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NOTES

A Framework to Evaluate Pharmaceutical Pay-for-Delays: A Balancing Test Based Upon Reasonableness

Jessica Hudson Bechtel

"[A balancing] test arguably represents a wholly new way of settling legal disputes . . . . [T]he test wrecks the doctrinal furniture; it unsettles, and indeed overthrows, the systems of rules worked out by generations of previous judges."

INTRODUCTION

THE United States pharmaceutical market is big business. In fact, as of 2010 the United States continued to lead the world as the largest pharmaceutical market, accounting for 40% of global sales. Americans spent over $307 billion on pharmaceuticals in 2010 and it is estimated that they will spend up to $420 billion in 2015. The industry affects most Americans; research shows that 50% use at least one or more prescription drug each month. Since pharmaceutical companies control access to and affordability of brand and generic prescription drugs, the public is left at the mercy of these large corporations to develop generic versions of drugs, which can cost 40% of the relevant branded drug or less.

As a policy matter, there is apparent tension between society's interest in promoting competition in the market to increase the availability of low-cost generic prescriptions and the pharmaceutical company's interest in profits and receiving incentives for the creation of novel drugs. This tension has manifested itself in pay-for-delays, agreements also referred to as reverse

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1 JD, expected May 2014, University of Kentucky College of Law.
4 Id.
payment settlements. The way in which we as a society approach and regulate these pay-for-delay cases will have a lasting impact on the prescription drug market and thus the availability of novel drugs and affordable generics.

Pay-for-delays arise when a brand drug maker initiates a patent infringement suit against a potential generic rival and decides, in lieu of litigating, to settle the matter by paying the generic rival to stay out of the market. Though pay-for-delays may appear relatively harmless, the effects are astounding, costing Americans an estimated additional $3.5 billion each year for their prescriptions and delaying the entry of generic drugs into the market by seventeen months.

The Supreme Court has yet to address this issue and circuit courts remain split on the legality of the pay-for-delay settlements. The Second, Federal, and Eleventh Circuits have evaluated these settlements using the scope of the patent test, which favors the pharmaceutical industry and allows reverse payments in situations where settlements do not restrict competition beyond the exclusionary zone of the patent. However, the Third Circuit recently adopted a competing test: the quick look test proposed by the Federal Trade Commission (FTC), which treats reverse payments as rebuttable prima facie evidence of an antitrust violation. Unfortunately, neither test strikes the proper balance between innovation and consumer access. This Note advocates for the adoption of a new balancing test that weighs several factors to determine whether a reverse settlement is in violation of antitrust laws.

Part I of this Note examines pay-for-delay settlements and how legislation has opened the door for this type of payment. Part II explains the former

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8 See id. at 205.

9 Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 2 (2010), available at http://www.ftc.gov/os/2010/07/100121payfordelayrpt.pdf [hereinafter Fed. Trade Comm'n, Pay-for-Delay]. A Federal Trade Commission Study found that agreements with compensation from the brand drug to the generic drug delayed the generic's entry into the market for nearly seventeen months longer than agreements without compensation and the seventeen months was statistically significant at the 99% confidence level. Id. at 7. The study calculated the cost of pay-for-delays at $3.5 billion by considering four factors: the consumer savings that result from generic competition in any given month, the likelihood that a generic manufacturer and brand name manufacturer will reach a settlement that delays entry in return for compensation, the length of delay to entry resulting from such settlement, and the combined sales volume of drugs for which settlements are likely. Id. at 8. The study recognized that this is only an estimate of the effect of pay-for-delays and presented high and low estimates of savings derived from the data ranges as $7.5 billion of annual purchaser savings and $0.6 billion of annual purchaser savings. Id. at 10.

10 See FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1308–09 (11th Cir. 2012), rev'd and remanded sub nom., FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1313, 1333, 1316–37 (Fed. Cir. 2008), abrogated by FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); In re Tamoxifen, 466 F.3d at 208–09, 213. FTC v. Watson Pharm., Inc. has since been reversed and remanded by FTC v. Actavis, Inc., discussed infra; however FTC v. Watson Pharm Inc. is still good law and relevant for discussion of competing analyses and the proposed balancing test contained in this note.

circuit split, focusing primarily on the prominent case that established the test for each side, the rationale underlying these decisions, and the disadvantages of each tests. Part III analyzes the Supreme Court’s recent decision, FTC v. Actavis, Inc., which failed to endorse either circuit’s test. Part IV suggests a different framework for courts to use to determine whether a reverse settlement is anticompetitive. This proposed balancing test, based on the reasonableness of the reverse settlement, better protects the interests of both sides. Part V concludes, explaining the necessity of a new test and summarizing the factors to be considered in such a determination.

I. The Pharmaceutical Industry

The United States pharmaceutical industry’s objective is to develop new drugs in anticipation of realizing additional profits. The process of research and development for each new drug is time-consuming and expensive: on average, pharmaceutical companies spend more than $800 million and 11.8 years to bring a single new drug to market. In 2011, pharmaceutical companies launched more new drugs than in any other year in the past decade, including nine drugs with new methods to treat existing diseases, thirteen drugs utilizing existing mechanisms, and twelve orphan drugs that treat rare diseases that affect less than 200,000 people.

Once a brand drug is created and FDA-approved, it is relatively straightforward and inexpensive for other pharmaceutical companies to manufacture a generic version without the initial investment for research and development. The generic versions of brand drugs are beneficial to society because, on average, generics drugs cost 30% to 80% less than their brand counterparts. Luckily for the public, 80% of prescriptions dispensed in 2011 were filled with generic drugs. Although the majority of prescriptions were generic, spending on generic drugs only accounted for 27% of total prescription spending.

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12 133 S. Ct. 2223 (2013).
sales in the United States. Based upon the ease with which brand drugs are replicated and the fact that generics are marketed at a fraction of the brand drug's price, pharmaceutical patent law is important to protect the brand manufacturer.

Patents protect pharmaceutical companies by providing them with a limited time monopoly over the development of their brand drugs in exchange for making the patent application available to the public. Even Judge Posner, a critic of the United States patent system, has called the pharmaceutical industry “the poster child for the patent system,” because the industry needs patent protection as an incentive for innovation. New drug development costs hundreds of millions of dollars; the patent term begins to run when the drug is patented and not when it is made, thereby shortening the effective patent term and the period during which the pharmaceutical company can recoup investments; and the cost of reproducing a generic version is very low. Once a patent expires on a new drug the brand pharmaceutical company stands to lose millions of dollars in profits. For example, between 2007 and 2012 over three-dozen drugs lost their patent protection, costing the brand pharmaceutical companies an estimated $67 billion dollars in annual sales.

20 Id. (“The prime example of an industry that really does need [patent] protection is pharmaceuticals. The reasons are threefold. First, the invention of a new drug tends to be extremely costly—in the vicinity of hundreds of millions of dollars. The reason is not so much the cost of inventing as the cost of testing the drug on animal and human subjects, which is required by law in order to determine whether the drug is safe and efficacious and therefore lawful to sell. Second, and related, the patent term begins to run when the invention is made and patented, yet the drug testing, which must be completed before the drug can be sold, often takes 10 or more years. This shortens the effective patent term, which is to say the period during which the inventor tries to recoup his investment by exploiting his patent monopoly of the sale of the drug. The delay in beginning to profit from the invention also reduces the company’s recoupment in real terms, because dollars received in the future are worth less than dollars received today. And third, the cost of producing, as distinct from inventing and obtaining approval for selling, a drug tends to be very low, which means that if copying were permitted, drug companies that had not incurred the cost of invention and testing could undercut the price charged by the inventing company yet make a tidy profit, and so the inventing company would never recover its costs. So pharmaceuticals are the poster child for the patent system.”).
A. Hatch Waxman Act

Congress has long recognized the careful balance between patent protection and the public’s need for less expensive generic alternatives: it addressed this issue with the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch Waxman Act. The goals of the Act were to assure that there were adequate incentives to invest in the development of new drugs and make less expensive generic copies of approved drugs more widely available. The Act attempted to accomplish these competing goals by establishing a streamline regime for generic challenges to brand name pharmaceutical patents while extending the life of brand name patents to twenty years to compensate for the time necessary to meet FDA drug safety and efficacy requirements.

Under the Hatch Waxman Act, after a pharmaceutical company has received FDA approval of a brand drug—and spent millions of dollars to conduct safety and efficacy studies—a generic company seeking FDA approval only has to file an application that demonstrates, among other things, the bioequivalence of its product compared with the brand. This Abbreviated New Drug Application (ANDA) allows the generic company to forgo the expensive safety and efficacy studies required of the brand companies, therefore decreasing the expense required to an outlay of only $1 million. Further, generic companies have an incentive to quickly file an ANDA after the brand drug is approved because the first generic company approved by the FDA receives exclusive rights for 180 days to market the generic drug, thus allowing for a duopoly. This exclusive right is worth millions of dollars to a generic drug company because it makes 60–80% of its potential profit for the generic during this 180-day period.

Generic manufacturers have choices when seeking this FDA approval. They can apply for post-expiration marketing to secure entry once the brand patent has expired or, they can seek pre-expiration marketing by asserting that the brand patent is either invalid or not infringed by the generic drug. If the

24 Id.
26 Id. at 1565.
27 Herman, supra note 23, at 1788–89.
28 Id. at 1797.
29 Hemphill, supra note 15, at 1565. "A generic firm might argue that the patent is invalid because it was procured inequitably, or inherently anticipated by the prior art, or because the drug’s initial testing violates the public use bar. Alternatively, the firm might contend that it has devised a noninfringing bioequivalent form of the drug—for example, a different crystalline structure of the same active ingredient, or a different way to accomplish some desirable time-release feature of the innovator’s drug." Id. at 1565–66 (footnotes omitted).
generic company chooses the pre-expiration marketing route then the brand pharmaceutical company has forty-five days to bring an infringement suit and a thirty-month automatic stay is put into place to allow the parties to resolve the infringement matter. This is the context in which pay-for-delays arise.

B. Pay-for-Delays in the Pharmaceutical Context

Pay-for-delay settlements are an alternative to patent litigation between brand pharmaceutical companies and their generic counterparts. Once litigation has begun, the brand pharmaceutical company "has little to gain and much to lose from litigating through to judgment. ... Even a litigation victory would not likely yield damages because the generic firm has yet to market its generic product. ... [and it] would not stop a different generic manufacturer from subsequently filing its own ANDA challenging the same patents." Additionally, a decision by the court stating that the patent is not infringed nor invalid would allow all generic drug companies to enter the market, causing the brand pharmaceutical to lose its patent-conferred monopoly.

Stuck in a lose-lose situation, the brand pharmaceutical company finds that it is in its best economic interest to pay the generic manufacturer a payment in exchange for delay of the generic drug into the market, thereby maintaining its monopoly. These reverse payment settlements—or pay-for-delays—are "typically in the tens or hundreds of millions of dollars." Even though a 2002 FTC study found that the generics prevailed in 73% of patent-infringement disputes that were fully litigated, generics still rather routinely accept the reverse settlement payment because it is to their economic advantage. Also concerning, these agreements sometimes extend beyond the patent, keeping the generic out of the market after the expiration of the patent or prohibiting the generic company from marketing another product not covered by the patent. Ultimately, pay-for-delay settlements result in brand and generic companies splitting the monopoly profits at the expense of consumers, who are denied access to affordable generic alternatives.

30 Id. at 1566 & n.49.
31 Herman, supra note 23, at 1800.
32 Id.
34 Hemphill, supra note 15, at 1568.
36 Foster, supra note 33, at 58.
37 Herman, supra note 23, at 1801.
For example, consider AndroGel, a topical gel that treats the symptoms of low testosterone in men. Solvay Pharmaceuticals received FDA approval to sell AndroGel in the United States and began marketing and selling the drug. Revenue from AndroGel sales between 2000 and 2007 totaled over $1.8 billion. Watson Pharmaceuticals then filed an ANDA in 2003 to create a generic version and sought pre-expiration marketing and patent litigation ensued. After extensive litigation, Watson determined that its generic would cost 75% less than Solvay's AndroGel, thereby decreasing sales of AndroGel by 90% and cutting Solvay's profits by $125 million per year. Prior to a decision by the court, the parties reached a pay-for-delay settlement. Watson agreed not to market generic versions of AndroGel until August 31, 2015. In exchange, Solvay agreed to share AndroGel profits with Watson through September 2015, with payments to Watson projected between $19 and $30 million per year.

Pay-for-delays, like the one illustrated in the case of AndroGel, are estimated to cost the public $3.5 billion per year, translating to $35 billion over the next ten years. From October 1, 2011 to September 30, 2012, 40 of 140 final resolutions of patent disputes between brand and generic drug manufacturers potentially involved pay-for-delays with compensation to the generic company and restrictions on the generic's entry into the market. These pay-for-delay settlements involved "[thirty-one] different branded pharmaceutical products with combined annual U.S. sales of approximately $8.3 billion." It is estimated that pay-for-delays from the past several years continue to "protect at least $20 billion in sales of brand-name pharmaceuticals from generic competition."

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39 Id. at 1304.
40 Id.
41 Id.
42 Id. at 1304–05.
43 Although, Watson agreed not to market the generic version until said date so long as no other manufacturer did so during that time period. Id. at 1305.
44 Id.
45 Fed. Trade Comm'n, Pay-for-Delay, supra note 9, at 2.
47 Id.
48 Fed. Trade Comm'n, Pay-for-Delay, supra note 9, at 2.
C. Antitrust Actions in the Context of Pharmaceutical Pay-for-Delays

These pay-for-delay settlements “have attracted significant antitrust scrutiny from both private plaintiffs and the government.” Arguably, large reverse payment settlements are invalid under antitrust laws. In theory, the pay-for-delay payment is indicative of the brand pharmaceutical company having a weak patent that likely would be invalidated during litigation. Therefore, the payment serves as a way for the brand pharmaceutical company to retain its monopoly, keeping the generic firm out of the market at the expense of American consumers. The FTC and the Department of Justice have argued extensively that pay-for-delays are presumptively unlawful under the Sherman Act as unreasonable restraints on trade.

The Sherman Act provides that “[e]very contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” A literal reading of the text would conclude that all agreements restraining trade are illegal. However the Supreme Court has long construed the Sherman Act to prohibit only unreasonable restraints on trade. In antitrust cases, the Court has consistently recognized that these analyses must “sensitively . . . reflect the distinctive economic and legal setting of the regulated industry to which it applies” and therefore have analyzed these situations with three different antitrust standards.

Generally, courts determine whether a restraint is reasonable based on the rule of reason test: “[T]he 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

49 Herman, supra note 23, at 1801.
50 Id.
51 Id.
52 Id.; see also FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1308–09 (11th Cir. 2012), rev’d and remanded sub nom., FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (“The FTC would like us to hold that reverse payment settlements, like the ones in this case, are presumptively unlawful restraints of trade. It argues that such settlements allow brand name and generic drug companies to be partners in unlawful monopolies.”); Brief for the United States in Response to the Court’s Invitation at 11, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (8th Cir. 2010) (No. 05-2851-cv(L)) (“Reverse payment agreements that delay entry by a potential generic competitor in exchange for a payment from a branded drug manufacturer with market power presumptively violate Section 1 of the Sherman Act.”).
54 In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), cert. granted and judgment vacated sub nom., Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013); see also State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) (“Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ this Court has long recognized that Congress intended to outlaw only unreasonable restraints.”).
history, nature, and effect."\textsuperscript{56}

Courts apply a second standard—the per se rule—where restraints on trade are predictable and have a very limited potential for pro-competitive benefits.\textsuperscript{57} Courts deem horizontal price fixing, output limitations, market allocation, and group boycotts as unlawful practices under the per se rule.\textsuperscript{58} "[T]o condemn a restraint as \textit{per se} illegal, the courts must have had sufficient experience with the particular type of restraint to be able to predict . . . the rule of reason would also condemn the same restraint."\textsuperscript{59}

A third standard, the "quick look" rule of reason analysis, falls between the full rule of reason inquiry and the rigid per se approach.\textsuperscript{60} This analysis is applied when a plaintiff can show "that the defendant has engaged in practices similar to those subject to per se treatment."\textsuperscript{61} Under this analysis the defendant is charged with the burden of demonstrating pro-competitive justifications and the plaintiff is relieved of showing anti-competitive effects within the market.\textsuperscript{62}

II. The Circuit Split

Prior to guidance from the Supreme Court, courts of appeals applied two different tests to determine the validity of pharmaceutical pay-for-delays.\textsuperscript{63} The Second, Federal, and Eleventh Circuits aligned and applied a scope of the patent test under which reverse payments are upheld so long as the exclusion does not exceed the patent's scope, the patent holder's claim of infringement was not objectively baseless, and the patent was not procured by fraud.\textsuperscript{64} The

\textsuperscript{56} \textit{In re K-Dur Antitrust Litig.}, 686 F.3d at 209 (quoting State Oil Co., 522 U.S. at 10) ("This inquiry has been divided into three parts. First, the plaintiff must show that the challenged conduct has produced anti-competitive effects within the market. If the plaintiff meets the initial burden, 'the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.' Finally, the plaintiff can rebut the defendant's purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective." (citations omitted)).

\textsuperscript{57} Id.

\textsuperscript{58} Id.

\textsuperscript{59} THOMAS V. VAKERICs, ANTITRUST BASICs § 1.03 (ALM Media Properties, LLC 2013).

\textsuperscript{60} \textit{In re K-Dur Antitrust Litig.}, 686 F.3d at 209.


\textsuperscript{62} \textit{In re K-Dur Antitrust Litig.}, 686 F.3d at 209.

\textsuperscript{63} Compare id. at 218 ("[T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as \textit{primafacie} evidence of an unreasonable restraint of trade . . . ."), \textit{with In re Tamoxifen Citrate Antitrust Litig.}, 466 F.3d 187, 213 (2d Cir. 2006), \textit{abrogated by FTC v. Actavis, Inc.}, 133 S. Ct. 2223 (2013) ("[A]bsent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.") (quoting Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993)).

\textsuperscript{64} See FTC v. Watson Pharm. Inc., 677 F.3d 1298, 1308 (11th Cir. 2012), \textit{revid and remanded}, 133
Third Circuit criticized this test and instead applied a quick look rule of reason test, which treats reverse settlements as prima facie evidence of an unreasonable restraint on trade.  

### A. Scope of the Patent Test

The Second Circuit first articulated the current scope of the patent test for pay-for-delay pharmaceutical settlements in *In re Tamoxifen Citrate Antitrust Litigation*. There, Imperial Chemical Industries ("Imperial") held the patent to tamoxifen, the most widely prescribed drug for treating breast cancer and the most prescribed cancer drug in the world. Four months after tamoxifen was patented by Imperial, Barr (a competing pharmaceutical company) filed an ANDA with the FDA seeking approval to market a generic version of tamoxifen.

Subsequently, Imperial filed a patent infringement suit against Barr. Eventually, the district court held Imperial's patent invalid because of Imperial's improper disclosure regarding testing of tamoxifen. Imperial appealed the lower court's ruling, but while the appeal was pending the parties reached a settlement. This settlement provided that the patent owner (now Zeneca) would pay Barr $21 million and give them a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label. Additionally, Zeneca agreed to pay Barr's raw material supplier $9.5 million and an additional $35.9 million over the following ten years. In return, Barr agreed that it would not market its own generic version of tamoxifen until Zeneca's patent expired. Barr also understood that if another generic pharmaceutical company attempted to market a version of tamoxifen then Barr would attempt to prevent this by invoking the 180-day exclusivity right it possessed as the first generic filer with the FDA. Pursuant to the settlement agreement, Barr and...
Zeneca filed a “Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below” which was granted by the circuit court, thereby vacating the district court’s earlier judgment that the patent was invalid.76

Zeneca brought subsequent patent infringement suits against other would-be generic competitors who attempted to gain approval for tamoxifen generics.77 Though litigation ensued, Zeneca was successful and the generic companies were prohibited from marketing their generic versions until Zeneca’s patent expired.78 While Zeneca was litigating with the generic companies, consumers and consumer groups filed thirty additional lawsuits challenging the legality of the 1993 Settlement Agreement between Barr and Zeneca.79 These claims were consolidated into In re Tamoxifen Citrate Antitrust Litigation as a class action complaint.80 At the center of the litigation was the claim that the settlement enabled Zeneca to evade the district court’s invalidation of its tamoxifen patent, which the plaintiff’s argued would have been affirmed by the circuit court.81 Such a ruling would have allowed Barr to receive approval to market its generic version of tamoxifen and, after the 180-day exclusivity period, allowed other generics to enter the market as well, substantially decreasing the cost of the drug.82 The district court granted Zeneca’s motion to dismiss and the plaintiffs appealed.83

On appeal, the Second Circuit applied the scope of the patent test and determined “that the Settlement Agreement did not unlawfully extend the reach of Zeneca’s tamoxifen patent,” and, therefore, the settlement did not restrain trade in violation of the antitrust laws.84 The court said that “as long as ‘the patent litigation is neither a sham nor otherwise baseless’ or beyond the patent’s scope, the patentee can enter into a settlement ‘to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.’”85 The court explained that any damage done to competition by reverse settlements is caused by the rightful monopoly

76 Id.
77 Id. at 194–95.
78 Id. at 196.
79 Id.
80 Id. at 196–97. “In the consolidated lawsuit, the plaintiffs alleged that the Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca’s continuing monopolization of the market for tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; and (5) prevented competition from other generic manufacturers of tamoxifen.” Id.
81 Id. at 197.
82 Id.
83 Id.
84 Id. at 213–14.
created by patent law, unless the terms of the settlement enlarge the scope of the monopoly. 86

Applying the test, the court first considered whether the settlement agreement extended the patent monopoly by “restraining the introduction or marketing of unrelated or non-infringing products” and found that it did not. 87 Second, the court considered whether the settlement agreement ended the litigation between Zeneca and Barr and opened the patent up to subsequent challenges by other potential generic manufactures, which the settlement did. 88 Lastly, the court considered whether all competition in the market was foreclosed by the settlement agreement and found that such competition was not totally stifled because the settlement “allowed Barr to begin marketing Zeneca’s version of tamoxifen eight months after the settlement agreement became effective,” thus adding a competitor into the market. 89 Based on these considerations, the court concluded that absent any plausible allegations that the settlement provided Zeneca with benefits outside the scope of the tamoxifen patent there was no claim for relief and thus no antitrust violation. 90

1. The Rationale Underlying the Scope of the Patent Test.—The Second Circuit and other courts justify the decision to apply the scope of the patent test upon encouraging settlements, continuing to encourage innovation, and being a natural byproduct of the Hatch-Waxman Act. 91

First, courts justify their decision by citing their general stance on encouraging settlements. Settlement agreements, even in the context of pay-for-delays, are favored because they provide a number of private and social benefits compared to litigation. 92 For instance, settlements allow for the conservation of judicial resources and save litigation expenses, which can reach millions of dollars per each side. 93

Next, the decision to use the scope of the patent test is premised on the fear that laws and decisions severely restricting patent settlements would increase litigation, heighten the uncertainty surrounding patents, and therefore delay

86 In re Tamoxifen, 466 F.3d at 212–13.
87 Id. at 213–14 ("Because Zeneca’s patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.").
88 Id. at 214–15.
89 Id. at 215.
90 Id. at 216.
91 In re Tamoxifen, 466 F.3d at 201–06; see also Hemphill, supra note 15, at 1573–77 (discussing four overlapping justifications that have “supported the courts’ willingness to overlook the allocative harm” pay-for-delays cause).
92 In re Tamoxifen, 466 F.3d at 202.
93 AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY 2011, at 35 (2011) (stating that in patent litigation with more than $15 million at risk the median expense per side of the litigation was $4.5 million).
innovation. Innovation is especially important to society in the context of pharmaceuticals. For example, in 2011, thirty-four new drugs were developed, the most in any year in the last decade. Courts are concerned that if pharmaceutical reverse settlements are discouraged then brand companies will lose part of their economic incentive for developing and creating new drugs. In essence, expensive new drugs are better than no new drugs at all.

Lastly, courts have noted that reverse settlements are a product of the regulatory framework of the Hatch Waxman Act. In this context, when the brand pharmaceutical patent holder brings a suit for patent infringement, the prospective generic has yet to incur substantial expenses in marketing or distributing their drug. Therefore, at the time of suit, the prospective generic company has relatively little to lose in litigation. Conversely, the brand pharmaceutical’s “risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly” and lose millions of dollars in profits. Based upon the fact that the Hatch Waxman Act “essentially redistributes the relative risk assessments” between the patent holder and the possible patent infringer, courts have recognized the need for settlement funds to protect the patent holder’s interests.

2. Disadvantages of Applying the Scope of the Patent Test.—Courts and commentators alike have heavily criticized the scope of the patent test. Critics argue that the “test’s almost unrebuttable presumption of patent validity . . . assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed.” Arguably, this test protects intellectual property on the strength of the pharmaceutical company’s wallet—and not on the strength of the patent. This is because a pharmaceutical company can provide a large reverse settlement to a generic company to end the litigation and continue its exclusive patent, regardless of the actual strength of the patent, so long as the antitrust litigation is not baseless

94 In re Tamoxifen, 466 F.3d at 203.
95 IMS INST. FOR HEALTHCARE INFORMATICS, supra note 14, at 6.
96 See In re Tamoxifen, 466 F.3d at 206–07; Hemphill, supra note 15, at 1577.
97 In re Tamoxifen, 466 F.3d at 206–07.
98 Id.
99 Id. at 207.
100 Id.
101 See id.
103 See id. at 215 ("[W]e question the assumption underlying the view of the Second Circuit and other courts that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger . . . [T]he high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation.").
or a sham. In reality, the validity of the patent should be the center of the antitrust analysis because if the patent is valid then a reverse settlement likely falls within the scope of the patent and avoids an antitrust problem. Whereas, if the patent is invalid then a reverse settlement resembles market allocation, a severe anticompetitive harm and violation of antitrust law, because the patent has to ability to exclude other manufacturers. A presumption that the patent is valid seems to be misplaced as generic pharmaceutical manufacturers have prevailed in 73% of patent infringement suits fully litigated between 1992 and 2000.

Additionally, critics argue that the scope of the patent test is inconsistent with the primary goal of the Hatch Waxman Act. The Act sought to increase the availability of low-cost generic drugs to the public by encouraging generic pharmaceutical manufacturers to challenge weak brand patents. But the test "entitles the patent holder to pay its potential generic competitors not to compete," without consideration of the validity of the patent. By allowing reverse settlements, brand drugs are able to monopolize the market and—even with a weak patent—charge consumers up to ten times more than a prospective generic alternative. Therefore, reverse settlements are limiting the public's access to affordable generics in direct opposition to the Hatch Waxman Act and at a cost to the American people of an estimated $3.5 billion a year.

B. Quick Look Rule of Reason Analysis

In 2012, the Third Circuit promulgated a new quick look test for pharmaceutical reverse settlements in In re K-Dur Antitrust Litigation. This litigation stemmed from a formulation patent held by Schering-Plough Corporation ("Schering") for a controlled release coating used in their K-Dur 20, a sustained-release potassium chloride supplement used to treat potassium deficiencies. Almost six years after the patent was issued, Upsher-Smith Laboratories ("Upsher") filed the first ANDA seeking approval to produce a generic version of K-Dur 20, causing Schering to sue Upsher for patent infringement. Upsher argued vehemently that its generic did not violate the patent due, to differences in the chemical composition of their controlled...
release coating.\textsuperscript{114} Upsher even went so far as to claim that Schering's claims of infringement were baseless and not made in good faith.\textsuperscript{115}

Predictably, as the district court considered the motions for summary judgment—and hours before the ruling was issued—the parties reached a settlement.\textsuperscript{116} The settlement provided that Upsher would refrain from marketing its generic or any similar product until September 1, 2001, and then it would receive a non-royalty non-exclusive license to sell a generic.\textsuperscript{117} Additionally, Upsher "granted Schering licenses to make and sell several pharmaceutical products Upsher had developed," an agreement made in response to Schering's concerns, raised during negotiations, about possible antitrust problems that might arise from providing a reverse settlement to Upsher.\textsuperscript{118} However, subsequent to the settlement, Schering abandoned plans to utilize the licenses obtained from Upsher.\textsuperscript{119} In return, Schering agreed to pay $60 million over three years plus additional smaller sums depending upon its use of the licenses provided by Upsher.\textsuperscript{120}

Subsequently, Schering entered into another settlement with a generic company to protect this same patent. ESI Lederle ("ESI") filed an ANDA to develop a generic version of K-Dur 20. Again, Schering sued for patent infringement and ESI defended on the grounds that its generic differed in the number of ingredients per layer of coating.\textsuperscript{121} Schering and ESI settled the case prior to the court rendering a decision: ESI agreed not to market the generic until January 1, 2004, when it would receive a royalty-free license, and represented that it was not developing or planning to develop any other potassium chloride product.\textsuperscript{122} In return, Schering agreed to pay ESI $5 million initially and then an additional payment ranging from $10 million to $625,000 depending upon when ESI's ANDA was approved.\textsuperscript{123}

As a result, various private parties filed a class action antitrust suit attacking these settlements as unreasonable restraints on trade.\textsuperscript{124} The district court applied the scope of the patent test, but the Third Circuit formulated their own quick look test to deal with pharmaceutical reverse settlements.\textsuperscript{125}

\textsuperscript{114} Id.
\textsuperscript{115} Id.
\textsuperscript{116} Id.
\textsuperscript{117} Id.
\textsuperscript{118} Id. at 205–06.
\textsuperscript{119} Id.
\textsuperscript{120} Id.
\textsuperscript{121} Id. at 206.
\textsuperscript{122} Id.
\textsuperscript{123} Id.
\textsuperscript{124} Id. at 206–07. The FTC also brought a complaint against Schering, ultimately ruling that the reverse payment settlement was illegal. This decision was overruled by the Eleventh Circuit. See Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005).
\textsuperscript{125} Id. at 208, 218.
court’s decision to apply this analysis highlights the court’s view that reverse payment settlements are by nature similar to transactions that are held to be *per se* unlawful, such as horizontal price fixing.”126 The quick look test specifically requires:

> [T]he finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro–competitive benefit.127

For a reverse settlement to beat this presumption of illegality, the court explained that a patent holder could argue that “there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry.”128 Alternatively, in rare situations the patent holder could argue that a reverse payment actually increased competition.129 To illustrate, the court noted that, “a modest cash payment that enables a cash–starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market.”130

1. The Rationale Underlying the Quick Look Rule of Reason Analysis.—The Third Circuit and proponents of the analysis justify their reliance on the quick look test on the basis that it is consistent with the Hatch Waxman Act and creates the correct presumption of illegality called for under antitrust laws.

First, proponents argue that the quick look rule of reason analysis is consistent with the Hatch Waxman Act’s goal of increasing the availability of low–cost generic drugs.131 The Act attempts to encourage generic manufacturers to litigate challenges against weak patents so consumers can ultimately benefit from lower drug prices.132 The quick look test furthers this goal by preventing brand pharmaceutical companies from entering into reverse settlements and assumes that without the settlements, litigation would continue and potentially result in invalidation of the brand patent. The ultimate result would allow that particular generic into the market and, after its 180–day exclusivity period, other generics would enter the market as well. This would increase the availability of low–cost generic pharmaceuticals to the general public and fulfill the primary objective of the Hatch Waxman Act.

Additionally, proponents argue that the quick look rule of reason test correctly presumes the illegality of reverse settlements. Arguably, the presumption created “is warranted because of the extremely anticompetitive

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126 Okada, supra note 61, at 327.
127 *In re K–Dur Antitrust Litig.*, 686 F.3d at 218.
128 Id.
129 Id.
130 Id.
131 See id. at 217–18.
132 Id. at 217 (citing S. REp. No. 107–167, at 4 (2002)).
nature of a reverse payment settlement in general."\textsuperscript{133} Proponents liken these pharmaceutical reverse settlements to horizontal price fixing, which has been deemed an unlawful antitrust practice.\textsuperscript{134} The applicable antitrust standard is then the quick look rule of reason analysis because the brand generics have engaged in practices similar to horizontal price fixing, which is subject to per se treatment.\textsuperscript{135}

2. Disadvantages of Applying the Quick Look of Reason Analysis.—There are many disadvantages of applying the quick look of reason analysis. The most compelling argument against the adoption of this analysis is that it disincentivizes the creation of new pharmaceuticals.

First, the quick look test could greatly hamper the innovation and development process of creating new drugs. Because reverse settlements increase the value of the brand’s underlying patent, they arguably enhance the consumer welfare by increasing the brand pharmaceutical’s “incentive to innovate, as well as its financial ability to research, develop, and market future drugs.”\textsuperscript{136} By applying a presumption of illegality to reverse settlements in the quick look rule of reason analysis, pharmaceuticals will have to choose either to abandon patent infringement suits against generics and lose profits as the generic enters the market, or fully litigate the patent infringement suit and expend millions of dollars on increased litigation expenses.\textsuperscript{137} Either option decreases the incentive to invest in research for new medications and technologies since companies’ ability to recoup their expenditures and keep generics out of the market has been greatly reduced. Though Americans want access to cheap generics, it seems that this analysis will hurt the public in general because it will limit their access to new medications that have increased effectiveness or fight novel or currently untreatable diseases.

Others dispute the above argument, but believe that the quick look rule of reason analysis would have several unintended consequences. First, it might actually discourage potential generic manufacturers from bringing patent challenges in the first place.\textsuperscript{138} Generic companies may lack adequate liquidity to fully defend against a patent infringement case and, with little hope for a settlement, might be discouraged from attempting to enter the market early in contravention of a brand patent based upon their economic position. This

\textsuperscript{133} Okada, supra note 61, at 331.
\textsuperscript{134} Id. at 327.
\textsuperscript{135} Id.
\textsuperscript{137} See Okada, supra note 61, at 333 ("Nevertheless, when companies are prohibited from settling with large reverse payment deals, they may choose to litigate patent challenge suits to the end . . . .").
\textsuperscript{138} Id. at 334.
would be contrary to the congressional intent underlying the Hatch Waxman Act.\textsuperscript{139}

Additionally, applying the quick look rule of reason analysis may not effectively eliminate reverse payment settlements\textsuperscript{140} because of its first exception, which provides that the presumption of illegality can be reversed by showing that the payment from the brand to the generic was for a purpose other than delayed entry.\textsuperscript{141} Therefore, this rule may encourage pharmaceutical companies to enter into settlement deals which attempt to "hid[e] reverse payments in a series of complex transactions" where the brand receives additional licensing rights, patent rights, or something else of value in addition to the generic agreeing not to enter the market.\textsuperscript{142} This would reverse the presumption, because arguably the payment from the brand company to the generic company was not for the generic company's agreement to stay out of the market, but instead for other considerations.

III. The Supreme Court's Decision in \textit{FTC v. Actavis}

The Supreme Court recently considered which test should be applied to pharmaceutical reverse settlements in \textit{FTC v. Actavis, Inc.}\textsuperscript{143} However, the Court failed to endorse either the scope of the patent test or the quick look rule of reason analysis. Instead, the Court decided that in this particular case, "the FTC should have been given the opportunity to prove its antitrust claim."\textsuperscript{144}

The Court's conclusion rested on five sets of considerations: "the specific restraint at issue 'ha[d] the potential for genuine adverse effects on competition';\textsuperscript{145} the "anticompetitive consequences will at least sometimes prove unjustified"; "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice"; "an antitrust action is likely to prove more feasible administratively"; and allowing for some type of antitrust analysis of reverse payments "does not prevent litigating parties from settling their lawsuits."\textsuperscript{146}

Additionally, the Court stated that a quick look rule of reason analysis is not appropriate because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services

\begin{itemize}
  \item \textsuperscript{139} \textit{Id.}
  \item \textsuperscript{140} See \textit{id.} at 335.
  \item \textsuperscript{141} \textit{In re K–Dur Antitrust Litig.}, 686 F.3d 197, 218 (3d Cir. 2012), \textit{cert. granted and judgment vacated sub nom.}, Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013).
  \item \textsuperscript{142} Okada, supra note 61, at 336.
  \item \textsuperscript{143} \textit{FTC v. Actavis, Inc.}, 133 S. Ct. 2223 (2013).
  \item \textsuperscript{144} \textit{id.} at 2234.
  \item \textsuperscript{145} \textit{id.} (quoting \textit{FTC v. Indiana Fed'n of Dentists}, 476 U.S. 447, 460 (1986)).
  \item \textsuperscript{146} \textit{id.} at 2234–37.
\end{itemize}
for which it might represent payment, and the lack of any other convincing justification." The Supreme Court instructed the lower court to reconsider the antitrust issue, but did not provide further guidance on how to determine whether a reverse payment violated antitrust law. The Court's closing remarks fail to help clarify the situation: "there is always something of a sliding scale in appraising reasonableness, and as such the quality of proof required should vary with the circumstances." 

IV. New Proposed Balancing Test

The Supreme Court's analysis leaves the lower courts still looking for a framework under which they can properly analyze a reverse settlement's anticompetitive effect. The Court determined that neither analysis struck the proper balance between the competing interests of the pharmaceutical industry and antitrust law. These interests include:

[O]n one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated.

Consequently, the Court determined that there is a need for a new mode of analysis, but failed to identify the proper test.

The best solution is to adopt a balancing test. This test will assess the reasonableness of the restraint on trade, consistent with antitrust law's recognition that potential antitrust analysis "must sensitively . . . reflect the distinctive economic and legal setting of the regulated industry to which it applies". This analysis fits squarely into the rule of reason test, which is utilized most frequently in antitrust contexts and involves determining whether there has been an unreasonable restraint on competition by considering "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." A balancing test is the

147 Id. at 2237.
148 Id. at 2237–38 (quoting California Dental Ass'n v. FTC, 526 U.S. 756, 780 (1999)) (internal quotations omitted).
149 See generally Actavis, Inc., 133 S. Ct. 2223.
152 In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), cert. granted and judgment vacated sub nom., Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013) (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) (citations omitted) ("This inquiry has been divided into three parts. First, the plaintiff must show that the challenged conduct has
superior mode of analysis because it "allows courts to analyze specific reverse-payment settlements contextually and then develop the analysis as they gain experience . . .". 153

The proper balancing test should weigh the strength of the patent at the time of the settlement, the settlement’s anticompetitive effect on the market, and the extent the reverse settlement is necessary to promote innovation. This test is a better fit because it considers the patent strength and then considers the anticompetitive effects, while also giving weight to the pharmaceutical company’s ability to recoup expenditures and maximize profits, thereby incentivizing new drug development.

A. Balancing Test Mechanics

1. First Consideration: Strength of the Patent.—First, in considering whether a pay-for-delay from a brand to a generic pharmaceutical manufacturer is reasonable, the courts should consider the strength of the patent at the time of the settlement. This is a crucial inquiry "[b]ecause the essence of a patent is the monopoly or exclusionary power it confers upon the holder, analyzing the lawfulness of the acquisition of a patent necessitates that we primarily focus upon the circumstances of the acquiring party and the status of the relevant product . . .". 154

If there is a judicial determination that the patent is valid then the brand pharmaceutical has the ability to exclude the generic for a specified time, based on an infringement claim. In this situation, a reverse settlement does not unreasonably restrain trade because the monopoly is valid under patent law. Therefore, a valid patent leans in favor of allowing the reverse settlement because its purpose is to defray litigation costs and end the controversy. However, if the judiciary has determined that the patent is invalid, then the monopoly that the brand is paying to retain is unjustified and tends to unreasonably restrict trade in violation of the antitrust laws.

In the absence of any findings by a court as to the strength or validity of the patent, the antitrust court should conduct its own mini trial on the patent-infringement merits. 155 A mini trial is advantageous because it avoids unnecessary costs and improves judicial efficiency. 156 This "allows the court to

produced anti-competitive effects within the market. If the plaintiff meets the initial burden, 'the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.' Finally, the plaintiff can rebut the defendant's purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective.").

153 Butler & Jarosch, supra note 136, at 114 (discussing the traditional rule of reason analysis).
154 SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981).
156 See id. at 785–88.
make use of a mini trial on the merits that has already occurred in the patent-infringement case to avoid rehashing the merits in antitrust.” 157

In cases without a completed action on the validity of the patent and infringement issue, or in the absence of a preliminary injunction in favor of the patent holder, employing this approach of a mini trial will increase litigation expenses. However, the cost is justified by the importance of the consideration and allows courts and parties to set further limits and restrictions, to prevent the mini trial from becoming a full-blown patent infringement suit.

2. Second Consideration: Settlement’s Anticompetitive Effect on the Market.— Second, in considering the reasonableness of a reverse settlement the court should consider the settlement’s effect on competition. This consideration focuses on whether the settlement has a procompetitive or an anticompetitive effect on the market. Courts should have ample leeway to consider all relevant concerns in this area. A settlement with a procompetitive effect or only a slight anticompetitive effect may be reasonable in light of the other considerations. Specific considerations include: the effect of side deals on the overall market competition, the strength of the brand’s particularized market, whether the scope of the patent was exceeded, the entrance date allowed by the reverse payment settlement, and the generic’s ability to market the drug without a reverse payment.

Courts should consider the effect of side deals on competition in the market as well. Including side deals in reverse settlements can help negate possible anticompetitive effects of the settlement by increasing competition for other drugs and resulting in procompetitive benefits. For example, if a reverse settlement includes the right or license for the brand pharmaceutical to market and sell drug A that at that time is sold by the generic company, then market competition has increased for drug A, likely resulting in lower consumer prices. 158 Side deals can increase the procompetitive effect of a settlement.

Courts should also examine the strength of the brand’s particularized market. A patent holder’s market power is an important consideration in determining the effect of limiting consumer access to a specific generic. A showing that the generic could not meaningfully increase competition in an already competitive market would suggest that the reverse settlement has no anticompetitive effect. 159

In addition, courts should compare the scope of the patent with the terms of the reverse settlement. If the settlement attempts to extend the monopoly

158 See In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), cert. granted and judgment vacated sub nom., Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013). As part of the reverse settlement, Upsher (the generic) granted Schering (the brand) licenses “to make and sell several pharmaceutical products Upsher had developed, including Niacor-SR, a sustained-release niacin product used to treat high cholesterol.” Id. at 205.
159 See Butler & Jarosch, supra note 136, at 116.
past the generic entry date as determined by law, or includes restrictions on other drugs or mechanisms not covered by the patent, then the settlement is anticompetitive. In such an agreement, even with a valid patent, the brand pharmaceutical company is prohibited from excluding more than what the patent protects in a settlement. Therefore, when a settlement's terms exceed the scope of the patent the settlement leans towards having an anticompetitive effect.

Courts should also recognize the procompetitive market effects of a reverse settlement that allows generic entry prior to the patent expiration. "If the negotiated entry date is significantly before the date that the patent will expire, the agreement is not likely to be anticompetitive" and instead, is actually increasing competition and consumers' access to low-cost generics.160

Another relevant factor to consider is whether, without the reverse settlement, the generic would have been capable of marketing the drug. Proof that a generic "would never have been able to market the generic drug without the reverse payment suggests that there is no anticompetitive effect."161 This will likely be applicable in limited situations where the generic drug company has limited liquidity, would not be able to afford a patent-infringement trial, or would likely go out of business prior to marketing the drug.162 In limited circumstances, a reverse settlement may have a procompetitive effect on the market because the payment may save the cash-poor generic manufacturer and allow for the generic to eventually enter the market at the time negotiated for in the settlement.163

3. Third Consideration: Encourage Innovation.—Lastly, in determining the reasonableness of a reverse settlement the court should consider the extent that the settlement is necessary to continue encouraging pharmaceutical companies to develop new drugs. Specifically, this is where the current tests—the scope of the patent test and the quick look rule of reason analysis—fail, as neither consider the important goal of promoting pharmaceutical innovation that increases consumer access to new or more effective drugs.

Therefore, to adequately incentivize drug innovation, brand pharmaceuticals need to be allowed to recoup reasonable expenses and collect some profit from their new drugs or technology. Courts should consider a brand manufacturer's total expenditure for developing and marketing its drug, compared with the amount of time it has operated a market monopoly and the amount of profits collected. With that said, courts should be weary of accepting exaggerated or inflated expenses and partial or incomplete profit estimates. To this end, courts should compare estimates to data available for other drugs similarly situated. In general, timing may play a crucial role in courts evaluating this factor. For

160 Id.
161 Id. at 118.
162 Id.
163 See id.
example, a reverse settlement may appear reasonable where the brand has only entered the market four months prior to a settlement, but would likely be considered unreasonable where the brand has had a monopoly for seven-and-a-half years. Courts should keep reasonableness in mind when evaluating this factor.  

B. Advantages

By balancing all of the relevant considerations and considering the context and effect of the reverse settlement, this reasonable test emerges as the clear winner. This test strikes a better balance because it encourages innovation through consideration of a settlement’s effect on incentivizing invention rather than unnecessarily favoring antitrust law or patent law, is flexible enough to meet the needs of the pharmaceutical context, and is consistent with antitrust law and American jurisprudence on settlements.

First, this test provides for a balancing of all the relevant interests and does not tilt the scale unnecessarily to one side. The scope of the patent test is too favorable to the pharmaceutical companies. It "assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed," therefore protecting intellectual property on the strength of the brand pharmaceutical manufacturer's wallet and not on the strength of the patent. On the other side of the spectrum, the quick look rule of reason analysis favors the other side by presuming that reverse settlements are always illegal unless a narrow exception applies. This balancing test finds a middle ground and gives a voice to each side. Patent law is protected by considering the validity of the actual patent, antitrust law is adequately represented by addressing the anticompetitive effect of the settlement on the whole market, and the importance of incentivizing innovation to increase the public's access to novel drugs and drug technologies is accounted for.

Second, this test is flexible enough to meet the needs of any pharmaceutical pay-for-delay settlement. The factors are broad enough that the court can consider all relevant factors involved in each individual case, allowing for a more particularized inquiry. This protects the pharmaceutical companies from overgeneralized rules that fail to adequately address the relevant concerns

164 Reasonableness is an important consideration. For example, if a drug company expended four times the average investment to develop a drug with a very limited market, and then entered into a reverse settlement after enjoying six years of a monopoly, the agreement might lean on the side of being an unreasonable restraint on trade in light of the circumstances. However, where a drug company has reasonably researched and developed a new drug and has had enjoyed only a short period of monopoly power, a reverse settlement might be a reasonable restraint on trade to protect the pharmaceutical companies and promote innovation for the American consumer.

165 See discussion supra Part II.A.2 (discussing scope of the patent test disadvantages).

and nuances in their cases. Additionally, with experience gained through implementation of the balancing test, courts may add to or take away from the current framework to provide for a better analysis and are not barred from doing so by unfounded presumptions against or for legality.

Third, this test is consistent with current jurisprudence. Regarding antitrust law, the scope of the patent test does not fit into traditional antitrust analysis and therefore fails to analyze the issue with respect to those considerations. Additionally, the application of the quick look rule of reason test is at odds with antitrust law because “[t]o apply the quick look, courts must find activity that has a clear and obvious anticompetitive nature.”167 Reverse payments do not meet this standard because they can either be procompetitive or anticompetitive.168 This balancing test is more consistent with antitrust law because it tracks the traditional rule of reason analysis for antitrust cases, which requires the finder of fact to determine whether the practice imposes an unreasonable restraint on competition while considering a variety of factors, including specifics about the particular business and the restraint’s history, nature, and effect.169 Further, unlike the quick look rule of reason analysis, this balancing test is also consistent with American jurisprudence that favors settlement over litigation.

**Conclusion**

In the pharmaceutical context, the intersection between patent law, antitrust law, and the Hatch Waxman Act leads to a unique issue of pay–for–delay settlements, which cost Americans $3.5 billion a year. The tension is palpable between patent law’s interest in encouraging innovation, promoting amicable settlements, and increasing judicial economy, and antitrust law’s and the Hatch Waxman Act’s vigorous support of competition to increase the availability of low–cost generic alternatives. The circuit split illustrated two modes of analysis, both of which failed to provide for a comprehensive framework to determine the legality of particular pharmaceutical reverse settlement. The scope of the patent test failed to engage in antitrust analysis, and the quick look rule of reason analysis incorrectly assumed that reverse settlements are anticompetitive. The Supreme Court did not endorse either test, however also did not provide enough guidance for lower courts on how to deal with reverse settlements.

This Note advocates for the adoption of a new balancing test that considers the reasonableness of the settlement and is consistent with antitrust traditional rule of reason analyses. The test properly weighs all of the competing interests in the pharmaceutical context by considering the validity or strength of the patent at the time of the settlement, the settlement’s anticompetitive effects, and the need for the settlement to promote innovation. The balancing test is

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167 Butler & Jarosch, supra note 136, at 114.
168 See id. at 115.
flexible enough to meet the particular needs of the pharmaceutical industry and provide protection to allow for some settlements, and yet is stringent enough to protect consumers from unfair restraints on trade. Additionally, the balancing test is in line with current antitrust reviewing standards and American jurisprudence favoring settlements. For these reasons, the balancing test offers the best judicial solution for determining whether a reverse settlement is legal.