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**PATENTS**

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# 'Reverse Payment' Realities: Challenging Pervasive Assumptions Underlying Calls for Broad Antitrust Scrutiny of Patent Infringement Settlements

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In *Federal Trade Commission v. Actavis Inc.*,[1] the U.S. Supreme Court for the first time subjected pharmaceutical patent infringement suit settlements to scrutiny under the antitrust laws. Specifically, the Court held that large and unjustified payments made by the brand name drug patent holder to the alleged infringer to settle litigation will subject the settlement to antitrust scrutiny under the rule of reason. The Court provided little explanation of its ruling, however, leaving to lower courts to determine where to draw the line between presumptively lawful settlements and those that merit a closer look.

Unsurprisingly, courts around the country have since drawn conflicting lines. The U.S. Court of Appeals for the Third Circuit will enter the debate this month, when it hears argument in *Louisiana Wholesale Drug Co. Inc. v. SmithKline Beecham Corp.*[2] In that case, the appellants are asking the Third Circuit to overturn the district

[1] 133 S. Ct. 2223 (2013).

[2] Case No. 14-1243 (3d Cir.) (oral argument scheduled for Nov. 19, 2014).

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court's decision that a settlement involving the conveyance of an exclusive license precluding the brand name drug manufacturer and patent holder from marketing a generic version of the drug for a limited time does not trigger antitrust review under *Actavis*. The appellants argue that brand and generic pharmaceutical companies should only be permitted to settle patent infringement suits if minimal or no consideration, no matter the form, passes from the brand to the generic company as part of the deal.

That view, which plaintiffs have asserted in other cases, rests on two pervasive assumptions this article seeks to challenge. For one, it presupposes that ''reverse payments'' occur as part of patent settlements for the sole purpose of delaying generic entry. As we and several economists argued to the Third Circuit,[3] economic principles reveal that a drug patent holder may provide consideration for many reasons that have nothing to do with delay. Second, short-term views of consumer welfare frequently dominate discussions regarding the appropriate scope of antitrust review under *Actavis*. Economic evidence shows that innovation in pharmaceuticals has brought about substantial gains in the standard of living. A longer-term view dictates that subjecting all settlements that include ''reverse payments'' to antitrust scrutiny likely would upset the current equilibrium between generic competition and innovation incentives, which would harm consumers.

As the first appellate court to hear the issue, the Third Circuit has an opportunity to shape the terrain. An affirmance might discourage the Federal Trade Commission (FTC) and class action attorneys from challenging settlements of patent infringement suits—especially those that do not involve cash payments. Less antitrust scrutiny, in turn, could increase the development and availability of new drugs, and even result in the earlier entry of generics. A reversal could very well have opposite effect, sparking additional litigation and inhibiting pharmaceutical innovation.

## Background

For more than 75 years, companies seeking to market new drugs have been required to submit New Drug Applications (NDAs) to the FDA, providing the FDA with the opportunity to determine, among other things, whether the drug is safe and effective, and whether the drug's benefits outweigh any potential risks. Since the mid-1980s, under a statutory scheme established by the Hatch-Waxman Act,[4] generic drugs have been subject to the less rigorous Abbreviated New Drug Application (ANDA) process. The difference in FDA requirements for the approval of new drugs versus generic drugs helps explain why generic drugs typically cost substantially less to develop, and therefore offer cost savings to consumers.[5] While it costs brand companies at least $1.3 billion to bring a new drug to market, the FTC estimates that the overall cost of developing a generic drug ranges from $1 million to $5 million.[6]

The patents that frequently protect branded drugs typically affect the timing of generic entry. The Hatch-Waxman Act recognizes that an applicable patent may provide the brand company with a lawful means of excluding generic competitors from the market for the life of the patent. An ANDA therefore must include a certification by the generic company regarding the patents that may prevent generic entry. The type of certification that often results in the patent infringement suits relevant here, called a ''Paragraph IV'' certification, requires a generic company to state that the brand company's patent is invalid or unenforceable, or will not be infringed by the generic product.

To accelerate the timetable for determining whether the brand company's patent affects generic entry, the Paragraph IV certification qualifies as potentially infringing activity. Brand companies, in turn, may file a patent infringement suit against the generic company, even before the generic version of the drug is marketed. If the brand company files the patent infringement suit within 45 days of the Paragraph IV certification, the suit stays final approval of the generic drug for 30 months, or until the court resolves the patent infringement suit in the generic company's favor, whichever comes first.

Generic companies have significant incentives to challenge patents, as the first generic company to file an ANDA with a Paragraph IV certification receives 180 days of market exclusivity during which other generic companies will not get final approval to launch.[7] Moreover, generic companies have little to lose, as their risk often does not exceed their litigation and minimum development costs; because they have not yet entered the market with a potentially infringing product, they cannot be liable for any damages.[8]

As with most civil litigation, Hatch-Waxman patent cases often settle before trial. Such settlements frequently include an agreed-upon generic entry date and sometimes also include a payment from the plaintiff brand company to the defendant generic company. Class action plaintiffs and the FTC have challenged many of these ''reverse payment'' settlements as unlawful under the Sherman Antitrust Act.[9] Before *Actavis*, courts disagreed about the appropriate scope of antitrust review: although most held reverse payment settlements that provided for generic entry before the patent expired presumptively lawful,[10] one court—the Third Circuit—concluded that any settlement including

[3] Brief of Antitrust Economists as *Amici Curiae* in Support of Defendants-Appellees, *Louisiana Wholesale Drug Co. Inc. v. SmithKline Beecham Corp.*, Case No. 14-1243 (3d Cir. June 3, 2014).

[4] The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[5] *See* Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation*, 2011 COLUM. BUS. L. REV. 637, 643 (2011) [hereinafter Lemley, *Antitrust Policy for Innovation*].

[6] FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION, 14 (2009), *available at* http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[7] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY (2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072851.pdf.

[8] *See* 21 U.S.C. § 355(j); *see also* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 316–17 (2005).

[9] 26 Stat. 209, 15 U.S.C. §§ 1–7.

[10] *E.g.*, *FTC v. Watson Pharms., Inc.*, 677 F. 3d 1298 (11th Cir. 2012).

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a payment by a brand to a generic was presumptively unlawful and anticompetitive.[11]

In 2013, the Supreme Court attempted to resolve at least part of this debate with a compromise. In *Actavis*, it held that, in the unique Hatch-Waxman patent litigation context, settlement involving ''large and unjustified'' reverse payments should be analyzed under the rule of reason. Courts are now struggling to determine what that means, and what the rule of reason analysis should look like when it applies. As they do so, and particularly as appellate courts enter the debate, two principles bear repeating: (1) there are many reasons other than delay why a patent holder would provide consideration as part of a settlement; and (2) antitrust scrutiny of the majority of patent infringement settlements may hurt consumers in the long run.

## 'Pay for [Reasons Other than] Delay'

Critics of ''reverse payment'' settlements often call them ''pay for delay'' deals. This nomenclature assumes that the conveyance of consideration by a patent holder to the infringer necessarily results in a delay in generic entry beyond what would be expected under litigation—or, put differently, beyond the date that is consistent with the parties' assessment of the strength of the brand company's patent case. But there are many other reasons why a brand company would be willing to provide consideration, while still accepting a generic entry date consistent with the expected entry date under a litigated outcome.

**Risk Aversion.** Branded pharmaceutical companies and their executives may be risk averse particularly with regard to patent infringement cases that could affect their key drugs. Losing the case could lead to a decrease in overall profitability, a decrease in the value of stock and stock options, inefficient allocation of resources, and even loss of employment. The more important the drug is to the brand company, its employees, and its executives, the more consideration the brand company would presumably be willing to provide while still accepting an entry date consistent with the strength of its patent case.

To think about why risk aversion could lead to the exchange of consideration having nothing to do with delayed entry, consider a lottery ticket with a 50 percent chance of losing (*i.e.*, a ticket that pays $0) and a 50 percent chance of winning $100 million. Under these circumstances, the lottery ticket has an expected payoff of $50 million. Most ticket holders would be willing to accept amounts far below $50 million to avoid the chance of losing.[12] If a ticket holder traded the ticket for $20 million, he or she would essentially be paying $30 million to eliminate the risk of losing. In the context of a patent litigation settlement, risk aversion could lead a brand company to accept a generic entry date consistent with the strength of its patent case while still providing consideration. Let's assume that the remaining life of the litigated patent is 10 years, and the brand company has a 50 percent chance of winning, which would mean 10 years of patent-related market exclusivity, and a 50 percent chance of losing, which would mean generic entry tomorrow. Under these circumstances, the expected life of the patent is five years. A risk-averse brand company might be willing to agree to generic entry three years from now to avoid the risk of losing. It might also be willing to ''purchase'' two extra years of exclusivity and settle for generic entry five years from now. Five years of patent exclusivity under these terms would be consistent with the expected result under litigation *and* would include a ''reverse payment.''

**Benefits of Certainty.** Consideration provided by a brand company to a generic company can also be attributed to the benefits associated with certainty. The level of investment in research, development, and marketing that a brand company undertakes depends on when generic entry will occur. When the company knows it has five years of remaining patent life, it may invest at a higher level than it would when facing litigation uncertainty, deciding instead to allocate resources elsewhere. Removing the uncertainty can provide value to the brand company by allowing it to make better investment decisions.[13] Decisions regarding research and development on the ''next-generation'' version of a brand company's drug or additional clinical trials establishing new indications for a drug could be better made when the date of generic entry for its original drug is known, for example. In that situation, the brand company would be willing to provide consideration to the generic company to gain more certainty as to when generic entry will occur, without delaying generic entry beyond the expected generic entry date under litigation.

Uncertainty in future cash flows associated with pending patent infringement litigation also increases companies' borrowing costs.[14] As a result, the discount rate used in valuations of the company also increases. More certainty in cash flows, even with no change in expected cash flows (*i.e.*, no change in the expected date of generic entry), can reduce borrowing costs and increase research and development investment.[15] A brand company may be willing to provide consideration under these circumstances to reduce its borrowing costs.

**Costs Associated with Losing.** A brand company might also be willing to provide consideration to an alleged infringer, while still accepting an entry date consistent with the expected litigated result, if there are additional costs associated with losing the patent litigation other than lost drug sales. For example, there may be costs associated with idling or laying off sales employees as the result of losing the patent case. These costs could be avoided if generic entry occurs at a certain date consistent with the expected litigated result.[16]

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

[12] *See* Charles A. Holt & Susan K. Laury, *Risk Aversion and Incentive Effects*, 92 Am. Econ. Rev. 1644, 1655 (2002).

[13] *See* Avinash K. Dixit & Robert S. Pindyck, Investment Under Uncertainty 6–9 (1994).

[14] *See* Steven A. Ross et al., Corporate Finance 392–420 (9th ed. 2010); Richard A. Brealey & Stewart C. Myers, Principles of Corporate Finance 152–179 (7th ed. 2003); Aswath Damodaran, Investment Valuation 383–422 (2nd ed. 2002).

[15] Research suggests that risk in the form of potential government intervention has led the market to demand higher returns for medical research and development firms (*i.e.*, increased financing costs for such firms), which in turn has substantially reduced medical research and development investments. *See* Ralph S.J. Koijen et al., *Financial Health Economics*, 41 (Nat'l Bureau of Econ. Research, Working Paper No. 20075, 2014).

[16] Such costs have been shown to drive merger activity. *See* Patricia M. Danzon et al., *Mergers and Acquisitions in the*

Changing existing drug supply contracts that were entered assuming later generic entry could also be costly, as could overproduction of the branded product. A brand company might be willing to pay to avoid these costs even when the agreed-upon generic entry date is entirely consistent with the expected litigated result.

**Difference in Bargaining Position.** Even when the parties completely agree about the strength of the brand company's patent case, differences in bargaining position may provide the generic company with the opportunity to extract consideration, even where the entry date is consistent with the expected litigated outcome. Generic companies are generally not at risk for damages, having been able to challenge the patents without entering the market under Hatch-Waxman. Even when the odds of winning are low, generic companies have an incentive to challenge patents given the substantial benefits from a six-month exclusivity award relative to the costs of mounting a challenge. By contrast, brand companies tend to rely on a smaller number of products for the bulk of their revenue, so a single drug can be extremely important to brand company profits.[17] The difference in bargaining positions may lead a brand company to agree to provide consideration in addition to agreeing to an entry date consistent with the expected litigated outcome.

**Necessity of Consideration.** Although the Supreme Court noted that it might be possible for the parties involved in a patent suit brought by a brand manufacturer against a generic manufacturer to settle without a payment by negotiating solely over the generic entry date,[18] there are several reasons why they might not be able to do so. Real-world complexities, such as asymmetric information, differing beliefs regarding the likelihood of prevailing in litigation, and differing discount rates, could all lead to deadlock.[19] Generic companies may be unwilling to wait the amount of time to enter that is consistent with the strength of the brand company's patent case because of uncertainty regarding the future size of the market, for example. In this situation, settlement without consideration may not be possible.

In addition, depending on the circumstances, offering an earlier entry date may provide little or no additional compensation to the generic company. For the first generic manufacturer to file an ANDA, its interest is largely in obtaining six months of exclusivity.[20] When precisely that exclusivity period occurs could have very little effect on its profits. Indeed, it is possible that later entry is more profitable if it allows the brand company to expand the market in the interim or enables the generic company to better prepare for generic launch. As a result, offering some other form of consideration beyond earlier entry dates may be necessary to provide an incentive for generic companies to settle.

And settlements may very well provide the quickest route to generic entry. Relative to the situation in which the generic litigates the patent case to verdict and wins, settlements are a more reliable and lower-cost mechanism to achieve generic entry before patent expiration.[21]

In *Actavis*, the Supreme Court focused on payments that could not be explained by ''traditional settlement considerations.''[22] The factors described above—risk aversion, the benefits associated with certainty, and the avoidance of costs associated with losing—are ''traditional settlement considerations.''[23] These factors represent the costs of not eliminating the risk of losing the patent case; collectively, they account for the full costs associated with litigation. Given these factors, as well as the differences in bargaining position between the parties and the need for consideration in certain instances, there is no foundation for a presumption that consideration provided by the brand to the generic is for the purposes of delaying generic entry beyond the expected litigated result.

## Taking the Long View

In addition to ignoring the many reasons a brand company may provide consideration to a generic company to settle a patent infringement suit other than delay, challengers of ''reverse payment'' settlements often focus on short-term consumer welfare, rather than taking the long view.

**Benefits of Pharmaceutical Innovation.** Consumers benefit both from efforts to develop new products—dynamic efficiency—and from improved access to lower priced versions of existing products—static efficiency. Though both types of efficiencies confer value, dynamic efficiencies attributable to innovation in healthcare and pharmaceuticals in particular are a major cause of improved standards of living over the last century. In fact, economic analysis shows that innovative pharmaceuticals have been responsible for much of the increase in U.S. life expectancy and the reduction in infant mortality over the past decades.[24] Economic studies of par-

*Pharmaceutical and Biotech Industries*, 28 MANAGERIAL & DECISION ECON. 307, 325 (2007) [hereinafter Danzon, *Mergers & Acquisitions*].

[17] *Id.* at 309.

[18] *Actavis*, 133 S. Ct. at 2237.

[19] *See generally* Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 667–77 (Fall 2004); Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 368, 368–400 (2010); Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements,inEconomic Approaches to Intellectual Property Policy* 251, 261–264 (Gregory K. Leonard & Lauren Stiroh eds., 2005).

[20] *See* Generic Pharm. Assoc., Comment to Fed. Trade Comm'n on Authorized Generic Drug Study, 2 (June 27, 2006), *available at* http://www.ftc.gov/system/files/documents/public_comments/2006/06 /062806gpha.pdf.

[21] *See Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[22] 133 S. Ct. at 2236.

[23] To see that risk aversion is a traditional settlement consideration, one only needs to look to decision analysis, a common tool used to calculate the value of a settlement agreement to a settling party. Decision analysis takes into account the settling party's risk aversion. *See* Craig B. Glidden et al., *Evaluating Legal Risks and Costs with Decision Tree Analysis*, in SUCCESSFUL PARTNERING BETWEEN INSIDE AND OUTSIDE COUNSEL, (Robert L. Haig ed., 2013); Robert B. Calihan et al., *The Role of Risk Analysis in Dispute and Litigation Management*, *presented at* American Bar Association 27th Annual Forum on Franchising (Oct. 6–8, 2004).

[24] *See* Lemley, *Antitrust Policy for Innovation*, *supra* note 5, at 638–39; Frank R. Lichtenberg, *Sources of the U.S. Longevity Increase, 1960–2001*, 44 Q. REV. ECON. & FIN. 369, 369 (2004); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medical Expenditure, 1990–2003: Evidence from*

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ticular drug classes demonstrate that societal returns from pharmaceutical development are not only large, but often far outpace the cost of innovation.[25]

The benefit derived from those dynamic efficiencies is significant, but the cost of creating that benefit—that is, the costs of pharmaceutical research and development—is exceptionally high.[26] Only a few initially promising experimental compounds—about one in 10,000—meet safety and efficacy benchmarks and are ultimately approved by the FDA, which drives a substantial portion of that cost.[27] In 2007, economists estimated that, including the cost of development failures, the average cost to develop and bring to market a single FDA-approved prescription drug was more than $1.3 billion.[28] And the cost is only expected to rise. One expert has noted that the number of new drugs invented per billion dollars of research and development investment has been cut in half every nine years.[29]

Innovator companies are able to recoup their high-risk investments in pharmaceutical products because of the patent protection their successful inventions receive.[30] ''[I]t is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection.''[31] One study concluded that about 65 percent of pharmaceutical inventions would not have been introduced into the market absent patent protection.[32]

**Hatch-Waxman Balance.** The Hatch-Waxman Act attempts to balance enhanced access to generic drugs and associated cost savings for consumers (static efficiency) with incentives for innovative efforts that result in new pharmaceutical products (dynamic efficiency).[33] On the one hand, the Act contributes to static efficiencies, as the low costs and large incentives to challenge patents, combined with the lack of damage exposure, encourage generic firms to challenge patents without regard to the likelihood of prevailing.[34] On the other hand, the Act allows brand companies to seek a 30-month stay if they sue for patent infringement and provides other incentives that favor innovation, including, for example, providing patent term extensions for drugs that were subject to regulatory review before the drug's commercial marketing.[35]

Exchange of consideration by parties settling patent infringement litigation has not altered the balance between dynamic and static efficiencies that Congress sought to achieve.[36] Such settlements have not displaced incentives for generics, decreased generic availability, or discouraged pharmaceutical patent challenges. [37] The share of generics in the marketplace has increased dramatically over time.[38] As of 2013, generic usage stood at 86 percent, a more than fourfold increase since Hatch-Waxman was enacted.[39] Indeed, much of the increase in availability and use of generic

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*Longitudinal, Disease-Level Data*, 97 AM. ECON. REV. 438, 442 (2007); Pierre-Yves Crémieux et al., *Pharmaceutical Spending and Health Outcomes in the United States*, in INVESTING IN HEALTH: THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION 59, 68 (I. Farquar, K. Summers & A. Sorkin, eds., 2001).

[25] *See, e.g.*, Tomas Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs*, 9 FORUM FOR HEALTH ECON. & POLICY, issue 2, art. 3, at 1–2 (2006) ($1 spent on HIV/AIDS drugs benefits society by approximately $18); David C. Grabowski et al., *The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence and Broaden Treatmen*t, 31 HEALTH AFF. 2276, 2280 (2012); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241, 241–245 (2001).

[26] Oxford Handbooks, *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, 2 (Patricia M. Danzon & Sean Nicholson eds., 2012).

[27] Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362, 364 (2001).

[28] *See* Joseph A. DiMasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 469 (2007).

[29] Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REVIEWS DRUG DISCOVERY 191, 191–92 (2012).

[30] *See* Lemley, *Antitrust Policy for Innovation*, *supra* note 5, at 643.

[31] *Id.*; *see also* Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 98–99 (2000) (pharmaceutical industry particularly sensitive to patent incentives); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*, 4 ANN. REV. ECON. 541, 548 (2012) (describing a survey that found that patents effectively increase innovation primarily in the pharmaceutical industry); B.N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545–56 (2008) (describing the pharmaceutical industry's unique dependence on patent protection to spur research and development investment).

[32] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 173, 175 tbl.1, 175–76 n.8 (1986).

[33] As Congressman Henry Waxman stated, ''[t]he law that became known as Hatch-Waxman represented a careful balance between access and innovation. Because both are vitally necessary to our nation's health.'' Henry A. Waxman, *Speech: Rep. Waxman Delivered a Speech to the Generic Pharmaceutical Association* (Jan. 28, 2003), *available at* http://waxman.house.gov/speech-rep-waxman-delivered-speech-generic-pharmaceutical-association.

[34] *See generally* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods*, 28 MANAGERIAL & DECISION ECON. 491, 495–96, 501 (2007) [hereinafter Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*]; Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, 9 CPI ANTITRUST CHRON., at 6 (Sept. 2012); C. Scott Hemphill et al., *When Do Generics Challenge Drug Patents*, 8 J. EMPIRICAL LEGAL STUD. 613, 624, 626 (2011) [hereinafter Hemphill, *When Do Generics Challenge Drug Patents*].

[35] 35 U.S.C. § 156.

[36] *See* C. Scott Hemphill et al., *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327–339 (2012).

[37] *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation*, 18 INT'L J. ECON. BUS. 177, 177–78, 181–198 (2011); Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. ECON. PERSP. 45, 62–63 (2002).

[38] *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993–96 (2007).

[39] IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE: A REVIEW OF THE USE OF MEDICINES IN THE UNITED STATES IN 2013, at 30 (2014), *available at* http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

drugs has occurred alongside the ''reverse payments'' made as part of patent infringement suit settlements.

Just as the conveyance of consideration has not displaced incentives for generics, neither has it systematically extended brand-drug market exclusivity. In fact, the average effective length of market exclusivity of brand-name pharmaceuticals has remained constant, if not decreased, as the rate of patent settlements involving exclusive license provisions has increased.[40] The average length of market exclusivity for drugs experiencing first generic entry in 1995 to 1996 was 13.5 years. During this period, conveyances of consideration from patent holders to generic companies as part of settlement agreements occurred infrequently.[41] Over time, more patent infringement settlements have included ''reverse payments,''[42] yet the average length of market exclusivity has decreased. For drugs experiencing first generic entry in 2011–2012, for example, average market exclusivity was only 12.9 years.[43]

**Risk of Decreased Patent Value.** Although the conveyance of consideration in patent infringement settlements has not undermined the balance between access and innovation that Congress sought to achieve in the Act, subjecting most patent litigation settlements that include the conveyance of consideration to antitrust review could very well have that effect.

Increased antitrust scrutiny would substantially decrease the value of the pharmaceutical patent rights. Specifically, having to defend third-party antitrust suits would reduce settlement options available in patent infringement litigation and increase the costs of litigation.[44] This, in turn, would decrease the economic value of patents held by the brand manufacturers.[45]

While restrictions on litigation outcomes reduce the value of any property right that is the subject of litigation, innovator pharmaceutical companies in particular frequently depend on the ability to settle patent challenges even when their chances of success in the litigation are high. That is because brand companies ''have a considerable incentive to avoid the uncertainty and large potential profitability losses associated with'' the resolution by courts of patent infringement cases.[46] Thus, settlement restrictions may affect the value of pharmaceutical patents more than one might expect.

Reduction in patent value could, in turn, reduce incentives to innovate.[47] Importantly, these decreases in dynamic efficiency (innovation) could more than offset the supposed short-term consumer gains from access to generic drugs. Indeed, one economic study analyzed the effects of eliminating drug patents and found that the reduced flow of new therapies would cause consumer losses *three times* the short-term gains from immediate generic competition on *all drugs*.[48]

## Conclusion

Rules of decision that fail to take these considerations into account will have long-term, seemingly unintended consequences for pharmaceutical companies and consumers alike. Although some view antitrust scrutiny of nearly all patent infringement settlements as appropriate, and even necessary, that scrutiny will not advance the goals underlying the statutory and regulatory regimes that intersect here. Instead, such scrutiny will decrease the value of pharmaceutical patents, regardless of the patents' scientific worth; upset the balance between dynamic and static efficiencies that Congress intended to set via the Hatch-Waxman Act; and harm consumers in the long run, undermining the goals of the Sherman Act. In a world in which ''pay'' is presumed to be ''for delay'' and only the short term counts, everyone loses.

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[40] *See* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods*, *supra* note 34, at 495–96, 501; Hemphill, *When Do Generics Challenge Drug Patents*, *supra* note 34, at 640–44.

[41] According to an FTC study of branded drugs whose patents were challenged between 1992 and 2001, only nine settlements contained agreements for the brand-name company to provide consideration. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION, 10, 25 (2002).

[42] The FTC concluded that while 18 percent of settlements reached with first filers from 2004 through 2009 included exclusive license provisions, by 2010 nearly 58 percent of such settlements included such a provision. FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, vi, n.14 (2011).

[43] *See* Henry G. Grabowski et al., *Recent Trends in Brand-name and Generic Drug Competition,* 1-8 J. MED. ECON. 1369, 1369 (2013).

[44] *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1049 (2004).

[45] *See* Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1087 (2004).

[46] Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126, 144 (2011).

[47] *See* Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech*, 4 (2009), *available at* http://www.compasslexecon.com/highlights/Documents/Orszag-Willig%20Statement%C20Re%C20FTC%C20Reverse%C20Payment%C20Settlement%Study.pdf.

[48] James W. Hughes et al., *Napsterizing Pharmaceuticals: Access, Innovation, and Welfare*, 3, 15–16 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2011).

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