Rebalancing Pay-For-Delay: Why the Hatch-Waxman Act Should Be Given More Weight in the Antitrust Analysis and What That Means for Reverse Payment Agreements

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I. INTRODUCTION

Eli Lilly & Co., a $10.9 billion per year pharmaceuticals giant, created one of the best selling drugs in history – Prozac.\(^1\) In 2000, the drug alone accounted for roughly one quarter of the company’s revenue.\(^2\) A year later, however, Lilly lost a legal battle with a generic manufacturer over the validity of the Prozac patent.\(^3\) Seemingly overnight, the drug, which previously reigned in $2.6 billion dollars per year, saw its quarterly sales drop sixty-six percent.\(^4\)

Recognizing the potentially disastrous consequences of losing patents for blockbuster drugs, large pharmaceutical companies began settling patent battles by making large payments to potential generic rivals. In exchange for payment, the generic manufacturers abandon lawsuits that would otherwise potentially allow the entry of generic drugs into the market and increase competition in the health care industry. These agreements between brand name pharmaceutical companies and generic manufacturers, however, do not exclude the generic product entirely. Rather, they postpone the entry of the generic for an agreed upon time frame. Still, these so called “pay-for-delay” settlements have attracted the attention of antitrust enforcement authorities because of their potential to hinder competition in the health care industry.

In the courts, these battles have produced inconsistent results. A handful of circuit courts have upheld the validity of these settlement agreements when the agreement was confined to the parameters of the patent.\(^5\) A few other courts have condemned these agreements on the basis that

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\(^2\) Id.
\(^3\) Id.
\(^4\) Id.
\(^5\) See generally In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003).
they are illegal restraints of trade. As an academic matter, pay-for-delay agreements raise longstanding debates about the proper balance between patent rights and consumer access.

This article examines the pay-for-delay dilemma as a need for balance among competing principles. The article begins with an overview of the relevant legal doctrines. It then moves to explain the regulatory design of the Hatch-Waxman Act and how reverse payments have become “a natural by-product of the Hatch-Waxman process . . . .” Section II concludes with a discussion of the purpose of the Hatch-Waxman Act. Section III then moves to show how the most widely advocated tests, the “per se illegal” and the “scope of the patent,” are largely imbalanced and often do not advance the dual goals of the Hatch-Waxman Act. Section IV argues that the Hatch-Waxman Act should be given the most weight in the analysis because it is industry-specific with a distinct purpose and is the most recent piece of legislation in the relevant area. Section V submits that, if the Hatch-Waxman Act is given more weight in the analysis, the proper method of analysis should be the quick-look rule of reason test because it adheres most to the dual purposes of the Hatch-Waxman Act.

II. BACKGROUND

A. Background Law

A reverse payment settlement involves three legal regimes – patent law, antitrust law, and food and drug law. On the one hand, the patent system grants innovators the right to exclude

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others from using the product. This right to exclude ultimately minimizes the gap between the value of the invention and the value that an inventor receives by allowing that inventor to charge a higher price to use the product. The patent system, therefore, incentivizes profit-motivated individuals to develop new technology and promotes technological progress.

On the other hand, the purpose of antitrust law is to maximize consumer benefit by protecting and promoting competition among firms. Through the competitive free market, the consumer benefits from low prices, high quality, and technological progress. The Supreme Court has described antitrust law generally, and the Sherman Act specifically, as the “Magna Carta of free enterprise.”

Finally, Congress began to construct federal food and drug law in an attempt to keep pace with pharmacological advancements and to set quality standards for both food and drugs. The main statutory authority of federal food and drug law, the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”), prohibits the sale of any new drug unless it is proven safe and effective. In


\[\text{footnote} 11\] JOHN W. SCHLICHER, PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 1:1 (2d ed. 2012).

\[\text{footnote} 12\] Id.


\[\text{footnote} 14\] Town of Concord, Mass. v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990). Justice Black stated that: The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conductive to the preservation of our democratic political and social institutions. But even were that premise open to question, the policy unequivocally laid down by the Act is competition.

\[\text{footnote} 15\] Northern Pacific R. Co. v. United States, 356 U.S. 1, 4-5 (1958).


order for a manufacturer to produce and sell a drug product, it must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA").\textsuperscript{18} The NDA requires large amounts of information including data from animal and laboratory testing and comprehensive information about the drug’s chemistry and pharmacology.\textsuperscript{19} The FDCA stipulates that the FDA may approve a drug when its safety has been demonstrated through “adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended or suggested . . .."\textsuperscript{20} In total, obtaining approval of an NDA is extremely costly and time consuming.\textsuperscript{21}

While the FDCA approval process was designed to protect consumers, it was not perfect. It required an NDA for all new drugs, including generics, even though generic drugs are “identical to brand name pharmaceuticals in dosage form, safety, strength, route of

\textsuperscript{18} § 355(b). The purpose of the NDA is to provide the FDA with enough information for the reviewer to determine: Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks; Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain; Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.


\textsuperscript{19} § 355(b).

\textsuperscript{20} § 355(d) In contrast, the FDA may not approve a drug if there is “a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested . . ..” Id.

\textsuperscript{21} There has been testimony stating that the average cost of bringing a blockbuster drug to market is $800 million dollars. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006). For a break down of how the $800 million dollar sum is accumulated, see Tufts Center for the Study of Drug Development, Backgrounder: A Methodology for Counting Costs for Pharmaceutical R&D (2001), available at http://csdd.tufts.edu/files/uploads/a_methodology_for_counting_costs.pdf; cf. MERRILL GROOZNER, THE $800 MILLION DOLLAR PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS, 237-46 (2004) (arguing that the true cost is about one-fifth that sum and that most drugs are developed from research conducted in universities or not-for-profit research centers with the help of taxpayer dollars).
administration, quality, performance characteristics and intended use.” Since the NDA process was extremely costly, it became a major hurdle for cash-strapped generic manufactures. As a result, many generic drugs, which often serve as a catalyst for driving down the price of designer drugs, were unable to reach the market.

B. Structure of the Hatch-Waxman Act

Recognizing the rising costs of health care and that generic drugs are estimated to save consumers between $8 billion and $10 billion each year, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”). Designed as complex regulatory scheme to increase generic competition in the pharmaceutical industry, the Act features mechanisms to streamline generic alternatives into the market place and provides incentives for manufacturers of generic drugs to challenge weak or invalid patents on brand name drugs. Both of these mechanisms foster competition and drive down the cost of prescription drugs.

One of the most important aspects of the legislation was the creation of an Abbreviated New Drug Application (“ANDA”) for the bioequivalent form of a drug already approved for

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24 Id.
26 H.R. REP. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (“The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.”). S. REP. No. 111-123, at 23 (2010) (“There is no doubt that consumer access to generic medicines is expedited any time these important products come to market prior to the patents expiring.”) (Statements of Senator Hatch).
27 See S. REP. NO. 107-167, at 4 (2002); S. REP. NO. 111-123, at 23 (2010) (“In other words, generic competition is infused into the market sooner rather than later—providing savings to the health care system. This was the purpose of the Hatch-Waxman Act, and it has worked.”) (Statements of Senator Hatch).
safety and effectiveness. ANDAs speed up the approval process because the generic manufacturer is not required to reproduce the clinical studies that were conducted for the original, brand name product. Instead, generic drug manufacturers must demonstrate that their product is the bioequivalent to a previously approved brand name product.

After this first condition has been proven, the filer must certify that: (I) no patent was filed for the brand name drug; (II) the patent for the drug has expired; (III) the patent will expire in the future and the generic will not be marketed until that date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. A filer that elects paragraph IV certification is required to notify each patent owner of its paragraph IV certification, stating that the listed patent is invalid or that its product does not infringe the patent.

Once the patent owner receives notification of the certification, the owner has forty-five days to bring a lawsuit for patent infringement against the ANDA filer. If the patent owner brings a suit for patent infringement, it triggers an automatic thirty-month stay against approval. The stay is lifted after the expiration of the thirty-month period or once a decision is issued by the district court as to the validity of the patent or the issue of infringement.

To encourage generic manufacturers to challenge weak or invalid patents through paragraph IV certification, the Hatch-Waxman Act offers the first successful paragraph IV filer

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30 Id. The FDA considers bioequivalent as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in [generic drugs] becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 320.1 (2012).
32 § 355(j)(2)(B). In addition, the filer must provide a “detailed statement of the factual and legal basis of the opinion of the [filer] that the patent is invalid or will not be infringed.” § 355(j)(2)(B)(iv).
33 § 355(j)(5)(B)(iii).
34 Id. If the patent owner neglects to bring a suit, then the generic is automatically approved.
35 Id. If the generic distributes its product after the thirty-month stay expires, but no judgment has been issued on the validity of the patent, the generic may later become liable for infringement if it is found. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 744 (E.D.N.Y. 2001).
the opportunity to market its generic exclusively for 180 days.\textsuperscript{36} This essentially creates a
duopoly between the brand name and the generic for the 180-day period.\textsuperscript{37} Notably, the 180-day
exclusivity period is only available to the first paragraph IV filer.\textsuperscript{38} Consequently, even if the
first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or
withdraws the litigation, that potential benefit will not pass to subsequent filers.\textsuperscript{39}

Recognizing the potentially disastrous effects that a lost patent could have on profits,
some patent holders began to settle infringement suits with the ANDA filers.\textsuperscript{40} These settlements
often involve payments from the patent holder to the alleged infringer to drop its patent
challenge and refrain from producing a generic drug for a negotiated period of time.\textsuperscript{41} Since the
payment flows from the patent holder to the would-be-generic manufacturer, these agreements
are called “reverse payment agreements.”\textsuperscript{42} Commentators note that the reverse flow of money
occurs because the Hatch-Waxman Act reallocates the risks and potential rewards between the
litigants.\textsuperscript{43} It is now the patent infringement plaintiff that stands to lose the most valued item –
the patent. In contrast, the alleged infringer stands to gain the most – the right to enter the
market. Thus, reverse payments are considered “a natural by-product” of the Hatch-Waxman
regulatory design.\textsuperscript{44}

\textsuperscript{36} § 355(j)(5)(B)(iv).
\textsuperscript{37} See Holman, supra note 23, at 509.
\textsuperscript{38} § 355(j)(5)(D).
\textsuperscript{39} Id. It has been suggested that the reason for this provision is that the first filer is usually the most motivated
challenger to the patent holder's claimed intellectual property. See Hemphill, supra note 7, at 1583.
\textsuperscript{40} See Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 806 (D.C. Cir. 2001).
\textsuperscript{41} See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012). In a non-Hatch-Waxman patent litigation, any
payment will typically flow from the alleged infringer to the patent holder. In contrast, a reverse payment is any sort
of patent settlement agreement that involves the transfer of consideration from the patent holder to an alleged
infringer. In exchange for this consideration, the alleged infringer generally agrees to delay developing or marketing
a product.
\textsuperscript{42} Holman, supra note 23, at 550.
\textsuperscript{43} Id.
\textsuperscript{44} In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003).
Realizing the potential anticompetitive effects of reverse payment agreements, Congress amended the Hatch-Waxman Act in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Those amendments require the brand name and generic pharmaceutical companies to file any settlement agreement with the Federal Trade Commission and the Department of Justice for antitrust review.

C. Purpose of the Hatch-Waxman Act

The Hatch-Waxman Act passed with the primary intention of jumpstarting generic competition with name brand pharmaceuticals. The Act encourages the production of more low-cost generic drugs through two means. First, it created an expedited approval process by allowing the generic manufacturer to piggyback on the safety and effectiveness data submitted by the brand name. This allows the generic manufacturer to avoid the costly and time-consuming clinical trials necessary to establish the safety and efficacy of the generic drug.

Second, the Act encourages generic manufacturers to challenge potentially invalid brand name patent rights by granting the first paragraph IV filer a 180-day period of market exclusivity. At the same time, the Act responded to the lobbying efforts of many pioneer drug companies. Since patent protection begins from the date of the filing and there is a lengthy

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46 § 355(j).
47 S. REP. NO. 111-123, at 23 (2010) (stating that the purpose of the Hatch-Waxman Act was to infuse the market quickly with generic competition thereby providing savings to consumers in the health care system).
48 H.R. REP. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (“The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.”). Id. at 15 (“The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development . . . . The incentive is the restoration of some of the time lost on the patent life while the product is awaiting pre-market approval.”).
50 Id. at 585-86.
approval process for pioneer drugs, pioneer companies sought legislation to restore lost patent life.\(^{53}\) Specifically, the Hatch-Waxman Act restored the time equal to the “regulatory review period for the approved product.”\(^{54}\) There are a number of limitations to the restoration extension, but the overarching purpose of the extension was to mitigate the adverse impact that the rest of the Hatch-Waxman Act would have on the incentives for large brand name pharmaceutical companies to invest in research and development of new drugs.\(^{55}\)

By creating the ANDA approval process and restoring lost patent life, the Hatch-Waxman Act is an effort “to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to the research and develop of new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”\(^{56}\) Although some consider it a compromise legislation, Congress has followed its traditional path in the area of intellectual property, stimulating innovation in industry while explicitly promoting the public interest.\(^{57}\) Nevertheless, the Hatch-Waxman Act principally serves the consumer interest. By extending the length of the patent, the Act continues to encourage large drug firms to invest in research and development of new drugs, and the creation of new drug products ultimately benefits the consumer. Meanwhile, the ANDA approval process and the paragraph IV certification operate as a means to streamline generics into the market place and drive down the costs of health care – again, benefiting consumers.\(^{58}\) As a result, the Act serves a singular purpose, to promote consumer welfare, through two parallel avenues.

\(^{53}\) Id.
\(^{54}\) 35 U.S.C. § 156(c). Administration of the second half of the Hatch-Waxman Act is split between the FDA and the Patent and Trademark Office. Id. § 156(e).
\(^{55}\) Weiswasser & Danzis, supra note 49, at 586.
\(^{56}\) Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990)). For a detailed account of how the Hatch-Waxman Act operates to achieve these goals, see Weiswasser & Danzis, supra note 49, at 590.
\(^{58}\) Id. at 14-15.
III. IMBALANCE BETWEEN INTELLECTUAL PROPERTY RIGHTS, COMPETITION LAW, AND THE HATCH-WAXMAN ACT

The issue of reverse payments has been considered by a number of district and circuit courts, and the process of review has varied. Some courts, under the per se illegal analysis, examine the antitrust implications of the agreement at the expense of any patent consideration. Other courts, under the scope of the patent analysis, focus extensively on the existence of a patent and ignore potential antitrust violations. The one underlying consistency, however, is that the courts have largely neglected the Hatch-Waxman Act as a material part of the analysis.

A. Per Se Illegal Analysis

Potential antitrust violations are generally reviewed under the “rule of reason.” That test directs the court to examine various factors that relate to the challenged action’s impact on competition. The rule of reason, however, provides little guidance on how those factors should be analyzed or weighed, and as a result, provides little predictability. The per se illegal rule is an outgrowth of the rule of reason’s lack of predictability. Restraints that are deemed per se violations are those which judicial experience has found lack any redeeming pro-competitive effect. When the per se rule applies, the plaintiff is not required to show that competition has been injured, and any pro-competitive justification by the defendant is moot.

Under the per se illegal rule, reverse payment settlements are conclusively presumed to be unreasonable restraints on trade, and as a result, they are deemed unlawful and invalid without

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59 See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) (applying the per se illegal rule and holding that a reverse payment is an illegal restraint of trade); In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012) (applying a quick look rule of reason test); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (applying the scope of the patent test and holding that the agreement is valid).
63 Id. at 436. Professor Cavanagh considers the per se rule to be a special spot on the rule of reason continuum.
65 HOVENKAMP, supra note 60, at 263.
any further analysis. The Supreme Court has stated that a per se rule of invalidity is only appropriate when the agreement is “manifestly anticompetitive.” If the court can predict with confidence that the agreement would be invalidated under traditional antitrust analysis, then the per se rule may apply. It would be invalid under traditional antitrust analysis if the agreement “would always or almost always tend to restrict competition and decrease output.”

Accordingly, the per se rule is not an appropriate framework for evaluating a reverse payment settlement because the underlying patent may be valid and infringed. If a valid patent does exist, then a settlement agreement is in accord with well-established patent principles. Since the patent may be valid and infringed, it is impossible to conclusively determine at this early stage whether the agreement is plainly and inherently anticompetitive. Ultimately, the per se illegal analysis deems patent validity irrelevant and invalidates the agreement on purely antitrust grounds.

Commentators note that the per se illegal analysis must look at two danger signals: “(1) the size of the [reverse] payment and (2) the impact of the [reverse] payment on third party entry prospects.” It has been argued that the greater the size of the reverse payment, the greater the

66 See JOHN MILES, HEALTH CARE AND ANTITRUST LAW § 2A:12 (2012). See also Cont’l T. V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49-50 (1977) (explaining that when an agreement is per se illegal it is conclusively presumed illegal without any further inquiry).
67 Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006) (“Per se liability is reserved for only those agreements that are ‘so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.’”) (quoting Nat’l Soc’y of Prof’l Engineers v. United States, 435 U.S. 679, 692 (1978)).
69 Id. at 886.
likelihood that the patent holder is protecting a weak or non-infringed patent.\textsuperscript{72} As a result, the probability of an antitrust violation increases as the size of the payment increases.\textsuperscript{73} Once the size of the payment surpasses the potential costs of the litigation, the probability of an antitrust violation rises drastically.\textsuperscript{74} Thus, a larger payment suggests that the patent is likely invalid, and the reverse payment has a high social cost because the exclusionary power of the patent is preserved for the defendant despite the patent’s invalidity.\textsuperscript{75}

However, the peculiarities of the patent system can undermine the reliability of these danger signals and per se treatment as a whole. First, a risk adverse patent-holding plaintiff may agree to pay the defendant to settle.\textsuperscript{76} It is the plaintiff who stands to lose his patent, which is the most valuable property in the litigation.\textsuperscript{77} As a consequence, the plaintiff may be pressured into settling the litigation even with a high probability of success based on the merits.\textsuperscript{78} As one commentator notes, if asymmetric information between the parties is added to the mix, a reverse settlement may become an attractive option despite a high likelihood of success for the plaintiff.\textsuperscript{79}

Second, a per se rule of invalidity, by neglecting to consider the nuances of the patent system, may cause significant and costly errors by prosecuting pro-competitive or business-

\textsuperscript{73} Id.
\textsuperscript{74} Hovenkamp, \textit{supra} note 71, at 25. For patent suits with less than $1 million at risk, the median estimated cost of discovery is $290,000, and the median estimated total litigation cost is $500,000. For suits with up to $25 million at risk, the median estimated cost of discovery is $1 million, and the median estimated total litigation cost is $2 million. For suits with over $25 million at risk, the median estimated cost of discovery is $2.5 million and the median estimated total litigation cost is $3.995 million. See AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, \textit{REPORT OF THE ECONOMIC SURVEY} 22 (2003).
\textsuperscript{75} Scott A. Backus, \textit{Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?}, 60 OKLA. L. REV. 375, 405 (2007).
\textsuperscript{76} See Kimberly A. Moore, \textit{Are District Court Judges Equipped to Resolve Patent Cases?}, 15 HARV. J.L. & TECH. 1, 2-3 (2001) (“[D]istrict court judges improperly construe patent claim terms in 33% of the cases appealed to the Federal Circuit.”).
\textsuperscript{77} Holman, \textit{supra} note 23, at 550.
\textsuperscript{79} Id. at 1807.
neutral conduct.\textsuperscript{80} For example, if an owner of a legitimate and infringed patent settles with the infringer and allows the infringer to enter the market during the period that the holder still has an exclusionary right, then the agreement would have pro-competitive effects. At least one commentator has argued that prosecuting this kind of legitimate conduct is an error that is more costly than allowing some anticompetitive conduct to go unchallenged.\textsuperscript{81}

In addition to disregarding patent rights, the per se analysis is not in line with the dual objectives of the Hatch-Waxman Act. As mentioned previously, the Act not only promotes the introduction of generics into the marketplace, it also extends the life of certain patents.\textsuperscript{82} This second quality increases the value of the patent and incentivizes brand name manufacturers to continue to fund research and development of new drug products.\textsuperscript{83} To deem reverse payment agreements as per se illegal reduces the value of the patent because it removes a method that the patent holder may use to protect its patent against infringement.\textsuperscript{84} A reduction in the value of the patent reduces the incentives for large research firms to invest in research and development of new drugs.\textsuperscript{85} A core purpose of the Hatch-Waxman Act, however, was to create a new incentive for increased expenditures in the research and development of new drug products.\textsuperscript{86} Very clearly, “[t]he incentive is the restoration of some of the time lost on patent life while the drug is awaiting pre-market approval.”\textsuperscript{87} Therefore, this reduction in value serves as a disincentive and

\textsuperscript{81} See Frank H. Easterbrook, \textit{The Limits of Antitrust}, 63 \textit{TEX. L. REV.} 1, 14-16 (1984).
\textsuperscript{83} Weiswasser & Danzis, \textit{supra} note 49, at 586.
\textsuperscript{85} See Butler & Jarosch, \textit{supra} note 80, at 120.
\textsuperscript{87} \textit{Id.}
undermines one of the objectives of the Act. Thus, the per se rule fails, in at least one respect, to consider and promote the dual objectives of the Hatch-Waxman Act.

Furthermore, by reducing the available settlement options, per se illegal treatment of reverse settlements may discourage generic firms from filing ANDAs. While a reverse payment may cause anticompetitive effects for a specific drug, reverse payments may encourage ANDA filings because they may be the most profitable course for ANDA filers. In addition, ANDA filers may not have the resources necessary to see the litigation through to completion and might prefer to push for a settlement that allows for early entry of the generic drug. Consequently, the per se analysis may actually reduce the number of ANDA filings and may cause fewer generics to enter the market early. This does not mean that reverse payment agreements are competitive. Rather, it illustrates that an absolute ban on reverse payments may reduce the incentives for generics to challenge brand name patents, threatening a core purpose of the Hatch-Waxman Act.

B. Scope of the Patent Analysis

On the other end of the spectrum is the scope of the patent test, which has developed into a per se rule of legality. The Eleventh Circuit first formulated the scope of the patent test in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* In that case, the Eleventh Circuit directed the district court to determine whether any part of the agreement went beyond the protections afforded by the patent and, if so, to apply traditional antitrust scrutiny only to those portions of

88 Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.”).
89 Butler & Jarosch, *supra* note 80, at 91.
the agreement. In a subsequent case, the Eleventh Circuit stated that its prior opinion did not call for an evaluation of the strength of the patent.

The Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation* adopted the Eleventh Circuit’s reasoning, applied a presumption of patent validity, and held that “there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” The only exceptions to this rule occur where there is evidence that the patent was procured by fraud or that the brand name infringement suit was objectively baseless. The current version of the scope of the patent test will find a reverse settlement agreement valid as long as a patent holder did not act in bad faith beyond the limits of the patent to restrain or monopolize trade.

Michael Carrier, Professor of Law at Rutgers School of Law, notes that the scope of the patent test has shred all nuance and evolved into a per se legal test. He notes two major flaws. First, the test assumes away the question being litigated – whether the underlying patent is valid. Professor Carrier, however, notes that the presumption of validity is merely procedural. That is, the presumption of validity merely governs the order in which proof is presented during trial; it is not substantive evidence of validity. Nevertheless, under the scope of the patent test, the courts have presumed that the patent is valid for the purposes of reviewing

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93 Id. at 1311-12.
94 FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1311, n. 8 (11th Cir. 2012) (explaining that “strength of the patent” refers to the patent’s exclusionary scope that appears on the face of the patent and does not consider the underlying merits of the infringement claim).
95 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006).
96 Id.
97 Id.
98 Id.
99 Carrier, *supra* note 91, at 5.
100 Id. at 6.
101 Id. at 5.
the settlement. In doing so, there remains the potential that the patent is invalid. As a result, the scope of the patent test may help a brand name exclude generic competition from the market even though it has no legal right to do so.

Professor Carrier also notes that when a brand name firm sues a generic firm for infringement, the brand name has the burden of proving infringement. The scope of the patent test cannot resolve this issue because it does not require the brand name to make any showing of infringement. There remains the potential that both the brand name and the generic patents are valid, but the generic patent does not infringe the brand name patent.

Ultimately, the scope of the patent test may help a brand name firm preserve the exclusionary power of an invalid patent or help a brand name exclude a non-infringing generic. In doing so, the scope of the patent test allows a brand name firm to undermine the Hatch-Waxman Act’s regulatory procedure that was designed to increase the number of generic products available to consumers on a timely basis. As a result, the consumer is denied the benefits of generic competition and suffers a high social cost. Thus, the scope of the patent test fails to address the central question of a paragraph IV certification and ultimately undermines the ability of the Hatch-Waxman Act to promote the consumer interest.

Since the fundamental question of patent validity is not answered under the scope of the patent analysis, it is extremely difficult to invalidate a reverse settlement. Consequently, no

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102 See, e.g., In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).
103 Carrier, supra note 91, at 7.
104 Id.
105 Hovenkamp, supra note 71, at 25.
106 S. REP. NO. 111-123, at 23 (2010) (stating that the purpose of the Hatch-Waxman Act was to infuse the market sooner with generic competition thereby providing savings to consumers in the health care system).
107 Hovenkamp, supra note 71, at 25. See also Backus, supra note 75, at 405 (“The social costs, also referred to as consumer harm, is the difference between what consumers would gain if the patent litigation were seen through to completion and what consumers actually receive as a result of the patent settlement.”).
reverse settlement has been invalidated under the scope of the patent test. Thus, the scope of the patent test has the potential for abuse. If a brand name fears that it will lose its patent, it can settle with the generic and that settlement will be upheld. As a result, the number of generic products entering the market may be suppressed as more reverse settlements are upheld.

Finally, the test fails to address antitrust issues. According to the Supreme Court, whether a restraint qualifies as an unreasonable restraint, and therefore violates antitrust law, is normally evaluated under the “rule of reason.” Applying the rule of reason, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” The scope of the patent test does not consider any of these factors. Rather, it considers only “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.” Essentially, the scope of the patent test will consider a patent settlement agreement valid as long as a patent holder did not act in bad faith “beyond the limits of the patent monopoly” to restrain or monopolize trade. The test merely applies competition law scrutiny to any part of the

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108 See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003).
109 Since the cost of losing a patent could be extraordinary, a brand name would be willing to pay a premium to settle.
111 Id.
112 Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1066 (11th Cir. 2005). An example of an action that exceeds the scope of the patent is an activity that serves as a device to circumvent antitrust law. Id. at 1067 (11th Cir. 2005); See also Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).
113 In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 197 (2d Cir. 2006).
agreement that exceeds the patent’s range. The test does not consider that if the patent is invalid, the effect of the restraint is significant, especially given that the relevant market has cost consumers exorbitant amounts—to the point that Congress passed the Hatch-Waxman Act as a means to reduce health care costs. A proper analysis would not bypass competition law so easily.

IV. The Hatch-Waxman Act Should Be Given More Weight in the Analysis

The courts, applying either the per se rule or the scope of the patent test, have elevated either patent or antitrust law, respectively, above the Hatch-Waxman Act at the expense of promoting the Act’s purpose. Patent and competition law are large bodies of law that apply broadly to a number of industries. Thus, the Hatch-Waxman Act, which applies specifically to the health care industry, should be given the most weight in the analysis. Moreover, patent and antitrust law have general aims while the Hatch-Waxman Act has a very specific purpose. Finally, the Hatch-Waxman Act is the most recent development related to competition in the pharmaceutical industry. Taken together, the Hatch-Waxman Act, its procedures and its purpose, must take precedence over patent and antitrust law.

A. The Hatch-Waxman Act is Sector-Specific

Patent and competition law are large, general bodies of law that encompass numerous industries. They can effectively reach every corner of the economy. For example, a patent is the government grant of exclusive rights to an invention for a limited period that is awarded to an inventor in exchange for the public disclosure of the invention. Governed by Title 35 of the United States Code, patents have a general set of legal rules that govern patentability in a wide

It has been stated that those standards are so flexible that they can encompass “anything under the sun that is made by man.” As a result, patents have applied to numerous products, and processes, such as smartphones, tablet computers, teeth whitener, and welding machines.

Competition law is just as broad. The purpose of competition law is to protect businesses from the free flow of the market and to protect the public from the failures of the market. Out of concern for the public wellbeing, competition law directs itself to disentrench conduct that unfairly destroys or reduces competition. Consequently, competition law condemns practices such as pricing agreements between competitors, mergers that result in conglomerates owning an unfair share of the market, and contracts between buyers and sellers that restrain trade. Essentially, competition law is so broad and far-reaching that the doctrine applies to any anticompetitive activity that involves or affects interstate commerce. As such, violations of competition law have been found in a variety of industries such as mattress manufacturing, college sports, and dentistry.

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119 Id.
120 Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1066 (Fed. Cir. 1997).
122 Mayer Hoffman McCann, P.C. v. Barton, 614 F.3d 893, 896 (8th Cir. 2010) (finding that covenants not to compete may be illegal).
In contrast, food and drug law concerns itself with physical things that are put into or onto, or are used with, the bodies of humans or animals.\textsuperscript{131} More specifically, the FDCA, which was later amended by the Hatch-Waxman Act, defines its jurisdictional terms as “food,” “drug,” “device,” and “cosmetic.”\textsuperscript{132} Even more specific are the Hatch-Waxman Act amendments to the FDCA. Those amendments extend the life of patent protection for brand name pharmaceuticals and provide a mechanism for generic manufacturers to challenge the validity of the brand name patents.\textsuperscript{133} The amendments apply directly to brand name pharmaceutical manufacturers and their generic rivals in the pharmaceutical industry.

Interestingly, veterinary drug products are not included under the Hatch-Waxman Act’s patent restoration provision. The inclusion of veterinary drug products was proposed at one point, but ultimately dropped from the final version of the Hatch-Waxman Act.\textsuperscript{134} Thus, as Congress intended, the Hatch-Waxman amendments only apply to human drugs – a very specific sector of the economy.\textsuperscript{135}

\textbf{B. The Hatch-Waxman Act Has a Specific Purpose}

Additionally, the Hatch-Waxman Act should be given more weight in the analysis because the Act has a very specific purpose within this specific sector. Senator Orrin Hatch, one of the principal drafters of the Hatch-Waxman Act, stated that the purpose of the Act was to infuse generic competition into the pharmaceutical market sooner rather than later, thereby

\begin{footnotesize}
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\item \textsuperscript{131} \textsc{The Food and Drug Law Institute, supra} note 52, at 9.
\item \textsuperscript{133} See 21 U.S.C. § 355 (2006).
\item \textsuperscript{134} \textsc{The Food and Drug Law Institute, supra} note 52, at 32.
\item \textsuperscript{135} \textit{Id.}
\end{itemize}
\end{footnotesize}
providing consumers with savings in the health care system.\textsuperscript{136} The Act serves one fundamental purpose – to bring generic drugs to market quickly.\textsuperscript{137}

Furthermore, the Hatch-Waxman Act indicates the means through which its purpose is to be carried out. The Act provides a mechanism for generic manufacturers to challenge brand name patents and provides significant incentives for generics to initiate these challenges.\textsuperscript{138} The Act also allows a brand name manufacturer to defend against these challenges by initiating a patent infringement suit.\textsuperscript{139} This design indicates that the drafters intended these patent challenges to be litigated.\textsuperscript{140} In addition, the legislative history shows that Congress intended to encourage generic manufacturers to challenge weak or invalid patents through the litigation process.\textsuperscript{141} The means to quickly infuse generic competition into the pharmaceutical market, therefore, is to litigate the validity of the brand name patents.\textsuperscript{142} Thus, the purpose of the Act is specific, and the means that Congress specified to achieve that purpose are equally specific. As a result, the Act’s principles and objectives should be given priority.

\textbf{C. The Hatch-Waxman Act Marks a Recent Accomplishment in Health Care Law}

Furthermore, the Hatch-Waxman Act is the most recent development. The Hatch-Waxman Act was a significant amendment to the 1938 FDCA.\textsuperscript{143} Passed in 1984, the Hatch-Waxman Act was then amended as a part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.\textsuperscript{144} Since it was passed, the Act has played a significant role in health

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\textsuperscript{136} S. REP. NO. 111-123, at 23 (2010).
\textsuperscript{139} See § 355(j)(5)(B)(iii).
\textsuperscript{140} H.R. REP. No. 98-857, pt. 1, at 71 (1984) ("The patent provisions of this bill also encourage . . . litigation over the validity of patents.").
\textsuperscript{141} S. REP. NO. 107-167, at 4 (2002).
\textsuperscript{142} See Hemphill, \textit{supra} note 7, at 1614.
\textsuperscript{143} THE FOOD AND DRUG LAW INSTITUTE, \textit{supra} note 131, at 31.
\textsuperscript{144} § 355(j).
\end{flushleft}
care law and the United States pharmaceutical market. One commentator notes that over the past few decades, pharmaceutical research, due in part to the Hatch-Waxman Act, has helped transform the health care industry.145

In contrast, Congress passed its first patent statute in 1770, and by 1836 all of the essential features of modern patent law were in place.146 Despite periodic revisions, the basic structure of the patent system has remained unchanged.147 Along a similar vein, the heart of U.S. federal antitrust law, the Sherman Antitrust Act, was passed in 1890.148 The Legislature intended the Act to be a federal enactment of the common law of restraints of trade, with courts having wide discretion in framing its rules and guidelines.149 Nevertheless, the Sherman Act is the main antitrust authority as each subsequent statute extends or refines its terms.150

V. THE QUICK-LOOK RULE OF REASON IS THE APPROPRIATE TEST FOR EVALUATING A REVERSE PAYMENT AGREEMENT

Accepting that the Hatch-Waxman Act must play a significant role in the antitrust analysis of reverse payments agreements leads to the conclusion that reverse payments must face significant antitrust scrutiny without being inherently unlawful. Consequently, courts should adopt a presumption that reverse payment agreements are unlawful and apply a quick-look rule of reason analysis to the agreement. Under the quick-look rule of reason framework, the analysis of a reverse payment agreement would treat patent and antitrust law as equals serving the dual purposes of the Hatch-Waxman Act.151 Courts should embrace the quick-look test because it

146 Burk & Lemley, supra note 116, at 1159.
147 Id.
151 See Mark A. Lemley, A New Balance Between IP and Antitrust, 13 Sw. J. L. & Trade Am. 237, 255 (2007) (arguing that the current trend is to elevate intellectual property rights above antitrust law, but intellectual property rights and antitrust law should be regarded as equals).
promotes the purposes of the Hatch-Waxman Act, lowers the cost of pharmaceuticals, and strikes a balance between patent and antitrust law.

Under a quick-look rule of reason analysis, courts consider the context and likely effect of the agreement sub judice before deciding to apply either the per se illegal rule or the rule of reason.\textsuperscript{152} The analysis falls in between the rigid per se rule and the complicated rule of reason.\textsuperscript{153} Typically, a restraint of trade falls within the quick-look category if it is highly suspicious, but some doubt still exists as to the true effect of the restraint.\textsuperscript{154} The quick-look rule of reason applies “in cases where per se condemnation is inappropriate, but where no elaborate industry analysis is required to demonstrate the anticompetitive character of an inherently suspect restraint.”\textsuperscript{155} It has been stated that the quick-look test is appropriate “when an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and markets.”\textsuperscript{156} Under the quick-look analysis, the competitive harm is presumed and the defendant must provide a pro-competitive justification for the action.\textsuperscript{157} Absent a reasonable pro-competitive justification for the restraint itself, “the presumption of adverse competitive impact prevails” and the action is deemed a naked restraint in violation of antitrust law per se.\textsuperscript{158} If the defendant offers a legitimate pro-competitive justification, however, the court will proceed to apply the rule of reason analysis.\textsuperscript{159}

\textsuperscript{153} In re K-Dur Antitrust Litig., 686 F.3d 197, 209 (3d Cir. 2012).
\textsuperscript{154} HOVENKAMP, supra note 60, at 265.
\textsuperscript{156} California Dental Ass’n v. F.T.C., 526 U.S. 756, 757 (1999).
\textsuperscript{157} Brown Univ., 5 F.3d at 669.
\textsuperscript{158} \textit{Id.}
\textsuperscript{159} \textit{Id.}
Ultimately, the purpose of the quick-look test is not to broaden the range of defenses for a restraint; rather, it ascertains quickly whether the restraint tends to promote competition.\textsuperscript{160}

The quick-look test is appropriate for the evaluation of a reverse payment agreement. A reverse payment occurs between two competitors and is considered a horizontal restraint.\textsuperscript{161} Since horizontal restraints occur between two competitors, the potential for an adverse impact on competition is great.\textsuperscript{162} No elaborate analysis is required to understand that an agreement between two horizontal competitors to refrain from competing in the relevant market is anticompetitive. Thus, horizontal agreements are often considered per se violations.\textsuperscript{163} A reverse payment, however, is complicated by the existence of a potentially valid and infringed patent. Accordingly, the patent holder may have lawful exclusionary rights. Thus, while the agreement itself is inherently suspect, per se condemnation is inappropriate. Whether the agreement is totally devoid of competitive effects is questionable.

Under the quick-look analysis, the existence of any payment from a brand name patent-holder to a generic, patent-challenger who in turn agrees to delay entry into the market is considered prima facie evidence of an unreasonable restraint of trade.\textsuperscript{164} The patent holder can rebut that presumption by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.\textsuperscript{165}

\begin{footnotes}
\textsuperscript{160} Hovenkamp, supra note 60, at 265.
\textsuperscript{161} Bus. Electronics Corp. v. Sharp Electronics Corp., 485 U.S. 717, 730 (1988) ("Restraints imposed by agreement between competitors have traditionally been denominated as horizontal restraints, and those imposed by agreement between firms at different levels of distribution as vertical restraints.").
\textsuperscript{163} Id.
\textsuperscript{164} In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).
\textsuperscript{165} Id. Under this framework, arguments that the patent is strong would not be admissible. See Supplemental Brief of Defendants-Appellees Bayer AG and Bayer Corporation in Response to the Brief of the United States at 4-8, In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)).
\end{footnotes}
One important corollary is that settlement policy is not a justification.\textsuperscript{166} Often, defendants argue that sound settlement policy favors upholding reverse settlements.\textsuperscript{167} They argue that the purpose of a settlement is to provide the parties with certainty and finality and to help relieve the burden on a congested court system.\textsuperscript{168} Consequently, they conclude that any rule that would deprive settlements of their finality or restrict the ability of the parties to enter into a settlement would be strongly contrary to sound settlement policy.\textsuperscript{169}

These arguments, while appealing, cannot rebut the presumption of an illegal restraint. The purpose of the quick-look test is it is to ascertain quickly whether the restraint tends promote competition.\textsuperscript{170} Sound settlement policy does not indicate anything about the pro-competitive effects of the agreement.

In addition, Scott Hemphill, Professor of Law at Columbia Law School, argues that the Hatch-Waxman Act normally operates to balance innovation and competition, and any settlement favoring more innovation at the expense of consumer access disrupts this balance.\textsuperscript{171} Taking that one step further, any settlement policy that favors the conservation of judicial resources and provides the parties with certainty and finality at the expense of consumer access is contrary to the purpose of the Hatch-Waxman Act.

\textit{A. The Quick-Look Rule of Reason Promotes the Purposes of the Hatch-Waxman Act}

Any test that reviews the legality of a reverse settlement should foster the dual purposes of the Hatch-Waxman Act. By creating the ANDA approval process and restoring lost patent

\textsuperscript{166} See HOVENKAMP, supra note 60, at 265.
\textsuperscript{168} Brief of Appellees and Appellants, supra note 166, at 22-27.
\textsuperscript{169} Id. at 36-37.
\textsuperscript{170} HOVENKAMP, supra note 60, at 265.
\textsuperscript{171} Hemphill, supra note 7, at 1614.
life, the Hatch-Waxman Act is an effort “to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.” Ultimately, the quick-look rule of reason is in the best position to foster these objectives.

First, the quick-look test does not devalue the patent as far as the per se illegal test. Making reverse payment agreements per se illegal reduces the value of the patent because it removes a method that the patent holder may use to protect its patent against infringement. The quick-look test, however, does not fully strip the brand name of this ability to defend its patent. While somewhat constricted, the brand name can still settle the litigation so long as the payment is not for delay or as long as the payment promotes competition. By granting the brand name the opportunity to defend the settlement, the value of the patent is not reduced as significantly. Therefore, the quick-look test will not serve as a disincentive for brand name companies to invest further in research and development.

As mentioned previously, per se illegal treatment of reverse settlements may discourage generic firms from filing ANDAs because it reduces the available settlement options. The quick-look rule of reason, however, does not prevent settlement altogether. It merely requires that the settlement be for something other than delayed entry. If that is not possible, then the agreement must have legitimate pro-competitive benefits. Therefore, the potential that the test will reduce the number of ANDA filings is not a significant issue.

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172 Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990)). See also Weiswasser & Danzis, supra note 49, at 590.
173 See supra Part III.A.
174 Langenfeld & Li, supra note 84, at 778.
175 See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).
176 Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.”).
Furthermore, a settlement is still attractive as long as the brand name and generic companies believe that they can rebut the presumption of settlement invalidity. As a result, firms would only structure reverse settlement agreements if they were reasonably sure that it would not be anticompetitive. In an example provided by the Third Circuit, a reverse payment agreement that has an overall effect of increasing the amount of competition in the market would be “a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug.”\footnote{K-Dur Antitrust Litig., 686 F.3d at 218.} In that sense, allowing for settlement in these rare situations fosters generic competition.


The economic goal of patent, antitrust, and the Hatch-Waxman Act is to maximize wealth by producing better items and producing items at a lower cost.\footnote{See id. at 247-48.} The three doctrines can achieve this goal by creating output expansion and avoiding output restriction.\footnote{Id. at 248.} Accordingly, antitrust law will permit anticompetitive activity, such as a monopoly, when that activity creates greater output.\footnote{Lemley, supra note 150, at 248.} Patent properly finds its way into the mix when it provides something that consumers value, but could not otherwise obtain without affording the developer the protections of a patent.\footnote{Lemley, supra note 150, at 247 (citing WARD BOWMAN JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL (1973)).} This too is output expansion. The Hatch-Waxman Act cuts straight down the middle in that it effectively increases the potential value of a patent by increasing its duration while creating a mechanism for which generics can foster competition against these patents.\footnote{See Hemphill, supra note 7, at 1614.} The result is creating output expansion by stimulating brand name innovation and generic competition.

\footnote{K-Dur Antitrust Litig., 686 F.3d at 218.}
\footnote{See id. at 247-48.}
\footnote{Id. at 248.}
\footnote{Lemley, supra note 150, at 247 (citing WARD BOWMAN JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL (1973)).}
\footnote{Lemley, supra note 150, at 248.}
\footnote{See Hemphill, supra note 7, at 1614.}
Reverse payments themselves do not restrict output. If the patent is valid and infringed, then a payment that allows both parties to avoid litigation and allows the generic to enter the market before the expiration of the patent increases output on two fronts. First, it further compensates the brand name firm, which in turn can fund more research. At the same time, the generic competitors can access the market earlier, thereby driving down prices.

In contrast, a reverse payment has the potential to create substantial output restriction if the settlement protects an invalid or non-infringed patent. In this situation, a brand name is able to keep the generic company at bay and make a substantial profit in an exclusive market even though the underlying patent is invalid or not infringed. These settlements would thus unduly restrict competition and, as a result, unnecessarily reduce consumer welfare. While allowing a settlement that protects a patent that is not valid or infringed is more costly than condemning a settlement where the patent is valid and infringed, the latter should not be completely condemned. A settlement that protects an invalid patent is the type of settlement agreement that must be avoided, but not completely at the expense of the second type of settlement.

The quick look test, which presumes that the settlement is illegal, gives proper weight to the effect of output restriction. It requires a high burden to overcome the presumption and prove that the settlement does not reduce output. If the patentee, however, can either prove that the agreement was for a purpose other than delayed entry or offers a legitimate pro-competitive benefit, then the court can be assured that the settlement expands output rather than restricts it. Since the patentee is in the best position to offer justifications for the settlement, a failure on the part of the patentee to do so strongly suggests that the agreement may restrict output. Ultimately,

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183 Lemley, supra note 150, at 253-54.
184 Hemphill, supra note 7, at 1596.
185 In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).
the more costly settlement, one that protects an invalid patent, will be avoided, but those rare settlements that increase competition will not be completely ignored.

C. The Quick-Look Rule of Reason Strikes a Proper Balance Between Patent and Antitrust Law

Mark Lemley, Professor of Law at Stanford Law School, argues that in order to have a balance between patent and antitrust, strong patent rights must be coupled with strong antitrust enforcement. In order to make this shift, Professor Lemley suggests that two processes must change. First, modern thinking has led to the conclusion that private decisions are efficient, not necessarily the free market. Private decisions, however, only produce efficient results because they are disciplined by an unforgiving market. Since the antitrust laws are designed to create a competitive and unforgiving market, private decisions require strong antitrust enforcement.

The quick-look rule of reason provides heightened antitrust scrutiny and allows for strong antitrust enforcement. Under the quick-look test, antitrust enforcement authorities have teeth to attack settlements that they view as restrictive. The test does not, however, fully render the brand name defenseless. As a result, the brand name can make a business decision to either see the infringement litigation through or settle with the generic. If the brand name opts to settle, it is aware that it must either settle in a manner that is not a payment for delay or in a way that promotes competition. Consequently, the brand name will make an efficient decision in response to the potential threat posed by enforcement authorities. If the brand name fails to do so, they will be disciplined. Therefore, private decisions will be met with strong antitrust enforcement.

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186 Lemley, supra note 150, at 254.
187 Id.
188 Id. at 255.
189 Id.
190 See id.
Second, Professor Lemley argues that “[w]hen patent rights get stronger, we want
antitrust to get stronger to prevent abuses of the right.” 191 In the pharmaceutical industry, drug
patents are coupled with strong patent protection in order to rein in large profits. 192 Strong
protection, however, poses high barriers for generic products to enter the marketplace. 193 In
addition, the potential for patent abuse has increased from the passing of the Hatch-Waxman Act,
which created the regulatory design that facilitates reverse settlements. Under the quick-look
analysis, antitrust no longer merely polices the borders of the patent. As a result, it can prevent
more settlements that protect invalid or non-infringed patents.

Furthermore, the quick-look rule of reason promotes fundamental principles of patent
law. Patents do not immunize settlements from antitrust scrutiny, but instead, patent law creates
limited monopolies in order to encourage innovation for the public good. 194 Invalid patents,
however, do not promote innovation for the public good, and as a result, they confer unlawful
monopoly rights on their holders. 195 Consequently, the Supreme Court has stated that “[i]t is as
important to the public that competition should not be repressed by worthless patents, as that the
patentee of a really valuable invention should be protected in his monopoly.” 196 The quick-look
rule of reason tests the validity of patents and resolves questions surrounding the validity of the

191 Id.
barriers include patents and other intellectual property licenses, control of essential or superior resources, entrenched
buyer preferences, high capital entry costs and economies of scale.”).
194 United States v. Line Material Co., 333 U.S. 287, 308 (1948) (“It is equally well settled that the possession of a
valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond
the limits of the patent monopoly.”). See also Standard Oil Co. of California v. United States, 337 U.S. 293, 307 (1949)
(“A patent . . . is at least prima facie evidence of [market] control.”); cf. Simone A. Rose, Patent
whether patent property rights confer monopoly power or power over price).
196 Id.
In resolving these important questions, the public can be ensured that drug patents that survive actually promote innovation for the public good. On the other hand, if the litigation finds that the patent is invalid, then the drug never had any lawful patent rights.

Ultimately, the quick-look rule of reason suggests a more balanced view between patent and antitrust. It is an examination where the strong patent rights of the pharmaceutical industry are met with strong antitrust enforcement. Since there is an inherent conflict between patent and antitrust law, having a balanced relationship between the two will serve to best promote the goals of the Hatch-Waxman Act.

VI. CONCLUSION

The Hatch-Waxman Act is an ambitious and complicated legislative accomplishment. Given the potential for a massive drop in profits that is often coupled with the loss of a patent, many brand name firms have exploited weaknesses in the Act through reverse settlements. Judicial review of these settlements has swung full force with either antitrust or patent principles. In doing so, review of the settlement has largely neglected the purpose of the Hatch-Waxman Act. The Hatch-Waxman Act, however, must be given the most weight in the analysis because it is aimed at a specific industry, embedded with a specific purpose, and representative of the most recent legislative accomplishment. Accepting that the Hatch-Waxman Act must be given the most weight in the analysis has an important consequence. That is, reverse payment agreements should be subjected to a quick-look rule of reason analysis because the quick-look test promotes the dual purposes of the Hatch-Waxman Act, fosters the economic goals of patent, antitrust, and

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198 See Lemley, supra note 150, at 254.
200 Yana Percersky, To Achieve Closure of the Hatch–Waxman Act’s Loopholes, Legislative Action is Unnecessary: Generic Manufacturers are Able to Hold Their Own, 25 CARDOZO ARTS & ENT. L.J. 775, 786 (2007).
the Hatch-Waxman Act, and strikes a proper balance between antitrust and patent law. Under the quick-look analysis, a reverse payment constitutes prima facie evidence of an unreasonable restraint of trade. The patent holder can rebut that presumption by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit. Under this framework, settlement policy is not a justification for the restraint. The effect is that either more cases will be litigated or that settlements will be made with legitimate pro-competitive benefits. Either scenario facilitates generic competition with brand name drugs. Thus, the quick-look rule gives the purpose of the Hatch-Waxman Act the most weight in the analysis. While the quick-look test is not perfect, it is a more balanced solution to a delicate problem.

201 See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).
202 Id.
203 See HOVENKAMP, supra note 60, at 265.