Federal Trade Commission
Report on Pharmaceutical Product Hopping

Congress directed the Federal Trade Commission (FTC) to report to the Committees on Appropriations of the House and Senate regarding the FTC's efforts to address pharmaceutical product hopping.[1] Product hopping is a strategy where a brand-name pharmaceutical company seeks to shift demand from a brand-name drug that faces generic competition to newly patented and/or exclusivity protected drugs that do not face generic competition. For example, a product hop can be executed by making modest non-therapeutic changes to a product that offer little or no apparent medical benefit to consumers and moving demand to that product. Product hopping can raise antitrust concerns when a brand introduces a reformulated product and then takes steps to impede competition on the merits between the original and the reformulated drug, thereby eliminating the prescription base for the original product before generics even have a chance to be substituted at the pharmacy. The House Committee on Appropriations "directs FTC to publish a report outlining the actions it has taken in the past 15 years to address these issues and other issues related to generic competition, and the principles it uses to assess whether a pharmaceutical industry practice is unlawful under the antitrust statutes."[2] To fulfill this directive, the Commission submits this report.[3]

FTC Approach to Assessing Pharmaceutical Practices

The Federal Trade Commission is a law enforcement agency charged by Congress with protecting the public against unfair methods of competition and unfair or deceptive trade practices.[4] The FTC's antitrust arm, the Bureau of Competition, is responsible for investigating and prosecuting unfair methods of competition that violate the FTC Act. The FTC shares with the Department of Justice responsibility for prosecuting violations of the Sherman Act and the Clayton Act.

The FTC seeks to foster a competitive and innovative pharmaceutical marketplace by promoting competition among brand-name pharmaceuticals, between brand and generic pharmaceuticals, and among generic pharmaceuticals. In particular, generic competition saves American consumers hundreds of billions of dollars in prescription drug costs each year, but brand-name drug companies sometimes use strategies to avoid generic competition and maintain monopoly profits. The FTC closely scrutinizes these practices for possible illegal anticompetitive conduct in the U.S. pharmaceutical system.

The FTC has aggressively used its enforcement, policy, and research tools to address

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1 The Joint Explanatory Statement, 166 Cong. Rec. H8436 (daily ed. Dec. 21, 2020), accompanying H.R. 133, The Consolidated Appropriations Act of 2021, incorporated by reference House Report No. 116-456, 116th Cong. 2d Sess. (2020), https://www.congress.gov/116/crpt/hrpt456/CRPT-116hrpt456.pdf.

2 *Id*. at 67-68.

3 This report focuses on the FTC's efforts to address product hopping by branded pharmaceutical companies. For the FTC's other activities relating to competition in generic pharmaceuticals, see generally FTC HEALTH CARE DIV. STAFF, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (2022), https://www.ftc.gov/system/files/ftc_gov/pdf/2022.04.08%20Overview%20Pharma%20%28final%29.pdf.

4 15 U.S.C. § 45.

anticompetitive conduct involving pharmaceutical products and their distribution.[5] Notably, the FTC has brought many enforcement actions in pharmaceutical markets. Enforcement actions address unilateral conduct by drug companies that may deter generic entry, unlawful mergers between drug companies, and illegal horizontal agreements between drug manufacturers.[6] In June 2022, the Commission issued a policy statement putting the drug industry on notice that paying rebates and fees to pharmaceutical benefit managers (PBMs) and other industry middlemen to exclude competitors offering lower-cost drug alternatives may violate the competition and consumer protection laws.[7] Using its unique research capabilities and authority, the Commission and its staff have also issued empirical studies that address the competitive dynamics of generic substitution for brand-name drugs[8] and recently launched a study into the role PBMs play in drug distribution and competition.[9] Further, when a court considers a case whose outcome may raise antitrust issues, the FTC may file an amicus brief, a "friend of the court" brief, to provide information that can help the court make its decision in a way that protects consumers or promotes competition.[10] The FTC has filed amicus briefs in cases involving the pharmaceutical sector.[11]

In March 2021, the FTC launched a task force comprised of several of its domestic and international counterpart competition enforcement agencies—the Canadian Competition Bureau, the European Commission Directorate General for Competition, the U.K.'s Competition and Markets Authority, the U.S. Department of Justice Antitrust Division, and Offices of State Attorneys General—to discuss ways to update their approaches to analyzing the effects of pharmaceutical mergers.[12] The task force culminated in a multilateral workshop to explore new

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5 *See generally* FTC HEALTH CARE DIV. STAFF, *supra* note 3.

6 *See generally id*.

7 Press Release, FTC, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middlemen that Block Cheaper Drugs (June 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

8 *See* FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (2011), http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 8-13 (1985), https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf (FTC Bureau of Economics Staff Report); FTC BUREAU OF CONSUMER PROTECTION, DRUG PRODUCT SELECTION (1979), https://www.ftc.gov/reports/staff-report-drug-product-selection (FTC Bureau of Consumer Protection Staff Report).

9 Press Release, FTC, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

10 *See generally* FTC, Amicus Briefs, https://www.ftc.gov/legal-library/browse/amicus-briefs.

11 *E.g.*, Brief of Amicus Curiae The FTC in Support of No Party, UFCW Local 1500 Welfare Fund v. AbbVie, Inc., sub nom. Mayor and City Council of Baltimore v. AbbVie Inc., 42 F.4th 709 (7th Cir. 2022), https://www.ftc.gov/system/files/documents/amicus_briefs/ufcw-local-1500-welfare-fund-et-al-v-abbievie-inc-et-al/ufcw_local_1500_welfare_fund_amicus_brief.pdf.

12 Press Release, FTC, Multilateral Pharmaceutical Merger Task Force Seeks Public Input (May 11, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/05/multilateral-pharmaceutical-merger-task-force-seeks-

approaches to enforcing the antitrust laws in the pharmaceutical industry.[13] The discussions provided additional insights that will inform our competition analysis and enforcement guidance in pharmaceutical markets going forward. Among other things, participants discussed how product hopping conduct might relate to merger review.

The Commission remains committed to bringing all our tools to bear on unlawful business practices that may increase prices for medicines.

FTC Actions Relating to Product Hopping

The FTC has taken a number of enforcement and policy actions involving product hopping. Issues relating to product hopping arose during the FTC's investigation into Warner Chilcott's alleged attempt to prevent generic competition for its branded birth control drug Ovcon.[14] The Hatch-Waxman Act establishes a process that gives generic pharmaceutical makers an incentive to enter the market for a particular drug, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.[15] According to the FTC complaint, generic company Barr planned to launch a generic version of Ovcon as soon as it received regulatory approval from the FDA, but instead entered into an allegedly illegal agreement in March 2004 with Warner Chilcott to delay generic entry.[16]

While the FTC's case was pending, the FTC learned that Warner Chilcott intended to execute a product hop. According to the FTC's complaint, Warner Chilcott planned to launch a new, chewable version of Ovcon and then stop selling the original formulation of Ovcon in order to convert consumers to the new product. Such a strategy could have destroyed the market for generic Ovcon because prescriptions would only be written for the new version of Ovcon, for which generics were not substitutable. As a result, even if the FTC had won at trial, generic entry, the relief sought by the FTC, would have resulted in little to no consumer benefit.

On September 25, 2006, the FTC sought a preliminary injunction that, if granted, would have required Warner Chilcott to continue to sell the original formulation of Ovcon to allow for the eventual entry of a generic version, until resolution of the case.[17] On the same day the FTC filed its injunction, Warner Chilcott waived the exclusionary provision in its agreement with Barr

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public-input (citing Press Release, FTC, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach-pharmaceutical-mergers).

[13] FTC, The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers (June 14–15, 2022), https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers.

[14] FTC v. Warner Chilcott Holdings, Co. III., Ltd., No. 1:05-cv-02179 (D.D.C. 2006), https://www.ftc.gov/enforcement/cases-proceedings/0410034/warner-chilcott-holdings-company-iii-ltd-warner-chilcott.

[15] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[16] Complaint for Injunctive and Other Equitable Relief, FTC v. Warner Chilcott Holdings, Co. III., Ltd., No. 1:05-cv-02179 (D.D.C. Nov. 7, 2005), https://www.ftc.gov/sites/default/files/documents/cases/2005/11/051107comp0410034.pdf.

[17] *See* Press Release, FTC, Consumers Win as FTC Action Results in Generic Ovcon Launch (Oct. 23, 2006), https://www.ftc.gov/news-events/press-releases/2006/10/consumers-win-ftc-action-results-generic-ovcon-launch.

that had prevented Barr from entering with its generic version of Ovcon. The following day, Barr announced its intention to start selling a generic version of the product. After the FTC and Warner Chilcott agreed to terms for a permanent injunction, within weeks, Barr began selling its lower-priced generic version of Ovcon. Following Barr's entry, Warner Chilcott also authorized Watson Pharmaceuticals to launch a competing generic Ovcon product. At the same time, Warner Chilcott decided to continue making and selling original Ovcon (rather than abandoning it), even as it started promoting its new chewable Ovcon product. Thus, filing the preliminary injunction motion led to four competing products in the market, where, absent the preliminary injunction, there would have been only one. The Commission and Warner Chilcott subsequently entered into a final order requiring Warner Chilcott to take steps to preserve the market for the tablet form of Ovcon providing Barr the opportunity to compete with its generic version.[18]

The Commission also entered into a stipulated permanent injunction with Barr Pharmaceuticals.[19] The settlement required Barr to refrain from entering into anticompetitive supply agreements with branded companies similar to Barr's agreement with Warner Chilcott regarding Ovcon, refrain from entering other agreements with branded manufacturers that unreasonably restrain competition, and notify the Commission of a broader group of agreements with branded companies that have the potential to harm competition. The terms of the proposed settlement expired after 10 years.[20]

In November 2012, the FTC filed an amicus brief in *Mylan Pharmaceuticals, Inc. v. Warner Chilcott*, a matter before the U.S. District Court for the Eastern District of Pennsylvania.[21] Plaintiffs alleged that Warner Chilcott engaged in a pattern of product switching, introducing three successive product reformulations of the Doryx antibiotic drug that, according to their complaints, offered little or no apparent medical benefit to consumers. The Commission amicus brief explained that a brand company can interfere with the mechanism by which generic drugs compete by making modest non-therapeutic changes to its product, and effectively prevent generic competition not because the reformulated product is preferred by consumers, but simply because it is different. By engaging in conduct that coerces patients and physicians to abandon the original product, the brand-name company may not only be denying consumers the opportunity to choose between the brand's original and reformulated versions, but plausibly could be inhibiting consumers' ability to select a generic version of the original formulation.[22] The court denied defendants' motions to dismiss, but later granted Warner Chilcott summary judgment finding (1) that plaintiffs had failed to offer evidence that Warner

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[18] Final Order and Stipulated Permanent Injunction, FTC v. Warner Chilcott Holdings Co. III, Ltd., No. 1:05-cv-02179 (D.D.C. Oct. 23, 2006), https://www.ftc.gov/sites/default/files/documents/cases/2006/10/finalorder.pdf.

[19] Final Order and Stipulated Permanent Injunction, FTC v. Barr Pharms., Inc., No. 1:05-cv-02179 (Nov. 27, 2007), https://www.ftc.gov/sites/default/files/documents/cases/2007/11/071127barrpharmafinalorder.pdf.

[20] Press Release, FTC, FTC Settles Charges Against Barr Laboratories, Protects Consumers from Anticompetitive Agreements in Prescription Drug Market (Nov. 29, 2007), https://www.ftc.gov/news-events/press-releases/2007/11/ftc-settles-charges-against-barr-laboratories-protects-consumers.

[21] FTC's Brief as Amicus Curiae, Mylan Pharms., Inc. v. Warner Chilcott Public Ltd. Co., 2015 WL 1736957 (E.D. Pa. 2015) (Civ. No. 12-3824), http://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf.

[22] *See* The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

Chilcott had monopoly power and (2) that Warner Chilcott's product hopping scheme was not exclusionary conduct.

On appeal to the Third Circuit, the Commission filed another amicus brief in September 2015, urging the appeals court to reverse the district court's ruling and remand it with instructions on applying the antitrust laws.[23] Without taking a position on the ultimate resolution of the case, the Commission argued that the district court erred by ignoring the unique characteristics of pharmaceutical markets in its analysis of monopoly power. The Commission explained that "[g]enerics are unique sources of competition for brand-name prescription drugs. Without automatic substitution, the disconnect between prescribing physicians and payors often insulates brand-name prescription drugs from effective price competition, and a given drug may be priced at monopoly levels even if other drugs are therapeutically similar."[24] The Commission also argued, "the very fact of product-hopping can itself be evidence of monopoly power. The manufacturer of a brand-name drug generally undertakes a product hop to preserve high profits that generic versions of the same drug would undercut but that no alternative drug, competing in the same market, has yet disciplined."[25] The Commission argued that the district court also erred in its analysis of exclusionary conduct when it "dismiss[ed] automatic substitution as a mere 'regulatory windfall' undeserving of antitrust protection."[26] The Commission explained, "a monopolist may not avoid antitrust liability simply because the efficient distribution mechanism it destroys was created in part by procompetitive government action."[27] The Third Circuit subsequently affirmed the district court decision.[28]

In 2019 and 2020 the FTC secured $60 million for consumers in a pair of settlements with Reckitt Benckiser Group plc and its former U.S. subsidiary Indivior to settle charges that they violated the antitrust laws through a deceptive scheme to thwart lower-priced generic competition to its branded drug Suboxone.[29] Suboxone is a drug that treats opioid addiction. This enforcement action is historic for two reasons: (1) it is the FTC's first-ever enforcement action alleging "product-hopping" in the pharmaceutical industry as an antitrust violation, resulting in two precedent-setting orders addressing that conduct; and (2) it is the FTC's largest disbursement to individual consumers in a competition case.

According to the FTC's complaint, before the generic versions of Suboxone tablets became available, Reckitt and its former subsidiary Reckitt Benckiser Pharmaceuticals, now known as Indivior, Inc., developed a dissolvable oral film version of Suboxone and worked to

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[23] Brief for Amicus Curiae FTC Supporting Plaintiff-Appellant, Mylan Pharms., Inc. v. Warner Chilcott Public Ltd. Co., 838 F.3d 421 (3d Cir. 2016), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf.

[24] *Id*. at 12.

[25] *Id*. at 13.

[26] *Id*. at 14.

[27] *Id*.

[28] Mylan Pharms., Inc. v. Warner Chilcott Public Ltd. Co., 838 F.3d 421 (3d Cir. 2016).

[29] FTC v. Reckitt Benckiser Group PLC, No. 1:19CV00028 (W.D. Va. 2019), https://www.ftc.gov/enforcement/cases-proceedings/131-0036/reckitt-benckiser-group-plc.

shift prescriptions to this patent-protected film.[30] Worried that doctors and patients would not want to switch to Suboxone Film, Reckitt allegedly employed a "product hopping" scheme where the company misrepresented that the film version of Suboxone was safer than Suboxone tablets because children are less likely to be accidentally exposed to the film product.

The FTC's investigation determined that Reckitt Benckiser and its former subsidiary Indivior used false and misleading safety claims to coerce customers into switching from Suboxone tablets—which faced imminent competition from lower-cost generics—to the new patent-protected Suboxone film. The complaints further charged that to buy more time to move patients to the film version of Suboxone, Reckitt, through Indivior, filed a sham citizen petition with the FDA reciting the same unsupported safety claims and requesting that the agency reject any generic tablet application, in an attempt to delay the approval of generic competitors, and eventually withdrew their Suboxone tablets from the market under the false guise of pediatric safety concerns. Through these tactics, Reckitt and Indivior were able to preserve their Suboxone monopoly and force doctors to prescribe and patients to use the film version rather than less expensive generic tablets.

In 2014, the FTC's non-public investigation of this conduct was largely put on hold due to a parallel federal criminal investigation for related conduct. The criminal investigation ultimately resulted in a $1.4 billion settlement and non-prosecution agreement with Reckitt, guilty pleas from two former Indivior executives and an Indivior subsidiary (Indivior Solutions, Inc.), and a civil settlement with Indivior.[31]

In its civil settlement with the FTC, Reckitt agreed to a stipulated order for equitable monetary relief and a permanent injunction, which bars Reckitt from similar future misconduct.[32] If Reckitt introduces a reformulated version of an existing product, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded drug, the order requires Reckitt to leave the original product on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the drug they prefer. The order also requires that if Reckitt files a citizen petition, the company must simultaneously submit any data or information underlying that petition to the FDA and FTC. As part of the order, Reckitt agreed to pay $50 million in equitable monetary relief.

In a follow-up settlement, Indivior agreed to pay $10 million to settle FTC charges regarding the same conduct. Indivior also agreed to a similar stipulated permanent injunction,

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30 Complaint for Injunctive and Other Equitable Relief, FTC v. Reckitt Benckiser Group PLC, No. 1:19CV00028 (W.D. Va. July 11, 2019), https://www.ftc.gov/system/files/documents/cases/reckitt_complaint_7-11-19.pdf.

31 Press Release, DOJ, Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution (July 24, 2020), https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

32 Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief, FTC v. Reckitt Benckiser Group PLC, No. 1:19CV00028 (W.D. Va. July 11, 2019) (entered July 12, 2019), https://www.ftc.gov/system/files/documents/cases/reckitt_joint_motion_for_stipulated_order_7-11-19.pdf.

which bars it from similar future misconduct.[33] The $10 million from this settlement was combined with the $50 million from the Reckitt settlement into a fund to provide payments to people who purchased Suboxone Oral Film.

On May 10, 2021, the FTC announced that it sent nearly $60 million in payments to consumers who were victims of the scheme.[34] The FTC identified more than 50,000 victims with an average payment of $1,139. Some patients who took Suboxone for an extended period received as much as $2,600.

Conclusion

The FTC is committed to fostering a competitive and innovative pharmaceutical marketplace. The Agency remains vigilant in this important area of the U.S. economy. The Commission will continue its efforts to address product hopping and other emerging anticompetitive issues in order to protect existing and future competition in pharmaceuticals.

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[33] Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, FTC v. Indivior Inc., No. 1:20-cv-00036 (W.D. Va. July 24, 2020) (entered Nov. 20, 2020), https://www.ftc.gov/system/files/documents/cases/jt_mtn.pdf.

[34] Press Release, FTC, FTC Returns Nearly $60 Million to Those Suffering from Opioid Addiction Who Were Allegedly Overcharged in Suboxone Film Scheme (May 10, 2021), https://www.ftc.gov/news-events/press-releases/2021/05/ftc-returns-nearly-60-million-those-suffering-opioid-addiction.