

Pharmaceutical Patent Settlements: Issues in Innovation and Competitiveness

-name redacted-
Visiting Scholar

January 14, 2014

Congressional Research Service

7-....

www.crs.gov

R42960

Summary

Although brand-name pharmaceutical companies routinely procure patents on their innovative medications, such rights are not self-enforcing. Brand-name firms that wish to enforce their patents against generic competitors must therefore commence litigation in the federal courts. Such litigation ordinarily terminates in either a judgment of infringement, which typically blocks generic competition until such time as the patent expires, or a judgment that the patent is invalid or not infringed, which typically opens the market to generic entry.

As with other sorts of commercial litigation, however, the parties to pharmaceutical patent litigation may choose to settle their case. Certain of these settlements have called for the generic firm to neither challenge the brand-name company's patents nor sell a generic version of the patented drug for a period of time. In exchange, the brand-name drug company agrees to compensate the generic firm, often with substantial monetary payments over a number of years. Because the payment flows counterintuitively, from the patent owner to the accused infringer, this compensation has been termed a "reverse" payment.

Since 2003, Congress has required that litigants notify federal antitrust authorities of their pharmaceutical patent settlements. That legislation did not dictate substantive standards for assessing the validity of these agreements under the antitrust law, however. That determination was left to judicial application of general antitrust principles. Facing different factual patterns, some lower courts had concluded that a particular reverse payment settlement constituted an antitrust violation, while others have upheld the agreement.

The June 17, 2013, decision of the U.S. Supreme Court in *Federal Trade Commission v. Actavis, Inc.* resolved this disagreement by holding that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach. However, the Court declined to hold that such settlements should be presumptively illegal under a "quick look" analysis. The lower courts now face the potentially complex task of applying the rule of reason to reverse payment settlements going forward.

Congress possesses a number of alternatives for addressing reverse payment settlements. One possibility is to await further judicial developments. Another option is to regulate the settlement of pharmaceutical patent litigation in some manner. In the 113th Congress, the Preserve Access to Affordable Generics Act (S. 214) would establish a presumption of either legality or illegality under the antitrust laws, along with consideration of relevant factors to be weighed by the courts. Another proposal, the FAIR Generics Act (S. 504), would introduce reforms to the food and drug laws that would reduce incentives for generic firms to settle with brand-name companies.

Contents

Introduction.....	1
Patent Disputes Under the Hatch-Waxman Act	2
Patent Fundamentals.....	2
FDA Approval Procedures.....	3
Resolution of Patent Disputes.....	4
Generic Exclusivity	5
Fundamentals of Reverse Payment Settlements	6
Antitrust Implications of Reverse Payment Settlements	9
General Antitrust Standards.....	9
Judicial Approaches to Reverse Payment Settlements	10
Issues and Observations.....	14

Contacts

Author Contact Information.....	15
---------------------------------	----

Introduction

The increasing costs of health care have focused congressional attention upon both the development and public availability of prescription drugs. Congress has long recognized that the patent system has an important role to play in the pharmaceutical industry in each respect. The Drug Price Competition and Patent Term Restoration Act of 1984,¹ commonly known as the Hatch-Waxman Act, in part reformed both the patent and food and drug laws in order to balance incentives for innovation and competition within the pharmaceutical industry.²

Recently, congressional attention has been directed towards one aspect of the patent system, the settlement of pharmaceutical patent litigation. Although brand-name pharmaceutical companies commonly procure patents on their innovative products and processes, such rights are not self-enforcing. If a brand-name drug company wishes to enforce its patents against generic competitors, it must pursue litigation in the federal courts. Such litigation ordinarily terminates in either a judgment of infringement, which typically blocks generic competition until such time as the patent expires, or a judgment that the patent is invalid or not infringed, which typically opens the market to generic entry.

As with other sorts of commercial litigation, however, the parties to pharmaceutical patent litigation may choose to settle their case. Certain of these settlements call for the generic firm to neither challenge the brand-name company's patents nor sell a generic version of the patented drug. In exchange, the brand-name drug company agrees to make cash payments to the generic firm. This compensation has been termed an "exclusion" or "exit" payment or, because the payment flows counterintuitively, from the patent proprietor to the accused infringer, a "reverse" payment.³ Some observers have also termed these settlements as "pay-for-delay" agreements.⁴

Commentators differ markedly in their views of reverse payment settlements. Some observers believe that they result from the specialized patent litigation procedures established by the Hatch-Waxman Act.⁵ Others conclude that when one competitor pays another not to market its product, such a settlement is anti-competitive and presumptively a violation of the antitrust laws.⁶

Since 2003, Congress has required that litigants notify federal antitrust authorities of their pharmaceutical patent settlements.⁷ To date, Congress has not stipulated substantive standards for assessing the validity of these agreements under the antitrust law, however. That determination

¹ P.L. 84-417, 98 Stat. 1585 (1984).

² See CRS Report R41114, *The Hatch-Waxman Act: Over a Quarter Century Later*, by (name redacted) and (name redacted).

³ See Alan Devlin & Michael Jacobs, "Anticompetitive Innovation and the Quality of Innovation," 27 *Berkeley Technology Law Journal* (2012), 1.

⁴ See Alyssa L. Brown, "Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements," 41 *University of Baltimore Law Review* (2012), 583.

⁵ See Henry N. Butler and Jeffrey Paul Jarosch, "Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation," 96 *Iowa Law Review* (2010), 57.

⁶ See Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," 108 *Michigan Law Review* (2009), 37.

⁷ See Medicare Prescription Drug, Improvement and Modernization Act of 2003, P.L. 108-173, 117 Stat. 2066.

was left to judicial application of general antitrust principles. Uniformity of results was not a hallmark of this line of cases. Facing different factual patterns, some lower courts have concluded that a particular reverse payment settlement constituted an antitrust violation, while others had upheld the agreement.⁸

The June 17, 2013, decision of the U.S. Supreme Court in *Federal Trade Commission v. Actavis, Inc.* resolved this disagreement by holding that the legality of reverse payment settlements should be evaluated under the “rule of reason” approach. However, the Court declined to hold that such settlements should be presumptively illegal under a “quick look” analysis. The lower courts now face the potentially complex task of applying the rule of reason to reverse payment settlements going forward.

Legislation before the 113th Congress also relates to reverse payment settlements. The Preserve Access to Affordable Generics Act (S. 214) would create a rebuttable presumption that certain reverse payment settlements were illegal. In addition, the FAIR Generics Act (S. 504) would introduce reforms to the Hatch-Waxman Act that would reduce incentives for generic firms to settle with brand-name companies. This legislation has not yet been enacted.

This report introduces and analyzes innovation and competition policy issues associated with pharmaceutical patent litigation settlements. It begins with a review of pharmaceutical patent litigation procedures under the Hatch-Waxman Act. The report then introduces the concept of reverse payment settlements. Next, the report analyzes the status of reverse payment settlements under the antitrust laws. The report closes with a summary of congressional issues and possible alternatives.

Patent Disputes Under the Hatch-Waxman Act

Patent Fundamentals

Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.⁹ USPTO officials, known as examiners, then assess whether the application merits the award of a patent.¹⁰ A patent application must include a specification that so completely describes the invention that skilled artisans are able to practice it without undue experimentation. Applicants must also draft at least one claim that particularly points out and distinctly claims the subject matter that they regard as their invention.¹¹

While reviewing a submitted application, the examiner will determine whether the claimed invention fulfills certain substantive standards set by the patent statute. Two of the most important patentability criteria are novelty and nonobviousness. To be judged novel, the claimed invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public

⁸ See Michael A. Carrier, “Why the ‘Scope of the Patent’ Test Cannot Solve the Drug Patent Settlement Problem,” 16 *Stanford Technology Law Review* (2012), 1.

⁹ 35 U.S.C. §111.

¹⁰ 35 U.S.C. §131.

¹¹ 35 U.S.C. §112.

domain.¹² The sum of these earlier materials, which document state-of-the-art knowledge that is accessible to the public, is termed the “prior art.” To meet the standard of nonobviousness, an invention must not have been readily within the ordinary skills of a competent artisan based upon the teachings of the prior art.¹³

If the USPTO allows the application to issue as a granted patent, the owner or owners of the patent obtain the right to exclude others from making, using, selling, offering to sell or importing into the United States the claimed invention.¹⁴ The term of the patent is ordinarily set at twenty years from the date the patent application was filed.¹⁵ Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits inventors to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market. In the pharmaceutical industry, for example, the introduction of generic competition often results in the availability of lower-cost substitutes for the innovative product.

A patent proprietor bears responsibility for monitoring its competitors to determine whether they are using the patented invention. Patent owners who wish to compel others to observe their intellectual property rights must often commence litigation in the federal district courts.

FDA Approval Procedures

Although the award of a patent claiming a pharmaceutical provides its owner with a proprietary interest in that product, it does not actually allow the owner to distribute that product to the public. Permission from the FDA must first be obtained. In order to obtain FDA marketing approval, the developer of a new drug must demonstrate that the product is safe and effective. This showing typically requires the drug’s sponsor to conduct both preclinical and clinical investigations. In deciding whether to issue marketing approval or not, the FDA evaluates the test data that the sponsor submits in a so-called New Drug Application (NDA).¹⁶

Prior to the enactment of the Hatch-Waxman Act, the federal food and drug law contained no separate provisions addressing marketing approval for independent generic versions of drugs that had previously been approved by the FDA. The result was that a would-be generic drug manufacturer had to file its own NDA in order to sell its product. Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug by submitting a so-called “paper NDA.” Because these sorts of studies were not available for all drugs, however, not all generic firms could file a paper NDA. Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval. The result was that some generic manufacturers were forced to

¹² 35 U.S.C. §101.

¹³ 35 U.S.C. §103.

¹⁴ 35 U.S.C. §271.

¹⁵ 35 U.S.C. §154(a)(2).

¹⁶ See FDA, Drugs: Development & Approval Process (Drugs): How Drugs Are Developed and Approved (April 23, 2010) (available at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/default.htm>).

prove once more that a particular drug was safe and effective, even though their products were chemically identical to those of previously approved pharmaceuticals.¹⁷

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process. These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.¹⁸

In response to these concerns, Congress enacted the Hatch-Waxman Act, a complex statute that sought compromise between brand-name and generic pharmaceutical companies.¹⁹ Its provisions included the creation of an expedited marketing approval pathway for generic drugs termed an Abbreviated New Drug Application, or ANDA. An ANDA allows an independent generic applicant to obtain marketing approval by demonstrating that the proposed product is bioequivalent to an approved pioneer drug, without providing evidence of safety and effectiveness from clinical data or from the scientific literature. The availability of ANDAs often allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. They may also allow an independent generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.²⁰

As part of the balance struck between brand-name and generic firms, Congress also provided patent proprietors with a means for restoring a portion of the patent term that had been lost while awaiting FDA approval. The maximum extension period is capped at a five-year extension period, or a total effective patent term after the extension of not more than 14 years. The scope of rights during the period of extension is generally limited to the use approved for the product that subjected it to regulatory delay. This period of patent term extension is intended to compensate brand-name firms for the generic drug industry's reliance upon the proprietary pre-clinical and clinical data they have generated, most often at considerable expense to themselves.²¹

Resolution of Patent Disputes

During its development of accelerated marketing approval procedures for generic drugs, Congress recognized that the brand-name pharmaceutical firm may be the proprietor of one or more patents directed towards that drug product. These patents might be infringed by a product described by a generic firm's ANDA or in the event that product is approved by the FDA and sold in the marketplace. The Hatch-Waxman Act therefore established special procedures for resolving patent disputes in connection with applications for marketing generic drugs.²²

¹⁷ See Colleen Kelly, "The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond," 66 *Food and Drug Law Journal* (2011), 417.

¹⁸ See Matthew Avery, "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments," 60 *Hastings Law Journal* (2008), 171.

¹⁹ See Timothy A. Cook, "Pharmaceutical Patent Litigation Settlements: Balancing Patent & Antitrust Policy Through Institutional Choice," 17 *Michigan Telecommunications and Technology Law Review* (2011), 417.

²⁰ See Michael R. Herman, "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation," 111 *Columbia Law Review* (2011), 1788.

²¹ See Ann Kotze, "Reining in Patent Term Extensions for Related Pharmaceutical Products Post-*Photocure* and *Ortho-McNeil*," 106 *Northwestern University Law Review* (2012), 1419.

²² See Linda P. Nussbaum and John D. Radice, "Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years (continued...)"

In particular, the Hatch-Waxman Act states that each NDA applicant “shall file” a list of patents that the applicant believes would be infringed if a generic drug were marketed prior to the expiration of these patents.²³ The FDA then lists these patents in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is more commonly known as the “Orange Book.”²⁴ Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market. Four possibilities exist:

- (1) that the brand-name firm has not filed any patent information with respect to that drug;
- (2) that the patent has already expired;
- (3) that the generic company agrees not to market until the date on which the patent will expire; or
- (4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted.²⁵

These certifications are respectively termed paragraph I, II, III, and IV certifications. An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements. An independent generic firm that files an ANDA including a paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the brand-name drug’s listed patent expires.²⁶

The filing of an ANDA with a paragraph IV certification constitutes a “somewhat artificial” act of patent infringement under the Hatch-Waxman Act.²⁷ The act requires the independent generic applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification. The patent owner may then commence patent infringement litigation against that applicant.²⁸

Generic Exclusivity

In order to encourage challenges of pharmaceutical patents, the Hatch-Waxman Act provides prospective manufacturers of generic pharmaceuticals with a potential reward. That reward consists of a 180-day exclusivity period awarded to the first ANDA applicant to file a paragraph IV certification.²⁹ Once a first ANDA with a paragraph IV certification has been filed, the FDA

(...continued)

Later: Successes, Failures, and Prescriptions for the Future,” 41 *Rutgers Law Journal* (2009), 229.

²³ 21 U.S.C. §355(b)(1).

²⁴ See Ian Hastings, “Dynamic Innovation Inefficiency in Pharmaceutical Patent Settlements,” 13 *North Carolina Journal of Law & Technology* (2011), 31.

²⁵ 21 U.S.C. §355(j)(2)(A)(vii).

²⁶ See Emily Michiko Morris, “The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act,” 22 *Fordham Intellectual Property Media & Entertainment Law Journal* (2012), 245.

²⁷ *Eli Lilly & Co. v. Medtronic*, 496 U.S. 1047 (1990). The act of infringement is “somewhat artificial” in that the generic drug company has merely filed a paragraph IV ANDA with the FDA, rather than actually making, using, or selling a competing product in the marketplace.

²⁸ See Morris, *supra*.

²⁹ 21 U.S.C. §355(j)(5)(B)(iv).

cannot issue marketing approval to a subsequent ANDA with a paragraph IV certification on the same drug product for 180 days. Because market prices could drop considerably following the entry of additional generic competition, the first paragraph IV ANDA applicant may potentially obtain more handsome profits than subsequent market entrants—thereby stimulating patent challenges in the first instance.³⁰

Following 2003 amendments to the Hatch-Waxman Act,³¹ in some circumstances a first paragraph IV ANDA applicant may lose its entitlement to the 180-day generic exclusivity period. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) established a number of “forfeiture events” that, if triggered, result in a relinquishment of generic exclusivity. Among the forfeiture events are: (1) failure to market its product promptly; (2) failure to obtain FDA approval to market the generic drug in a reasonably timely manner; and (3) all of the certified patents that entitled the applicant to the 180-day generic exclusivity period have expired. The possibility of forfeiture was intended “to prevent the practice of ‘parking’ the exclusivity period and to force generic manufacturers to market promptly.”³²

Fundamentals of Reverse Payment Settlements

As discussed previously, a generic firm’s filing of a paragraph IV ANDA may result in a patent infringement suit brought by a brand-name drug company. In such litigation, if the NDA holder demonstrates that the independent generic firm’s proposed product would violate its patents, then the court will ordinarily issue an injunction that prevents the generic drug company from marketing that product. That injunction will expire on the same date as the NDA holder’s patents. Independent generic drug companies commonly amend their ANDAs in this event, replacing their paragraph IV certifications with paragraph III certifications.³³

On the other hand, the courts may decide in favor of the independent generic firm. The court may conclude that the generic firm’s proposed product does not infringe the asserted patents, or that the asserted patents are invalid or unenforceable. In this circumstance, the independent generic firm may launch its product once the FDA has finally approved its ANDA.³⁴

In addition to the issuance of final judgment in favor of either the brand-name drug company or generic firm, another resolution of pharmaceutical patent litigation is possible. This legal situation led to a number of cases with varying details, but a common core fact pattern. Upon filing a paragraph IV ANDA, a generic firm would be sued for patent infringement as provided by the Hatch-Waxman Act. The NDA holder and generic applicant would then settle their dispute. The settlement would call for the generic firm to neither challenge the patent nor produce a generic version of the patented drug, for a period of time up to the remaining term of the patent. In

³⁰ See Scott Hemphill & Mark A. Lemley, “Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act,” 77 *Antitrust Law Review* (2011), 947.

³¹ P.L. 108-173, 117 Stat. 2066.

³² Brian Porter, “Stopping the Practice of Authorized Generics: Mylan’s Effort to Close the Gaping Black Hole in the Hatch-Waxman Act,” 22 *Journal of Contemporary Health Law and Policy* (2005), 177 (citation omitted).

³³ 21 C.F.R. §314.94(a)(12)(viii)(A).

³⁴ 21 U.S.C. §355(j)(5)(B)(iii).

exchange, the NDA holder would agree to compensate the ANDA applicant, often with substantial monetary payments over a number of years.³⁵

Opinions about the effects of reverse payment settlements upon social welfare have varied. Some commentators believe that such settlements are anticompetitive. They believe that many of these agreements may amount to no more than two firms colluding in order to restrict output and share patent-based profits. Such settlements are also said to eliminate the possibility of a judicial holding of patent invalidity, which may open the market to generic competition and benefit consumers.³⁶

On the other hand, some commentators have found nothing inherently troublesome about reverse payment settlements. Among their observations is that there is a general judicial policy in favor of promoting settlement.³⁷ Settlements can allow the parties to avoid the expenses of litigation,³⁸ achieve a resolution to the dispute in a timely manner, and avoid the risk of an uncertain result in the courtroom. The settlement of litigation further serves the goal of resolving disputes in a peaceful manner, and also preserves scarce judicial resources.³⁹ Second, any settlement of litigation between rational actors necessarily involves an exchange of benefits and obligations. As Judge Richard Posner has explained:

[A]ny settlement agreement can be characterized as involving “compensation” to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden “reverse payment,” we shall have no more patent settlements.⁴⁰

Third, certain reverse payment settlements have allowed for the introduction of generic competition prior to the date the relevant patent expires. It is possible, for example, for the brand-name and generic firms to divide the remaining patent term between them, with the generic firm being allowed to market a competing product prior to the running of the full patent term. Such agreements may potentially benefit consumers, certainly in comparison to a judgment that the patent is not invalid and infringed.⁴¹

Finally, the dispute settlement procedures established by the Hatch-Waxman Act may themselves promote the use of reverse payment settlements in pharmaceutical patent litigation. In patent litigation outside the Hatch-Waxman Act context, the accused infringer is ordinarily using or marketing the patented technology. A judicial finding of infringement would expose the accused infringer to an injunction, along with damages awarded for past uses and sales. As a result, the

³⁵ See C. Scott Hemphill, “Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem,” 81 *New York University Law Review* (2006), 1560.

³⁶ See Carrier, *supra*.

³⁷ See Cory J. Ingle, “Reverse Payment Settlements: A Patent Approach for Defending the Argument for Illegality,” 7 *I/S: A Journal of Law and Policy for the Information Society* (2012), 503 (identifying this policy).

³⁸ The American Intellectual Property Law Association estimated the average cost of patent infringement litigation at \$6,018,000 per side for a case worth more than 25 million dollars. See AIPLA Report of the Economic Survey I-153-54 (2011).

³⁹ See Alex Corona, “Stuck in Neutral: The Future of Reverse Payments Agreements in Hatch-Waxman Litigation,” 7 *Seton Hall Circuit Review* (2010), 201.

⁴⁰ *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) (emphasis in original).

⁴¹ See Corona, *supra*.

accused infringer may well be willing to compensate the patent proprietor in order to avoid the risk of such a holding.⁴²

Some observers believe that the structure of the Hatch-Waxman Act alters the traditional balance of risks between the plaintiff-patentee and accused infringer. As explained by one federal district court:

[I]n creating an artificial act of infringement (the ANDA IV filing), the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales.... Because of the Hatch-Waxman scheme, [the generic firm's] exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but has an enormous downside—losing the patent.⁴³

As a result, some commentators believe that it is entirely predictable that the unique procedures of the Hatch-Waxman Act have resulted in the new phenomenon of reverse payment settlements.⁴⁴

At the present time, congressional action on pharmaceutical patent litigation settlements has been limited. In the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA),⁴⁵ Congress mandated that the Department of Justice (DOJ) and the Federal Trade Commission (FTC) receive copies of certain patent settlements agreements in the pharmaceutical field. The filing requirement applies to agreements executed on or after January 7, 2004, between an ANDA applicant, on one hand, and either the NDA holder or an owner of an Orange Book-listed patent, on the other.⁴⁶ Such agreements trigger the statutory notification requirement if they relate to one of three topics:

- (1) The manufacture, marketing, or sale of the brand-name drug that is the listed drug in the ANDA;
- (2) The manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or
- (3) The 180-day generic exclusivity period as it applies to that ANDA, or to another ANDA filed with respect to the same brand-name drug.⁴⁷

The MMA stipulates that certain agreements are not subject to this filing requirement. In particular, agreements that solely consist of purchase orders for raw materials, equipment and facility contracts, employment or consulting contracts, or packaging and labeling contracts do not need to be submitted to the DOJ or FTC.⁴⁸ The FTC reported that during FY2012 (October 1,

⁴² See Scott Bergeson, "A Vaccine Approach to the Reverse Payment Illness," 18 *Richmond Journal of Law and Technology* (2012), 14.

⁴³ *In re Ciprofloxacin Antitrust Litigation*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

⁴⁴ See Thomas F. Cotter, "Antitrust Implications of Patent Settlements Involving Reverse Payments: Defining a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship," 71 *Antitrust Law Journal* (2004), 1069.

⁴⁵ P.L. 108-173, 117 Stat. 2066.

⁴⁶ MMA, §1112(a)(1).

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*, at §1112(c)(1).

2011, to September 30, 2012), the agency received “140 final resolutions of patent disputes between a brand and a generic, of which 40 settlements may involve pay-for-delay payments.”⁴⁹

Although the MMA imposed a filing obligation upon certain patent settlements between pharmaceutical firms, that legislation did not set substantive standards as to the validity of these agreements. Both prior and subsequent to congressional enactment of the MMA, however, various government and private actors asserted that certain reverse payment settlements violated the antitrust laws. In order to resolve these claims, different courts applied general principles of antitrust law. Facing different factual patterns, the courts ultimately reached varying results. After introducing the basic concepts of antitrust law, this report next reviews several judicial opinions that address reverse payment settlements.

Antitrust Implications of Reverse Payment Settlements

General Antitrust Standards

The primary legal mechanism for addressing conduct alleged to be anti-competitive—including reverse payment settlements—consists of the antitrust laws. The antitrust laws are comprised of the Sherman Act, the Clayton Act, the Federal Trade Commission Act, and other federal and state statutes that prohibit certain kinds of anticompetitive economic conduct. Although a complete review of the antitrust laws exceeds the scope of this report, other sources provide more information for the interested reader.⁵⁰

Section 1 of the Sherman Act declares “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade ... to be illegal.” The courts have long interpreted this language as applying only to unreasonable restraints of trade. The determination of whether particular conduct amounts to an unreasonable restraint of trade is commonly conducted under the “rule of reason.” Under this approach, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”⁵¹ The rule of reason essentially calls upon courts to reach a judgment of reasonableness by balancing the anticompetitive consequences of a challenged practice against its business justifications and potentially procompetitive impact.⁵²

Other sorts of restraints are deemed unlawful *per se*. *Per se* illegality is appropriate “[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the

⁴⁹ See Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2000, Overview of Agreements Filed in FY2012: A Report by the Bureau of Competition (available at <http://www.ftc.gov/os/2013/01/130117mmareport.pdf>), 1.

⁵⁰ See, e.g., Federal Trade Commission, *FTC Guide to the Antitrust Laws* (available at <http://www.ftc.gov/bc/antitrust/>).

⁵¹ *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

⁵² See Meredith Bateman, “*In re K-Dur Antitrust Litigation*—Reverse Payments: Against Prices, Purchasers, and Policy,” 15 *Tulane Journal of Technology and Intellectual Property* (2012), 293.

rule of reason will condemn it.” The Supreme Court has explained that “there are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.”⁵³ Among the practices that have been judged *per se* violations are price fixing, group boycotts, and market division.⁵⁴

In some circumstances, courts apply an antitrust standard that falls between the *per se* illegality standard and the rule of reason. The so-called “quick look” or “truncated rule of reason” approach applies when the plaintiff demonstrates that the defendant has engaged in practices similar to those previously held to be subject to *per se* treatment. In these circumstances, the defendant must then demonstrate that the practice has pro-competitive justifications in order to avoid liability for an antitrust violation.⁵⁵

Judicial Approaches to Reverse Payment Settlements

The courts have differed in their antitrust approaches to reverse payment settlements in pharmaceutical patent litigation.⁵⁶ The first two appellate courts to address this issue, from the District of Columbia and Sixth Circuits, subjected such agreements to strict antitrust scrutiny.⁵⁷ The Sixth Circuit opinion in *In re Cardizem CD Antitrust Litigation* is representative of this approach.⁵⁸ There the Court of Appeals held that a reverse payment settlement agreement between Hoescht Marion Roussel Inc. and Andrx Pharmaceuticals was *per se* invalid. The Sixth Circuit reasoned that the HMR-Andrx agreement was appropriately classified as a so-called horizontal agreement; that is to say, a restraint of trade involving businesses at the same level of competition. Such agreements had long been classified as antitrust violation *per se*, the Court of Appeals explained.

Despite this early precedent, three subsequent Courts of Appeals to consider the matter—from the Second, Eleventh, and Federal Circuits—reached a different result, ruling that reverse payment settlements were permissible so long as they do not authorize arrangements that exceed the scope of the patent.⁵⁹ One representative case, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,⁶⁰ involved agreements Abbott Laboratories reached with two different generic firms, Zenith Goldline Pharmaceuticals and Geneva Pharmaceuticals. At trial, the district court held that the two settlement agreements constituted a horizontal market allocation that was *per se* illegal under the Sherman Act. The Eleventh Circuit reversed on appeal, concluding that the standard of *per se* illegality was “premature” and inappropriate. Instead, the Court of Appeals remanded the matter

⁵³ Northern Pacific Railroad Co. v. United States, 356 U.S. 1, 5 (1957).

⁵⁴ See *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007).

⁵⁵ See *California Dental Association v. FTC*, 526 U.S. 756 (1999).

⁵⁶ See Einer Elhauge & Alex Krueger, “Solving the Patent Settlement Puzzle,” 91 *Texas Law Review* (2012), 283.

⁵⁷ See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Andrx Pharms. Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001).

⁵⁸ 332 F.3d 896 (6th Cir. 2003).

⁵⁹ See *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

⁶⁰ 344 F.3d 1294 (11th Cir. 2003).

for a determination of whether any part of the agreement went beyond the protections afforded by the brand-name firm's patent and, if so, to apply antitrust scrutiny only to those portions of the agreement. Under this "scope of the patent" approach, reverse payment settlements are permitted so long as (1) the commercial arrangement dictated by the settlement does not extend beyond the scope of the patent; (2) the patent holder's claim of infringement was not objectively baseless; and (3) the patent was not obtained by defrauding the USPTO.

On July 16, 2012, the Court of Appeals for the Third Circuit addressed the antitrust status of reverse payments settlements in *K-Dur Antitrust Litigation*.⁶¹ The Third Circuit rejected the scope of the patent test, explaining that "that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition."⁶² The Third Circuit believed that courts following the scope of the patent test had placed too much weight on the presumption of validity accorded to granted patents. This presumption was merely a procedural device, not a substantive right of the patent holder, the Court of Appeals explained.⁶³

The Court of Appeals also recognized the judicial preference for private settlements, but reasoned that this practice should not displace congressional goals underlying the Hatch-Waxman Act—including the invalidation of improvidently granted patent through litigation.⁶⁴ In the view of the Third Circuit, the scope of the patent test essentially prevented antitrust authorities from reviewing settlement agreements involving weak or narrow patents that would not have blocked generic competition.⁶⁵ In place of the scope of the patent test, the Third Circuit adopted a "quick rule of reason" test that presumed that reverse payments were anticompetitive. However, the parties to the agreement could rebut that conclusion by demonstrating that the payments were for a purpose other than delayed entry or offered some pro-competitive benefit.⁶⁶

In view of this conflict between the lower courts, the Supreme Court agreed to hear the case of *Federal Trade Commission v. Actavis, Inc.*⁶⁷ There, the Court held that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach.⁶⁸ However, the Court declined to hold that such settlements should be presumptively illegal under a "quick look" analysis.⁶⁹

Solvay Pharmaceuticals is the NDA holder of the testosterone-replacement drug ANDROGEL®. When generic firms Actavis and Paddock Laboratories filed paragraph IV ANDAs, Solvay brought charges of patent infringement in keeping with the Hatch-Waxman Act. The parties ultimately settled the case, with the generic firms receiving substantial sums of money in

⁶¹ 686 F.3d 197 (3rd Cir. 2012).

⁶² *Ibid.*, at 214.

⁶³ *Ibid.*, at 214-15.

⁶⁴ *Ibid.*, at 217-18.

⁶⁵ *Ibid.*, at 217.

⁶⁶ *Ibid.*, at 218.

⁶⁷ 570 U.S. ____ (June 17, 2013). Citations are to the slip opinion.

⁶⁸ *Ibid.*, slip op. at 20-21.

⁶⁹ *Ibid.*

exchange for the promise not to market their products until August 31, 2015, 65 months before Solvay's patent expired.⁷⁰

The FTC subsequently charged the settling parties with a violation of Section 5 of the Federal Trade Commission Act⁷¹ by unlawfully agreeing “to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.”⁷² The District Court for the Northern District of Georgia rejected the FTC’s claims,⁷³ and on appeal the Eleventh Circuit affirmed. Applying the “scope of the patent” standard that had been developed in earlier cases, the Court of Appeals explained that “absent sham litigation or fraud in obtaining a patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the exclusionary potential of the patent.”⁷⁴

The Supreme Court subsequently granted certiorari and, in a 5-3 ruling, reversed the judgment of the Eleventh Circuit and remanded. Writing for the majority, Justice Breyer accepted that the anticompetitive effects of the agreement between Solvay and the generic firms fell with the scope of its patent. However, this fact by itself did not immunize the agreement from antitrust scrutiny, he reasoned. The majority explained that while the holder of a valid patent may be exempt from antitrust liability when enforcing the exclusionary right, litigation under the Hatch-Waxman Act involves assertions of patent invalidity or noninfringement. If the generic firm successfully makes either case, the patent proprietor would not enjoy the right to exclude the proposed generic product from the marketplace. As a result, such agreements may have significant adverse effects on competition.

Justice Breyer therefore reasoned that “it would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”⁷⁵ Observing that its precedent had held that certain patent-related settlements can violate the antitrust laws, the Court summarized its patent-antitrust case law as follows:

[R]ather than measure the length or amount of a restriction solely against the length of the patent’s term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.⁷⁶

The Court also concluded that the structure of the Hatch-Waxman Act—including its patent challenge provisions, requirement of notification of settlements to the antitrust authorities, and its “general procompetitive thrust”—was consistent with subjecting reverse payment settlements to antitrust scrutiny.⁷⁷

⁷⁰ *Ibid.*, at 5-6.

⁷¹ 15 U.S.C. § 45.

⁷² *Slip op.* at 6.

⁷³ 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

⁷⁴ 677 F.3d 1298, 1312 (11th Cir. 2012).

⁷⁵ 570 U.S. at ____, *slip op.* at 8-9.

⁷⁶ *Ibid.*, at 9-10.

⁷⁷ *Ibid.*, at 13.

Justice Breyer acknowledged that the strong judicial policy favoring the settlement of disputes supported the holding of the Eleventh Circuit. But he cited five considerations in support of a contrary result:

[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.⁷⁸

Finally, Justice Breyer declined to adopt the Commission’s suggestion that reverse payment settlements should be presumptively unlawful and subject to a “quick-look approach.” According to the majority, this approach was appropriate only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”⁷⁹ This treatment was inappropriate here because the likelihood of a reverse payment bringing about anticompetitive effects depends upon a number of factors, including the size of the payment, its scale in relation to the payor’s anticipated litigation costs, its independence from other consideration within the settlement, and the lack of any other convincing justification. Instead, the Court concluded that the FTC must establish antitrust liability using the traditional rule of reason analysis.⁸⁰

Chief Justice Roberts contributed a dissent that was joined by Justices Scalia and Thomas. The dissent would have held that a reverse payment settlement violates antitrust law only when it exceeds the scope of the patent, the patents were obtained by fraud, or the patentee engages in sham litigation.⁸¹ The dissenters feared that the majority holding would dissuade generic firms from challenging patents in the first place,⁸² discourage settlement of patent litigation,⁸³ and weaken the protection afforded to innovators by patents.⁸⁴

Although the Supreme Court’s opinion in *Actavis* does not eliminate the ability of pharmaceutical firms to settle litigation under the Hatch-Waxman Act, the contracting parties will have to structure and explain their agreements carefully. Parties that lack the appetite for such an effort will be left to litigate their pharmaceutical patent cases to a final conclusion. With respect to existing agreements, the lower courts have been assigned the potentially complex task of giving substance to the rule of reason in Hatch-Waxman cases. Justice Breyer was of the view that Hatch-Waxman antitrust cases would not routinely involve a detailed examination of the validity and infringement of the underlying patent. However, the Chief Justice expressed concern that the

⁷⁸ *Ibid.*, at 19-20.

⁷⁹ *Ibid.*, at 20.

⁸⁰ *Ibid.*, at 20-21.

⁸¹ Slip op. at 3.

⁸² *Ibid.*, at 17.

⁸³ *Ibid.*, at 11.

⁸⁴ *Ibid.*, at 18.

issues of patent invalidity and infringement lie at the core of the antitrust dispute. In his view, resolution of these issues could prove extremely intricate and costly.

Issues and Observations

In view of this landscape, several options are available for Congress. One possibility is to await further judicial developments. The Supreme Court's *Actavis* decision arguably resolved the split among the courts of appeal with respect to reverse payment settlements, but it remains to be seen how the lower courts will continue to refine this case law.

Another option is to regulate the settlement of pharmaceutical patent litigation in some manner. Two bills in the 113th Congress pertain to reverse payment settlements. The Preserve Access to Affordable Generics Act, S. 27, would declare that certain reverse payment settlements constitute acts of unfair competition. In particular, that bill would amend the Federal Trade Commission Act to provide that an agreement “shall be presumed to have anticompetitive effects and be unlawful if—(i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.” That presumption would not apply if the parties to the agreement demonstrated by clear and convincing evidence that the procompetitive benefits of the agreement outweighed the anticompetitive effects of the agreement. S. 27 includes a list of factors to be weighed by the courts in such circumstances.⁸⁵

In addition, the Fair and Immediate Release of Generics Act, S. 504, would make a number of changes to the Hatch-Waxman Act in order to discourage reverse payments settlements. In particular, S. 504 would grant any generic firm the right to share the 180-day regulatory exclusivity if it wins a patent challenge in the district court or is not sued for patent infringement by the brand company.⁸⁶ The legislation would also obligate generic firms to abide by any deferred entry date agreed to in their settlements with brand-name firms, even if relevant patents were struck down previously.⁸⁷ Finally, brand-name firms would be required to make a decision to enforce their patents within 45 days of being notified of a patent challenge by a generic firm under the Hatch-Waxman Act.⁸⁸

The settlement of pharmaceutical patent litigation forms an important issue because such litigation is itself important to our public health system. Our patient population relies upon brand-name drug companies to develop new medicines, but it also relies upon generic firms to increase access to such medications once they have been developed. The Hatch-Waxman Act provides for patent litigation between these two traditional rivals as a primary vehicle through which these competing demands are mediated. When concluded in a manner that comports with antitrust principles, such settlements may further the public policy goals of encouraging the labors that lead to medical innovation, but also distributing the fruits of those labors to consumers.

⁸⁵ S. 27 at §3.

⁸⁶ S. 504 at §2.

⁸⁷ *Ibid.*, at §3(a).

⁸⁸ *Ibid.*, at §3(b).

Author Contact Information

(name redacted)

Visiting Scholar

[redacted]@crs.loc.gov, 7-....

EveryCRSReport.com

The Congressional Research Service (CRS) is a federal legislative branch agency, housed inside the Library of Congress, charged with providing the United States Congress non-partisan advice on issues that may come before Congress.

EveryCRSReport.com republishes CRS reports that are available to all Congressional staff. The reports are not classified, and Members of Congress routinely make individual reports available to the public.

Prior to our republication, we redacted names, phone numbers and email addresses of analysts who produced the reports. We also added this page to the report. We have not intentionally made any other changes to any report published on EveryCRSReport.com.

CRS reports, as a work of the United States government, are not subject to copyright protection in the United States. Any CRS report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS report may include copyrighted images or material from a third party, you may need to obtain permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

Information in a CRS report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to members of Congress in connection with CRS' institutional role.

EveryCRSReport.com is not a government website and is not affiliated with CRS. We do not claim copyright on any CRS report we have republished.