

Pharmaceutical Patent Litigation Settlements: Implications for Competition and Innovation

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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 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 proprietor to the accused infringer, this compensation has been termed a "reverse" payment.

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

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 courts have concluded that a particular reverse payment settlement constituted an antitrust violation, while others have upheld the agreement.

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 111th Congress, S. 369, the Preserve Access to Affordable Generics Act, would establish a presumption that certain reverse payment settlements are unlawful. S. 369 then establishes relevant factors to be weighed in deciding whether that presumption has been overcome through a showing that the procompetitive benefits of the settlement outweigh its anticompetitive effects.

This report will be updated as needed.

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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,[2] in part reformed the patent laws to balance incentives for innovation and competition within the pharmaceutical industry. Congress subsequently amended this legislation on several occasions, most recently via the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[3]

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.[4] 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.[5] 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"[6] or "exit"[7] payment or, because the payment flows counterintuitively, from the patent proprietor to the accused infringer, a "reverse" payment."[8]

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.[9] Others conclude that when one competitor pays another not to market its product, such a settlement is anti-competitive and a violation of the antitrust laws.[10]

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[1] P.L. 84-417, 98 Stat. 1585 (1984).

[2] *See, e.g.,* Laura J. Robinson, "Analysis of Recent Proposals to Reconfigure Hatch-Waxman," 11 *Journal of Intellectual Property Law* (2003), 47.

[3] P.L. 108-173, 117 Stat. 2066.

[4] 35 U.S.C. § 281 (2006).

[5] *See* John Fazzio, "Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property and Antitrust Law Require a Return to the Rule of Reason," 11 *Journal of Technology Law and Policy* (2006), 1.

[6] *See* Herbert Hovenkamp *et al.*, "Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments," 88 *Minnesota Law Review* (2004), 712.

[7] Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003).

[8] *See* Thomas F. Cotter, "Refining the 'Presumptive Illegality' Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley," 87 *Minnesota Law Review* (2003), 1789.

[9] *See* Kent S. Bernard & Willard K. Tom, "Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles," 15 *Federal Circuit Bar Journal* (2006), 617.

[10] *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.

Since 2003, Congress has required that litigants notify federal antitrust authorities of their pharmaceutical patent settlements.[11] To date, Congress has not stipulated 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. Uniformity of results has not been a hallmark of this line of cases.[12] Facing different factual patterns, some courts have concluded that a particular reverse payment settlement constituted an antitrust violation,[13] while others have upheld the agreement.[14] The judicial tendency is towards a more favorable view of reverse payment settlements, however.[15] In the 111th Congress, one legislative proposal would take a different approach. The Preserve Access to Affordable Generics Act (S. 369) would establish a presumption that certain reverse payment settlements are unlawful. S. 369 then establishes relevant factors to be weighed in deciding whether that presumption has been overcome through a showing that the procompetitive benefits of the settlement outweigh its anticompetitive effects.

This report introduces and analyzes innovation policy issues concerning 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 alternatives.

Patent Disputes Under the Hatch-Waxman Act

Patent Fundamentals

In order to obtain patent protection, individuals and firms must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[16] USPTO officials, known as examiners, then assess whether the application merits the award of a patent.[17] Under the Patent Act of 1952,[18] a patent application must include a specification that so completely describes the invention that skilled artisans are able to practice it without undue experimentation. The Patent Act also requires that applicants draft at least one claim that particularly points out and distinctly claims the subject matter that they regard as their invention.[19]

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

[11] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 173 ,117 Stat. 2066, § 1112(a).

[12] *See* John R. Thomas, *Pharmaceutical Patent Law* (2005), 572-73.

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

[14] *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[15] *See* James C. Burling, "Hatch-Waxman Patent Settlements: The Battle for a Benchmark," *20-SPG Antitrust* (2006), 41.

[16] 35 U.S.C. § 111 (2006).

[17] 35 U.S.C. § 131 (2006).

[18] P.L. 593, 66 Stat. 792 (1952).

[19] 35 U.S.C. § 112 ¶ 2 (2006).

domain.[20] 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.[21]

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.[22] The term of the patent is ordinarily set at twenty years from the date the patent application was filed.[23] 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.[24]

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 usually 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.[25] 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.[26] 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).

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.[27] The result was that a would-be generic drug manufacturer had to file its own NDA in order to sell its product.[28] 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,

[20] 35 U.S.C. § 102 (2006).

[21] 35 U.S.C. § 103 (2006).

[22] 35 U.S.C. § 271(a) (2006).

[23] 35 U.S.C. § 154(a)(2) (2006).

[24] *See* Jayanta Bhattacharya & William B. Vogt, "A Simple Model of Pharmaceutical Price Dynamics," 4 *Journal of Law & Economics* (2003), 599.

[25] CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV.

[26] *See* G. Lee Skillington & Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law and Business* (2003), 1.

[27] *See* Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389.

[28] *See* James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984," 34 *Catholic University Law Review* (1986), 433.

however, not all generic firms could file a paper NDA.[29] 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.[30] The result was that some generic manufacturers were forced to prove once more that a particular drug was safe and effective, even though their products were chemically identical to those of previously approved pharmaceuticals.

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process.[31] 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.[32]

In response to these concerns, Congress enacted the Hatch-Waxman Act, a statute that has been described as a "complex and multifaceted compromise between innovative and generic pharmaceutical companies."[33] Its provisions included the creation of two statutory pathways that expedited the marketing approval process for generic drugs. The first of these consist of Abbreviated New Drug Applications, or ANDAs. 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 second are so-called § 505(b)(2) applications, which are sometimes still referred to as "paper NDAs." Like an NDA, a § 505(b)(2) application contains a full report of investigations of safety and effectiveness of the proposed product. In contrast to an NDA, however, a § 505(b)(2) application typically relies, at least in part, upon published literature providing pre-clinical or clinical data.

The availability of ANDAs and § 505(b)(2) applications often allow 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.[34]

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.[35] The scope

[29] *See* Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interest or Survival of the Fittest?," 57 *Food & Drug Law Journal* (2002), 247.

[30] *Id.*

[31] *See, e.g.,* Justina A. Molzon, "The Generic Drug Approval Process," 5 *Journal of Pharmacy & Law* (1996), 275 ("The Act streamlined the approval process by eliminating the need for [generic drug] sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.").

[32] *See* Jonathan M. Lave, "Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?," 64 *University of Pittsburgh Law Review* (2002), 201 ("Hatch-Waxman has also increased the generic drug share of prescription drug volume by almost 130% since its enactment in 1984. Indeed, nearly 100% of the top selling drugs with expired patents have generic versions available today versus only 35% in 1983.").

[33] Natalie M. Derzko, "A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?," 44 *IDEA: Journal of Law and Technology* (2003), 1.

[34] *See, e.g.,* Sarah E. Eurek, "Hatch-Waxman Reform and Accelerated Entry of Generic Drugs: Is Faster Necessarily Better?," 2003 *Duke Law & Technology Review* (Aug. 13, 2003), 18.

[35] 35 U.S.C. § 156(b) (2006).

of rights during the period of extension is generally limited to the use approved for the product that subjected it to regulatory delay.[36] 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.[37]

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 § 505(b)(2) application 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.

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.[38] 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."[39] Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA or § 505(b)(2) 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.[40]

These certifications are respectively termed paragraph I, II, III, and IV certifications.[41] An ANDA or § 505(b)(2) application certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[42] An independent generic firm that files an ANDA or § 505(b)(2) application including a paragraph III certification must, even after

[36] 35 U.S.C. § 156(b)(1) (2006).

[37] *See* CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, and CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, both by Wendy H. Schacht and John R. Thomas.

[38] 21 U.S.C. § 355(b)(1) (2006).

[39] *See, e.g.,* Jacob S. Wharton, "'Orange Book' Listing of Patents Under the Hatch-Waxman Act," 47 *St. Louis University Law Journal* (2003), 1027.

[40] 21 U.S.C. § 355(j)(2)(A)(vii) (2006).

[41] *See* Douglas A. Robinson, "Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now In Exchange for Less Pharmaceutical Innovation Later?," 81 *Washington University Law Quarterly* (2003), 829.

[42] 21 U.S.C. § 355(j)(5)(B)(i) (2006).

meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[43]

The filing of an ANDA or § 505(b)(2) application with a paragraph IV certification constitutes a "somewhat artificial" act of patent infringement under the Hatch-Waxman Act.[44] The act requires the independent generic applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification.[45] The patent owner may then commence patent infringement litigation against that applicant.

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.[46] Once a first ANDA with a paragraph IV certification has been filed, the FDA 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 could potentially obtain more handsome profits than subsequent market entrants—thereby stimulating patent challenges in the first instance.[47]

As originally enacted, the Hatch-Waxman Act stipulated that the first paragraph IV certification triggered entitlement to the 180-day generic exclusivity period. The ANDA applicant need take no further steps whatsoever. In particular, the statute did not require the generic applicant to pursue a favorable judgment with respect to the challenged patent, seek FDA approval of the ANDA, or market its generic product once the FDA granted marketing approval.[48] Some commentators believed that the legislation led to abuses by certain first paragraph IV ANDA applicants, who "parked" their period of exclusivity in order to bar generic competition, rather than actively pursue the marketing of their own generic products. As pharmaceutical patent expert Alfred Engelberg has asserted:

> Experience has shown that the first ANDA applicant to file a patent challenge may never trigger the start of the 180-day period, thereby blocking the FDA from granting approval to any generic product. More often than not, the first generic challenger will enter into a lucrative cash settlement with the patent owner that results in a judgment in favor of the patent and prohibits the challenger from marketing a product under its ANDA until the patent expires. Therefore, the 180-day exclusivity period never starts. And no subsequently filed ANDA can be approved unless a final judgment adverse to the patent is obtained by one of the subsequent applicants. But even in that circumstance, the winning party would be

[43] 21 U.S.C. § 355(j)(5)(B)(ii) (2006).

[44] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 1047 (1990).

[45] 21 U.S.C. § 355(j)(2)(B)(i) (2006).

[46] 21 U.S.C. § 355(j)(5)(B)(iv) (2006). Section 505(b)(2) applications do not qualify for the 180-day generic exclusivity period. U.S. Department of Health & Human Services, FDA, Center for Drug Evaluation & Research, "Guidance for Industry, Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, As Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," at 5 n.14 (Oct. 2004).

[47] *See generally* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

[48] Thomas, *supra* note 12, at 356.

> compelled to wait 180 days before enjoying the fruits of its victory and would not receive any exclusivity of its own. This result is dictated by the fact that, under the language of the statute, the 180 days of exclusivity belong solely to the first challenger and not to the first winner.[49]

When Congress amended the Hatch-Waxman Act in 2003, it responded to this concern over "bottlenecking" by generic firms. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) established a number of "forfeiture events" that, if triggered, cause a first paragraph IV ANDA applicant to lose its entitlement to the 180-day generic exclusivity.[50] 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.[51] If the first paragraph IV ANDA applicant forfeits its exclusivity, then this period does not "roll over" to the second such applicant. In that event, no generic firm enjoys exclusivity at all.[52] The possibility of forfeiture was intended "to prevent the practice of 'parking' the exclusivity period and to force generic manufacturers to market promptly."[53]

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 a 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 or § 505(b)(2) applications in this event, replacing their paragraph IV certifications with paragraph III certifications.[54]

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.[55] In this circumstance, the independent generic firm may launch its product once the FDA has finally approved its ANDA or § 505(b)(2) application.

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

[49] Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: The Journal of Law and Technology* (1999), 389.

[50] P.L. 108-173, 117 Stat. 2066.

[51] 21 U.S.C. § 355(j)(5)(D)(i) (2006).

[52] Thomas, *supra* note 12, at 366.

[53] 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).

[54] 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(i) (2006).

[55] Although patents enjoy a presumption of validity, 35 U.S.C. § 282 (2006), that presumption is not uncontestable. Accused infringers may demonstrate that the patent does not meet the standards established by the Patent Act, and as a result should not have been issued by the U.S. Patent and Trademark Office. *Id.* In addition, an accused infringer may demonstrate that the patent is unenforceable on a number of grounds, among that its owner has engaged in "misuse" of the patent. *Id.*

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

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.[56] 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.[57]

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. Settlements can allow the parties to avoid the expenses of litigation, achieve a resolution to the dispute in a timely manner, and avoid the risk of an uncertain result in the courtroom.[58] The settlement of litigation further serves the goal of resolving disputes in a peaceful manner, and also preserves scarce judicial resources.[59] 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.[60]

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 "split" the remaining patent term, 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.[61]

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

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[56] *See* John E. Lopatka, "A Comment on the Antitrust Analysis of Reverse Payment Patent Settlements: Through the Lens of the Hand Formula," 79 *Tulane Law Review* (2004), 235.

[57] *See* Jonathan M. Lave, "Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?," 64 *University of Pittsburgh Law Review* (2002), 201.

[58] *See generally* Chris Guthrie, "Better Settle Than Sorry: The Regret Aversion Theory of Litigation Behavior," *University of Illinois Law Review* (1999), 43.

[59] *See* Stephen McG. Bundy, "The Policy in Favor of Settlement in an Adversary System," 44 *Hastings Law Journal* (1992), 1.

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

[61] *See* Marc G. Schildkraut, "Patent-Splitting Settlements and the Reverse Payment Fallacy," 71 *Antitrust Law Journal* (2004), 1033.

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 accused infringer may well be willing to compensate the patent proprietor in order to avoid the risk of such a holding.[62]

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.[63]

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.[64]

At the present time, the congressional response to pharmaceutical patent litigation settlements has been limited. In the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA),[65] 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.[66] 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 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.[67]

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

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[62] *See* Kristopher L. Reed, "A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements Under the Hatch-Waxman Act," 40 *Gonzaga Law Review* (2004), 457.

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

[64] Cotter, *supra* note 10.

[65] P.L. 108-173, 117 Stat. 2066.

[66] MMA, §1112(a)(1).

[67] MMA, §1112(a)(1).

facility contracts, employment or consulting contracts, or packaging and labeling contracts do not need to be submitted to the DOJ or FTC.[68] Further, the filing obligation applies only to ANDAs that include a paragraph IV certification. In particular, agreements with respect to § 505(b)(2) applications need not be filed.

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.[69] 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.[70] After introducing the basic concepts of antitrust law, this report next reviews several of the more notable judicial opinions analyzing reverse payment settlements.

Antitrust Implications of Reverse Payment Settlements

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.[71]

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."[72] 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.

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 rule of reason will condemn it."[73] The Supreme Court has explained that "there are certain

[68] *Id.* at §1112(c)(1).

[69] *See* Thomas, *supra* note 12, at 571.

[70] *See* M. Elaine Johnston, *et al.*, "Antitrust Aspects of Settling Intellectual Property Litigation," 867 *Practising Law Institute/Patent* (June 2006), 159.

[71] *See* CRS Report RL31026, *General Overview of United States Antitrust Law*, by Janice E. Rubin.

[72] *Id.* at 906 (quoting Arizona v. Maricopa City Medical Soc., 457 U.S. 332, 343 n.13 (1982)).

[73] *Id.*

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."[74] Among the practices that have been judged *per se* violations include price fixing, group boycotts, and market division.[75]

As this report will review, the courts have differed in their approaches to reverse payment settlements in pharmaceutical patent litigation. The Court of Appeals for the Sixth Circuit has held that one reverse payment settlement constituted a *per se* violation of the antitrust laws. The Courts of Appeals for the Second, Eleventh, and Federal Circuits have declined *per se* treatment to reverse payment settlements, employing a more permissive mode of analysis based upon the traditional rule of reason approach.[76] This report next reviews the facts and holdings of significant judgments addressing the antitrust implications of reverse payment settlements.

Sixth Circuit

In *In re Cardizem CD Antitrust Litigation*,[77] the Court of Appeals for the Sixth Circuit held that a reverse payment settlement agreement between Hoescht Marion Roussel Inc. (HMR) and Andrx Pharmaceuticals was *per se* invalid under the antitrust laws. HMR marketed the prescription drug CARDIZEM CD® and owned several patents pertaining to that product. Andrx was the first generic firm to file a paragraph IV ANDA pertaining to CARDIZEM CD®. HMR subsequently sued Andrx for patent infringement as provided by the Hatch-Waxman Act.

Shortly after the FDA tentatively approved Andrx's ANDA, HMR and Andrx agreed to an interim settlement. Under the terms of that deal, Andrx agreed to refrain from marketing a generic version of CARDIZEM CD® until one of three events occurred: namely, that Andrx obtained a final, unappealable judgment in its favor with respect to its patent claims; that HMR licensed Andrx to market a generic version of CARDIZEM CD®; or that HMR licensed a third party to do so. Andrx further agreed to continue pursuing its ANDA at the FDA and not to relinquish or transfer its 180-day period of generic marketing exclusivity. In exchange, HMR paid Andrx $10 million per quarter.[78]

Various purchasers of CARDIZEM CD® subsequently brought suit against HMR and Andrx, alleging several violations of state and federal antitrust laws. The District Court for the Eastern District of Michigan subsequently concluded that the HMR-Andrx agreement constituted a horizontal market allocation agreement that was *per se* illegal under the antitrust laws.[79] Following an appeal, the Court of Appeals for the Sixth Circuit affirmed.

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

[75] Rubin, *supra* note 71.

[76] *See generally* Larissa Burford, "*In re Cardizem* & *Valley Drug Co.*: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform," 19 *Berkeley Technology Law Journal* (2004), 365; Richard D. Chaves Mosier & Steven W. Ritcheson, "*In re Cardizem* and *Valley Drug*: A View from the Faultline Between Patent and Antitrust in Pharmaceutical Settlements," 20 *Santa Clara Computer & High Technology Law Journal* (2004), 497.

[77] 332 F.3d 896 (6th Cir. 2003).

[78] *Id.* at 901-03.

[79] 105 F. Supp. 2d 682, 699 (E.D. Mich. 2000).

The court of appeals characterized the deal as one in which HMR and Andrx agreed to eliminate competition in the CARDIZEM CD® market. Because Andrx was entitled to the 180-day generic exclusivity, and because its agreement occurred prior to the 2003 amendments to the Hatch-Waxman Act,[80] Andrx was able to "park" its generic exclusivity and prevent all other generic firms from marketing. 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 explained.[81]

In reaching this conclusion, the Sixth Circuit explicitly rejected several arguments offered by HMR and Andrx. The defendants asserted that because the courts did not have extensive experience with reverse payment settlements, they lacked a sufficient basis for declaring them *per se* illegal. The Sixth Circuit instead noted that "[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike."[82] Judge Oberdorfer further stated 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."[83]

The first court of appeals to address reverse payment settlements, the Sixth Circuit is thus far the only appellate court to apply a rule of illegality *per se* to reverse payment settlements. Subsequent courts, facing somewhat different factual circumstances, gave these settlements less strict antitrust oversight by applying an analysis that more closely resembled the traditional rule of reason approach. This report next reviews these developments, which arose from judicial opinions issued by the Eleventh and Second Circuits.

Eleventh Circuit

In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[84] the U.S. Court of Appeals for the Eleventh Circuit declined to employ the *per se* rule employed by the Sixth Circuit. Instead, the Eleventh Circuit adopted a more permissive method of analysis that resembles the traditional rule of reason. The *Valley Drug* case involved an arrangement Abbott Laboratories had reached with two different generic firms, Zenith Goldline Pharmaceuticals and Geneva Pharmaceuticals. Abbott was the NDA holder of the drug HYTRIN®, prescribed for treatment of hypertension and enlarged prostate. Abbott also owned several patents pertaining to HYTRIN®, including U.S. Patent No. 5,504,207 (the '207 patent). Zenith and Geneva each filed paragraph IV ANDAs with respect to HYTRIN®, resulting in patent infringement litigation.[85]

Abbott subsequently negotiated separate settlement agreements with Zenith and Geneva. In both agreements, the generic firm promised not to sell any pharmaceutical product containing terazosin hydrochloride, the active ingredient in HYTRIN®, until a relevant Abbott patent

[80] *See supra* notes 48-49 and accompanying text.

[81] 105 F. Supp. 2d at 907.

[82] *Id.* at 908 (quoting United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 222 (1940)).

[83] *Id.*

[84] 344 F.3d 1294 (11th Cir. 2003).

[85] *Id.* at 1298-99.

expired or was held invalid, or someone else introduced a generic version of this drug. Each generic firm also promised not to transfer or sell its rights to a 180-day exclusivity under the Hatch-Waxman Act. In return, Abbott promised to pay each generic firm a significant sum of money each month, subject to a number of termination events, including introduction of a generic version of HYTRIN® by a third party.[86]

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. According to the district court, the generic houses were poised to market a generic version of HYTRIN®, but simply agreed not to enter the market due to their deal with Abbott.[87]

Following an appeal, the Eleventh Circuit reversed the district court's opinion and remanded for further proceedings. In reaching this result, the court of appeals held that the standard of *per se* illegality was "premature" and inappropriate.[88] According to Judge Anderson, the district court had not appropriately factored the existence of the '207 patent into the analysis. The court of appeals explained that:

> [A] patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and that is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agreements as territorial market allocations agreements, the district court did not consider that the '207 patent gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride until October of 2014, when it is due to expire. To the extent that Zenith and Geneva agreed to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.[89]

Rather, the court of appeals identified several factors that should be considered by the district court on remand, including:

> (1) the scope of the exclusionary potential of the patent;
>
> (2) the extent to which the agreements exceed that scope; and
>
> (3) the resulting anticompetitive effects.[90]

In its subsequent decision in *Schering-Plough Corp. v. FTC*,[91] the Eleventh Circuit confirmed the approach taken in *Valley Drug*. This case concerned the Schering-Plough Corp. (Schering) drug K-DUR 20®, which is used to treat or prevent low potassium levels in the blood. Although the drug's active ingredient, potassium chloride, lies in the public domain, Schering's U.S. Patent 4,863,743 claims an extended-release coating used in K-DUR 20®. The '743 patent expired on September 5, 2006.[92] When two generic firms, Upsher-Smith Laboratories (Upsher) and ESI

[86] *Id.* at 1300-01.

[87] *Id.* at 1301-03.

[88] *Id.* at 1304.

[89] *Id.* at 1305.

[90] *Id.* at 1312.

[91] 402 F.3d 1056 (11th Cir. 2005).

[92] *Id.* at 1057.

Lederle Inc. (ESI), filed paragraph IV ANDAs, Schering promptly brought suit for patent infringement.

Schering subsequently resolved its differences with Upsher and ESI via two separate agreements. During its negotiations with Upsher, Schering refused to pay Upsher merely to "stay off the market."[93] Schering did agree to license five of Upsher's products, however. In addition, Upsher promised not to market a generic version of K-DUR 20® prior to September 1, 2001.[94] In exchange, Schering promised to pay Upsher a $60 million up-front royalty, along with $10 million in milestone royalty payments and royalties of 10% or 15% on sales.[95]

Under the ESI settlement, Schering agreed to allow ESI to market a generic version of K-DUR 20® on January 1, 2004. Schering also agreed to pay $5 million to cover ESI's legal fees, as well as $10 million if ESI received FDA approval to market its generic product by a certain date. Finally, Schering obtained the right to license two generic products from ESI for $15 million.[96]

Following a complaint by FTC counsel, the FTC Commission held that these arrangements were anticompetitive under the rule of reason.[97] Schering and Usher appealed the Commission's decision to the Eleventh Circuit, which reversed. Confirming its analysis under the contours laid out in *Valley Drug*, the Eleventh Circuit first observed that the '743 patent enjoyed a statutory presumption of validity.[98] Further, under the terms of their agreements with Schering, Upsher was able to market a generic product a full five years before the '743 patent's expiration, while ESI could market two years in advance.[99]

The Eleventh Circuit next concluded that the licenses granted to Schering constituted adequate consideration for the payments made by Schering, rather than amounting to thinly disguised payoffs to delay the introduction of generic competition. According to Judge Fay, Schering had long been interested in licensing those products. As a result, the Schering-Upsher and Schering-ESI agreements were legitimate settlements within the scope of the '743 patent's exclusionary power.[100]

Finally, the court of appeals compared the scope of the '743 patent with that of the Schering-Upsher and Schering-ESI agreements. Judge Fay concluded that they were commensurate, with each specifically addressing controlled release microencapsulated potassium chloride tablets. As a result the agreements could not be said to be overly broad, nor did they delay the entry of other generic products.[101] As a result, the decision of the FTC was reversed.[102]

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[93] *Id.* at 1059.

[94] *Id.*

[95] *Id.* at 1060.

[96] *Id.* at 1060-61.

[97] *In re* Schering-Plough Corp., Docket No. 9297 (Dec. 8, 2003) (available at 2003 WL 22989651).

[98] 402 F.3d at 1068.

[99] 402 F.3d at 1067-68.

[100] *Id.* at 1068-72.

[101] *Id.* at 1073.

[102] *Id.*

Second Circuit

The issue of reverse payment settlements came before the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*.[103] This judicial opinion resulted from extremely complex factual and legal circumstances. Zeneca was the owner of patent covering tamoxifen, the most widely prescribed drug for the treatment of breast cancer. A generic firm, Barr Laboratories, filed an ANDA that it subsequently amended to include a paragraph IV certification. Zeneca responded by filing a charge of patent infringement in keeping with the procedures of the Hatch-Waxman Act. In an opinion issued in 1992, the district court held that the tamoxifen patent was invalid and unenforceable[104]

Zeneca appealed the district court's judgment. While the appeal was pending, Zeneca and Barr entered into a confidential settlement agreement. As part of that deal, Barr agreed to amend its ANDA to include a paragraph III certification and further agreed not to sell its own generic version of tamoxifen until the patent's expiration in 2002. In exchange, Zeneca agreed to pay Barr $21 million and to provide Barr with a non-exclusive license to sell an "authorized generic" version of tamoxifen—that is to say, an Zeneca-manufactured tamoxifen under Barr's label.[105] The parties further agreed that if the tamoxifen patent were declared invalid or unenforceable, then Barr could revert to its paragraph IV certification.[106]

Pursuant to the settlement, and consistent with governing law at that time, the court of appeal remanded the case to the district court, which then vacated its judgment of invalidity and unenforceability.[107] Following the settlement between Zeneca and Barr, three other generic firms—Novopharm Ltd., Mylan Pharmaceutical, Inc., and Pharmachemie B.V.—filed tamoxifen ANDAs with paragraph IV certifications.[108] Zeneca once more filed charges of patent infringement against each of these firms as allowed by the Hatch-Waxman Act. In each of these three cases, the court refused to rely upon the vacated 1992 judgment to hold that Zeneca's tamoxifen patent was invalid. Further, the courts hearing the Noveopharm and Pharmachemie cases upheld the validity of Zeneca's tamoxifen patent.[109] The Mylan case ended with a consent order that FDA approval of the generic application would not become effective prior to the expiration of the tamoxifen patent.[110]

While those three cases were pending, the FDA granted tentative approval for Pharmachemie to market a generic version of tamoxifen. However, Barr petitioned the FDA to recognize that Barr was entitled to 180 days of generic marketing exclusivity[111] as the first paragraph IV ANDA

[103] 429 F.3d 370 (2d Cir. 2005).

[104] *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

[105] 429 F.3d at 377. For further discussion of authorized generics, see CRS Report RL33605, *Authorized Generic Pharmaceuticals: Effects on Innovation*, by John R. Thomas.

[106] 429 F.3d at 378.

[107] Subsequent to that decision, the Supreme Court held in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994), that mootness by reason of settlement does not justify vacatur of a federal civil judgment. *See U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed. Cir. 1995). The Supreme Court's ruling did not have retroactive effect, however, and as a result the tamoxifen patent remained extant.

[108] 429 F.3d at 378-79.

[109] *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, 2000 WL 34335805 (D. Mass. Sept. 11, 2000).

[110] *Zeneca UK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239 (W.D. Pa. 2000).

[111] *See supra* notes 46-47 and accompanying text.

applicant. The effective result was that the FDA prevented the marketing of other generic versions of tamoxifen until either the Zeneca patent expired, or 180 days elapsed from the date that Barr sold its own generic version of tamoxifen. Of course, because Barr was already distributing Zeneca's "authorized generic," Barr apparently had little incentive to launch its own generic product.[112]

Consumers and consumer groups subsequently filed numerous lawsuits challenging the settlement between Zeneca and Barr on antitrust grounds. The trial court rejected these claims, however, and on appeal the Second Circuit affirmed.[113] The Second Circuit began by observing that although a tension existed between antitrust law and patent law, the courts have long favored settlements of litigation. The court of appeals saw the law as well-settled that "'where there are legitimately conflicting [patent] claims ... , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act,' although such a settlement may ultimately have an adverse effect on competition."[114]

In view of longstanding policies favoring the settlement of litigation, the court of appeals concluded that "without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar—antitrust or otherwise—to the defendants' settling the litigation at the time that they did is unpersuasive."[115] The Second Circuit largely based its conclusion upon the fact that the outcome of patent litigation was unpredictable. That the 1992 judgment had found the tamoxifen patent invalid was, by itself, not of great moment: "That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it."[116] While holding that the reasonableness of the settlement must be judged at the time the agreement was concluded,[117] the court of appeals further observed that federal district courts in the later lawsuits disagreed with the 1992 judgment and upheld the tamoxifen patent.[118]

The Second Circuit next declined to condemn the existence of reverse payments in a pharmaceutical patent settlement as an antitrust violation *per se*. Agreeing with the analysis of the Eleventh Circuit in the *Schering-Plough* case that the Hatch-Waxman changed the relative risk profiles of the patent holder and accused infringer, the court of appeals found "no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent."[119]

The court of appeals further disagreed with the plaintiffs' contention that the Zeneca-Barr settlement was unlawful because "[t]he value of the consideration provided to keep Barr's product off the market ... greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic

[112] 429 F.3d at 379-80.

[113] *In re Tamoxifen Citrate Antitrust Litigation*, 277 F.Supp.2d 121(E.D.N.Y. 2003).

[114] *Id.* at 386 (quoting *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931)).

[115] *Id.* at 389.

[116] *Id.* at 389.

[117] *Id.* at 388.

[118] *Id.*

[119] *Id.* at 391.

product."[120] To the contrary, the Second Circuit reasoned, it may well make economic sense for the patent proprietor to pay its generic rival more than its expected earnings. The reason, of course, is that the total profits of the patent holder and generic firm in a competitive market would be less than the supracompetitive profits earned by the patentee alone, and that the patent proprietor might find it sensible to pay a portion of that difference to the generic firm. The Second Circuit further held that "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumptively entitled: a lawful monopoly over the manufacture and distribution of the patented product."[121]

The Second Circuit's analysis continued with a review of the terms of the Zeneca-Barr settlement agreement. Citing *Schering-Plough*, the court of appeals framed the question as "whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'"[122] The court of appeals characterized the tamoxifen patent as a compound patent, rather than one directed towards a more limited formulation. As a result, although the settlement precluded Barr from manufacturing any generic form of tamoxifen, so too did Zeneca's compound patent. The settlement agreement therefore did not restrain the marketing of non-infringing products, the court reasoned.[123]

The Second Circuit further explained that the Zeneca-Barr settlement also allowed Barr to introduce a authorized generic market into the tamoxifen market. Although the price difference between the Zeneca and Barr products was modest, this consumer benefit nonetheless occurred almost nine years before Zeneca's patent was due to expire. As a result, the settlement agreement produced more competition than would have occurred had the parties not settled and Zeneca had prevailed on appeal.[124] As a result, the Second Circuit affirmed the trial court's conclusion that the Zeneca-Barr settlement did not violate the antitrust laws.

Federal Circuit

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*,[125] the Federal Circuit agreed with the Second and Eleventh Circuits that reverse payment settlements should be analyzed under the rule of reason to determine whether they impose an unreasonable restraint on competition or not. That litigation involved a patent claiming ciprofloxacin hydrochloride, the active ingredient in the antibiotic CIPRO®. That patent is owned by Bayer AG and Bayer Corp. (collectively "Bayer"). When a generic firm, Barr Labs., Inc. ("Barr"), filed a paragraph IV ANDA, Bayer responded by bringing suit for patent infringement under the provisions of the Hatch-Waxman Act on January 16, 1992. That litigation resulted in an agreement where Bayer would sell CIPRO® to Barr for resale or make quarterly payments to Barr of $49.1 million.[126] Bayer paid Barr a total of $398 million under this agreement.[127]

[120] *Id.* at 391-92.

[121] *Id.* at 392.

[122] *Id.* at 397 (quoting *Schering-Plough*, 402 F.3d at 1076).

[123] *Id.* at 398.

[124] *Id.* at 399-400.

[125] 544 F.3d 1323 (Fed. Cir. 2008).

[126] *Id.* at 1327-29. Other generic drug companies associated with Barr also concluded agreements with Bayer. *Id.*

[127] *Id.* at 1329 n.5.

In 2000 and 2001, purchasers of Cipro and several advocacy groups brought antitrust action claiming that the agreements violated the antitrust law. The district court rejected these arguments,[128] and on appeal the Federal Circuit affirmed. The Federal Circuit initially concluded that a rule of *per se* illegality was inappropriate because the courts could not confidently predict that reverse payment settlements had an anticompetitive effect with limited potential for procompetitive benefit. As a result, the court of appeals concluded that rule of reason was the appropriate mode of analysis.[129]

Applying the rule of reason, the Federal Circuit confirmed that the plaintiffs had failed to demonstrate that the settlements agreements violated the antitrust laws. The court of appeals reasoned that the scope of the Bayer-Barr agreement did not exceed that of Bayer's patent. As a result, Bayer's rights as a patentee allowed it to exclude generic firms from profiting from its invention.[130] The court of appeals further concluded that, in the absence of evidence of fraud before the USPTO or sham litigation, the court need not consider the validity of the patent in its antitrust analysis. Judge Prost observed that a patent is presumed valid, and held that a "settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention."[131]

In upholding the settlement, the Federal Circuit cited with favor the district court's observation that no evidence demonstrated that it blocked other generic firms from challenging Bayer's patent. Indeed, Judge Prost observed, the patent survived subsequent challenges by four other generic manufactures.[132] Finally, the court of appeals also cited "a long-standing policy in the law in favor of settlements" in support of its conclusion.[133]

Issues and Observations

In the absence of explicit congressional guidance, the federal courts have applied general principles of antitrust law to reach varying results with respect to pharmaceutical patent litigation settlements. It is significant that the different cases considered by these courts have each involved their own, distinct set of facts. Nonetheless, the difference between the *per se* rule on one hand, and alternative approaches similar to the rule of reason on the other, have arguably contributed to different judicial outcomes.

Several options are available for Congress. One possibility is to await further judicial developments. While the United States Supreme Court has not yet addressed pharmaceutical litigation patent settlements, it is possible that the highest Court may do so in the future. Supreme Court review would resolve the arguable split among the courts of appeal with respect to this issue. Continuing case law developments in the lower courts could also lead to an informed consensus on the antitrust consequences of reverse payment settlements.

[128] *Id.* at 1329-30.
[129] *Id.* at 1331-32.
[130] *Id.* at 1333.
[131] *Id.* at 1337.
[132] *Id.* at 1340.
[133] *Id.* at 1333.

Another option is to regulate the settlement of pharmaceutical patent litigation in some manner. In the 111th Congress, S. 369, titled the Preserve Access to Affordable Generics Act, would so address reverse payment settlements. That legislation was introduced on February 3, 2009, by Senator Kohl. The Committee on the Judiciary reported the legislation with an amendment in the nature of a substitute on October 15, 2009.

S. 369 would amend the Federal Trade Commission (FTC) Act to allow the FTC to initiate a proceeding against the parties to any agreement resolving or settling a patent infringement claim in connection with a drug product. The legislation would create a presumption that such an agreement has anticompetitive effects and be unlawful if the ANDA filer receives anything of value and the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time. This presumption of unlawfulness shall not apply if the parties to the agreement demonstrate by clear and convincing evidence that the precompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement. In considering whether the settling parties have met that burden, the legislation requires consideration of (1) the remaining term of the relevant patent, compared with the agreed upon entry date of the ANDA product; (2) the value to consumers of the competition from the ANDA product; (3) the form and amount of consideration provided to the ANDA filer; (4) the revenue the ANDA filer would have received by winning the patent litigation; (5) the reduction in the NDA holder's revenues if it had lost the patent litigation; (6) the time period between the date of the agreement conveying value to the ANDA filer and date of the settlement of the patent case; and (7) any other relevant factor.[134]

Under S. 369, in determining whether the settling parties have met their burden of overcoming the presumption of unlawfulness, it shall not be presumed that entry of the ANDA product would not have occurred until the expiration of the relevant patent or statutory exclusivity. Nor shall it be presumed that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the determination. Further, S. 369 expressly does not prohibit a resolution or settlement of a patent litigation claim in which the consideration granted by the NDA holder to the ANDA applicant includes only one or more of the following: (1) the right to market the ANDA product prior to the expiration of any relevant proprietary rights; (2) a payment for reasonable litigation expenses not to exceed $7.5 million; and (3) a covenant not to sue the ANDA product for patent infringement. The penalty for violating this provision consists of an injunction and other equitable relief, as well as a civil fine not to exceed three times the value received by a party that is attributable to the violation.[135]

Other alternatives are also possible. For example, in the 110th Congress, S. 316, also titled the Preserve Access to Affordable Generics Act, proposed to outlaw such agreements. In particular, that bill would amend the Clayton Act to provide in part:

> It shall be unlawful under this Act for a person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim [in] which—(A) an ANDA filer receives anything of value; and (B) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.[136]

[134] S. 369, § 3.

[135] *Id.*

[136] S. 316, § 3 (110th Congress).

This proposed legislation would have effectively made reverse payment settlements a *per se* antitrust violation, as the Sixth Circuit concluded in the *Cardizem CD* case. That legislation was not enacted.

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.

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