>

<sup>10</sup> U.S. Federal Trade Commission, Amicus Brief filed in Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC, November 10, 2022, <https://www.ftc.gov/legal-library/browse/amicus-briefs/jazz-pharmaceuticals-inc-v-avadel-cns-pharmaceuticals-llc>

<sup>11</sup> Patients for Affordable Drugs, “July 2022 Price Hikes Report,” July 19, 2022, <https://patientsforaffordabledrugs.org/2022/07/19/july-2022-price-hikes-report/>

<sup>12</sup> *Id.*

<sup>13</sup> American Economic Liberties Project and Initiative for Medicines, Access, and Knowledge (I-MAK), “The Costs of Pharma Cheating,” May 2023, p. 2, [https://www.economicliberties.us/wp-content/uploads/2023/05/AELP\\_052023\\_PharmaCheats\\_Report\\_FINAL.pdf](https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf)

<sup>14</sup> *Id.*, p. 4; U.S. Food and Drug Administration, “Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices,” Ryan Conrad and Randall Lutter, December 2019, pp. 2-3, <https://www.fda.gov/media/133509/download>

Last month, we sent a letter to FDA Commissioner Robert Califf urging the agency to take steps to enforce their Orange Book guidelines, strengthen oversight of proper listings, and prevent further abuses of the drug patent system.<sup>15</sup> The FTC now has the chance to hold Big Pharma accountable for these anti-competitive business tactics. We support your decision to discuss this critical issue at tomorrow’s open meeting and encourage you to release a strong policy statement declaring that the listing of sham patents in the Orange Book is an unfair method of competition that is reducing access to essential drugs and hurting patients.<sup>16</sup>

Sincerely,



---

Elizabeth Warren  
United States Senator



---

Pramila Jayapal  
Member of Congress

CC: Dr. Robert M. Califf, Commissioner of Food and Drugs, U.S. Food and Drug Administration

---

<sup>15</sup> Letter from Senator Warren and Representative Jayapal to the U.S. Food and Drug Administration, August 28, 2023, <https://www.warren.senate.gov/imo/media/doc/2023.08.28%20Letter%20to%20FDA%20re%20drug%20patents.pdf>

<sup>16</sup> U.S. Federal Trade Commission, “FTC Announces Tentative Agenda for September 14 Open Meeting,” press release, September 7, 2023, <https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-announces-tentative-agenda-september-14-open-meeting>