

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

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GENERIC PHARMACEUTICALS

-- Note by the United States --

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More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.

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1. This note updates the United States of America’s October 2009 submission on generic pharmaceuticals.¹ Here we discuss the U.S. antitrust agencies’ ongoing efforts to foster a competitive and innovative pharmaceutical marketplace, primarily by promoting competition between brand-name and generic pharmaceuticals.

2. Efforts to promote competition in pharmaceutical markets include stopping what the U.S. Federal Trade Commission (FTC or Commission) and Department of Justice (DOJ) refer to as pay for delay, reverse payment, or exclusion payment settlements. These agreements cost American consumers an estimated \$3.5 billion per year.² The FTC secured a significant victory last year at the Supreme Court in *FTC v. Actavis* when the Court reversed a decision by a lower court that had effectively immunized many of these settlements from antitrust scrutiny. Additionally, the U.S. antitrust agencies have examined unilateral conduct by brand-name drug companies that may deter generic entry and reviewed agreements and mergers between generic drug companies. The agencies have also engaged in legislative initiatives, advocacy efforts, and amicus brief filings in non-FTC litigation in order to promote generic competition. Finally, the FTC uses research and study to better understand the competitive potential of generic markets, including recently enacted U.S. law governing “biosimilar” and “interchangeable” biologic drugs.

1. Background on Generic Drug Competition

3. Competition between brand-name and generic pharmaceutical manufacturers provides consumers enormous savings. Pharmaceutical industry studies indicate that the first generic competitor enters the market at a price that averages approximately 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.³ Subsequent generic firms may enter at even lower prices—often discounted 80 percent or more off the price of the brand-name drug—and prompt the earlier generic entrants to reduce their prices. Thus, as the number of generics increases, prices to consumers decrease even further. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture approximately 90 percent of brand-name sales within the first full year after a generic product launches.⁴

4. State laws permitting, or in some cases mandating, generic substitution for the brand-name equivalent contribute significantly to the reduction of drug costs and the use of generic drugs.⁵ Generic substitution is the dispensing of a generic bioequivalent drug that contains the same active ingredient(s) as

¹ See *Generic Pharmaceuticals*, Contribution from the United States, OECD Competition Committee, Oct. 14, 2009, available at <http://www.ftc.gov/sites/default/files/attachments/us-submissions-oecd-and-other-international-competition-fora/genericpharma.pdf>.

² See Fed. Trade Comm’n, *Pay-For-Delay: How Drug Company Pay-offs Cost Consumers Billions* (2010) (Pay for Delay Study) at 10, available at <http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

³ See Fed. Trade Comm’n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impacts* (August 2011) (Final Authorized Generic Report) at 48, available at <http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

⁴ See Pay for Delay Study at 8.

⁵ See Fed. Trade Comm’n, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies* (Aug. 2005) (PBM Report) at 12-13, available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Fed. Trade Comm’n, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (Sept. 1985), available at <http://www.ftc.gov/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection>.

the brand-name drug.⁶ In the U.S., generic substitution generally occurs when a consumer presents a prescription to a pharmacist for a brand-name drug. State substitution laws in all states allow pharmacists to fill a prescription written for a brand-name drug with its bioequivalent generic counterpart. These laws usually lead to widespread substitution of generic drugs instead of the brand-name equivalent.⁷ In addition, because generic drugs are substantially less expensive than the brand-name versions, generics offer substantial savings not only to consumers, but also to pharmacies, health plans, prescription benefit managers, and federal and state government pharmaceutical assistance programs such as Medicare and Medicaid. As discussed below, both federal and state laws provide substantial incentives for consumers to use generic versions of drugs. The combination of these incentives leads to greater generic substitution, which in turn significantly lowers prescription drug costs.⁸

5. In recognition of the need to balance the importance of preserving incentives to develop new and innovative drugs against the significant competition that generic drugs can provide, Congress enacted the Hatch-Waxman Act in 1984. Congress intended that Hatch Waxman would “make available more low-cost generic drugs,” while fully protecting legitimate patent claims.⁹ Hatch Waxman establishes a process that gives generic pharmaceutical makers an incentive both to enter the market for a particular drug and to challenge the validity and application of any patents on that drug.

6. A brand-name manufacturer seeking to market a new drug product must first obtain approval from the Food and Drug Administration (FDA) by filing a New Drug Application (NDA) that, among other things, demonstrates the drug’s safety and effectiveness. The NDA filer also must provide the FDA with certain categories of information regarding patents that cover that drug.¹⁰ Upon receipt of the patent information, the FDA lists it in the FDA publication Approved Drug Products with Therapeutic Equivalence, commonly known as the Orange Book.¹¹

7. Hatch-Waxman also allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application (ANDA) upon showing, among other things, that the new drug is bioequivalent to an approved drug.¹² This is of particular importance to generic drug manufacturers, who may use the ANDA process to secure approval of their generic versions of the drug.

8. Hatch-Waxman establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic drug prior to the expiration of a patent or patents relating to the brand-name version of that drug. In such cases, the applicant must: (1) certify to the FDA that the patent is

⁶ There are additional requirements that the generic is, among other things, chemically identical to the brand product in strength, concentration, dosage form, and route of administration.

⁷ By comparison, switching between brand-name drugs requires a change of prescription from a physician. The time, cost, and effort of obtaining that change may reduce price competition between brand-name drugs.

⁸ See John Dicken, Assistant Dir. for Health Care Issues, U.S. Gen. Accounting Office, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy 32 (June 26, 2003). As of 2005, there were approximately 10,000 brand drugs on the U.S. market, and approximately 8,000 generic equivalents. See Food and Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations (25th ed. 2005), available at <http://www.fda.gov/cder/orange/obannual.pdf> (commonly known as the Orange Book). Generic drugs account for nearly 50% of all prescriptions dispensed in the U.S. PBM Report, *supra* note 5, at 13.

⁹ H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2661.

¹⁰ 21 U.S.C. § 355(b)(1).

¹¹ *Id.* § 355(j)(7)(A).

¹² 21 U.S.C. § 355(j).

invalid or is not infringed by the generic product (known as a Paragraph IV certification),¹³ and (2) notify the patent holder of the filing of the certification. If the patent holder files a patent infringement suit against the generic within 45 days, FDA approval of the generic drug automatically is stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

9. To encourage generic drug manufacturers to challenge questionable patents (or to invent around valid ones), the Hatch-Waxman Act provides that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity once it has launched its product. During that 180-day period, the FDA may not approve a potential competitor's ANDA.¹⁴ Although a first-filer can forfeit its exclusivity under certain conditions,¹⁵ ordinarily it will be entitled to 180 days of exclusivity beginning on the first day it begins marketing its generic version of the drug.¹⁶ Even if the first-filer substantially delays marketing its product, a later ANDA filer may not enter the market until the first-filer's 180-day period of marketing exclusivity has expired.¹⁷

10. Against this regulatory backdrop, the FTC has taken many actions to preserve and protect competition in the pharmaceutical sector. Part 2 of this submission focuses on efforts by the FTC and private parties designed to stop pay for delay agreements in which a brand-name company settles patent infringement litigation by compensating the generic challenger to stay out of the market for a period of time. In addition to its own litigation, the FTC has provided *amicus curiae* support in non-FTC litigation, and supported legislative proposals that would ban such anticompetitive agreements. Part 3 discusses unilateral conduct by brand-name companies that may deter generic entry such as: (1) product hopping, where a brand-name pharmaceutical company might seek to remove from the market a brand-name drug that has lost its patent protection, while shifting demand to newly patented drugs that provide no new substantive benefits; and (2) improper use of restricted drug distribution programs, where brand-name companies manipulate Risk Evaluation and Mitigation Strategies to prevent generic competitors from conducting bioequivalence testing, a prerequisite to FDA approval. Part 4 focuses on antitrust enforcement actions that have prevented anticompetitive agreements between generic drug companies. Part 5 surveys recent FTC merger enforcement designed to promote competition in generic drug markets. Finally, part 6 briefly describes ongoing FTC efforts to study an emerging pharmaceutical competition policy issue, the treatment of potential "generic" competition to biologic drugs, protein-based drugs derived from living matter.

2. Stopping Pay for Delay Efforts

11. Generic competition against brand-name drugs usually results in substantial consumer savings. Such competition can arise most rapidly when a generic entrant challenges the patent held by the brand-name manufacturer, either on the ground that the patent is not valid or that the generic does not infringe the patent. A successful patent challenge means that there will be nearly immediate competition between the brand-name drug and the generic equivalent. An unsuccessful challenge, however, means that competition may not occur until the expiration of the patent. The consumer savings from generic entry can be significant. For example, generic competition following successful patent challenges involving just four major brand-name drugs saved consumers an estimated \$9 billion.¹⁸

¹³ *Id.* § 355(j)(2)(A)(vii)(IV).

¹⁴ *Id.* § 355(j)(5)(B)(iv).

¹⁵ *Id.* § 355(j)(5)(D). For example, the 180 days of exclusivity may be forfeited by a failure to market by a specified date, a failure to obtain tentative FDA approval, withdrawal of the ANDA, amendment of the ANDA to non-Paragraph IV status, commission of an antitrust violation, or expiration of the patent.

¹⁶ *Id.*

¹⁷ *See id.* § 355(j)(5)(B)(iv).

¹⁸ The four drugs examined are Prozac (fluoxetine), Zantac (ranitidine), Taxol (paclitaxel), and Platinol (cisplatin). *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the*

12. This section first describes the economic incentives facing brand and generic pharmaceutical companies to limit brand-generic competition. It then describes the consumer harm created by settlements of patent infringement litigation that limit competition between the two, known as pay for delay, reverse payment, or exclusion payment settlements. It proceeds to discuss the FTC's early legal challenges against such settlements. We next explain how the use and the harm of pay for delay deals increased following early judicial rulings. Finally, we look at recent litigation, including the FTC's important win in the Supreme Court, *FTC v. Actavis*, and the Commission's ongoing amicus efforts and encouragement of legislative initiatives to stop pay for delay settlements.

2.1 *Economic Incentives for and Consumer Harm from Pay for Delay Settlements*

13. The competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. In a typical pay for delay settlement of patent infringement litigation, the brand-name manufacturer will pay the potential generic entrant something of value. In exchange, the generic company will delay its entry into the market. In the absence of such a payment, the generic could be expected to enter at an earlier date, at least if the parties nevertheless reached a settlement. Thus, by making an exclusion payment, the brand-name company has paid for delayed entry by the generic. The Hatch-Waxman Act regulatory regime, described in part 1, makes such agreements attractive to both brand-name and generic companies.

14. The reason for such agreements is simple: in nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount to the price of the brand-name product. The difference between the brand's loss and the generic's gain is the money consumers would otherwise save. Consequently, it may be more profitable for both companies if the brand pays the generic to settle the patent dispute and agrees to defer entry.¹⁹

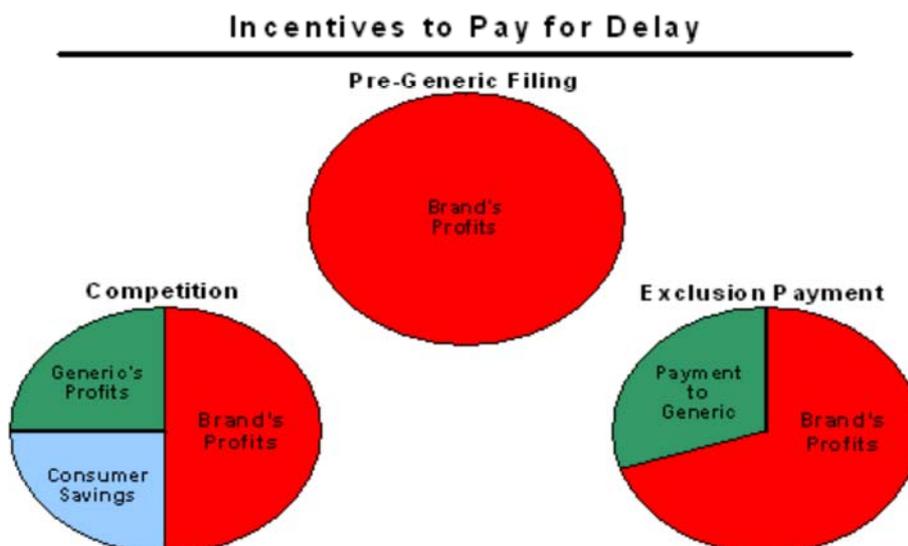
15. By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because the generic company would have prevailed in the lawsuit (significantly, a 2002 FTC study found that generic challengers enjoyed a success rate in excess of 70 percent),²⁰ or because the parties would have negotiated a settlement with an earlier entry date absent the payment.²¹ Instead, consumers pay higher prices because such early generic entry is delayed, as illustrated in the following chart.

Senate Commerce Comm., 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, available at <http://www.gpo.gov/fdsys/pkg/CHRG-107shrg90155/html/CHRG-107shrg90155.htm>.

¹⁹ See generally Michael Salinger et al., *Economics at the FTC: Pharmaceutical Patent Dispute Settlements and Behavioral Economics*, 31 *Review of Industrial Organization* 85–105 (2007); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in *Innovation Policy and the Economy, Volume 4*, 145–87 (Adam B. Jaffe et al. eds. 2004); Carl Shapiro, *Antitrust Limits To Patent Settlements*, 34 *RAND Journal of Economics* 391 (2003).

²⁰ Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration (July 2002) (Generic Drug Study)*, available at <http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study>.

²¹ For example, for a hypothetical patent infringement claim with a 50% chance of success, with 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years of competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and



16. Consumer harm from pay for delay settlements is significant. In 2010, the FTC estimated that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from a ban on such settlements would be approximately \$3.5 billion. This calculation takes into account four factors: (1) the consumer savings that result from generic competition in any given month; (2) the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation; (3) the length of entry delay resulting from such a settlement; and (4) the combined sales volume of drugs for which settlements are likely.²²

2.2 *Early FTC Litigation against Pay for Delay Settlements*

17. Because of the potentially significant anticompetitive effects of settlements between brand-name companies and potential generic entrants, the FTC has, over the past fifteen years, sought to use antitrust enforcement to stop or remedy pay for delay settlements. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower priced, generic drugs is delayed, sometimes for many years.

18. Beginning in the late 1990s, the FTC filed antitrust complaints against brand and generic companies alleging unlawful pay for delay settlements and other misuse of the Hatch-Waxman patent challenge process. The FTC brought two cases that resulted in consent decrees involving a payment from a brand-name manufacturer to a potential generic entrant as part of a settlement of patent claims.²³ In another matter, resolved by entry of a consent order, the FTC's complaint alleged that a brand-name drug company engaged in inequitable conduct before the U.S. Patent and Trademark Office and made false statements to

the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward.

²² See Pay for Delay Study at 8.

²³ *In the Matter of Abbott Laboratories*, Docket No. C-3945 (May 22, 2000) (consent order), available at <http://www.ftc.gov/os/2000/03/abbott.do.htm>; *In the Matter of Hoechst Marion Roussel, Inc.*, Docket No. 9293 (May 8, 2001) (consent order), available at <http://www.ftc.gov/sites/default/files/documents/cases/2001/04/hoechstagr.pdf>.

the FDA to obtain and list patents in the FDA's Orange Book as a strategy to prevent the entry of generic competition.²⁴

19. After bringing these initial cases, the FTC sought additional information about the prevalence of such settlements and related practices by brand-name pharmaceutical companies to limit timely generic entry. The FTC issued subpoenas to over 70 brand-name and generic drug companies requesting information about patent settlements. The information received in response to the subpoenas was described in the FTC's 2002 study on generic drugs.²⁵ Among the central findings was that pay for delay settlements had declined significantly shortly after FTC actions challenging such settlements as anticompetitive became public. The study made several recommendations regarding the Hatch-Waxman framework, including one that called for brand and generic companies that enter into settlements to report them to the FTC. Following up on this recommendation, Congress included a requirement that all such settlements be filed with the FTC and the Department of Justice as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), giving the FTC access to this information. This filing requirement enables FTC staff to review, among other things, settlements of patent cases brought under the Hatch-Waxman Act.

20. The FTC's first fully litigated pay for delay case was brought against Schering-Plough Corporation (Schering).²⁶ Schering, the manufacturer of a brand-name drug called K-Dur 20, settled patent litigation with two potential sellers of generic counterparts, Upsher-Smith Laboratories, Inc. (Upsher) and American Home Products Corporation (AHP). Both generic manufacturers agreed to delay marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling \$60 million to Upsher and \$5 million to AHP.²⁷ After a full administrative trial, the Commission concluded that Schering paid its generic competitors to defer entry and that the settlements provided Schering with more protection from competition than settlements without payments would have afforded. The FTC concluded that absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise. The Commission found that as a result of these agreements, Schering continued to enjoy supracompetitive profits from the sale of K-Dur 20 for several more years, at consumers' expense.

21. Schering appealed the decision and the Eleventh Circuit Court of Appeals set aside the Commission's decision.²⁸ In so deciding, the court focused on whether the agreement exceeded the exclusionary potential of Schering's patent. The court concluded that the patent provided Schering with "the legal right to exclude Upsher and [AHP] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"²⁹ and noted that there was no allegation that the patent claim was a "sham."³⁰ In particular, the court ruled that a payment by the patent holder, accompanied by an agreement by the challenger to defer entry, could not support an inference that

²⁴ *In the Matter of Bristol-Myers Squibb Co.*, Docket No. C-4076 (April 18, 2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>.

²⁵ Generic Drug Study, note 20, *supra*.

²⁶ *In the Matter of Schering-Plough Corp.*, Docket No. 9297, Opinion of the Commission (Dec. 18, 2003), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>, vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

²⁷ The agreement further provided an additional \$10 million to AHP if its product received FDA approval.

²⁸ *Schering*, 402 F.3d at 1058.

²⁹ *Id.* at 1066-67.

³⁰ *Id.* at 1068.

the challenger agreed to a later entry date than it otherwise would have accepted in return for such payment.³¹

22. Despite the court's decision in *Schering*, the Commission continued to pursue its legal arguments in other cases involving reverse payments. In one case brought by private parties where the FTC participated as *amicus curiae*, another U.S. court of appeals issued a decision that effectively immunized pay for delay patent settlements so long as the settlement restrictions did not exceed the scope of the patent. In the *Tamoxifen* case, the plaintiff alleged that AstraZeneca (the brand) paid Barr (the generic) \$21 million to keep its generic off the market until patent expiration. The Second Circuit, in a 2-1 decision, affirmed the district court's dismissal of the complaint. Like the Eleventh Circuit opinion in *Schering*, the majority found no antitrust violation for payments of any size, except where the generic agrees not to market beyond the brand's patent term or where the infringement suit is a sham.³² The Second Circuit followed that precedent in a subsequent case, despite having requested and received an amicus brief from the DOJ urging the same general position as the FTC urged in other cases.³³ Indeed, some of what had been appealed to the Second Circuit was, for technical jurisdictional reasons, transferred to the Federal Circuit, where the FTC also submitted an amicus brief along similar lines.³⁴ In that matter, the Federal Circuit held that using payments to exclude a competitor until patent expiration is legal if the patent was not procured by fraud, the infringement suit settled by the agreement was not a sham, and the exclusion is limited to the scope of the patent claims.³⁵

23. In contrast to these decisions, the Sixth Circuit ruled in a private case that what amounted to a negotiated preliminary injunction (extending beyond the patent claims) keeping a generic off the market pending the litigation's final outcome, in return for payments, was a per se violation of the antitrust laws. The Sixth Circuit explained that: "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."³⁶

2.3 *The Use of Pay for Delay Settlements Increased Following Early Court Decisions*

24. Following these unfavorable judicial rulings in pay for delay cases, pay for delay settlements proliferated. Based on information obtained through the MMA's filing requirement, the FTC determined that by 2004, following early FTC actions challenging these agreements, settlements with payments to a generic patent challenger had essentially stopped. In that year, of the 14 settlements reported to the FTC, not one involved a payment to a generic. Soon, however, pay for delay settlements became commonplace. The FTC staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of the final patent settlements filed with the agencies, 14 of 28, involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some

³¹ *Id.* at 1076.

³² *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

³³ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Case No. 05-cv-2851 (2d Cir.) Amicus Brief for the United States, available at <http://www.justice.gov/atr/cases/cipro.htm>.

³⁴ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009), Fed. Trade Comm'n Amicus Brief available at http://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-ciprofloxacin-hydrochloride-antitrust-litigation/ciprobrief.pdf.

³⁵ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009).

³⁶ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

period of time.³⁷ Overall, between 2005 and 2012, 47 percent (117 of 247) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.³⁸ Given their dramatic growth, the U.S. antitrust agencies became increasingly concerned about the consumer harm caused by such agreements.

25. Not only did pay for delay agreements increase in number following the legal setbacks, but the companies became more creative about how to pay the generics to delay entry. For example, the FTC has encountered settlements involving an agreement licensing the generic to promote or sell the brand-name product instead of entering independently. Other settlements involve overpayment for an unrelated patent, or payment for ingredient supplies or other products rather than a direct cash payment. And brand-name companies also have entered into co-development deals with generics that appear to provide the generic with more than fair market value for the services rendered.

26. A particularly important method of paying for delay that has become popular is the use of authorized generic rights. As explained above, generally, the first generic does not face competition from other generics for the first six months after launch. The 180-day exclusivity provision for the first generic entrant does not, however, prevent the brand from launching a lower-cost, generic-label version of its brand-name drug, known as an authorized generic. In other words, while Hatch-Waxman provides a generic entrant with exclusivity vis-à-vis third-party generic entrants, it does not prevent the brand-name pharmaceutical manufacturer from producing and selling its own generic version of the brand-name drug. Recently, it has become common for a generic to agree to delay its entry as part of the patent settlement and, in exchange, the brand agrees that during that first 180 days, it will not compete by launching its own authorized generic. Two recent FTC studies shed light on how such agreements impact brand and generic drug profits.

27. The FTC undertook an in-depth study of authorized generics in response to concerns raised by Congress that authorized generics may diminish the incentive of other drug manufacturers to produce generic versions of the drug and to challenge a brand's patent protection. In order to address these questions, the FTC conducted a thorough analysis of the market consequences of the introduction of authorized generics and how a brand's commitment to not launch its own generic may play a role in pay for delay settlements. The FTC issued reports of its analysis in 2009 and 2011, both of which used accounting data and documentary evidence obtained under compulsory process from more than 100 brand-name and generic manufacturers, as well as commercially available sales data, to study these issues.

28. The Interim Authorized Generic Report, issued in June 2009, examines the short-term effects of authorized generic competition during the Hatch-Waxman 180-day marketing exclusivity period.³⁹ This

³⁷ See Bureau of Competition Report, Fed. Trade Comm'n, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition (Jan. 2007) available at <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/mmareport2006.pdf>.

³⁸ See Bureau of Competition Report, Fed. Trade Comm'n, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Overview of Agreements Filed in FY 2012: A Report by the Bureau of Competition (Jan. 2013) available at <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>; Bradley S. Albert, Deputy Ass't Dir., Fed. Trade Comm'n, *Are Reverse Payments Dead?* Presentation before ABA Sec. of Antitrust Law, Healthcare & Pharms. Comm. (Nov. 10, 2011).

³⁹ FEDERAL TRADE COMMISSION, AUTHORIZED GENERICS: AN INTERIM REPORT (June 2009) (Interim Authorized Generic Report), available at <http://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf>.

report concludes that: (1) during the exclusivity period, retail and wholesale drug prices are lower when authorized generics are marketed against a single generic drug than when they are not; (2) authorized generic entry during the exclusivity period substantially reduces the revenues of a first-filer generic firm; and (3) patent litigation settlement agreements that delay the introduction of both independent generics and authorized generics can harm consumers by delaying generic drug entry.

29. The Final Authorized Generic Report, issued in August 2011, presents the findings of a thorough review of brand and generic company internal documents relating to authorized generics, in addition to an expanded empirical analysis.⁴⁰ The documentary evidence is consistent with new data analysis confirming the Interim Report's findings with respect to prices and revenues during the exclusivity period, and expands the analysis to consider the long-term impacts of authorized generics. The new empirical analysis found that not only did authorized generic competition cause the first-filer to lose substantial revenues during the exclusivity period, as discussed in the Interim Report, but the effect also persisted even after the exclusivity expired. These findings imply that a brand's promise to not introduce an authorized generic may be very valuable to a first-filer.

30. The loss of first-filer revenues both during and outside of the exclusivity period decreases the profitability of patent challenges by generic manufacturers and thus raises an important question regarding whether the impact is large enough to decrease the number of patent challenges significantly. The FTC's analysis of the impact of authorized generic competition on the incentives to file a Paragraph IV challenge shows that such an effect is limited to relatively small markets or situations where the generic had little chance of winning the patent suit, and is unlikely to affect challenges of higher-revenue drugs. This finding is consistent with data showing that generic companies continue to pursue patent challenges even when they expect to share first-filer status, and thus the exclusivity period if one is granted, with other generic manufacturers.⁴¹

31. The Final Report also considered whether authorized generics might reduce price competition in the long term. Generic drug prices in markets that include an authorized generic competitor were found to be no higher than generic drug prices in markets with the same number of generic competitors, but without an authorized generic competitor.

32. While the FTC has not yet brought an enforcement action against a brand-name drug company for agreeing not to launch an authorized generic during the first-filing generic's exclusivity period in payment for the generic company's agreement to delay entering the market, it has filed amicus briefs urging the U.S. District Courts for the Eastern District of Pennsylvania,⁴² and the District of New Jersey,⁴³

⁴⁰ FEDERAL TRADE COMMISSION, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACTS (August 2011) (Final Authorized Generic Report), available at <http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

⁴¹ Multiple Paragraph IV ANDA filers may hold concurrent exclusivity if they file Paragraph IV certifications as to a patent listed in the Orange Book covering the same brand-name drug on the same day. See Food and Drug Admin. Center for Drug Evaluation and Research, Guidance for Industry, 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (July 2003) available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf>. Exclusivity also may be divided among different ANDA filers on, for example, different strengths of the same drug.

⁴² *In re Wellbutrin XL Antitrust Litig.*, Case No. 2:08-cv-2431, 2433 (E.D. Pa). Fed. Trade Comm'n Amicus Brief available at http://www.ftc.gov/system/files/documents/amicus_briefs/wellbutrin-xl-antitrust-litigation-re/130926wellbutrinbrief.pdf.

as well as the U.S. Court of Appeals for the Third Circuit,⁴⁴ to treat such agreements the same as payments in pay for delay settlement cases.

2.4 Ongoing FTC Litigation against Pay for Delay Settlements

33. The FTC currently has two active pay for delay litigations. In the first, filed in 2008, the FTC charged that Cephalon, Inc. engaged in illegal conduct to prevent competition to its brand-name drug, Provigil, by paying four firms, all first filers, to refrain from selling generic versions of the drug until 2012. The four companies had filed ANDAs with the FDA seeking approval to market a generic formulation of Provigil, contending that their products did not infringe the only remaining patent on Provigil, the formulation patent related to the size of the particles used in the drug, and that the patent was invalid. After Cephalon filed suit alleging infringement, Cephalon entered into agreements with these companies, paying more than \$300 million in exchange for agreements not to sell a generic version of Provigil until 2012. Other generics were prevented from entering the market until all four first-filers relinquished their marketing exclusivity or 180 days had elapsed after one of them entered the market. The FTC's complaint alleges that Cephalon's conduct in entering into patent litigation settlement agreements that included payments designed to prevent generic competition, including payments for unneeded intellectual property licenses and overpayment for co-development deals, constituted an abuse of monopoly power that is unlawful under section 5 of the FTC Act. The case is pending in federal district court in Philadelphia.⁴⁵

34. In 2009, the FTC sued Solvay Pharmaceuticals, Inc. (later acquired by Abbott), as well as two generic drug makers, alleging that Solvay paid to generics to delay generic entry. Solvay marketed a testosterone replacement drug, AndroGel, a prescription pharmaceutical with annual sales in 2009 of more than \$400 million. In May 2003, Watson (later acquired by Actavis) and Paddock, which partnered with Par, each filed applications for FDA approval to market generic versions of AndroGel. Solvay's patent on AndroGel had been issued in January 2003, with an expiration date of August 2020. By early 2006, Watson had received final approval to market its generic product. According to the complaint, it was well known that if Watson or Par were to enter with lower-priced generic versions of AndroGel, Solvay's AndroGel sales would plummet and consumers would benefit from the lower prices. The FTC's complaint alleges that Solvay, realizing the devastating effect generic entry would have on its AndroGel franchise, acted unlawfully to eliminate this threat: Solvay paid Watson and Par a share of its AndroGel profits to abandon their patent challenges and agree to delay generic entry until 2015. The complaint further states that the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing.

35. Prior to discovery, on defendants' motion, the U.S. District Court for the Northern District of Georgia dismissed the case. The FTC then appealed to the Eleventh Circuit, which affirmed the lower court's dismissal, relying on the Eleventh Circuit's "scope of the patent" test governing its prior rulings, including the FTC's *Schering* case.⁴⁶

36. Meanwhile, the private parties in the class action antitrust litigation challenging the same pay for delay settlements at issue in *Schering* appealed to the Third Circuit challenging the New Jersey district

⁴³ *In re Effexor XR Antitrust Litig.*, Case No. 3:11-cv-05479 (D.N.J.). Fed. Trade Comm'n Amicus Brief available at <http://www.ftc.gov/policy/advocacy/amicus-briefs/2013/08/re-effexor-xr-antitrust-litigation>.

⁴⁴ *In re Lamictal Direct Purchaser Antitrust Litig.*, Case No. 14-1243 (3d Cir.). Fed. Trade Comm'n Amicus Brief available at http://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf.

⁴⁵ *FTC v. Cephalon*, Case No. 2:08-cv-2141 (E.D. Pa.).

⁴⁶ *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012) (citing *Schering-Plough Corp. v. FTC*, 402 F.3d 1056) (11th Cir. 2005).

court's grant of defendants' motions for summary judgment. The United States filed an amicus brief in the *In re K-Dur Antitrust Litigation*, asserting that pay for delay settlements should be treated as presumptively unlawful; a U.S. Deputy Solicitor General presented an oral argument on behalf of the United States.⁴⁷ The Third Circuit agreed with the government and rejected the scope of the patent test, finding that pay for delay settlements are prima facie evidence of unreasonable restraints of trade.⁴⁸ The Third Circuit's opinion created a clear split between it and the Second, Eleventh, and Federal Circuits.

37. Following the Eleventh Circuit's dismissal of its AndroGel complaint, the FTC petitioned the Supreme Court for review, which was granted in December 2012. In June 2013, the Supreme Court in *FTC v. Actavis* reversed the Eleventh Circuit and remanded the case to the district court to be tried under a rule of reason analysis. The Supreme Court held that antitrust concerns may arise when, in exchange for the settlement of patent litigation, a brand-name drug manufacturer pays a generic drug manufacturer to defer generic competition. The Court rejected a legal rule that conferred "near-automatic antitrust immunity" on patent settlements when the alleged anticompetitive restraints do not extend beyond the patent's expiration date. Instead, the Court reaffirmed that the legality of an agreement not to compete between a patent holder and a would-be rival is to be assessed using "traditional antitrust factors."⁴⁹ The case is pending in the federal district court in Georgia.⁵⁰

2.5 Legislative Activity

38. Congress has also recognized the anticompetitive effects of pay for delay arrangements and there have been a number of attempts to pass federal legislation addressing those arrangements. In June 2009, the FTC testified in favor of proposed legislation (H.R. 1706) that would ban anticompetitive pay for delay patent settlements.⁵¹ In its testimony, the FTC described the harm to consumers and to the health care system resulting from pay for delay settlements, and concluded that congressional action to prohibit these settlements was both appropriate and timely. Although the House of Representatives adopted a provision similar to H.R. 1706 as part of a comprehensive health care reform measure, the provision was never enacted.

39. Since 2009, the FTC has testified before Congress on numerous occasions about the problem of pay for delay deals and proposed legislation to address it. In July 2010, for example, then-Chairman Jonathan Leibowitz told the House Judiciary Subcommittee on Courts and Competition Policy that the FTC's top competition priority was to stop pay for delay agreements, and that legislation would be the most effective way to do this.⁵² In December of that year, the Director of the FTC's Bureau of Competition

⁴⁷ *In re K-Dur Antitrust Litig.*, Case Nos. 10-2077, 10-2078, 10-2079 (3d Cir.). See <http://www.justice.gov/atr/cases/f271300/271395.pdf> and http://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-k-dur-antitrust-litigation/110518amicusbrief.pdf.

⁴⁸ *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

⁴⁹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 570 U.S. __ (2013).

⁵⁰ *FTC v. Actavis, Inc.*, Case No. 1:09-cv-955 (N.D. Ga.).

⁵¹ *Anticompetitive Pay for Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs* (June 3, 2009) (prepared statement of the Fed. Trade Comm'n presented by Dir. of Bureau of Competition Richard Feinstein), available at <http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf>.

⁵² *Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Division*, Statement before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. (July 27, 2010) (prepared statement of the Fed. Trade Comm'n presented by Chairman Jon Leibowitz), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-federal-trade-commission-bureau-competition/100727antitrustoversight.pdf.

appeared before the same Subcommittee and again said that stopping pay for delay deals was a top priority.⁵³ In 2013, at antitrust oversight hearings before both the House and the Senate Judiciary Committees, the Commission's testimony also identified ending anticompetitive pay for delay agreements as a top priority for the FTC over the past decade.⁵⁴

40. The most recent hearing that Congress held specifically to address pay for delay agreements was in July 2013, just one month after the Supreme Court's ruling in *Actavis*. As explained above, in that case, the Court overruled the "scope of the patent" test adopted by various federal circuit courts that created sweeping antitrust immunity based on mere possession of a patent. At that hearing, Chairwoman Ramirez praised the Supreme Court decision and indicated that the FTC would continue to challenge anticompetitive pay for delay agreements in court. The Chairwoman also indicated that despite the Supreme Court ruling, she continued to support legislation making pay for delay agreements presumptively illegal because it would enhance clarity, create a stronger deterrent effect, and help the FTC move more quickly to stop these harmful agreements.⁵⁵

3. *Unilateral Conduct of Brand-Name Drug Companies*

41. In addition to pay for delay settlements, brand-name companies have devised other methods that may deter generic competition. This part discusses two of those methods, product hopping and manipulation of restricted drug distribution programs.

3.1 *Product Hopping*

42. According to some commentators, brand-name pharmaceutical firms may seek to forestall competition by introducing newly patented products that have minor or no substantive improvements, and driving demand to these newer products, preventing pharmacies from substituting lower-priced generic products for the old brand-name product.⁵⁶ Such product hopping may occur when generic entry is (or is expected to be) imminent.⁵⁷ A brief review of some litigated matters involving product hopping is set forth below.

⁵³ *Antitrust Enforcement in the Health Care Industry*, Statement before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. (Dec. 1, 2010) (prepared statement of the Fed. Trade Comm'n presented by Dir. of the Bureau of Competition Richard A. Feinstein), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-antitrust-enforcement-health-care-industry/101201antitrusthealthcare.pdf.

⁵⁴ *Oversight of the Enforcement of the Antitrust Laws*, Statement before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary, 113th Cong. (Nov. 15, 2013) (prepared statement of the Fed. Trade Comm'n presented by Chairwoman Edith Ramirez), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-enforcement-antitrust-laws-presented/131115antitrustlawtestimony.pdf.

⁵⁵ *Pay for Delay Deals: Limiting Competition and Costing Consumers*, Statement before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights of the S. Comm. on the Judiciary, 113th Cong. (July 23, 2013) (prepared statement of the Fed. Trade Comm'n presented by Chairwoman Edith Ramirez), available at http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pay-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf.

⁵⁶ See, e.g., Mark A. Lemley, *Ignoring Patents*, 2008 Mich. St. L. Rev. 19 at 30 (product hopping involves "[p]atent holders . . . changing the product they sell and restarting the regulatory clock once their patent on the existing product expires or is invalidated"), available at http://www.msulawreview.org/wp-content/uploads/2012/10/2008-1_Lemley.pdf.

⁵⁷ Product hopping raises sensitive policy questions as to whether the new product represents a welfare-increasing innovation or is used simply to delay significantly generic competition and thereby harm consumer welfare.

43. Issues related 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. According to the FTC complaint, generic company Barr planned to launch a generic version of Ovcon as soon it received regulatory approval from the FDA, but instead entered into an agreement in March 2004 with Warner Chilcott to delay generic entry.⁵⁸ Under this agreement, Warner Chilcott had an option to pay Barr \$20 million to secure Barr's agreement not to bring its generic version of the drug to market for five years. Barr also agreed that it would be available as a supplier of Ovcon to Warner Chilcott. In April 2004, Barr received FDA approval to make and sell its generic version of Ovcon. Several weeks later, Warner Chilcott paid Barr the \$20 million required under the agreement, preventing Barr from selling a generic version of Ovcon until May 2009.

44. While the FTC's case was pending, the FTC learned that Warner Chilcott intended to execute a "switch strategy" related to Ovcon. According to the FTC, 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 it would have precluded generic substitution. As a result, even if the FTC had won at trial, generic entry, the relief sought by the FTC, would have resulted in no consumer benefit.

45. To prevent this development, 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. On the same day the FTC filed its injunction, Warner Chilcott waived the exclusionary provision in its agreement with Barr 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.

46. Other lawsuits involved direct allegations of anticompetitive product hops. In *Abbott Laboratories v. Teva Pharmaceuticals U.S.A., Inc.*, generic company Teva alleged that Abbott had "responded to the threat of generic entry . . . by changing the formulation of TriCor [a brand-name drug], not to improve the product, but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor"⁵⁹ in violation of Section 2 of the Sherman Act.⁶⁰ Abbott withdrew TriCor capsules from the market and substituted tablets with different dosage strengths that were not automatically substitutable for the original strengths. Abbott sought to have the antitrust claims dismissed on the grounds that: (1) the introduction of improved formulations and new products is per se legal; (2) generic pharmaceutical producers were not totally foreclosed from the market in question because they could still sell their generic products; and (3) Abbott was under no obligation to help its competitors "free ride" on the TriCor brand. In refusing to dismiss the antitrust case, the reviewing federal district court rejected all three of Abbott's claims.

47. Specifically, the court found that: (1) a rule of reason, not a rule of per se legality, should apply to this new product introduction and that plaintiffs did not need to prove that the new formulations were not

⁵⁸ See *FTC v. Warner Chilcott Holdings, Co., et al*, Case No. 1:05-cv-02179 (D.D.C.). <http://www.ftc.gov/sites/default/files/documents/cases/2005/11/051107comp0410034.pdf>.

⁵⁹ 432 F. Supp. 2d 408 (D. Del. 2006).

⁶⁰ *Id.* at 415.

better than the old versions; (2) the relevant test was whether Abbott's actions "severely restricted the market's ambit," not whether Abbott had completely foreclosed generics from the market; and (3) plaintiffs had not alleged that Abbott had failed to help them, but, rather, that Abbott suppressed competition by blocking the introduction of a generic product.

48. In another case involving allegations of product hopping, *Walgreen Co. v. AstraZeneca Pharmaceuticals*, a federal district court rejected plaintiffs' product hopping claim on the grounds that the brand did not withdraw its branded product from the market.⁶¹ Plaintiffs alleged that as the brand-name drug Prilosec was about to lose patent protection, AstraZeneca introduced Nexium, a drug that plaintiffs claimed was "virtually identical" to Prilosec and offered no medical benefit over it. Plaintiffs asserted that defendant's introduction of Nexium and its effort to switch patients from Prilosec to Nexium, through a major advertising campaign, were aimed at impeding generic competition and maintaining AstraZeneca's monopoly in the relevant market, in violation of Section 2 of the Sherman Act. AstraZeneca claimed that Nexium offered clinical benefits over Prilosec. In granting defendant's motion to dismiss, however, the court did not address that point. Rather, it held that plaintiffs had failed to allege "exclusionary behavior" that is a prerequisite for a finding of a Section 2 violation. Specifically, the court stressed that AstraZeneca had not withdrawn any product from the market or otherwise limited consumer choice. Rather, according to the court, AstraZeneca had actually *added* choices by introducing a new drug to compete with already established drugs (both its own and others) and with the generic substitutes for at least one of the established drugs.

49. In November 2012, the FTC filed an amicus brief in a matter before the U.S. District Court for the Eastern District of Pennsylvania explaining that minor, non-therapeutic changes to a brand-name drug product that harm generic competition can constitute exclusionary conduct that violates U.S. antitrust laws. In that matter, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott*, the FTC stated that the potential for anticompetitive product design is particularly acute in the pharmaceutical industry, in part because a product hop may be profitable even if consumers do not prefer the reformulated version of the product to the original.⁶² In switching its 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.⁶³

3.2 *Misuse of Restricted Drug Distribution Programs*

50. Another way that brand name drug companies may try to prevent generic competition is through the abuse of restricted drug distribution programs. The Food and Drug Administration Amendments Act of 2007 gave FDA authority to require from drug manufacturers approved strategies and policies for safeguarding the distribution of certain drugs or biological products.⁶⁴ Brand-name drug manufacturers may attempt to deter generic entry by manipulating these strategies and policies, known as Risk Evaluation and Mitigation Strategies (REMS). REMS are drug distribution restrictions either mandated by the FDA to ensure that the benefits of the drug outweigh its risks, or imposed by the brand-name company itself on drugs not subject to an FDA-mandated REMS. Examples of REMS range from something as simple as a

⁶¹ 534 F. Supp. 2d 146 (D.D.C. 2008).

⁶² *Mylan Pharms, Inc. v. Warner Chilcott PLC*, Case No. 2:12-cv-03824 (E.D. Pa.).

⁶³ Fed. Trade Comm'n Amicus Brief available at 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.

⁶⁴ See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2011), as amended by the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, 121 Stat. 823 (Sept. 27, 2007).

medication guide or patient package insert, to safety protocols and elements to assure safe use that may limit distribution between a drug seller, wholesalers, and buyers.

51. In order to receive approval from the FDA, generic firms are required to conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the brand-name drug. This testing requires generic firms to purchase a limited amount of the brand-name product. By denying generic competitors access to samples of the drugs needed for bioequivalence testing, a brand-name company can preclude them from meeting FDA requirements and thus exclude generic competition from the market.

52. In March 2013, the FTC filed an amicus brief in the U.S. District Court for the District of New Jersey explaining that brand-name drug companies may improperly use restricted drug distribution programs to impede generic competition. In *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, generic firms Actavis, Apotex, and Roxane alleged that Actelion imposed distribution restrictions preventing them from buying samples of Actelion’s brand-name drugs through customary distribution channels, and that Actelion refuses to sell the drugs directly, thereby precluding them from meeting FDA requirements for developing generic versions of the drugs.⁶⁵ Among other claims, the generic firms alleged that Actelion’s conduct violates the federal antitrust laws. Actelion, meanwhile, sought a broad declaration that it is under “no duty or obligation” to sell its products to potential competitors. Although Actelion contended that its distribution restrictions are required by the FDA, it argued that its right to refuse to sell to the generic firms would apply even without an FDA mandate.

53. The FTC’s amicus brief asserted that Actelion’s legal position, if adopted by the court, could pose a significant threat to competition in the pharmaceutical industry. The FTC’s brief described how the generic firms’ allegations in this case fit within established Supreme Court precedent holding that a monopolist’s refusal to sell to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act. It also clarified that a distribution agreement between a brand-name drug manufacturer and its distributors may violate Section 1 of the Sherman Act, even when the agreement involves a patented product.⁶⁶

54. Recently, Mylan Pharmaceuticals sued Celgene Corporation alleging that Celgene violated the Sherman Act by using its REMS to prevent generic firms, including Mylan, from acquiring necessary samples for bioequivalence testing of two blockbuster brand-name cancer drugs, Thalomid and Revlimid, even though the FDA had determined that Mylan’s testing protocols for the proposed generics were sufficient.⁶⁷ Mylan’s complaint further alleges that Celgene stalled Mylan’s efforts to obtain samples of the drugs by imposing voluminous and unnecessary requests for information, requests that were a pretext to allow Celgene to delay providing samples with an intention of foreclosing potential competition.

4. Anticompetitive Agreements Involving Generic Drug Companies

55. FTC efforts to ensure competitive pharmaceutical markets are not limited to competition between brands and generics, but extend to competition between generics. An early example of these efforts is the FTC’s lawsuit against Mylan Laboratories, Inc. The FTC’s complaint charged that Mylan and three of its generic competitors, Cambrex Corporation, Profarmaco S.R.L., and Gyma Laboratories of America, Inc. carried out a plan designed to give Mylan the power to raise the prices of generic lorazepam and clorazepate tablets by depriving its other generic competitors of the active pharmaceutical ingredient (API)

⁶⁵ *Actelion Pharms Ltd. v. Apotex Inc.*, Case No. 1:12-cv-05743 (D.N.J.).

⁶⁶ Fed. Trade Comm’n Amicus Brief *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

⁶⁷ *Mylan Pharms. v. Celgene Corp.*, Case No. 2:14-cv-02094 (D.N.J.).

necessary to manufacture each product. After foreclosing its competitors from access to the API and becoming the only generic manufacturer of lorazepam and clorazepate in the market, Mylan raised the prices of the two drugs substantially—by 2000-3000 percent, depending on bottle size and strength. The FTC settled the litigation and Mylan paid \$100 million in disgorged profits to compensate injured consumers and state agencies.⁶⁸

56. In the Hatch-Waxman context, generic competition may not only be delayed by brand-name and generic company agreements, it may also be restricted by agreements once the generic enters the market. As explained above in the discussion concerning authorized generics at pp. 9-10, a first generic filer usually faces no competition from other generics during the first 180 days of marketing. Thus, a brand-name drug company's agreement to defer launching its own generic product in exchange for later generic entry not only harms consumers by increasing the length of time that the brand-name product is the only choice available, but also because once the first-filer generic finally enters, it faces no competition from the brand-name company (the only company that *could* compete) for an additional six months. A "no authorized generic" agreement therefore, is not only a payment in exchange for delay, it is also a reciprocal agreement not to compete, independently subject to a rule of reason analysis.⁶⁹

57. Generic manufacturers may also seek to avoid direct competition through manipulation of the Hatch-Waxman Act, where, for example, two generic companies each possess 180 days of marketing exclusivity on a separate dosage level of the same drug. For example, in 2002, the FTC charged that Biovail Corporation and Elan Corporation agreed unreasonably to reduce competition in the market for generic hypertension drug Adalat CC.⁷⁰ Elan was the first to file an ANDA with the FDA on the 30 mg Adalat dosage, while Biovail was the first to file an ANDA on the 60 mg dosage. Pursuant to the Hatch-Waxman Act, Elan qualified for 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail qualified for 180 days of exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second firm to file an ANDA on the dosage for which the other was the first-filer. The two companies entered into agreement that, among other things, provided that Elan would appoint Biovail as the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products and allow Biovail to profit from the sale of both products. The FTC found that this agreement provided the companies substantial incentives not to compete against each other in the market for the 30 mg and 60 mg dosage forms of Adalat. Consistent with this finding, the two companies maintained separate monopolies in the two dosage categories and shared profits, rather than competing against each other in each category. Biovail and Elan agreed to a consent decree with the FTC under which the companies terminated their agreement and agreed not to enter into similar agreements in the future.

58. In 2004, the generic drug manufacturers Alpharma, Inc. and Perrigo Company agreed to surrender \$6.25 million in allegedly illegal profits to settle FTC charges that their agreement to limit competition for over-the-counter (OTC) store-brand children's liquid ibuprofen drove up prices and violated federal law.⁷¹ According to the FTC's complaint in Federal District Court for the District of Columbia, Perrigo paid Alpharma—the only other manufacturer of OTC store-brand children's liquid ibuprofen approved by the FDA—to eliminate Alpharma as a competing supplier. Although Alpharma was the first-filer, and entitled to 180 days of marketing exclusivity, it instead agreed to waive those exclusivity rights so that Perrigo, which was next in line as a generic entrant, would secure the 180-day exclusivity

⁶⁸ *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d (D.D.C. 1999).

⁶⁹ See Fed. Trade Comm'n Amicus Brief in *In re Lamictal Direct Purchaser Antitrust Litig.*, note 42, *supra*.

⁷⁰ *In the Matter of Biovail Corporation and Elan Corporation, PLC*, Docket No. C-4057 (Aug. 15, 2002), available at <http://www.ftc.gov/sites/default/files/documents/cases/2002/10/biovailcmp.pdf>

⁷¹ *FTC v. Perrigo Company and Alpharma Inc.*, Case No. 1: 04-cv-01397 (D.D.C.), available at <http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf>.

period. In exchange, Alharma agreed not to compete with Perrigo for seven years and received a share of Perrigo's profits. Thus, Alharma took itself out of competition with Perrigo in exchange for a share of Perrigo's revenue. The settlements called for Perrigo to pay \$3.75 million and Alharma to pay \$2.5 million to the FTC. In addition, the companies were required to pay state attorneys general \$1.5 million to resolve their claim challenging the same agreement. The FTC's settlements barred the companies from entering into agreements not to compete when either party is the first-filer of an ANDA with the FDA. The settlements also required the companies to notify the FTC of agreements that fall within four narrow exceptions to the general prohibition.

59. U.S. antitrust enforcers other than the FTC have also sought to rein in anticompetitive agreements between generic companies. In February 2014, the State of New York Attorney General challenged an agreement between generic drug competitors Ranbaxy and Teva. Ranbaxy and Teva had agreed to shield dozens of their drugs from legal and regulatory challenges by the other where one of the two held a first-filer exclusivity status in a patent challenge to a brand-name drug. The agreement contained a "no-challenge" provision that protected each company's market position and reduced the risk that each would face generic competition for its products. The consent agreement between the New York Attorney General and the two generics required the parties to terminate the no-challenge agreement, refrain from entering similar agreements in the future, and pay New York State \$300,000.⁷²

5. Generic Pharmaceutical Mergers

60. In recent years, the U.S. antitrust enforcement agencies have sought to stop mergers, or those portions of mergers, that may result in substantial lessening of competition. In many cases, the anticompetitive effects of a transaction can be averted without blocking the entire transaction, thereby preserving merger-produced efficiencies that may benefit consumers. Recent pharmaceutical merger enforcement by the FTC (the U.S. antitrust agency primarily responsible for reviewing pharmaceutical mergers) is summarized below.

61. The FTC has brought a number of merger challenges to protect competition among generic pharmaceuticals. Competition between generics can drive prices as low as 80% or more below the price of the brand name drug, and the FTC's work has shown that, up to a point, pricing is heavily influenced by the number of generic firms in the market for a particular drug. Transactions that reduce the number of competitors producing generic drugs can result in higher prices. Since 2010, the Commission has challenged twelve transactions involving either two generic manufacturers, or one generic and one brand-name company where the competitive overlap involved generic drugs, all of which were resolved by divestitures: Watson and Arrow;⁷³ Hikma and Baxter;⁷⁴ Valeant and J&J;⁷⁵ Valeant and Sanofi-Aventis;⁷⁶ Perrigo and Paddock;⁷⁷ Teva and Cephalon;⁷⁸ Watson and Actavis;⁷⁹ Novartis and Fougera;⁸⁰ Actavis and

⁷² Press Release, State of N.Y. Office of the Attorney General, A.G. Schneiderman Announces Settlement With Generic Pharmaceutical Companies For Entering Into Anticompetitive Arrangement, (Feb. 19, 2014) available at <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-generic-pharmaceutical-companies-entering>.

⁷³ *In the Matter of Watson Pharm., Inc. and Robin Hood Holdings, Ltd.*, Docket No C- 4276 (Jan. 19, 2010).

⁷⁴ *In the Matter of Hikma Pharm. PLC*, Docket No. C-4320 (June 7, 2011).

⁷⁵ *In the Matter of Valeant Pharmaceuticals International, Inc. (Johnson & Johnson)*, Docket No. C-4343 (Feb. 22, 2012).

⁷⁶ *In the Matter of Valeant Pharmaceuticals International, Inc. (Sanofi)*, Docket No. C-4342 (Feb. 22, 2012).

⁷⁷ *In the Matter of Perrigo Company and Paddock Laboratories, Inc.*, Docket No. C-4329 (June 26, 2012).

⁷⁸ *In the Matter of Teva Pharm. Indus., Ltd., and Cephalon, Inc.*, Docket No. C-4335 (Oct. 7, 2011).

⁷⁹ *In the Matter of Watson Pharm., Inc. and Actavis, s Ltd.*, Docket No. C-4276 (Jan. 19, 2010).

Warner Chilcott,⁸¹ Mylan and Strides,⁸² Endo and Boca,⁸³ and Akorn and HiTech.⁸⁴ In each case, the Commission identified one or more markets in which the proposed merger would cause significant anticompetitive harm to consumers by eliminating a current or future generic competitor. These competitive concerns were remedied by requiring the divestiture of one of the overlapping products or assets.

62. Mergers that bring together brand-name pharmaceuticals and potential generic competitors can also raise competitive concerns. In certain cases, the first generic competitor is entitled to a statutory period of exclusivity. Mergers and acquisitions involving suppliers of a brand-name pharmaceutical and its first-to-file generic equivalent may reduce competition in two ways. First, during the generic's period of exclusivity, direct competition between the brand-name (or its authorized generic) and generic pharmaceutical suppliers could be eliminated. Second, competition may be reduced prior to launch if, as is sometimes the case, the brand-name supplier and the first-filer generic are involved in patent litigation, as the consolidation could distort incentives to vigorously defend against patent infringement and promptly launch the generic version. In such circumstances, divestiture may resolve the competitive concerns. Transactions raising these types of concerns include Novartis's acquisition of Fougera,⁸⁵ Teva's acquisition of Cephalon,⁸⁶ and Actavis's acquisition of Warner Chilcott.⁸⁷

6. Emerging Pharmaceutical Competition Policy Issues

63. Finally, the FTC's efforts in the generic pharmaceutical sector are not limited only to competition matters threatening immediate competitive harm. The FTC monitors developments in the pharmaceutical sector to inform both current and future enforcement and advocacy. New business models, technological innovations, and new or modified laws and regulations may affect pharmaceutical competition. The FTC responds to these changes through research, policy recommendations and advocacy, and, when appropriate, enforcement actions to ensure that consumers benefit from these changes.

6.1 Biosimilar and Interchangeable Biologic Drugs

64. The introduction of biosimilar and interchangeable biologic drugs represents one example of an emerging competition issue involving generic drugs. Biologic drugs are protein-based drugs that are derived from natural sources and recombinant DNA technology. Biologics are far more complex and much larger than the chemically synthesized, small molecules that form the basis of most pharmaceutical

⁸⁰ *In the Matter of Novartis AG*, Docket No. C-4296 (Oct. 1, 2010).

⁸¹ *In the Matter of Actavis, Inc. and Warner Chilcott PLC*, Docket No. C-4414 (Dec. 11, 2013).

⁸² *In the Matter of Mylan, Inc.*, Docket No. C-4413 (Dec. 18, 2013).

⁸³ *In the Matter of Endo Health Solutions Inc. and Boca Life Science Holdings, LLC*, Docket No. C-4430 (March 21, 2014).

⁸⁴ *In the Matter of Akorn Enterprises Inc. and Hi-Tech Pharmacal Co. Inc.*, Docket No. C-4452 (April 14, 2014).

⁸⁵ *In the Matter of Novartis AG*, Docket No. C-4296 (Oct. 1, 2010) (transaction that eliminated competition between brand-name diclofenac sodium gel and first-to-file generic version resolved by divestiture of rights to generic version).

⁸⁶ *In the Matter of Teva Pharm. Indus., Ltd., and Cephalon, Inc.*, Docket No. C-4335 (Oct. 7, 2011) (transaction that eliminated competition between authorized generic modafinil and a first-to-file generic version during exclusivity period resolved by supply of authorized generic to marketing partner).

⁸⁷ *In the Matter of Actavis, Inc. and Warner Chilcott PLC*, Docket No. C-4414 (Dec. 11, 2013) (transaction that eliminated competition in four oral contraceptive markets between brand-name or authorized generic version and current or future generic resolved by divestiture and supply agreement).

products, and they usually are far more expensive. They comprise the fastest growing sector within pharmaceuticals, and target such difficult to treat diseases as cancer, diabetes, and multiple sclerosis.⁸⁸

65. In 2010, the U.S. created an abbreviated licensure pathway for follow-on biologic drugs. The pathway is known as the Biologics Price Competition and Innovation Act (BPCIA).⁸⁹ Like the Hatch-Waxman Act,⁹⁰ which created an abbreviated pathway for generic small molecule drugs, the goal of the BPCIA is to create competition for biologic drugs, leading to better patient access and lower costs.

66. The BPCIA pathway includes separate provisions for “biosimilar” and “interchangeable” biologic drugs. A biologic drug is biosimilar if data shows that the product is highly similar to an approved biologic drug and there are no clinically meaningful differences between the products.⁹¹ A biologic drug is interchangeable if it is expected to give the same clinical result as the approved product and, for a product administered more than once, the interchangeable and approved product can be switched without increasing safety risks.⁹² Collectively, biosimilar and interchangeable biologic drugs are often referred to as “follow-on biologics” or “FOBs.”

67. The FDA is promulgating rules to approve biosimilar and interchangeable biologic drugs. At the same time, several states’ legislatures are addressing state-specific provisions related to FOB substitution. Meanwhile, other jurisdictions with approval pathways similar to that of the U.S. have begun to experience FOB competition.

68. On February 24, 2014, the FTC held a workshop to address each of these issues.⁹³ The Commission explored: (1) how state substitution laws may affect the development of FOB competition; (2) how naming conventions may affect FOB competition; (3) how FOB competition has evolved in other countries with comparable prescription drug regimes; and (4) how FOB competition is evolving in the U.S. The Commission will use the evidence collected at the 2014 workshop, together with independent research, to continue to monitor FOB competition policy developments.

⁸⁸ *Health Policy Brief: Biosimilars*, Health Affairs 1 (Oct. 10, 2013), available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_100.pdf (“[Biologics] account for a substantial and increasing share of the pharmaceutical market and a growing share of health care costs”).

⁸⁹ See Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A, §§ 7001–7003 of the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119, 804–21 (2010).

⁹⁰ See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* (2011), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98–417, 98 Stat. 1585 (codified as amended in scattered sections of 21 & 35 U.S.C.), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, § 1112, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. § 355).

⁹¹ 42 U.S.C. §262(i)(2).

⁹² 42 U.S.C. §262(i)(3).

⁹³ *Follow-on Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, available at <http://www.ftc.gov/news-events/events-calendar/2014/02/follow-biologics-workshop-impact-recent-legislative-regulatory>. The workshop built on the Commission’s prior study published in its June 2009 report. See Fed. Trade Comm’n, *Emerging Health Issues: Follow-On Biologic Drug Competition* (June 2009), available at <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>. The FTC concluded that: (1) the likely market dynamics of FOB competition will resemble brand-to-brand drug competition, rather than brand-generic drug competition under the Hatch-Waxman Act because, unlike generic drug entry, FOB entry does not result in steep price discounting or rapid acquisition of market share by FOB manufacturers; (2) the existing U.S. patent system and market-based pricing are likely to be sufficient to support continued pioneer and FOB biologic drug innovation; and (3) erecting entry barriers in the form of additional regulatory exclusivity periods and special patent resolution procedures would likely harm consumers by delaying FOB entry and decreasing the pace of biotech innovation.