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ROUNDTABLE ON GENERIC PHARMACEUTICALS

-- Contribution by the Delegation of the United States --

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ROUNDTABLE ON GENERIC PHARMACEUTICALS

-- Note by the United States --

1. This paper discusses the efforts of the United States Government to foster a competitive and innovative pharmaceutical marketplace, principally (but not exclusively) by promoting competition between branded and generic pharmaceuticals. Restrictions on such competition, often accomplished through what the Federal Trade Commission (“FTC”) has termed “pay for delay” settlements or “exclusion payments” are among the biggest barriers to competition in the United States, costing consumers an estimated \$3.5 billion per year. This note also briefly touches upon policies other than the promotion of competition between branded and generic pharmaceuticals that are aimed at producing a more competitive pharmaceutical marketplace. These policies include efforts to combat restraints on competition that involve agreements or mergers between branded drug producers; agreements or mergers between generic drug producers; and regulatory distortions of competition (including through merger). Finally, the paper briefly describes the competitive potential of “biologic” drugs.

1. Introduction

2. The patent system is essential to a dynamic and innovative pharmaceutical industry. Patent protection is widely acknowledged to promote innovation in the pharmaceutical industry by allowing companies to recoup the costs of their innovations.¹ In particular, patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of pharmaceuticals.² Moreover, by disclosing inventions in the patent application process, the patent system encourages generic companies to innovate by designing around brand-name company patents.³ United States law further encourages generic competition by permitting generic applicants to rely on the brand-name company’s proprietary data demonstrating the safety and efficacy of the brand-name drug product.⁴

3. Competition between branded and generic pharmaceutical manufacturers provides consumers enormous savings. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 70 to 80 percent of the brand-name counterpart, and gains

¹ Several commentators have argued that patents are particularly important to stimulating innovation in the pharmaceutical industry. See W.M. Cohen, R.R. Nelson and J.P. Walsh, *Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, National Bureau of Economic Research, Working Paper 7552 (Feb. 2000, rev. 2004); Richard Levin, Alvin Klevorick, Richard Nelson, and Sidney Winter, *Appropriating the Returns from Industrial Research and Development*, Brookings Papers on Economic Activity 783-820 (1987, no. 3); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Management Science*, 173-181 (1986).

² Federal Trade Commission, *To Promote Innovation: The Proper Balance Of Competition And Policy* (Oct. 2003) (“IP Report”), Ch. 3, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

³ IP Report, Ch. 3, at 9.

⁴ *Id.*, Ch. 3, at 9-10.

substantial share from the brand-name product in a short period of time.⁵ Subsequent generic entrants may enter at even lower prices – 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 increase, 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 from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.⁶

4. Generic substitution laws in most states within the United States contribute significantly to the reduction of drug costs and the use of generic drugs instead of the branded equivalent.⁷ This, too, benefits consumers. Generic substitution is the dispensing of a generic bioequivalent drug product that contains the same active ingredient(s) as the brand name drug.⁸ In the United States, generic substitution generally occurs when a consumer presents a prescription for a branded drug. All states allow pharmacists to fill a prescription written for a branded drug with its bioequivalent generic equivalent. These laws generally lead to rapid substitution (or uptake) of generic drugs instead of the branded equivalent.⁹ In addition, because generic drugs are substantially less expensive than their brand name counterparts, generics offer substantial discounts to pharmacies and health plans and health plans, HMOs, and federal and state government provide substantial incentives for patients to use generic versions of drugs. The combination of these incentives means that generic substitution significantly lowers prescription drug costs.¹⁰

5. In recognition of the importance of preserving incentives for innovation that would continue to bring new drugs to market, as well as the important competition that generic drugs can provide, Congress enacted the Hatch-Waxman Act in 1984. Congress intended that the Act would “make available more low cost generic drugs,” while fully protecting legitimate patent claims.¹¹ The Act sets up a process that was

⁵ See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) (“CBO Study”), available at <<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>> (hereinafter “CBO Study”); see generally David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87.

⁶ CBO Study, xiii.

⁷ See FEDERAL TRADE COMMISSION, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL ORDER PHARMACIES 12-13 (Aug. 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Alison Masson and Robert L. Steiner, FTC Bureau of Economics Report, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (Sept. 1985).

⁸ 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.

⁹ By comparison, switching between branded drugs requires a change of prescription from a physician, the time, cost, and effort of which reduces price competition between branded drugs.

¹⁰ See John Dicken, Assistant Director 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 United States 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 United States. PHARMACY BENEFIT MANAGERS REPORT, *supra* note 7, at 13.

¹¹ H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2661.

intended to give generic pharmaceutical makers both an incentive to enter the market for a particular drug market and to challenge any applicable patents on that drug to test their validity and application.

6. A brand-name drug 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 product’s safety and efficacy. When it files the NDA, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.¹² Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled “Approved Drug Products with Therapeutic Equivalence,” commonly known as the “Orange Book.”¹³

7. The Hatch-Waxman Act 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.¹⁴ This is of particular importance to generic drug manufacturers, who may use the ANDA process to secure approval of its generic version of the drug.

8. The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand-name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent is invalid or is not infringed by the generic product (known as a “Paragraph IV certification”);¹⁵ and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically 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, 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, during which the FDA may not approve a potential competitor’s ANDA.¹⁶ Although a first-filer can forfeit its exclusivity under certain conditions,¹⁷ ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.¹⁸ Even if the first filer substantially delays marketing its product, under the prevailing interpretation of the Hatch-Waxman Act, a later ANDA filer may not enter the market until the first filer’s 180-day period of marketing exclusivity has expired.¹⁹

10. Against this regulatory backdrop, the FTC has taken numerous steps to preserve or enhance competition in the pharmaceutical sector. These efforts are described in this note, which is divided into six parts, including this introductory section. Part 2 of this note focuses on efforts by the FTC and private parties designed to combat anticompetitive agreements between branded and generic producers aimed at delaying generic entry into the market. Although these efforts have resulted in litigation, the FTC recently

¹² 21 U.S.C. § 355(b)(1).

¹³ *Id.* § 355(j)(7)(A).

¹⁴ 21 U.S.C. § 355(j).

¹⁵ *Id.* § 355(j)(2)(A)(vii)(IV).

¹⁶ *Id.* § 355(j)(5)(B)(iv).

¹⁷ *Id.* § 355(j)(5)(D).

¹⁸ *Id.*

¹⁹ *See id.* § 355(j)(5)(B)(iv).

has supported legislative proposals that would ban such anticompetitive agreements. Part 3 of this note focuses on FTC actions that have prevented anticompetitive agreements between generic pharmaceutical companies. Part 4 describes the anticompetitive potential of “product hopping,” whereby a branded pharmaceutical company might seek to introduce new patented pharmaceutical products that provide no real benefits but are designed to forestall generic competition. Recent litigation aimed at blocking alleged product hopping is summarized. Part 5 surveys FTC merger enforcement designed to promote competition in pharmaceutical markets. Finally, part 6 briefly describes ongoing FTC efforts to study emerging pharmaceutical competition policy issues, including the treatment of “biologic” drugs (protein-based drugs derived from living matter) and “authorized generic” drugs (generic drugs introduced by brand name pharmaceutical producers).

2. Reverse Payments Litigation Under the Hatch-Waxman Act

11. Competition by generic drugs against branded pharmaceuticals has the potential for substantial consumer savings. Such competition can arise most rapidly when a generic entrant challenges the patent held by the branded pharmaceutical manufacturer, either on the ground that the patent is not valid or that the generic does not infringe the patent. A successful challenge means that there will be nearly immediate competition between the branded drug and the generic equivalent. An unsuccessful challenge, however, means that meaningful competition may be delayed for many years, until the expiration of the patent. The consumer savings can be significant. Generic competition following successful patent challenges involving just four major brand-name drugs is estimated to have saved consumers more than \$9 billion.²⁰

12. This Section describes first the economic incentives facing branded and generic pharmaceutical manufacturers to limit competition between each other. It then describes the consumer harm created by settlements of patent litigation that limit competition between the two, known as “pay for delay” settlements, or “exclusion payments.” It proceeds to describe the investigatory efforts the FTC has taken as well as the challenges the FTC has brought regarding such settlements. The following subsections describe the FTC’s concerns with recent judicial rulings regarding pay for delay settlements, continued litigation efforts by the FTC, and legislative initiatives that would make pay for delay settlements unlawful.

2.1 The 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, the branded manufacturer will pay the potential generic entrant some amount of money. In exchange, the generic company will delay its entry into the market. In the absence of such an exclusion payment, the generic could be expected to enter at an earlier date. Thus, by making an exclusion payment, the branded pharmaceutical company has paid for delayed entry by the generic. The Hatch-Waxman Act regulatory regime, described in Section 1, makes such agreements easily possible.

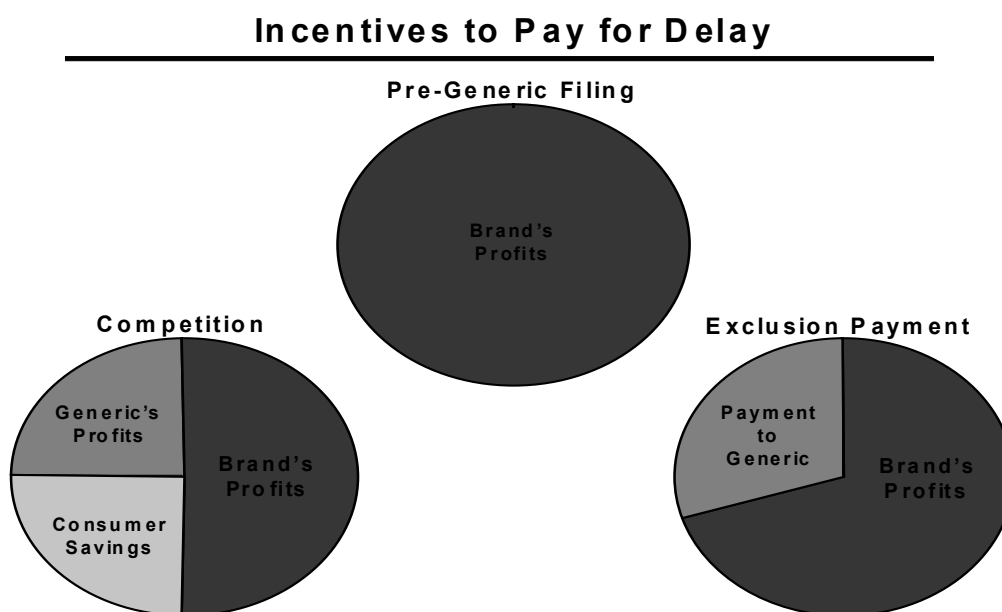
14. The reason for such agreements is simple: in nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand-name product. The difference between the brand’s loss and the generic’s gain is the money consumers save. Consequently, it will typically be more profitable for both

²⁰ *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass’n) at 12, available at <http://commerce.senate.gov/hearings/042302jaeger.pdf>.

companies if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry.²¹

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 companies 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),²² or because the parties would have negotiated a settlement with an earlier entry date absent the payment.²³ Instead, consumers pay higher prices because such early generic entry is delayed, as illustrated in the following chart.

16. Consumer harm from pay for delay settlements is significant. An FTC study has estimated that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from



²¹ 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).

²² FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* (July 2002) (“Generic Drug Study”), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

²³ 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 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. The appellate courts’ approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee’s claims.

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 settlement; and (4) the combined sales volume of drugs for which settlements are likely.²⁴ Overall, the calculation determines how much delay of entry such settlements create, and how much each month of delay costs consumers in the form of higher prices during the period of delay when there is no generic competition.

17. The FTC calculated the \$3.5 billion estimate in the following way. First, on average, consumers save 77% in a mature market in which generic drugs exist relative to pre-generic price levels.²⁵ Next, the FTC determined that agreements with delay payments on average delay entry for 17 months (1.4 years) longer than agreements without payments. Thus, for that 17-month period, consumers do not benefit from generic competition and the lower prices it brings. Third, approximately \$90 billion of branded drug sales are subject to patent litigation.²⁶ Accordingly, \$90 billion is the total value of sales that pay for delay settlements could affect. Based on historical averages, roughly 15% of these challenges will end in settlement, and 24% of settlements include an exclusion payment.²⁷ This means that the total value of drug sales affected by pay for delay settlements is about \$3.2 billion per year.²⁸ Thus consumers lose savings of 77% on that amount each year, for 17 months, leading to an annual cost to consumers of \$3.5 billion.²⁹

2.2 *Litigation by FTC Against Pay for Delay Settlements*

18. Because of the potentially significant anticompetitive effects of settlements between branded pharmaceutical companies and potential generic drug entrants, the FTC has over the past decade sought to use antitrust enforcement to stop pay for delay settlements. These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product. 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.

19. In the late 1990s, the Commission began to bring antitrust challenges to some settlements reached under this patent challenge process that Hatch-Waxman established. The FTC brought two cases that resulted in consent decrees involving a payment from a branded-drug manufacturer to a potential

²⁴ See Jon Leibowitz, Speech at Center For American Progress, “Pay-for-Delay Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution)” (June 23, 2009), at 12, *available at* <http://ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf> (“Pay for Delay Speech”).

²⁵ Pay for Delay Speech, at 13. This figure derives from a combination of the average 85% savings of a generic drug in lieu of the branded equivalent multiplied by the typical 90% of market share that the generic obtains.

²⁶ *Id.* at 13. The figures are based on industry health data and FDA listings of drugs subject to challenge under Hatch-Waxman.

²⁷ *Id.* at 14.

²⁸ \$90B X 15% X 24%.

²⁹ Pay for Delay Speech, at 14. The Bureau of Economics also calculated savings under differing assumptions of lower and higher settlement rates and different length of delay. Under the most conservative assumption of lower settlement rates and shorter delays for generic entry pursuant to settlement, the consumer costs of settlements was \$.7 billion per year. Under the most liberal assumptions, with lengthier delays and higher settlement rates, the cost to consumers was \$7.5 billion per year.

generic entrant as part of a settlement of patent claims.³⁰ In addition, the FTC reached a consent decree in another matter involving a related strategy of listing patents in the FDA’s Orange Book in order to prevent the entry of generic competition for two anti-cancer drugs and an anti-anxiety agent.³¹

20. After bringing these initial cases, the FTC sought additional information about the prevalence of such settlements and related practices by branded pharmaceutical companies to limit timely generic entry. The FTC, pursuant to its statutory authority, issued subpoenas to over 70 branded and generic drug manufacturers requesting information about patent settlements. The information received in response to this subpoena was described in the FTC’s 2002 study on generic drugs.³² Among the central findings was that such settlements had occurred, but 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 companies that enter into settlements to report them to the FTC. Congress enacted a requirement that all such settlements be filed with the FTC and the Department of Justice in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA Act”), giving the FTC access to this information. This filing requirement enables FTC staff to review all settlements of patent cases brought under the Hatch-Waxman Act.

21. The first fully litigated case brought by the FTC was against Schering-Plough Corporation (“Schering”).³³ Schering, the manufacturer of a brand-name drug called “K-Dur 20,” settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. (“Upsher”) and American Home Products Corporation (“AHP”). The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling \$60 million to Upsher and \$5 million to AHP.³⁴ A full trial was held before an administrative law judge, and the Commission reviewed the entire record *de novo*. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment. This was the result either because a settlement with an earlier entry date might have been reached, or because continuation of the litigation without settlement would yield a greater prospect of competition at an earlier date. The Commission found that, as a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

22. The court of appeals set aside the Commission’s decision in *Schering*.³⁵ The court assessed whether the agreement exceeded the exclusionary potential of Schering’s patent. The court relied on the supposition 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

³⁰ See Abbott Laboratories, No. C-3945 (May 22, 2000) (consent order), *available at* <http://www.ftc.gov/os/2000/03/abbott.do.htm>; Hoechst Marion Roussel, Inc., No. 9293 (May 8, 2001) (consent order), *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>.

³¹ Bristol-Myers Squibb Co., No. C-4076 (April 18, 2003), *available at* <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>.

³² Generic Drug Study, note 22, *supra*.

³³ *In the Matter of Schering-Plough Corp., Upsher-Smith Labs., and American Home Products 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 (11 Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

³⁴ The agreement further provided an additional \$10 million to AHP if its product received FDA approval.

³⁵ *Schering*, 402 F.3d, at 1058.

Schering's patent,"³⁶ and noted that there was no allegation that the patent claim was a "sham."³⁷ 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 the challenger agreed to a later entry date in return for such payment, even if there was no other plausible explanation for the payment.³⁸

23. Despite the court's decision in *Schering*, the Commission has continued to pursue its legal arguments in other cases involving reverse payments. In one recent case, brought by private parties but in which the FTC participated as an *amicus curiae*, another United States court of appeals also issued a decision that effectively immunized reverse payment patent settlements. In the *Tamoxifen* case, the plaintiff alleged that Zeneca (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 would allow payments of any size to be made, except where the generic agrees not to market beyond the brand's patent term or where the infringement suit is a sham.³⁹ Third, the FTC participated as an *amicus curiae* in a pay for delay case appealed to the Federal Circuit. In that matter, the Federal Circuit held that using exclusion payments to exclude a competitor until patent expiration is *per se* legal.⁴⁰

24. In contrast to these cases, the Sixth Circuit ruled in a private case that a pay for delay settlement was a *per se* violation of the U.S. antitrust laws, explaining 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."⁴¹

25. In 2008, the FTC charged that Cephalon, Inc. engaged in illegal conduct to prevent competition for its branded drug, Provigil, by paying four firms to refrain from selling generic versions of the drug until 2012. Provigil is used to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shiftwork sleep disorder. The four companies had applied to the Food and Drug Administration for approval to market a generic formulation. In the ensuing patent case, the generic companies argued 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 challenged the validity of the patent. Cephalon entered into agreements with these companies, paying more than \$200 million in exchange for agreements not to sell a generic version of Provigil until 2012. No other generic company could enter the market until all four "first filers" relinquished their marketing exclusivity or 180 days had elapsed after one of them entered the market. By these agreements, Cephalon effectively prevented any generic from entering the market until at least 2012. The FTC's complaint before the federal district court alleges that Cephalon's conduct in entering into patent litigation settlement agreements that included payments designed to prevent generic competition constituted an abuse of monopoly power that is unlawful under section 5 of the FTC Act. The case remains pending in the federal district court in Philadelphia.

26. Most recently, the FTC sued Solvay Pharmaceuticals, Inc., as well as two generic drug makers. Solvay manufactures a testosterone-replacement drug, AndroGel, a prescription pharmaceutical with

³⁶ *Id.* at 1066-67.

³⁷ *Id.* at 1068.

³⁸ *Id.* at 1076.

³⁹ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

⁴⁰ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 577 U.S. ___ (U.S. June 22, 2009) (No. 08-1194).

⁴¹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

annual sales of more than \$400 million. In May 2003, Watson 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 cheaper generic versions of AndroGel, Solvay's AndroGel sales would plummet and consumers would benefit from the lower prices. The 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. As a result, the complaint states that the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing. The case is pending in federal court in Georgia.

2.3 *Current Status of Reverse Payment Jurisprudence*

27. The prospects for effective antitrust enforcement against anticompetitive agreements between branded and generic pharmaceutical manufacturers are substantially less encouraging today than they were in 2001. Four U.S. circuit courts have examined the competitive effects of settlements featuring exclusion payments from the patent holder of a branded drug to a potential generic entrant (or entrants) that agreed not to enter the market until a later date. One circuit found an agreement *per se* illegal in which the generic manufacturer received payments and agreed not to compete during the pendency of the litigation using the product at issue or any non-infringing product.⁴² Three other circuits have not found antitrust liability.⁴³ However, recently, as *amicus curiae* in a case before the United States Court of Appeals for the Second Circuit, the United States Department of Justice took the position that a settlement that involves a payment from a branded to a generic firm in exchange for an agreement not to compete and to withdraw a patent validity challenge in the context of the Hatch-Waxman Act is presumptively anticompetitive. If the plaintiff shows that the generic manufacturer withdrew its challenge to the patent's validity; that money (or other consideration serving the same purpose) flowed from the patent holder to the generic drug firm; and that the payment accompanied the agreement to withdraw the validity challenge, it has established a *prima facie* case.⁴⁴

2.4 *The Decisions by Courts Have Resulted in Continued Use of Pay for Delay Settlements*

28. These judicial rulings on reverse payments have had a noticeable effect on the settlements occurring in such patent cases. Based on data obtained through the MMA Act, settlements with payments to the generic patent challenger had essentially stopped by 2004. In that year, of the 14 settlements reported to the FTC, not one involved a payment to generic.⁴⁵ In 2005, most of which occurred before the

⁴² *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

⁴³ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

⁴⁴ See Brief for the United States as *amicus curiae* in response to the Court's invitation in *In re: Ciprofloxacin Hydrochloride Antitrust Litigation* (2d Cir. July 6, 2009), available at <http://www.usdoj.gov/atrl/cases/f247700/247708.htm>.

⁴⁵ Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition, 7 fig. 3 (May 2008), available at <http://www.ftc.gov/os/2008/05/mmaact.pdf> ("2008 MMA Report"); Bureau of Competition Report, Federal Trade Commission, 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 (Apr. 2007), available at

decision in *Schering*, only 3 out of 11 settlements involved a payment to the generic company. However, by 2006 half of the settlements reported (14 of 28) involved a payment to the generic. And in 2007, 14 out of 33 involved a payment. The staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of all of the final patent settlements (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 period of time. Overall, since 2005, 69 percent (22 of 32) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry.⁴⁶ Given this burgeoning activity, the U.S. antitrust agencies are increasingly concerned about the consumer harm caused by such agreements. When a patent holder makes a payment to a challenger to induce it to agree to a later entry than would otherwise occur, consumers are harmed – either because a settlement with an earlier entry date might have been reached, or because continuation of the litigation without settlement would yield a greater prospect of competition.

29. Moreover, there are several other ways that a brand can compensate a generic to delay its entry. For example, as explained above, generally, the first generic does not face competition from other generic for the first six months after it is launched. For example, the FTC has encountered settlements in which the generic is licensed to promote or sell the branded product instead of entering with its own generic. Other settlements may involve overpayment for an unrelated patent, ingredient supplies, or other products instead of a direct cash payment for delay. And branded companies have also entered into co-development deals with generics that appear to provide the generic with more than fair value with respect to the generic's share.

30. A particularly important method of paying for delay that has recently arisen is through the use of authorized generic rights. The 180-day exclusivity provision for the first generic entrant does not prevent the brand from launching its own generic (known as an "authorized generic"). In other words, while a generic entrant has exclusivity vis-à-vis third-party generic entrants, the branded pharmaceutical manufacturer is not limited under the Hatch-Waxman Act from producing and selling its own generic version of the branded drug. Recently, it has become common for the 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 with an authorized generic. Such a promise by the brand can substantially increase the generic's revenues when it does enter.

31. A recent FTC study determined that over the past five years, branded companies have frequently used a promise not to compete with the generic through use of an authorized generic, as part of a patent

<http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

⁴⁶ Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition* (May 2008), available at <http://www.ftc.gov/os/2008/05/mmact.pdf>; Bureau of Competition Report, Federal Trade Commission, *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* (Apr. 2007), available at <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

settlement agreement.⁴⁷ During the period 2004-2008, 38 drug patent settlements were reported to the FTC under the MMA Act in which authorized generics were limited by the terms of the agreement. Of those 38 settlements, 20 included a provision explicitly barring the branded drug manufacturer from creating an authorized generic to compete with the entering generic during the period of marketing exclusivity.⁴⁸ Another 10 settlements involved similar provisions that either barred an authorized generic or provided strong disincentives to the branded company to introducing an authorized generic.⁴⁹ The remaining 8 settlements used authorized generic rights in other ways that provided benefits to the entering generic.⁵⁰

2.5 *Legislative Activity*

32. 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 is both appropriate and timely. The FTC concluded that legislation is likely to be swifter and more comprehensive than litigation in preventing anticompetitive settlements, and the arguments made by some supporters of pay for delay settlements are “contradicted by experience in the market.” The testimony concluded that the provisions of H.R. 1706 – legislation introduced by House Committee on Energy and Commerce Waxman and other to bar pay for delay settlement – “offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements.” The prospects for the passage of such legislation are uncertain and remain in the hands of Congress. This testimony built on several previous testimonies by the Commission regarding this legislative proposal and other similar ones in recent years.⁵²

33. In July 2009, the House Commerce and Energy Committee approved H.R. 1706 and incorporated into its Health Care Reform Bill. A companion bill awaits action in the Senate Judiciary Committee.

3. **Anticompetitive Agreements Involving Competing Generic Pharmaceutical Producers**

34. The benefits of generic entry, outlined above, may be severely curtailed if pharmaceutical companies agree to limit competition among their generic products. The FTC has been vigilant in combatting anticompetitive arrangements of this sort. Generic manufacturers may avoid direct competition

⁴⁷ FEDERAL TRADE COMMISSION, AUTHORIZED GENERICS: AN INTERIM REPORT (June 2009), available at <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf> (“*Authorized Generics Report*”). As discussed in part 6 of this note, however, authorized generics do have a precompetitive potential, when not misused as part of a restrictive agreement to defer generic entry by generic pharmaceutical firms.

⁴⁸ *Authorized Generics Report*, Ch. 2, at 6-9.

⁴⁹ *Id.*, Ch. 2, at 9-10.

⁵⁰ *Id.*, Ch. 2, at 10.

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 Federal Trade Commission presented by Director of Bureau of Competition Richard Feinstein), available at <http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf>.

⁵² See, e.g., *How Pay for Delay Settlements Make Consumers and the Federal Government Pay More For Much Needed Drugs*, Statement Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 111 Cong. (2009) (prepared statement of the Fed. Trade Comm’n presented by Comm’r J. Thomas Rosch.), available at <http://www.ftc.gov/os/2009/03/P859910payfordelay.pdf>.

through manipulation of the Hatch-Waxman Act, because its framework facilitates anticompetitive agreements. In these cases, two generics, each entitled to 180-day exclusivity on their generic variants of a branded drug, may agree to limit competition between them. The possibility arises because the two different dosage levels each were entitled to separate 180-day exclusivity periods.

35. In 2002, the FTC charged that Biovail Corporation and Elan Corporation agreed to unreasonably reduce competition in the market for a generic hypertension drug, Adalat CC.⁵³ Elan was the first to file with the FDA an Abbreviated New Drug Application (ANDA) on the 30 mg Adalat dosage, and 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 which, 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.

36. In 2004, the generic drug manufacturers Alpharma, Inc. and Perrigo Company agreed to give up \$6.25 million in 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.⁵⁴ 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 U.S. Food and Drug Administration (FDA) – to eliminate Alpharma as a competing supplier. Although Alpharma was the first filer, and entitled to 180 days of 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 period. In exchange, Alpharma agreed not to compete for seven years with Perrigo and received a share of Perrigo's profits. Thus, Alpharma 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 Alpharma 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 abbreviated new drug application (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.

⁵³ *In the matter of Biovail Corporation and Elan Corporation, PLC*, Docket No. C-4057, Complaint (Aug. 15, 2002), available at <http://www.ftc.gov/os/2002/08/biovalcmp.pdf>.

⁵⁴ *FTC v. Perrigo Company and Alpharma Inc.*, Civil Action No. 1: 04CV01397 (RMC), Complaint (D.D.C. Aug. 12, 2004), available at <http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf>.

4. “Product Hopping”

37. According to some commentators, brand name pharmaceutical firms may seek to forestall competition by introducing new patented products that have minor or no substantive improvements but prevent pharmacies (and thus consumers) from substituting lower-priced generic products for the old branded product.⁵⁵ Such “product hopping” may occur when generic entry is (or is expected to be) imminent.⁵⁶ A brief review of a few litigated matters involving “product hopping” is set forth below. This case law is very limited; judicial analysis of this topic is at an early stage.

38. Issues related to product hopping arose in the FTC’s investigation of the Warner Chilcott pharmaceutical company’s attempt to stifle generic competition for the prescription birth control drug Ovcon.⁵⁷ According to an FTC complaint filed in 2005, the pharmaceutical company Barr planned to launch a generic version of Ovcon as soon it received regulatory approval from the U.S. Food and Drug Administration (FDA). A 2005 FTC complaint alleged that Warner Chilcott entered into a March 2004 agreement with Barr to forestall generic entry. Under this agreement, Warner Chilcott would have 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 if Warner Chilcott so requested. 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. While the case was pending in court, the FTC learned that Warner Chilcott intended to execute a “switch strategy” related to Ovcon. The plan, according to the Commission, was to launch a new, chewable version of Ovcon, and then to stop selling Ovcon, in order to convert consumers to the new product. Such a strategy could have essentially destroyed the market for generic Ovcon before the resolution of the trial, because if regular Ovcon were unavailable, generic substitution at the pharmacy would be unavailable. As a result, even if the FTC had won at trial, generic entry (the relief sought by the FTC) would have been meaningless.

39. To prevent this development, on September 25, 2006, the FTC filed for a preliminary injunction that, if granted, would have required Warner Chilcott to continue to make regular Ovcon to allow for the eventual entry of a generic version, until the case could be resolved on the merits. The day that the FTC filed the papers, Warner Chilcott waived the exclusionary provision in its agreement with Barr that prevented Barr from entering with its generic version of Ovcon. The next day, Barr announced its intention to start selling a generic version of the product. The FTC and Warner Chilcott agreed to terms for a permanent injunction. The FTC’s action thus prevented the company from taking action that would have frustrated the purpose of generic substitution laws that bring lower prices to consumers.

⁵⁵ See, e.g., Mark A. Lemley, *Ignoring Patents*, 2008 MICH. STATE L. REV. 19, 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”), citing 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 12.5 (perm. ed. & Supp. 2008).

⁵⁶ Product hopping raises sensitive policy questions as to whether the new product represents a welfare-increasing innovation or is merely used to delay significantly generic competition and thereby harm consumer welfare.

⁵⁷ The Warner Chilcott matter is described in *Consumers Win as FTC Action Results in Generic Ovcon Launch* (FTC press release), available at <http://www2.ftc.gov/opa/2006/10/chilcott.shtm>.

40. In *Abbott Labs. v. Teva Pharmaceuticals U.S.A., Inc.*,⁵⁸ the generic pharmaceutical company Teva alleged that Abbott had “responded to the threat of generic entry . . . by changing the formulation of TriCor [a branded drug], not to improve the product, but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor.”⁵⁹ Abbott had withdrawn TriCor capsules from the market and had substituted them with tablets having different dosage strengths; Abbott sought to bar generic sale of tablets through patent infringement suits. Teva and other generic producers alleged that Abbott’s actions amounted to attempted monopolization and monopolization in violation of the Sherman Act. 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. Specifically, the court found that a rule of reason, not a *per se* rule, should apply to this new product introduction (and that plaintiffs need not prove that the new formulations were absolutely no better than the old versions); that 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 that 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.

41. In *Walgreen Co. v. AstraZeneca Pharmaceuticals*,⁶⁰ a federal district court rejected plaintiffs’ “product hopping” complaint that (unlike the situation in *Abbott Labs. v. Teva*) did not involve actual withdrawal of a product from the market. Plaintiffs alleged that as the branded drug Prilosec (omeprazole) was about to lose patent protection, AstraZeneca introduced Nexium (esomeprazole magnesium), 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 “omeprazole/esomeprazole” market, in violation of Section 2 of the Sherman Act. AstraZeneca claimed that Nexium had statistically significant 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.

5. Pharmaceutical Mergers

42. In pharmaceuticals, as in all other markets, the U.S. antitrust enforcement agencies seek to block only those mergers, or those portions of mergers, that will result in substantial reductions in competition, and in so doing to ensure that firms are not prevented from achieving efficiencies that benefit consumers. Recent pharmaceutical merger enforcement by the FTC (the U.S. antitrust agency primarily responsible for reviewing such mergers) is summarized below.

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

⁵⁹ 432 F. Supp. 2d at 415.

⁶⁰ 534 F. Supp. 2d 146 (D.D.C. 2008).

43. Through its pharmaceutical merger work, the FTC has protected different types of competition. Early in the pharmaceutical life cycle, competition among branded drugs is based on innovation – with firms competing at the product development stage to be the first to market with a product for treating a particular disease or condition. The winner of that race can (appropriately) earn significant rewards – which provide economic incentives for firms to create new products and bring them to market faster, in turn providing consumers more choice. Non-price competition also produces incentives for firms to expand the use of their existing products by exploring new drug indications or to make other improvements. Later in its life cycle, however, the branded product will likely face direct competition from the first generic equivalent on the market and less competitive interaction with other branded products. In those situations, the FTC will look closely at a merger eliminating the only generic competition with a branded product. Finally, at the latest stages of a drug’s life cycle, it is likely that the closest competition will not include the branded product, which often sells at a premium, but the multiple generics that have entered the market.

44. The FTC has aggressively sought to protect these incentives to develop new drugs and new indications. For example, in its challenge to Sanofi’s acquisition of Aventis in 2004,⁶¹ the FTC acted to protect potential competition for branded Factor Xa inhibitors, which are drugs that are used to treat excessive blood clot formation. Aventis’s Lovenox product had a 90% marketshare. Sanofi marketed the competing drug, Arixtra, but was also pursuing FDA approval for new indications, which were expected to increase the drug’s competitive significance. The Commission challenged the transaction and negotiated a remedy that required Sanofi to divest Arixtra to Glaxo Smith-Kline (“GSK”) and to assist GSK in completing key clinical trials in order to preserve the potential benefits of the new indications.

45. Protecting price competition is also a core component of the FTC’s merger work in pharmaceutical markets. As previously discussed, the first generic competitor typically enters the market at a price that is 70 to 80 percent of its brand-name counterpart, and quickly gains substantial share from the brand name product.⁶² Because this price drop produces obvious and substantial benefits for consumers, the FTC acts when a merger threatens to eliminate this competition. For example, a 2004 transaction between Cephalon and Cima⁶³ would have combined Cephalon, which had a monopoly in the market for treating cancer pain, and Cima, which was poised to enter that market with its own drug. Cephalon’s ownership of both branded products could have allowed it to thwart generic entry by shifting patients from its product to Cima’s, which had later expiring patents. The “switch” strategy would have deprived consumers of the full benefits of generic competition. The Commission remedied these potential anticompetitive effects by requiring Cephalon to license its patents, and to transfer all of its technological know-how to a third-party generic drug company, to expedite entry of a lower priced generic version of Cephalon’s drug.

⁶¹ In the Matter of Sanofi-Synthelabo and Aventis, FTC Docket No. C-4112, Complaint

(July 28, 2004), *available at* <http://www.ftc.gov/os/caselist/0410031/040728cmp0410031.pdf>.

⁶² See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* <<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>> (hereinafter “CBO Study”); see generally David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 *REVIEW OF ECON. & STAT.* 37-79 (2005).

⁶³ *Cephalon, Inc./Cima Labs, Inc.*, FTC Docket No. C-4121, Complaint (Sept. 20, 2004), *available at* <http://www.ftc.gov/os/caselist/0410025/040924comp0410025.pdf>; Decision and Order (Sept. 20, 2004), *available at* <http://www.ftc.gov/os/caselist/0410025/040924do0410025.pdf>.

46. In addition, the FTC is concerned about maintaining competition among competing branded pharmaceuticals. In February 2009, the FTC issued a final consent order to settle its charges that King Pharmaceuticals, Inc.'s proposed \$1.6 billion acquisition of rival drug-maker Alpharma Inc. would be anticompetitive.⁶⁴ The consent order required King to divest the rights to Alpharma's branded oral long-acting opioid (LAO) analgesic drug Kadian to Actavis, restoring the competition between Kadian and King's branded LAO Avinza that would be lost as a result of the acquisition. (Actavis was well-positioned to acquire the Kadian assets, as it had manufactured the drug for King at its plant in Elizabeth, New Jersey.) In 2003, the FTC charged that Pfizer's acquisition of Pharmacia would eliminate competition between two of the three branded makers of combination hormone replacement therapies (HRT).⁶⁵ The FTC's consent agreement with the parties restored competition that otherwise would have been lost by requiring Pfizer to divest all of its rights and assets related to its branded HRT product, including its intellectual property. Thus, the FTC preserved competition by maintaining three independent HRT competitors in the market.

47. The FTC will not hesitate to challenge consummated pharmaceutical mergers that have anticompetitive effects. In December 2008, the FTC filed a complaint in the Federal District Court for the District of Minnesota, challenging Ovation Pharmaceuticals, Inc.'s January 2006 acquisition of the drug NeoProfen.⁶⁶ That acquisition eliminated Ovation's only competitor for the treatment of a serious and potentially deadly congenital heart defect affecting more than 30,000 babies born prematurely each year in the United States. When it acquired NeoProfen, Ovation already held the rights to Indocin I.V., the only other drug used to treat this serious condition. After ensuring that it would not face competition from NeoProfen, Ovation promptly raised the price of Indocin nearly 1,300 percent, from \$36 to nearly \$500 per vial. When it launched NeoProfen in July 2006, Ovation set a similarly inflated price. The FTC is seeking divestiture of assets related to one of the two treatments, and disgorgement of all unlawfully obtained profits obtained from the sale of these two treatments.

48. The FTC also has brought merger challenges directed at protecting the aggressive price competition that occurs among generic pharmaceutical manufacturers. As previously noted, generic competition can drive prices as low as 80 percent 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. Since 2005, the Commission has challenged nine transactions between generic manufacturers, all of which were resolved by divestitures. These challenges were directed at transactions involving: Novartis and Eon,⁶⁷ Teva and Ivax,⁶⁸ Barr and Pliva,⁶⁹ Watson and Andrx,⁷⁰

⁶⁴ *In the Matter of King Pharmaceuticals, Inc. and Alpharma Inc.*, FTC Docket No. C-4246, Complaint (Feb. 2, 2009), available at <http://www.ftc.gov/os/caselist/0810240/090203alpharmacmpt.pdf>.

⁶⁵ *Pfizer, Inc., and Pharmacia Corp.*, No. C-4075 (Apr. 14, 2003), Analysis to Aid Public Comment at 3, available at <http://www.ftc.gov/os/caselist/c4075.htm>.

⁶⁶ *FTC v. Ovation Pharmaceuticals Inc.*, FTC File No. 0810156, Complaint (Dec. 16, 2008), available at <http://www.ftc.gov/os/caselist/0810156/081216ovationcmpt.pdf>.

⁶⁷ *In the Matter of Novartis AG*, FTC Docket No. C-4150, Complaint (September 21, 2005), available at <http://www.ftc.gov/os/caselist/0510106/0509236comp0510106.pdf>.

⁶⁸ *In the Matter of Teva Pharmaceutical Industries Ltd., and IVAX Corporation*, File No. 051-0214, FTC Docket No. C-4155, Complaint (January 20, 2006), available at <http://www.ftc.gov/os/caselist/0510214/0510214complaint.pdf>.

⁶⁹ *In the Matter of Barr Pharmaceuticals, Inc.*, File No. 061 0217, FTC Docket No. C-4171, Complaint (October 19, 2006), available at <http://www.ftc.gov/os/caselist/0610217/0610217barrcomplaint.pdf>.

⁷⁰ *In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corporation*, File No. 061- 0139, FTC Docket No. C-4172, Complaint (Oct. 21, 2006), available at <http://www.ftc.gov/os/caselist/0610139/0610139complaint.pdf>.

Hospira and Mayne;⁷¹ Actavis and Arbika;⁷² Mylan and Merck;⁷³ Barr and Teva;⁷⁴ and Sun Pharmaceutical and Taro.⁷⁵ In each case, the Commission identified several markets in which the proposed merger would cause significant anticompetitive harm to consumers by eliminating a current or future generic product.

49. Pharmaceutical mergers may also harm consumer welfare by allowing firms to manipulate government regulations. A behavioral remedy may sometimes be appropriate in such cases. This is illustrated by the FTC's 2008 action to block an acquisition that would have achieved such an anticompetitive result through a regulatory abuse of the United States Medicare reimbursement program.⁷⁶ The FTC challenged Fresenius Medical Care Ag & Co. KGaA's (Fresenius) proposed acquisition of an exclusive sublicense from Luitpold Pharmaceuticals, Inc. (Luitpold), a wholly owned U.S. subsidiary of the Japanese firm Daiichi Sankyo Company, Ltd.⁷⁷ Under the sublicense, Fresenius would manufacture and supply the intravenous iron drug Venofer to dialysis clinics in the United States. The FTC's complaint charged that the proposed vertical agreement would provide Fresenius, the largest provider of end-stage renal disease (ESRD) dialysis services in the United States, with the ability to increase Medicare reimbursement payments for Venofer. This is possible because after the transaction, the competitive market will no longer determine the price that Fresenius's clinics will pay for intravenous (IV) iron. That amount will instead become an internal transfer price reported by Fresenius to the United States Government Center for Medicare & Medicaid Services. A consent order settling the FTC's complaint and allowing the companies to consummate the transaction barred Fresenius from reporting intra-company transfer prices higher than certain levels specified in the order. Those levels are derived from current market prices.

50. The FTC focuses its enforcement work so as not to prevent efficient mergers. One merging firm may have expertise in bringing products to market quickly or gaining market acceptance that will increase the use of a product that the other firm has in development. The Commission credits these efficiencies. The FTC's review of the Genzyme/Ilex merger demonstrates the agency's appreciation of efficiencies that

⁷¹ *In the Matter of Hospira, Inc. and Mayne Pharma Limited*, File No. 071-0002, FTC Docket No. C-4182, Complaint (January 18, 2007), available at <http://www.ftc.gov/os/caselist/0710002/070118cmp0710002.pdf>.

⁷² *In the Matter of Actavis Group, HF.*, File No. 071-0063, FTC Docket No. C-4182, Complaint (Apr. 16, 2007), available at <http://www.ftc.gov/os/caselist/0710063/0710063cmp.pdf>.

⁷³ *In the matter of Mylan Laboratories Inc. and E. Merck oHG*, FTC Docket No. C-4200, Complaint (Sept. 26, 2007), available at <http://www.ftc.gov/os/caselist/0710164/070921cmp0710164.pdf>.

⁷⁴ *In the Matter of Teva Pharmaceutical Industries Ltd. and Barr Pharmaceuticals, Inc.*, FTC Docket No. C-4242, Complaint (Dec. 18, 2008), available at <http://www.ftc.gov/os/caselist/0810224/081219cmp0810224.pdf>.

⁷⁵ *In the Matter of Sun Pharmaceutical Industries Ltd.*, FTC Docket No. C-4230, Complaint (Aug. 12, 2008), available at <http://www.ftc.gov/os/caselist/0710193/080813sunpharmcmpt.pdf>.

⁷⁶ Although the Medicare Program (which provides medical care for the elderly) is specific to the United States, other countries may have their own regulatory schemes that could be manipulated to an anticompetitive end. Thus, the example discussed in this paragraph may serve as a general cautionary tale about the importance of evaluating the competitive effects of regulatory programs affecting pharmaceuticals.

⁷⁷ *In the matter of Fresenius Medical Care AG & Co. KGaA and Daiichi Sankyo Company, Ltd.*, FTC Docket No. C-4236, Decision and Order (Oct. 20, 2008), available at <http://www2.ftc.gov/os/caselist/0810146/081021freseniusdo.pdf>.

benefit innovation.⁷⁸ That case also demonstrates the flexibility that can emerge from an analysis focused on the particular facts rather than rigid structural rules.

51. The drugs at issue in the Genzyme/Ilex matter provide acute therapy for solid organ transplants by suppressing the immune system during initial organ transplant and during episodes of acute rejection. Genzyme was the leading supplier of such drugs with its product, Thymoglobulin. Ilex sold Campath, which the FDA had approved for the treatment of chronic lymphocytic leukemia, but which doctors also prescribed off-label for transplants. The merger would have lessened competition in the market for acute therapy drugs used in solid organ transplant by eliminating this competition between Genzyme and Ilex. Instead of requiring that the merged firm divest all of its interests in Campath, however, and eliminating efficiencies that would have been produced from the acquisition of Campath by Genzyme, the FTC negotiated a consent decree that required the divestiture to Schering of the firm's contractual rights, including earnings, involving Campath's use for solid organ transplant only. This unique remedy maintained competition in the market for solid organ transplant drugs, while preserving the efficiencies of the transaction.

6. Emerging Pharmaceutical Competition Policy Issues

52. The FTC continues to monitor competition policy developments in the pharmaceutical sector. New business models, technological innovations, and the enactment of federal health care reforms (through legislation or regulation) may affect pharmaceutical competition in ways that cannot currently be predicted. The FTC will respond to these changes through new research, public policy recommendations, and, when appropriate, enforcement actions. The precise nature of these initiatives must await future developments. Special mention should be made, however, of two recent FTC policy-oriented reports, which deal with topics that are expected to loom large in future competition policy deliberations – the treatment of “authorized generics” and of “follow-on biologics.”

53. In its June 2009 *Authorized Generics Report*,⁷⁹ the FTC examined the short-term effects of authorized generics during the initial period of generic competition (the 180-day marketing exclusivity period). The *Authorized Generics Report* concluded that: (1) during the initial period, both 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 initial period also 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. The FTC plans to release a report setting forth the long-term competitive effects of authorized generics.

⁷⁸ *In the matter of Genzyme Corp. and Ilex Oncology, Inc.*, FTC Docket No. C-4128, Complaint (December 21, 2004) available at <http://www.ftc.gov/os/caselist/0410083/041220comp0410083.pdf>.

⁷⁹ The *Authorized Generics Report* is discussed in part 2.2 of this note at paragraph 22, *supra*.

54. Another emerging policy issue that the FTC has studied is biologic drug competition. Biologic drugs are protein-based drugs that are derived from living matter or manufactured in living shells using recombinant DNA technologies. Biologics are far more complex and much larger than the chemically synthesized, small molecules that form the basis of most pharmaceutical products, and they are also far more expensive. The United States Congress is currently drafting various legislative proposals to provide an abbreviated regulatory pathway for follow-on biologic (“FOB”) drugs to encourage FOBs to enter and compete with pioneer biologics once a pioneer drug’s patents have expired. In a June 2009 Report (“*Biologics Report*”),⁸⁰ the FTC provided an independent analysis of how the legislative proposals would likely affect consumers. The FTC’s *Biologics Report* 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; (2) the existing United States patent system and market-based pricing are likely to be sufficient to support continued pioneer and FOB biologic drug innovation; and (3) inclusion of 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.⁸¹ FTC Commissioner Pamela Jones Harbour presented the findings and recommendations of the *Biologics Report* on behalf of the Commission in a June 11, 2009 testimony before Congress, and answered questions posed by the Committee with Michael S. Wroblewski, Deputy Director Office of Policy Planning, lead author of the *Biologics Report*.⁸² The ultimate decision how to devise an abbreviate FOB regulatory approval pathway rests with Congress.

⁸⁰ 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>.

⁸¹ See *id.* at iii-x.

⁸² *FTC Testifies on “Competition Issues and Follow on Biologic Drugs”* (FTC press release describing June 11, 2009 testimony by FTC Commissioner Pamela Jones Harbour before the Subcommittee on Health of the U.S. House of Representatives Committee on Energy and Commerce), available at <http://www.ftc.gov/opa/2009/06/biologicdrugs.shtm>.