

Reverse Payment Settlements: A Patent Approach to Defending the Argument for Illegality

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Abstract: This note proposes a new strategy to address the challenges of reverse payment settlements in pharmaceutical patent licensing. Many voices have long been critical of suspicious reverse payment settlements, yet little has been done by the courts to restrict these deals under current antitrust law. However, shifting the fight to the realm of patent law may be a better means of attack for these challengers. Instead of scrutinizing the settlements under doctrines of antitrust law, utilizing previously developed patent law and policy could be a much more fruitful endeavor. Specifically, reverse payment settlements could be examined under an expanded version of the doctrine of patent misuse. While patent misuse is similar to antitrust analysis, the policy issues underlying patent misuse make it more sympathetic to the view of restricting suspicious reverse payment settlements. Following an in-depth look into relevant patent policy, this note proposes new procedural and slight substantive changes to the doctrine of patent misuse, which would adapt the doctrine to properly target suspicious reverse payment settlements. Through this adaptation, the richly developed legal theory of patent misuse can be applied to the circumstances of a reverse payment settlement while maintaining its policy goals.

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INTRODUCTION: REVERSE PAYMENT SETTLEMENT SUSPICIONS

Unsurprisingly, the United States' patent law and antitrust law regimes often come into severe conflict with one another, as one creates legal monopolies while the other seeks to outlaw them. One circumstance creating such conflict is reverse payment settlements for pharmaceutical patent licensing.¹ In a reverse payment settlement, a patent infringement plaintiff, usually a name-brand drug company, pays the patent infringement defendant, usually a generic drug company, in return for the defendant's agreement to not make, use, or sell the allegedly-infringing generic drug for some period of time.² The nature of the settlements is unusual, since the payment goes from patent infringement plaintiff to infringement defendant.³ These reverse payments, while uncommon in most circumstances, are a natural by-product of the United States' generic pharmaceutical introduction scheme under the Hatch-Waxman Act.⁴

¹ Reverse payment settlements are sometimes also referred to as exclusion payments. See Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1729 n.130 (2003) ("Exclusionary payment refers to "situations in which the [infringement] defendant, often a generic pharmaceutical company, never has an opportunity to enter the market, and is paid not to enter, as well as situations in which the defendant is paid to exit a market in which it already competes"). See, e.g., *in re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 189 (2d Cir. 2006). "Name-brand" and "pioneer" will be used interchangeably throughout this note to describe drug companies who hold the original patent for the "first drug that contains a particular active ingredient that is approved by the FDA for a specified use," as compared to generic drug makers who make drugs "containing the active ingredient of but not necessarily the same excipient substances . . . as the pioneer drug marketed under a brand name." BLACK'S LAW DICTIONARY 535 (8th ed. 2004).

² Thomas F. Cotter, *Refining the Presumptive Illegality Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1797 (2003).

³ *Id.*

⁴ See Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 (2006) (informally known as the Hatch-Waxman Act). The Hatch-Waxman Act is the statutory scheme which sets the modern guidelines for introduction of generic pharmaceuticals to the United States market. The Hatch-Waxman Act provisions create an environment where reverse payment settlements are particularly attractive. See *Tamoxifen*, 466 F.3d at 206 ("reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them"); *accord in re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (2003) [hereinafter *Cipro II*] ("reverse payments are a natural bi-product of the Hatch-Waxman process"); see also Hovenkamp et al *supra* note 1, at 1757 ("[e]xclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments").

For example, in a recent case, Cephalon, Inc., a name-brand pharmaceutical company, settled a patent infringement case by collectively paying four generic drug makers \$200 million per year to keep their generic version of Provigil off the market until 2012.⁵ The CEO of Cephalon was quoted: “We were able to get six more years of patent protection. That’s \$4 billion in sales that no one expected.”⁶ Since the introduction of a generic drug drastically lowers the selling price of that drug, the deal made economic sense for both parties. The generics likely profited more from the settlement than they could in sales of the generic drug on the market.⁷ Additionally, the name-brand drug maker can maintain its high prices for the drug.⁸ With both pioneer and generic drug companies profiting on the deal, the general public is left with costly drug prices.⁹ Ironically, these settlements which keep generic drugs off the shelves are largely due to the very legislation that encourages generics to enter the market.

Under the framework of the Hatch-Waxman Act, a pioneer drug maker often contests that a generic drug maker is infringing on its pharmaceutical patent and proceeds with infringement litigation.¹⁰ However, in pursuing litigation, weak patents are placed in major jeopardy of being invalidated or ruled as having a narrow scope.¹¹ To

⁵Jon Leibowitz, Chairman, Fed. Trade Comm’n, “Pay for Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution), Remarks at the Center for American Progress 5 (Jun. 23, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

⁶*Id.*

⁷See Joe Mullin, *Reversal of Fortune? Pharmaceutical Industries’ Reverse-Payment Settlements*, IP LAW & BUS., Oct. 2009. The Mullin article is an excellent introductory source of information regarding reverse payment settlements for observers who are unfamiliar with the state of the controversy.

⁸*Id.*

⁹*Id.*

¹⁰21 U.S.C. § 355 (2006). Under the Hatch-Waxman Act, generics are offered an incentive to assert that pioneer patent is not infringed or invalid. This is usually followed by the pioneer filing an infringement suit. See CRAIG A. NARD, *THE LAW OF PATENTS* 710 (Aspen Publishers 2008).

¹¹However weak a patent, it is still presumed valid. See 35 U.S.C. § 282 (2006). A patent is only invalidated under an invalidity defense established by clear and convincing evidence. See *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983).

remedy this realistic injury to the pioneer drug maker, instead of seeing through the litigation, a settlement may be agreed upon between the pioneer drug maker and the potential generic drug maker.¹² In agreeing to the payment, the validity of the patent is not jeopardized, as would be the case had the patent's validity been tried in court through patent litigation.¹³ However, particularly when reverse payments are very large, there is suspicion that the patent would have been invalidated or found not to be infringed if litigated to its end.¹⁴

Reverse payment settlements have recently come under intense antitrust scrutiny. Challengers to the settlements claim that they prevent competition in the market and wrongfully extend the rights of patent holders, making the settlements unlawful.¹⁵ However, courts have upheld almost all reverse payment settlements as legal under the antitrust laws.¹⁶ Critics are especially suspicious of settlements where the infringement defendant is paid in excess of the value they could have realized had they continued through litigation and invalidated the patent.¹⁷ Standards have been proposed where a settlement would

¹² See Mullin, *supra* note 7.

¹³ *Id.*

¹⁴ See Hovenkamp et al., *supra* note 1, at 1758-59 (Large exclusionary payments suggest inherent uncertainty as to the validity or scope of the patent).

¹⁵ See *id.*; see 15 U.S.C. § 1 (prohibiting restraint on trade); see *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) ("horizontal" restraints on trade amongst competitors are *per se* violations of section 1 of the Sherman Act).

¹⁶ See *Tamoxifen*, 466 F.3d at 206 ("Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation."); see, e.g., *Valley Drug Co. v. Geneva Phar., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003); but see *in re Cardizem Antitrust Litig.*, 332 F.3d 896, 911 (6th Cir. 2003) ("calling a forty-million-dollar reverse payment to a generic manufacturer "a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers").

¹⁷ See *Tamoxifen*, 466 F.3d at 211 ("The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent."); see *in re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005) [hereinafter *Cipro III*] ("the greater the chance a court would

be presumptively illegal if the patent is likely invalid or not being infringed, or the settlement payment is unusually large (likely signifying that the patent is invalid or not being infringed).¹⁸

An approach advocating presumptive illegality of suspicious settlements is supported by patent policy in favor of weeding-out weak and potentially invalid patents. Sound patent policy should stand for only enforcing patent rights which are deserved. Weak patents, undeserving of monopoly power, can be discovered through identifying suspicious reverse payment settlements.¹⁹ Additionally, while patents are presumed valid,²⁰ the courts have gone to substantial ends to enable weak or “bad”²¹ patents to be invalidated or deemed them unenforceable for having too narrow of claim scope.²² In a legal landscape where patent rights are often viewed as at-odds with antitrust law, the two legal regimes can find common ground in refusing to afford weak patents undeserved monopoly power.

This note proposes to explore reverse payment settlements in pharmaceutical drug markets in view of the existing and developing patent law regime in the United States. Pulling together concepts from across patent law and upon applying them to the framework of antitrust related reverse payment settlements, we will shed new insight on the topic. Through a patent framework, a new approach can be applied to limit undeserved monopolistic drug pricing caused by suspicious reverse payment settlements. Specifically, this note proposes that the doctrine of patent misuse could logically be broadened to be used as a mode of attack on suspicious reverse payment settlements.

Part I provides a detailed look into the phenomenon of reverse payment settlements, including an in-depth review of the Hatch-

hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment”).

¹⁸ See *infra*, Part II.A.

¹⁹ See Hovenkamp et al., *supra* note 1, at 1757-58 (Large exclusionary payments suggest inherent uncertainty as to the validity or scope of the patent).

²⁰ Patents are presumed valid under the Patent Act. 35 U.S.C. § 282.

²¹ The term “bad patent,” for our purposes, will be defined by any patent that would be invalidated, ruled unenforceable, or non-infringed if litigated. For a discussion on bad patents, see generally Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181 (2008).

²² See *infra*, Part III.

Waxman Act. Special emphasis will be placed on the evolving story of the conflict between patent and antitrust policy. Further, Part I discusses how the courts have dealt with the antitrust legality of reverse payment settlements.

Part II examines several proposed solutions to the problem of anticompetitive reverse payment settlements. Antitrust commentators are extremely concerned with the proposition of weak patents being afforded monopoly rights, and are in support of steps which would effectively weed out bad patents that are at the center of some of the reverse payment settlements. Central to the critics' proposed solutions is the examination of patents for their scope and validity. Part II also explains that courts share these same concerns.

Part III examines reverse payment settlements through a patent policy lens. Specifically, this section will focus on how patent policy is in favor of scrutinizing suspicious reverse payment settlements. The patent policy discussion will center on the contrasting policy levers of exposing weak patents as opposed to the desire for certainty and the presumption of validity in granted patents. Explanations of patent law and policy will lead to the conclusion that an analysis of suspicious reverse payments under a patent policy framework leads to a particularly critical view of suspicious reverse payment settlements.

Part IV proposes a process by which reverse payment settlements could be scrutinized through a patent policy doctrine rather than through an antitrust analysis. Specifically, the doctrine of patent misuse will serve as a foundation for a test in which the reverse payment settlements are analyzed according to patent laws. The patent policies discussed in Part III aid in allowing patent misuse to target reverse payment settlements. Furthermore, a specific procedure is proposed in which an expanded patent misuse doctrine is used to examine and potentially attack suspicious reverse payment settlements.

I. BACKGROUND ON REVERSE PAYMENT SETTLEMENTS

A. WHAT MAKES A REVERSE PAYMENT SETTLEMENT CONTROVERSIAL?

In a normal patent licensing settlement, a licensee, based on the consideration of the use of the licensor's patent rights, enters into an agreement where the licensee pays the licensor. These settlements take place routinely and lay at the backbone of the largely successful exclusive rights doctrine of patent protection.²³ Additionally,

²³ See NARD, *supra* note 10, at 629.

traditional licensing leaves the option for a licensee to seek the invalidation of the patent through litigation, thus weeding out bad patents.²⁴

Now consider an agreement in which a patent owner pays a potential licensee a large sum of money so that the potential licensee does not enter the market and does not threaten the validity of the patent through litigation. This is the case in a reverse payment settlement.²⁵ These settlements most commonly take place in the context of pharmaceutical patents, specifically when generic drug makers attempt to enter the market. Tremendously popular and profitable drugs such as Nolvadex,²⁶ K-Dur 20,²⁷ Hytrin,²⁸ and Cipro²⁹ have all been subject to reverse payment settlements. The existence of these peculiar settlements arises from the unique statutory structure for generic drug market entrance, under the Hatch-Waxman Act.³⁰ Under the Hatch-Waxman Act, it is often beneficial for the generic drug company to claim that the pioneer drug maker's patent is invalid or not infringed.³¹ Litigation for patent infringement ensues, though is commonly resolved through settlement.

Courts generally favor settlements in patent infringement disputes over extended and costly litigation.³² However, the reverse payments are often for more money than a generic drug could ever make on the market.³³ Also, often the patents which the settlements surround

²⁴ See *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) (rejection of the doctrine of licensee estoppel).

²⁵ See *Hovenkamp et al.*, *supra* note 1.

²⁶ See *Tamoxifen*, 466 F.3d at 193 (“In 2001, Zeneca's domestic sales of tamoxifen amounted to \$442 million”).

²⁷ See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058-59 (11th Cir. 2005) (“K-Dur 20 itself was the most frequently prescribed potassium supplement”).

²⁸ See *Valley Drug Co.*, 344 F.3d at 1296.

²⁹ See *Cipro II*, 261 F. Supp. 2d at 191.

³⁰ See Hatch-Waxman Act, *supra* note 4.

³¹ See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

³² See *Schering-Plough*, 402 F.3d at 1075 (“There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation”).

³³ *Hovenkamp et al.*, *supra* note 1.

could likely be invalidated or are not infringed.³⁴ This situation, in which a settlement is made between competitors not to compete, gives rise to the obvious question of an antitrust violation.³⁵ Furthermore, because the patent infringement litigation is settled, there is no opportunity for bad patents to be invalidated.

While some in the industry have applauded the acceptance of reverse payment settlements by the courts,³⁶ academics have long criticized these settlements as a violation of the antitrust laws.³⁷ Commentators suggest that reverse payment settlements fall outside of antitrust legality because of their anticompetitive effects, as they may extend a patent owner's rights beyond those afforded by the issuance of the patent.³⁸ Additionally, suspicions often arise concerning the validity of the patents which are at the center of the reverse payment settlements, especially when the payment is large.³⁹ However, courts in all but a few particular cases have upheld the settlements as pro-competitive and legal.⁴⁰

As United States medical reform has become a hotly-debated issue, reverse payment settlements are now seen as an obstacle to maintaining a long-term, cost-effective health care system in the

³⁴ See *infra*, Part II.

³⁵ See Mullin, *supra* note 7.

³⁶ *Id.* ("One reason that courts approve of the agreements, their defenders say, is that they allow both parties to balance the different risks they bring to the negotiating table If reverse payments get reined in . . . the result could mean more cases going to trial rather than settling. That would mean less predictable litigation costs, which would lead to fewer ANDA filings, and fewer generic drugs, leaving consumers the ultimate losers.").

³⁷ See Hovenkamp et al., *supra* note 1, at 1749-50.

³⁸ See NARD, *supra* note 10, at 711 ("Challengers of exclusion payments have argued that all settlements with exclusion payment should create a presumption that the patent holder exceeded the scope of its patent").

³⁹ *Cipro III*, 363 F. Supp. 2d at 534 ("the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment").

⁴⁰ *Tamoxifen*, 466 F.3d at 206 ("Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.").

United States.⁴¹ Accordingly, the Obama Administration has taken steps towards pushing reverse payment settlements towards illegality.⁴² The Department of Justice (DOJ) has recently, and for the first time, taken a negative view towards reverse payment settlements, calling for their presumed illegality.⁴³ The DOJ now joins the Federal Trade Commission (FTC) in criticizing the legality of reverse payment settlements.⁴⁴

Current FTC Chairman Jon Leibowitz has taken a particularly strong position against reverse payment settlements, calling them “sweetheart deals” for pioneer drug companies.⁴⁵ The FTC continues to use considerable resources to fight the settlements in court,⁴⁶ and hopes that due to the recent political shift within the executive branch in Washington and unison in policies amongst the DOJ and FTC,⁴⁷ a resolution to reverse payment settlements can be attained. However, despite all the criticisms of courts’ adoption of a policy of permissibility of reverse payment settlements, it persists today. Courts have continually struck down the government’s attacks on the settlements, which are based solely on United States antitrust law.⁴⁸

⁴¹ The price of prescription drugs is very determinative to the total medical costs of the United States. *See* Mullin, *supra* note 7 (according to FTC “delayed entry of generic drugs into the market adds about \$3.5 billion to U.S. consumers’ health care tab per year.”).

⁴² Brent Kendall, *DOJ Shifts Policy on Generic Drug Patent Settlements*, WALL ST. J. ONLINE, July 6, 2009, <http://online.wsj.com/article/SB124691728092502381.html> (last visited Mar. 12, 2011).

⁴³ *Id.* (“The department’s antitrust division said in a court filing that drug patent settlements should be presumed unlawful when branded drug makers pay their generic counterparts to abandon patent challenges that could lead to early market entry of competing generic medicines.”) (“[t]he Justice Department under the Bush administration did not embrace the FTC’s viewpoint that the deals violated antitrust laws”).

⁴⁴ *See* Mullin, *supra* note 7.

⁴⁵ *See id.* (“Leibowitz sees [reverse payment settlements] as straightforward violations of antitrust law: companies colluding to monopolize, control, and divide up markets.”).

⁴⁶ *Id.* (“[t]he FTC’s 30-lawyer health care division stills spends more time investigating and litigating what the agency has dubbed “pay-for-delay” deals than on any other issue.”).

⁴⁷ *See id.* (“This has been percolating for a number of years without movement. The political atmosphere is ripe for something to happen.”).

⁴⁸ *See* cases cited *supra* note 16.

B. STRUCTURE OF THE HATCH-WAXMAN ACT

The Hatch-Waxman Act, formally the Drug Price Competition and Patent Term Restoration Act, governs the introduction of generic pharmaceuticals into the domestic marketplace.⁴⁹ Its original goals were to facilitate a balance between pioneer and generic drugs, and to promote generic drugs' quick entrance into the market by ensuring prompt resolution of patent infringement disputes between pioneers and generic entrants.⁵⁰

Under the scheme, a pioneer drug company files a New Drug Application (NDA) for all pioneer drugs they hope to have approved by the FDA.⁵¹ Along with filing the NDA, the name-brand drug company must list in the Orange Book⁵² all patents which may be interfered with by a generic company in an attempt to create a bioequivalent⁵³ drug. In return for listing patents which may be infringed by a generic drug maker, the pioneer drug company has the potential to secure a thirty-month delay of FDA approval for a generic drug.⁵⁴

A generic company who wishes to produce the drug can file an Abbreviated New Drug Application (ANDA) with the FDA.⁵⁵ One advantage of filing an ANDA is that it involves a much less rigorous

⁴⁹ See Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 (2006). For a discussion of the architecture of the Hatch-Waxman Act, see generally NARD, *supra* note 10, at 709-10.

⁵⁰ Hovenkamp et al., *supra* note 1 at 1752; see 21 U.S.C. § 355(j)(5); *Schering-Plough*, 402 F.3d at 1059 n.2 ("The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the name-brand pharmaceutical companies; and (3) create an abbreviated new drug application ("ANDA") to bring generic drugs to the market.").

⁵¹ See 21 U.S.C. § 355(a)-(b).

⁵² *Id.* § 355(b)(1)(F). The "Orange Book" is the informal name for the book "Approved Drug Products and Therapeutics Equivalents," which is published by the FDA, available at www.fda.gov/cder/ob.

⁵³ A bioequivalent drug is a drug which is similar to but not identical to another drug in various chemical properties. See § 355(j)(8)(B)-(C). A generic drug must be a bioequivalent of a pioneer drug to be eligible for an Abbreviated New Drug Application (ANDA). § 355(j)(2)(iv).

⁵⁴ See 21 U.S.C. § 355(j)(5)(B)(iii).

⁵⁵ See *id.* § 355(j).

application and approval process.⁵⁶ Generics filing an ANDA do not need to undergo clinical trials as would an NDA applicant.⁵⁷ These trials are especially lengthy and costly to a drug company.⁵⁸ Instead, the generic drug company only needs to prove bio-equivalence between the generic drug and the pioneer drug.⁵⁹

The ANDA application can be filed pursuant to several options within the Hatch-Waxman Act if a patent is listed in the Orange Book for the specific pioneer drug. One such option, and usually the most attractive to the generic drug maker, is to file a Paragraph IV certification which alleges that the pioneer's patent is invalid or not infringed.⁶⁰ This has become an especially attractive option for generic drug makers because it grants a 180 day exclusivity period to the first generic drug company to file under Paragraph IV. This exclusivity period bars other generic drug companies the right to market their generic versions of the drug for 180 days after the first generic drug is commercialized, or until the brand name drug patent is invalidated or held not infringed.⁶¹ This provision is intended to give the first generic to challenge a patent's validity a special reward in return.

Once a Paragraph IV ANDA has been launched, the generic company must inform the brand name drug company with formal notice of its filing. Within twenty days, the generic drug maker must inform the name-brand maker of the specific patent in question and whether that patent is not infringed or is invalid.⁶²

If the pioneer files a patent infringement suit within forty-five days of receiving notice, it can enact the thirty-month stay provision.⁶³ If no suit is filed, the ANDA is approved immediately.⁶⁴ Usually a suit is

⁵⁶ See *Schering-Plough*, 402 F.3d at 1059 n.2.

⁵⁷ *Id.*

⁵⁸ Three clinical phases of drug testing are required for new drug approval. NARD, *supra* note 10, at 709.

⁵⁹ See *Schering-Plough*, 402 F.3d at 1059 n.2.

⁶⁰ See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

⁶¹ See *id.* § 355(j)(5)(B)(iii).

⁶² See *id.* § 355(j)(2)(B)(i)-(ii).

⁶³ See *id.* § 355(j)(5)(B)(iii).

⁶⁴ See *id.* § 355(j)(2)(B)(i)-(ii). However, the brand name maker can still sue for damages for infringement at a later date. See NARD, *supra* note 10, at 710.

filed, and the case goes to a federal district court to determine if the patent is infringed or invalid.

If the generic drug maker prevails in court, its ANDA is approved. If the pioneer company prevails, the ANDA is not approved and an injunction is placed on the generic maker, barring them from entering the market prior to the expiration of the pioneer's patent.⁶⁵ However, it is important to note that when litigation is completed to judgment, the patent is exposed to a potential finding of invalidity.⁶⁶

Settlement often seems attractive to both parties. A ruling of invalidity can be devastating for a name-brand drug company. Many drug patents have an extremely high value, and can secure a multi-million dollar revenue for the life of the patent.⁶⁷ Additionally, a generic that proceeds through litigation will be rewarded with no more than 180 days of being the only generic on the market and will sometimes not be able to enter the market for thirty months past the commencement of the litigation.⁶⁸ Thus, under the Hatch-Waxman framework, it is often economically advantageous for both of the parties to settle. This is especially true when the pioneer drug company is willing to offer more in settlement than the generic could profit by entering the market. Following settlement, the patent is no longer in jeopardy of invalidation, and the pioneer drug maker can maintain a monopoly in the market. The special circumstances laid out in the Hatch-Waxman Act create the perfect conditions for these creative settlements to take place.

C. PATENT AND ANTITRUST AT ODDS

There is often turbulence in the relationship between antitrust and patent law. While antitrust law seeks to promote competition by explicitly illegalizing monopolies,⁶⁹ patent law establishes a regime of legal monopolies.⁷⁰ Patent law in the United States springs from an

⁶⁵This resolution of the litigation verifies the validity or invalidates the patent and determines the scope of the patent.

⁶⁶Some reverse payment settlements are made with specific arrangements which provide a *vacatur* of a ruling of invalidity at a low court. See *Tamoxifen*, 466 F.3d at 190.

⁶⁷*Id.*

⁶⁸See 21 U.S.C. § 355(j)(5)(B)(iv); see *id.* § 355(j)(5)(B)(iii).

⁶⁹See 15 U.S.C. § 2.

⁷⁰See 35 U.S.C. § 271(a).

enumerated power of Congress to “promote the Progress of [...] useful Arts.”⁷¹ This common constitutional thread passes through all laws relating to patents, and is the starting point to the analysis of the validity of any patent law.⁷² The goal of patent policy is to stimulate innovation and ultimately to stimulate competition. Patent law grants an innovator “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited term of years.⁷³ On the other hand, antitrust law has the ultimate goal of stimulating competition and innovation by prohibiting “[e]very contract, combination [...] or conspiracy, in restraint of trade or commerce among the several States,”⁷⁴ and “monopoliz[ation],”⁷⁵ under the Sherman Act. Courts have held that only unreasonable restraints on trade are in violation of Section One of the Sherman Act.⁷⁶ Violations of Section Two monopolization charges have been held by the courts to require both a monopolization of the market as well as the willful maintenance of that monopoly by the monopolizer.⁷⁷

Courts often discuss the dichotomy of patent and antitrust law, and must resolve problems arising at the intersection of the two

⁷¹ U.S. CONST. art. I, § 8, cl. 8.

⁷² See e.g. *Graham v. John Deere Co.*, 383 U.S. 1, 4 (1966).

⁷³ 35 U.S.C. § 154(a)(1)-(2); *Tamoxifen*, 466 F.3d at 201-02.

⁷⁴ 15 U.S.C. § 1.

⁷⁵ 15 U.S.C. § 2.

⁷⁶ *Tamoxifen*, 466 F.3d at 202 n.13 (“Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ th[e Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints.’ Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered *per se* unreasonable because it has ‘such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit.’ In most cases, however, conduct will be evaluated under a ‘rule of reason’ analysis, ‘according to which 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.’”) (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)).

⁷⁷ *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (“The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”).

regimes.⁷⁸ Reverse payment settlements are at the center of this intersection.⁷⁹ However, courts and commentators have largely analyzed the antitrust implications of reverse payment settlements through an antitrust law lens. Somewhat missing from the analysis is how patent law and policy arguments may be in agreement with antitrust arguments. Both regimes seek to ultimately stimulate the economy. Therefore, a desirable solution to the treatment of reverse payment settlements is to find some common ground at the crossroads of patent and antitrust law. This idea will be developed later in this note.

D. CURRENT LEGAL TREATMENT

Generally, courts have found that most reverse payment settlements are not in conflict with the antitrust laws of the Sherman Act.⁸⁰ Courts in all but one case have rejected a *per se* illegal standard for reverse payment settlements.⁸¹ The standard which has been accepted by a number of circuit courts states that “unless the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent’s protection’” there is no antitrust violation.⁸² Some courts have

⁷⁸ See *Schering-Plough*, 402 F.3d at 1067 (“Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes.”).

⁷⁹ See *Tamoxifen*, 466 F.3d at 201-02 (“It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal.”); see *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) (“[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”).

⁸⁰ *Tamoxifen*, 466 F.3d at 206 (“Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.”).

⁸¹ *Id.*

⁸² *Id.* at 212 (quoting *Cipro III*, 363 F. Supp. 2d at 538); accord *Schering-Plough*, 402 F.3d at 1076. However, the majority in *Tamoxifen* explicitly states in a footnote that “A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants ‘with benefits exceeding the scope of the tamoxifen patent.’ Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is

gone on to require a showing that the patent was “procured by fraud” or “shown to be objectively baseless” in order to prove an antitrust injury.⁸³ Objectively baseless is defined as “no reasonable litigant could realistically expect success on the merits.”⁸⁴ The objectively baseless standard is a standard similar to that found in sham litigation cases.⁸⁵

Cardizem was the exception noted above, where the agreement was found *per se* illegal.⁸⁶ However, courts have distinguished the findings of *Cardizem* because it involved a settlement which stipulated that related drugs not be developed by the generic drug maker, regardless of their relationship to the pioneer drug’s patent.⁸⁷ Thus, in *Cardizem*, the patent rights were extended through the settlement, making it *per se* illegal.⁸⁸

While the Supreme Court has had opportunities to deal with reverse payment settlements, they remain silent on the issue.⁸⁹ Thus,

hardly, we think, ‘the . . . standard,’ post at 227, as the dissent posits in order to take issue with it. *Tamoxifen*, 466 F.3d at 213 n.27.

⁸³ *Id.* at 213 (“Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, 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.”) (quoting *Cipro III*, 363 F. Supp. 2d at 535); accord *Asahi Glass Co., Ltd. v. Pentech Phar., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003); but see *Tamoxifen*, 466 F.3d at 213 n.27 (stating that contrary to the dissent’s beliefs, there is not a pleading standard involving a “sham” requirement).

⁸⁴ *Tamoxifen*, 466 3d at 213.

⁸⁵ See *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) (“We now outline a two-part definition of “sham” litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”).

⁸⁶ *Cardizem*, 332 F.3d at 911 (“calling a forty-million-dollar reverse payment to a generic manufacturer “a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers”).

⁸⁷ *Tamoxifen*, 466 F.3d at 213-14 (“It is thus unlike the agreement the Sixth Circuit held *per se* illegal in *Cardizem*, 332 F.3d at 908, which included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products”) (discussing *Cardizem*, 332 F.3d 896).

⁸⁸ See *id.*

⁸⁹ Circuit Courts have largely agreed and there does not appear to be a circuit split at this point. See *Cardizem*, 332 F.3d 896, *cert. denied sub nom*; *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); see *Valley Drug Co.*, 344 F.3d 1294, *cert. denied sub nom*;

if further delay is undesirable, Congressional action may be a proper response. The Court may grant certiorari in the near future, however, considering the newfound importance being placed on the issue by the Obama Administration, as well as the recent agreement amongst the DOJ and the FTC on the issue of reverse payment settlements.⁹⁰ In summary, the courts have been tremendously pro-reverse payment settlements when they have had an opportunity to find judgment.

II. THE CRITICAL PROBLEM SURROUNDING BAD PATENTS IN REVERSE PAYMENT SETTLEMENTS

A. IDENTIFYING SUSPICIOUS REVERSE PAYMENT SETTLEMENTS

Commentators have voiced various opinions on how to deal with an antitrust suit concerning a reverse payment settlement.⁹¹ However, one common thread runs through all of the arguments: the strength of a patent is of major concern when it is associated with an agreement that may be anticompetitive.⁹² Many of the brightest minds in antitrust law have confronted the issue of weak patents being given more rights than they should be afforded when a reverse payment settlement is entered into.

Intuitively, weak patents are more likely to be the subject of reverse payment settlements. Conversely, a strong patent, or a patent which is very likely being infringed upon by a generic drug maker, is less likely to be subject to a reverse payment settlement. Herbert Hovenkamp, in his treatise, states the situation most clearly:

[I]f the patent is very likely worthless or not infringed, then the patentee stands to lose much by litigating to a judicial decision. In that case it will pay any amount up to the expected value of the monopoly that will be lost from the new entry. ... Many of the pharmaceutical settlement agreements that have provoked antitrust

Walgreen Co. v. Abbott Labs., 543 U.S. 939 (2004); see FTC v. Schering-Plough Corp., 548 U.S. 919 (2006).

⁹⁰ See Mullin, *supra* note 35.

⁹¹ See generally Hovenkamp et al., *supra* note 1; Cotter, *supra* note 2; Daniel A. Crane, Ease Over Accuracy in Assessing Patent Settlements, 88 MINN. L. REV. 698, 709 (2004).

⁹² See *infra* Part II.B.

litigation have involved large payments from patentees to challengers. Payments of this magnitude indicate that the parties harbored significant doubt that the patents in question were valid or infringed, which entails a significant possibility that, if pursued to a judicial outcome, generic competition would have entered the market.⁹³

Both the courts and commentators acknowledge the fact that reverse payment settlements present situations in which a potentially invalid patent is shielded from being invalidated by pre-judgment settlement. This allows for otherwise valueless patents to maintain immense value. The following sections consider how commentators support a policy where bad patents would increasingly be exposed for what they are. While courts resist antitrust illegality, they consistently are troubled by the prospect of bad patents escaping invalidity through settlement. Of special concern is weeding out bad patents.

B. CRITICS' CONCERNS WITH THE VALIDITY OF PATENTS IN REVERSE PAYMENT SETTLEMENTS

Many commentators have attempted to address how a reverse payment settlement should be examined in an antitrust analysis. Among the most notable and most widely cited is the theory set forth by Hovenkamp, Janis, and Lemly (hereafter the "Hovenkamp analysis").⁹⁴ This theory proposes that some reverse payment settlements surrounding a Hatch-Waxman Act generic infringement dispute should be presumed illegal.⁹⁵

Hovenkamp's analysis begins with examining whether the presence of IP rights is relevant in an antitrust challenge to an IP settlement.⁹⁶ For instance, sometimes the settlement is clearly not anticompetitive⁹⁷ while in other circumstances, some settlements

⁹³ HERBERT HOVENKAMP, ANTITRUST LAW: VOLUME XII 332-33 (2d ed. 2005).

⁹⁴ See Hovenkamp et al., *supra* note 1.

⁹⁵ *Id.* at 1759.

⁹⁶ *Id.* at 1724.

⁹⁷ *Id.*

would be illegal even if the patent in dispute was fully enforceable.⁹⁸ In these two circumstances, the IP rights in question need not be considered. However, a middle group exists where the settlement would likely be an antitrust violation if not for the IP monopoly rights.⁹⁹ In these cases, it may be necessary to examine, at least to some degree, the strength of the patent rights that are at the center of the licensing agreement.¹⁰⁰ In this middle class, Hovenkamp argues that the case should be decided on IP grounds rather than a traditional antitrust rule of reason approach.¹⁰¹

Examining the strength and scope of patent rights within an antitrust trial can be overly burdensome and complex for the court.¹⁰² Therefore, commentators like Hovenkamp have developed guidelines for when the validity and scope of a patent should be probed more thoroughly to properly evaluate the anticompetitive nature of the licensing settlement.¹⁰³ The commentators developed various thresholds, largely dependent upon when a settlement appears to be suspicious in light of economic effects which only make sense if a patent will likely be invalidated in litigation.¹⁰⁴

For example, Hovenkamp supports a presumption of antitrust illegality.¹⁰⁵ This presumption may be rebutted by the patent holder (antitrust defendant) if they show “both (1) that the *ex ante* likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.”¹⁰⁶ Of the widely cited theories, Hovenkamp’s is the harshest on antitrust defendants, since it

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 1724-25.

¹⁰¹ *Id.* at 1724. The rule of reason is a judicial doctrine holding that a trade practice violates the Sherman Act only if the practice is an unreasonable restraint of trade, based on the totality of the circumstances. See *Nat'l Soc. of Prof'l Eng'rs. v. U.S.*, 435 U.S. 679, 687-92 (1978).

¹⁰² See Cotter, *supra* note 2, at 1807-12.

¹⁰³ See Hovenkamp, *supra* note 1, at 1759.

¹⁰⁴ See *id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

places the burden of proof on the defendant and allows for the settlement to be for no more than the cost of potential litigation and collateral costs.¹⁰⁷

Cotter proposes a similar approach to Hovenkamp et al., with the only major difference being the size of the agreement for determining the threshold of presumptive illegality.¹⁰⁸ The burden of proof is still placed on the antitrust defendants.¹⁰⁹ As compared with Hovenkamp et al.'s threshold of litigation costs, Cotter advocates a more expansive approach in evaluating settlement value.¹¹⁰ Cotter suggests that where reverse payment settlements are "below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial."¹¹¹ However, he states that when the reverse payment is higher than the expected damages, danger of anticompetitive behavior becomes higher.¹¹² Cotter advocates a standard under which the patent infringement plaintiff would have to prove either that the patent is valid and infringed, or that the payment is "consistent with a high probability of success on the merits, in light of the parties' expected gains and losses."¹¹³ However, Cotter does acknowledge that stating specific "rules" for various settlement amounts may be impossible.¹¹⁴

A third approach, proposed by Crane, supports a standard more favorable to the antitrust defendants (the settling parties).¹¹⁵ Unlike Hovenkamp et al. and Cotter, the burden of proof is not shifted to the

¹⁰⁷ *See id.*

¹⁰⁸ Cotter, *supra* note 2, at 1795-97, 1802.

¹⁰⁹ *Id.* at 1815.

¹¹⁰ *See id.* at 1814.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* *supra* note 2, at 1815.

¹¹⁴ *See id.* ("To state an applicable 'rule' with more precision, however, may be impossible.").

¹¹⁵ Crane, *supra* note 91, at 709.

antitrust defendants.¹¹⁶ However, emphasis is still placed on the likelihood that the patent is valid and infringed.¹¹⁷

While there is a spectrum of standards proposed for antitrust evaluation, it is noteworthy that while the value of the settlement is integral to each analysis, the likelihood of prevailing in the patent infringement lawsuit is paramount under each of the proposed standards. Each of the tests seek to identify and punish settlements surrounding patents that do not deserve exclusionary rights because they would be invalidated.

In review, each commentator weighs the threat to antitrust law against the burden of making an antitrust defendant prove, to some degree, the validity of his patent.¹¹⁸ Hovenkamp et al. are very concerned with disallowing patents that do not have a “significant” chance of prevailing when litigation is carried through.¹¹⁹ Cotter is concerned with the validity of patents, especially in cases in which the reverse payment is particularly large.¹²⁰ Crane acknowledges that there is “relatively little social cost” in mandating the settlers to take steps to prove the validity of the patent to some degree.¹²¹ While the standards vary considerably, a constant emphasis appears to be placed on scrutinizing the strength of the patent to ensure that undeserved exclusionary rights are not being exploited in violation of antitrust laws.

C. COURTS’ CONCERNS WITH THE VALIDITY OF THE PATENTS IN REVERSE PAYMENT SETTLEMENTS

Courts are also deeply concerned with the potential for weak patents to be protected through reverse payment settlements. While the courts have continually found no antitrust violation in reverse

¹¹⁶ *Id.*

¹¹⁷ *Id.* Under Crane’s analysis, a critical point to consider is whether “the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated.”

¹¹⁸ For a discussion on varying standards of analyzing patent validity and scope during an antitrust trial, see Cotter, *supra* note 2, at 1807-12 (antitrust tribunal could conduct a patent trial-within-a trial, a minimal inquiry, or a truncated inquiry).

¹¹⁹ Hovenkamp et al., *supra* note 1, at 1759.

¹²⁰ Cotter, *supra* note 2, at 1814-15.

¹²¹ Crane, *supra* note 91, at 709; accord *Tamoxifen*, 466 F.3d at 227.

payment settlements, they have acknowledged critics' concerns of the "troubling dynamic that is at work in these cases."¹²² An important concern is that reverse payments are more likely to occur when the patent in question is weak and not being infringed upon or is invalid.¹²³

Courts shelter themselves from this reality by simplistically announcing that even weak patents are afforded the allowance of a settlement.¹²⁴ The Second Circuit in *Tamoxifen* only reluctantly conceded that abuse is likely occurring pertaining to bad patents which would be held as invalid or non-infringed as a result of litigation.¹²⁵ The court stated that "[s]o long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved."¹²⁶ This submission to such an obvious and pertinent factor should not be acceptable, especially when one considers that a sizeable number of reverse payment settlements occur surrounding patents in substantial jeopardy of being invalidated as the result of litigation.¹²⁷

In *Valley Drug*, the Eighth Circuit acknowledged the problem of parties possibly lacking good faith in the validity of their patents.¹²⁸ The court concluded that the size of the settlement alone cannot indicate whether the settlement was entered in bad faith, or whether

¹²² See *supra* note 17.

¹²³ See *Tamoxifen*, 466 F.3d at 211 ("The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.").

¹²⁴ See *id.* at 208 ("[O]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law.") (quoting *Asahi Glass Co.*, 289 F. Supp. 2d at 991).

¹²⁵ *Id.* at 211.

¹²⁶ *Id.* (settlement included a *vacatur* of holding of invalidity from the district court).

¹²⁷ See *id.*

¹²⁸ *Valley Drug Co.*, 344 F.3d at 1300, 1309-10 (generic firm was paid roughly \$75 million to keep generic drug maker out of the market).

the patent would be found invalid at the conclusion of litigation.¹²⁹ However, the court did not directly confront the claim that some showing of proof should be made that the patent is valid.¹³⁰

Courts also have defended against the inherent issue of weak or invalid patents being afforded undeserved monopoly power following a reverse payment settlement by observing that a settlement cannot prevent other generic drug makers from filing ANDA's and challenging the validity of the given patent.¹³¹ Courts quickly conclude that a series of settlements would not be possible for a pioneer drug manufacturer, due to the costs of each settlement.¹³² However, this stance assumes both a receptive generic drug making market, which will seize the opportunity for developing a generic drug from a weak patent, as well as an economic climate in which numerous settlements would quickly drive the profitability of the pioneer drug down to nothing. Both of these assumptions are far from definite.¹³³ In fact, in a recent reverse payment case, four separate generic drug makers were involved in a reverse payment settlement.¹³⁴

Dissenters in the court have proposed a test which would directly address the problem of bad patents being used in reverse payment settlements.¹³⁵ For example, Judge Pooler of the Second Circuit would

¹²⁹ *Id.*

¹³⁰ *See id.* at 1309-11.

¹³¹ *See Cipro III*, 363 F. Supp. 2d at 534 ("But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid."); *accord Tamoxifen*, 466 F.3d at 211 (quoting *Cipro III*).

¹³² *See Tamoxifen*, 466 F.3d at 211-12 ("There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.").

¹³³ For a discussion on the economics of a generic drug entering the market, *see generally* Richard G. Frank, *Generic Entry and the Price of Pharmaceuticals*, 7 J. ECON. & MGMT. STRATEGY 75, 89 (1997).

¹³⁴ Leibowitz, *supra* note 5, 5 (four generic drug makers were paid in a settlement).

¹³⁵ *See, e.g., Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting) ("Thus, in assessing the reasonability of a Hatch-Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled[.]").

look primarily to the strength of the patent at the time of the settlement.¹³⁶ Only as secondary factors would a settlement's other circumstances, such as payment amount and profit forecasting of the generic drug, enter the antitrust rule of reason analysis.¹³⁷ An emphasis has clearly been placed on the potential invalidity of the patent. Courts are aware of the problems of weak patents in reverse payment settlements, but largely disregard the issue.

III. PATENT POLICY IN AGREEMENT WITH A STRICT STANDARD FOR ILLEGALITY OF REVERSE PAYMENT SETTLEMENTS

While courts have not readily accepted the prospect of examining the scope and validity of a patent at issue in a settlement under antitrust analysis, most commentators agree that it is necessary in some cases. This is because in some cases the antitrust analysis will turn on the validity and scope of a patent and not on the traditional rule of reason developed surrounding antitrust law. Furthermore, if we accept at any level that in these circumstances patent law should be central to the analysis, patent law and policy should be examined in greater depth to reveal what they actually have to say in context of reverse payment settlements.

Since it is now apparent that patent law should play a role in the reverse payment analysis, further investigation is required concerning the policy concerns revealed through a patent law inspection of the settlements. In this section, I will explain that when the competing interests within patent policy are weighed in the context of reverse payment settlements, it is clear that a very strict approach should be employed as to when a patent's validity and scope are analyzed within an antitrust analysis. The threshold should be low, in agreement with scholars such as Hovenkamp and Cotter, as opposed to the very high threshold applied by most courts. Specifically, within the reverse payment situation, two major patent policy levers become clearly at odds: (1) the preference that invalid patents be exposed through litigation and (2) the presumption of validity and certainty that comes

¹³⁶ See *id.*

¹³⁷ See *id.* ("I would rely . . . secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period.").

with the issuance of a patent from the United States Patent and Trademark Office.

A. INVALIDATING AND REDUCING THE SCOPE OF PATENTS FOR THE PUBLIC GOOD

The first lever of patent policy I will examine is the desire for weak or invalid patents to be identified as such, so they are exposed as powerless to hold undeserved monopoly power. This task can be carried out through infringement litigation or declaratory judgments for invalidity. Courts and lawmakers have left substantial clues of their favor for policies and practices which identify weak patents and weed them out. Such clues can be found in the context of licensee estoppel, the intent of the Hatch-Waxman Act, the expansion of declaratory judgments in patent law, as well as other patent policy reforms. These clues form pieces of a puzzle that when fitted together show an ever-growing sentiment that weak patents have no place in creating pharmaceutical monopolies.

1. LICENSEE ESTOPPEL

The Supreme Court expanded the power to weed out bad patents in *Lear, Inc. v. Adkins*.¹³⁸ *Lear* centers on the right of a licensee to challenge the patent of the licensor for invalidity.¹³⁹ Prior case law prohibited these challenges under the doctrine of licensee estoppel.¹⁴⁰ However, the Supreme Court made a shift in policy and rejected the longstanding doctrine.¹⁴¹

The Supreme Court reasoned that it was for the public good to weed out patents as the Court quoted the landmark case *Pope Manufacturing.*, stating, “[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[.]”¹⁴² This language signals the Court’s continuing

¹³⁸ See *Lear*, *supra* note 24.

¹³⁹ See generally *id.*

¹⁴⁰ *Id.* at 656.

¹⁴¹ *Id.* at 671.

¹⁴² *Id.* at 663-64 (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

intolerance for bad patents being given protection from findings of invalidity and non-infringement.

However, even if the mechanisms favoring a policy of weeding out bad patents are in place, some party must actually initiate the litigation that can end in patent invalidation or non-infringement. There are few individuals or groups who have the means to challenge and weed out a significant amount of bad patents. At the same time, pharmaceutical consumers are the truly affected group following a reverse payment settlement, because they can expect to see no drop in the price of their pharmaceuticals. If generic pharmaceutical companies cannot or will not sue due to the terms of a reverse payment settlement, the existing mechanisms for findings of invalidity in place are worthless.

Therefore, licensees (the generics) are the natural party responsible for utilizing the invalidity mechanisms, thus ensuring that the public is not harmed by bad patents. In the context of licensee estoppel, the Supreme Court in *Lear* supported this reasoning in stating “[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”¹⁴³ Here, the Court appealed to the public interest when considering that a potential infringer must be available to challenge a patent’s validity.¹⁴⁴ This is the same public interest that is at the heart of the antitrust policy in the United States, i.e. consumer welfare. In applying this policy, the Court found that contract law should sometimes be preempted by the policy favoring the public’s interest in weeding out bad patents.¹⁴⁵

In the case of a reverse payment settlement, a contract also stands in the way of testing a patent for invalidity. A limited number of companies have the resources to represent the public in invalidating bad pharmaceutical patents. Applying the noted policy to reverse payment settlements would suggest that it is not favorable to allow the settlement agreement’s contract terms to outweigh the public interest in at least examining the validity of the patent at issue. The reverse

¹⁴³ *Id.* at 670.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 670-71 (“We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued.”).

payment is in effect “muzzling” the appropriate parties from invalidating the patents. Therefore, patent policy suggests that the reverse payment settlement scheme as a whole is unfavorable since the limited number of public protectors (the generics) are disallowed from pursuing the mechanisms of patent invalidation.

2. DECLARATORY JUDGMENTS

Courts have also confronted similar policy issues in the context of when a declaratory judgment may be issued on the validity or scope of a patent. In *MedImmune, Inc. v. Genentech, Inc.*, the Supreme Court was confronted with the question of whether a patent licensee must terminate or breach its license agreement before it can seek a declaratory judgment that the patent is invalid, unenforceable, or not infringed.¹⁴⁶ The party seeking the declaratory judgment for validity argued that the licensee should not have to expose itself to liability before seeking a declaratory judgment.¹⁴⁷ The case turned on whether an “actual controversy” was present, as is required under the Declaratory Judgment Act.¹⁴⁸ The Court held that a required “actual controversy” existed even when no breach of the licensing agreement had taken place.¹⁴⁹

Also included in the opinion was a direct criticism of the Federal Circuit’s standard for whether an “actual controversy” exists under the Declaratory Judgment Act.¹⁵⁰ Reacting to *MedImmune*, the Federal Circuit revised its standard for obtaining a declaratory judgment.¹⁵¹

¹⁴⁶ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 120-21 (2007).

¹⁴⁷ *Id.* at 122.

¹⁴⁸ *Id.* at 120-21; see 28 U.S.C. § 2201(a) (2006) (“In a case of *actual controversy* within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”) (emphasis added).

¹⁴⁹ *MedImmune*, 549 U.S. at 118.

¹⁵⁰ *Id.* at 132 n.11.

¹⁵¹ *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007) (“In *MedImmune*, the Supreme Court in a detailed footnote stated that our two-prong ‘reasonable apprehension of suit’ test ‘conflicts’ and would ‘contradict’ several cases in which the Supreme Court found that a declaratory judgment plaintiff had a justiciable controversy.”) (discussing *MedImmune*, 549 U.S. 118).

The reasonable apprehension test¹⁵² was overruled and changed to a standard of “whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality[.]”¹⁵³ Thus, the requirements for seeking a declaratory judgment were substantially eased, allowing for the validity of more patents to be tested by the court.

The new “actual controversy” standard was then applied in several situations. In one case, the Federal Circuit held that a statement by a patent owner that it would not sue its competitor did not eliminate the justiciable controversy created by the patent holder in approaching the competitor about a licensing agreement.¹⁵⁴ The Federal Circuit also applied the standard in a generic/pioneer pharmaceutical patent case,¹⁵⁵ in which it held that a declaratory judgment was proper even when a patent infringement suit was not imminent.¹⁵⁶

In creating the new declaratory judgment standard for patent infringement, the court indicated its favor for a patent policy that seeks to weed out bad patents. In expanding declaratory judgment jurisdiction, more bad patents can be targeted and exposed as invalid or narrow in scope. And while *MedImmune* and subsequent Federal Circuit cases lack much direct discussion about policy considerations for weeding out patents, especially as compared with *Lear*, their results are totally inconsistent with the findings of presumptive legality of reverse payment settlements that shelter bad patents from exposure.

¹⁵² See *id.* (The reasonable apprehension test is “a two-part test to determine if an ‘actual controversy’ exists in a general declaratory judgment action for patent non-infringement or invalidity. This test requires both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity.”) (citation omitted).

¹⁵³ *MedImmune*, 549 U.S. at 127.

¹⁵⁴ *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1382-83 (Fed. Cir. 2007).

¹⁵⁵ See generally *Teva Pharm.*, 482 F.3d 1330.

¹⁵⁶ *Id.* at 1339-40.

3. THE ARCHITECTURE OF THE HATCH-WAXMAN ACT

Verification of the policy preference for exposing weak patents through litigation comes directly from the most common applications of the Hatch-Waxman Act. As stated previously in Part I.B., routinely the best course of action for a generic pharmaceutical company seeking an ANDA is to allege that the brand name drug patent is either invalid or not infringed.¹⁵⁷ The incentive of exclusive distribution of its drug for a time is provided to the first generic to test the validity of a pioneer's patent.¹⁵⁸ This incentive is to promote generics by testing the strength of the brand name's patent. The entire structure of the Hatch-Waxman Act rests on the realization that some patents will be challenged. In building into the act procedures for testing a patent's validity,¹⁵⁹ the last thing the drafters of the Act wanted was to build a scheme in which drug patents were not challenged for their enforceability over bioequivalent generic drugs.

4. OTHER CLUES ABOUT PATENT POLICY

Recently, patent policy has shifted towards a stance that acknowledges weak patents and seeks to limit their harm.¹⁶⁰ In *In re Seagate Technology, L.L.C.*, the Federal Circuit declared that willful infringement requires proof by clear and convincing evidence that the infringer "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."¹⁶¹ This approach allows potential infringers to read patents and decide whether they want to challenge a patent's validity or design around the patent without risking the increased damages associated with willful infringement. Either way, weak patents are exposed.

Additionally, the Supreme Court in *EBay, Inc. v. MercExchange, L.L.C.* held that lower courts' injunctions are a matter of equitable discretion.¹⁶² This policy holding allows district courts to fittingly deal

¹⁵⁷ See sources cited *supra* note 10.

¹⁵⁸ See 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

¹⁵⁹ See *id.* § 355(j)(2)(A)(vii)(IV) (2006).

¹⁶⁰ See Brief of Amicus Curiae of 22 Law and Bus. Professors in Support of Appellants at 26-27, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

¹⁶¹ *In re Seagate Tech., L.L.C.*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc).

¹⁶² *EBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006).

with bad patents by making an equitable decision as to injunctive relief. Courts have continued to push towards better regulation of weak patents.

B. CERTAINTY OF PATENT RIGHTS OUTWEIGHED

Underlying the entire dilemma of examining the scope of a patent in the context of an antitrust analysis is the strong policy presumption of the validity of a patent and the certainty of those claims made in the patent. The Patent Act directly guarantees a presumption of validity to any issued patent.¹⁶³ However, several concerns arise when putting weight in a patent's certainty and validity. These include the reality of patent prosecution and the standard the court uses in infringement hearings. I will also consider the limitations of good policy in the insurance defense. This defense maintains that a license is much like an insurance policy and specific payments have little to do with the specifics of the patent's strength. While a patent's presumption of validity cannot be ignored, it is not a more influential policy lever than promoting the public good by weeding out weak pharmaceutical patents in the reverse payment context.

1. REALITIES OF THE PATENT PROSECUTION PROCESS

When the USPTO issues a patent, the patented concept is put through a reasonably rigorous test of its novelty, non-obviousness, and utility. Indeed, the entire field of patent prosecution seeks to create a system where patents are issued in a fair manner to the appropriate limits mandated by law. However, this highly idealized situation is often disputed.¹⁶⁴ Limited PTO resources mixed with situations ripe for patent attorneys to abuse the system may be a more accurate representation.¹⁶⁵ While the penalties for attorney misconduct are great, the system is far from perfect, with patents routinely issued that cannot stand up in court.

¹⁶³ 35 U.S.C. § 282 (2006).

¹⁶⁴ Many commentators recognize that the PTO does not have the resources to thoroughly investigate all applications. See Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 181 (2008) (“[T]he U.S. Patent and Trademark Office (PTO) is issuing far too many bad patents.”); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1495 (2001) (stating that USPTO does not spend enough time examining each patent).

¹⁶⁵ See *supra* note 164.

2. THE STANDARD TO EVALUATE PATENT VALIDITY

The Patent Act guarantees presumptive validity to all issued patents.¹⁶⁶ Courts have interpreted this to mean that the presumption can only be overcome with “clear and convincing evidence” of invalidity.¹⁶⁷ However, commentators have suggested that the standard is not as rigid as it may appear,¹⁶⁸ and that it may shift to a lesser standard in the near future.¹⁶⁹ A lessening of this standard would translate into a more limited presumption of validity.

Commentators are open to the examination of how strong the presumption of validity should be. Some claim that a “clear and convincing” evidentiary standard for disproving the presumption is too strict.¹⁷⁰ Observers say that there is nothing in the statutorily mandated presumption of validity¹⁷¹ that is inherently connected to the “clear and convincing” standard.¹⁷² It may make more sense to set a standard that is more in touch with the current state of patent

¹⁶⁶ 35 U.S.C. § 282 (2006).

¹⁶⁷ *E.g.*, *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984) (The Federal Circuit rejected a “beyond a reasonable doubt standard” and firmly established the “clear and convincing evidentiary standard.”).

¹⁶⁸ The Federal Circuit Court of Appeals has treated the evidentiary standard of “clear and convincing” with fluidity. *See* Mark D. Janis, *Reforming Patent Validity Litigation: The “Dubious Preponderance,”* 19 *BERKELEY TECH. L.J.* 923, 930 (2004) (“[I]t would be a mistake to assume that, because the words of the standard have remained constant throughout the Federal Circuit’s tenure, the message of the presumption of validity has likewise remained constant or that there is a tight connection between the words of the standard and specific case outcomes.”).

¹⁶⁹ The policy will likely change within the lifetime of currently pending patent applications. *See* Dennis Crouch, *Challenging the Strong Presumption of Patent Validity* (Apr. 15, 2009), <http://www.patentlyo.com/patent/2009/04/challenging-the-strong-presumption-of-patent-validity.html>. (Apr. 15, 2009).

¹⁷⁰ *E.g.*, Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 *STAN. L. REV.* 45, 49 (2007) (proposing that the “clear and convincing evidence” presumption be replaced with weaker “preponderance of the evidence” standard).

¹⁷¹ 35 U.S.C. § 282 (2006).

¹⁷² Janis, *supra* note 168, at 930 (“[T]here is no strict, inevitable correlation between the words of the evidentiary standard and the overlying message delivered by the presumption of validity.”).

practice where patents are routinely issued by the PTO that do not deserve monopoly power.¹⁷³

3. CERTAINTY IN PATENT CLAIM INTERPRETATION

A further rationale in patent policy is the desire for certainty surrounding the interpretation of patent claims.¹⁷⁴ However, the rationale that certainty is paramount is deeply undercut when one reflects on all of the uncertainty present in the system.¹⁷⁵ Consider that interpretive rules are constantly in flux because infringement litigation concerning invalidity does not carry over to other litigants unless the patent is found invalid, and that the Federal Circuit routinely overturns lower court decisions about claim construction.¹⁷⁶ Furthermore, a little more uncertainty in pharmaceutical patents will not likely affect the market because there are many other sources of uncertainty surrounding the pharmaceutical industry as a whole, including FDA trials and huge liability due to side effects.¹⁷⁷ More uncertainty in pharmaceutical patents will not be especially significant to the economic realities of the current pharmaceutical market.

4. THE INSURANCE DEFENSE TO REVERSE PAYMENT SETTLEMENTS

Closely tied with the idea of certainty of patent rights is the position that one should be able to “insure” against the loss of patent rights. This position centers on the uncertainty in defending a patent in litigation.¹⁷⁸ Courts note that when the infringement plaintiffs are at all uncertain as to the validity of their patents, they seek to, and have a right to, “insure” the validity of their patents through settlement.¹⁷⁹

¹⁷³ See *supra* note 164.

¹⁷⁴ Lichtman et al., *supra* note 170, at 56-57.

¹⁷⁵ See *id.* at 57-59.

¹⁷⁶ *Id.* at 57.

¹⁷⁷ *Id.* at 58.

¹⁷⁸ See *Asahi Glass Co.*, 289 F. Supp. 2d at 992-93 (“No one can be *certain* that he will prevail in a patent suit.”) (emphasis in original); *Tamoxifen*, 466 F.3d at 187.

¹⁷⁹ *Tamoxifen*, 466 F.3d at 210 (An infringement plaintiff may want to settle even when they believe his or her patent is infringed “to *insure* against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. Whatever the degree of the patent holder's certainty, there is

When a license agreement is created, consideration on the part of the licensor includes the prohibition from suing for infringement.¹⁸⁰ In return, the licensee receives assurance that it will not be sued for patent infringement.¹⁸¹ This, in effect, allows the licensor to create an insurance policy for the validity of the patent by using the threat of an infringement suit based on the presumptively valid patent as a bargaining chip. The leverage of an infringement suit only carries weight because the patent is presumed valid. Effectively, a bad patent can undeservingly be allowed to use its presumptive validity as a leveraging weight for insuring its validity. A patent that should be powerless is presumed to have power, which allows it to maintain its power. This should be a major concern.

Speaking unfavorably about insurance theories surrounding patent licensing,¹⁸² the Supreme Court rejected the idea that a licensee is afforded an insurance policy against being sued for infringement as consideration for the license agreement.¹⁸³ On many fronts, insuring the validity of a patent through a reverse payment settlement is not favored by patent law.

IV. POTENTIAL SOLUTIONS: PATENT MISUSE AS A FRAMEWORK

Reverse payment settlements can be viewed through a lens of patent law and policy. Thus, any solution to the problem of suspicious

always some risk of loss that the patent holder might wish to *insure* against by settling.” (citation omitted) (emphasis added); *Schering-Plough*, 402 F.3d at 1075 (“Due to the ‘asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”) (quoting *Valley Drug Co.*, 344 F.3d at 1310).

¹⁸⁰ *MedImmune*, 549 U.S. at 134-35 (rejecting the argument that “[p]ermitting [licensee] to challenge the validity of the patent without terminating or breaking the agreement alters the deal, allowing the licensee to continue enjoying its immunity while bringing a suit, the elimination of which was part of the patentee’s *quid pro quo*.”).

¹⁸¹ *Id.*

¹⁸² *See id.* (“When a licensee enters such an agreement, they contend, it essentially purchases an insurance policy, immunizing it from suits for infringement so long as it continues to pay royalties and does not challenge the covered patents. Permitting it to challenge the validity of the patent without terminating or breaking the agreement alters the deal, allowing the licensee to continue enjoying its immunity while bringing a suit, the elimination of which was part of the patentee’s *quid pro quo*. . . . [T]he point seems to us mistaken.”).

¹⁸³ *Id.*

reverse payment settlements ought to stem from the richly developed doctrines of patent law. These doctrines, independent of antitrust law, may be a stepping stone for solving this problem.

The most logical doctrine within patent law to substantively apply to a reverse payment situation is patent misuse. This is because the patent misuse doctrine is closely intertwined with the antitrust laws of the United States. The specifics of misuse, as well as how a misuse framework could be applied will be explored in the following sections.

A. BASICS OF THE PATENT MISUSE DOCTRINE

A patent owner is guilty of misuse when the owner violates antitrust laws or “extends” a patent’s rights beyond its legal scope.¹⁸⁴ If misuse is found, courts hold the patent unenforceable until the misuse has been purged.¹⁸⁵ Misuse developed as a common law, equitable doctrine that is used as an affirmative defense to a suit for patent infringement.¹⁸⁶ A successful assertion of patent misuse requires the infringer to show that the “physical or temporal scope” of the patent has been broadened with an anticompetitive effect.¹⁸⁷ Traditionally, patent misuse has been successfully employed in scenarios involving product tying and other traditional areas of antitrust analysis.¹⁸⁸

However, substantial differences exist between the patent misuse doctrine and the developed antitrust laws of the United States. Patent misuse arose out of the doctrine of unclean hands long before Congress enacted any form of antitrust legislation.¹⁸⁹ The Supreme Court has relied not on the antitrust laws, but rather on the public

¹⁸⁴ DONALD S. CHISUM, CHISUM ON PATENTS § 19.04 (2010).

¹⁸⁵ *Id.*

¹⁸⁶ *See, e.g.,* Windsurfing Int’l Inc. v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986).

¹⁸⁷ *Id.*

¹⁸⁸ *See* CHISUM, *supra* note 184, § 19.04[3] (“The three classic acts of misuse are (1) requiring the purchase of unpatented good for use with patented apparatus or processes, (2) prohibiting production or sale of competing goods, and (3) conditioning the granting of a license under one patent upon the acceptance of another and different license.”).

¹⁸⁹ *See* C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998); B. Braun Med., Inc. v. Abbott Lab., Inc., 124 F.3d 1419, 1427 (Fed. Cir. 1997) (“Patent misuse arose, as an equitable defense available to the accused infringer, from the desire ‘to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.’”).

policy found in the ends and means of the patent laws of the United States when ruling in misuse cases.¹⁹⁰ For example, misuse can be applied in some situations where there is no antitrust violation.¹⁹¹ At the heart of the misuse doctrine is the Court's intent to disallow one to abuse the policy considerations of the Patent Act.¹⁹² Through the Court's inception and development of the misuse doctrine, patent policy of benefit to the public interest has been the chief concern.¹⁹³

Because patent policy is at the center of misuse, the patent policy levers discussed in Part III become critical. If a misuse framework is applied, these patent policy levers now become some of the deciding factors in a case as opposed to antitrust doctrine as is currently employed by the courts. Next, I explore the challenges of adapting misuse to a reverse payment setting.

B. TAILORING MISUSE FOR THE REVERSE PAYMENT SITUATION

The misuse doctrine, as it exists today, is of little help in the reverse payment context. While the substantive patent misuse doctrine is very similar to antitrust analysis, the limitations on the applicability of patent misuse in the context of reverse payment settlements are glaring. Most notably, misuse is used to defend against infringement, not to target misuse on behalf of societal interests. Additionally, damages cannot be attained from an assertion of patent misuse, as is the case in a claim of an antitrust violation. Therefore, while antitrust can be thought of as a sword, misuse has been used exclusively as a shield.¹⁹⁴ In the context of reverse payment settlements, the shield is a useless tool, as the infringer, who would

¹⁹⁰ CHISUM, *supra* note 184, § 19.04[2].

¹⁹¹ *Id.*; *see also* Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 140 (1969) (“[I]f there was . . . patent misuse, it does not necessarily follow that the misuse embodies the ingredients of a violation of either § 1 or § 2 of the Sherman Act[.]”).

¹⁹² *See* W.L. Gore & Assoc., 529 F.2d 614, 622 (3d Cir. 1976) (“[M]isuse may be a violation of the public policy embodied in the patent law itself.”).

¹⁹³ *See* Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 492 (1942) (“The grant to the inventor of the special privilege of a patent monopoly carries out a public policy adopted by the Constitution and laws of the United States, ‘to promote the Progress of Science and useful Arts[.]’ . . . It is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest.”) (quoting U.S. CONST.).

¹⁹⁴ NARD, *supra* note 10, at 619.

hold the shield, is in on the deal. It is clear that the currently developed procedural aspects of the doctrine of misuse would serve as little help.

However, the ideas imbedded within the misuse doctrine of serving the public interest are consistent with and could serve as a basis in altering or forming a new class of misuse, which targets reverse payment settlements. This would require substantial reworking and expansion of the misuse doctrine as it exists today, particularly in its procedural aspects. However, it is the doctrine's intense interest and rooted history in patent policy that makes it a starting point for potential exploration. To address the problem of reverse payment settlements, this note proposes sufficiently broadening patent misuse doctrine to make it capable of targeting suspicious reverse payment settlements.

First, the misuse shield would need to become an antitrust-type sword. A new misuse doctrine could take on many of the procedural characteristics of an antitrust claim, where stakeholders independently file suit on the colluding settlement makers. Specifically, the misuse doctrine would have to be applied to settling parties, rather than two parties who are in an infringement dispute. This requires a procedural change. However, the important difference between the antitrust allegations currently being employed and a misuse procedure would be the standard applied: patent misuse policy arguments rather than antitrust rule of reason analysis.

Second, the misuse doctrine would have to be expanded to deal with the exact issues of reverse payment settlements. The standard of patent misuse, broadening the scope of a patent with an anticompetitive effect, is reasonably present in some reverse payment settlements. For example, it could be argued that a weak patent is likely being afforded broadened scope when it is used to quell a non-infringing generic from entering the market. The patent is broadened because it is being used as a bargaining chip when it may in fact be worthless if no infringement is found. Additionally, the anticompetitive nature of the agreement is clearly present. While this would be a notable addition of the doctrine, it would not appear to be an unachievable step since misuse has continued to develop for the past century into a broad range of categorical cases.¹⁹⁵

¹⁹⁵ See CHISUM, *supra* note 184, § 19.04[3][a]-[l]. Acts of misuse include tying arrangements, covenants not to deal in competing goods, package licensing, post-expiration royalties and restraints, royalty based on total sales, refusal to license, excessive or discriminatory royalties, price fixing, territorial limitations, resale restraints, field-of-use and consumer limitations, grant-back clauses, restraints on the patentee, covenants not to license, suppression, and compulsory licensing.

C. SPECIFICS OF THE PROPOSED NEW PATENT MISUSE PROCEDURE

The misuse doctrine could be applied to a reverse payment settlement under the following procedure. First, a government agency such as the FDA, DOJ, FTC, or a private party, such as a class action group or an organization such as AARP, could charge the settling parties with a claim of misuse. Standing for these groups would be appropriate within the patent policy framework of misuse since the Court has explicitly stated that the public interest is critical as a policy lever.¹⁹⁶

Next, a court would examine the reverse payment settlement and identify whether the settlement is suspicious and presumptively illegal. The standard for this judgment would be based on the models discussed previously in Part II.B., such as those proposed by Hovenkamp, Cotter, or Crane. This note does not seek to determine the exact standard, as many academics have previously squared off in that arena,¹⁹⁷ however, some standard of presumptive illegality would be applied.

If the settlement was found to fall into the presumptively illegal group, the patent would become unenforceable under misuse. The burden of showing that the brand name pharmaceutical company's patent was infringed would fall to the settling parties (misuse defendants).¹⁹⁸

At this point, the settling parties would have the opportunity to prove that the patent was in fact infringed at a patent misuse hearing. Again, the standard by which this would be judged is open for argument. The "clear and convincing" standard currently used for patent invalidity could be employed. However, since the presumption of illegality has been previously made during the initial misuse examination, the settling parties would then have to prove with clear and convincing evidence that the patent was infringed, making the

¹⁹⁶ *Lear*, 395 U.S. at 670-71. The standing requirements could take on a model such as used for environmental law, where the government, along with watchdog groups like the Sierra Club, routinely patrols for violations. However, standing is an issue that should be more closely examined in future works.

¹⁹⁷ *See supra* Part II.B.

¹⁹⁸ The presumed unenforceability of the patent may seem like a harsh punishment on the settlers, since the settlers have not yet been afforded the chance to prove that the patent is valid and being infringed by the generic pharmaceutical company. However, the process employed here would not be the issue. Rather, the standard employed for the initial presumptive illegality would be the factor causing a harsh punishment to the settlers.

settlement terms legitimate. Finally, if the settlers could clear this obstacle, their settlement would again be held as legal and the patent would return to an enforceable state.

The patent misuse hearing would function similarly to a patent infringement trial. All of the doctrines of patent law would apply, including construing the claims and deciding on infringement, as well as any infringement defenses that may be relevant. All of the infringement defenses would apply. Therefore, arguments could be made that the patent is invalid, or that the patent is valid but not being infringed. Examples include invalidating the patent based on a finding of prior art, a violation of a statutory bar, or patent attorney misconduct. As in traditional infringement litigation, the settlers would bear the burden of presenting evidence of patent infringement. Additional prior art or other key information such as proof of early sales would be presented by the charging party.

In summary, the charging party would take on a similar role to a traditional infringement defendant, while the settling parties would take on the role of the patent holder asserting an infringement claim. The methods of patent infringement litigation do not need to be altered to any significant degree.

To make the suggested procedure more clear, consider an example. Assume a reverse payment settlement has been made between GloboCorp, a drug patent holder and name-brand pharmaceutical company, and GenericDrugs, Inc., a generic drug company. The payment made to GenericDrugs, Inc. was in excess of the costs of litigation and collateral costs attending the lawsuit (Hovenkamp's proposed threshold for presumptive illegality).¹⁹⁹ At this point, a party such as the FTC could file a suit claiming violation of patent misuse. If the court used the Hovenkamp threshold, the patent would be presumed unenforceable upon the filing of a patent misuse suit.

Soon after, GloboCorp would be entitled to a patent misuse hearing. The hearing would function similarly to a patent infringement lawsuit. GloboCorp would seek to prove that the patent would have been infringed by GenericDrugs, Inc. when the settlement was made. The FTC would seek to prove that the patent was not being infringed. To do this, the FTC could bring new prior art to the table or assert other infringement defenses. To aid in gathering these resources, the FTC could be assisted by any interested group, such as AARP or other public interest lobbies.

¹⁹⁹ See *supra* Part II.B.

If the settling parties failed to prove infringement, the patent would be found to be misused, and would thus be unenforceable. If the patent was not invalidated completely at the patent misuse hearing, the patent's power could be revived if the reverse payment settlement was effectively undone, which may include paying back the money given to the generic in the settlement. If the patent was found to be valid but there was not infringement, GloboCorp would still suffer an injury because other generics can then move in and begin to make the drug.

GenericDrug, Inc. would be in an interesting situation, likely wanting to keep its reverse payment settlement, so it could side with GloboCorp to show the patent was infringed and the settlement was legitimate. However, if GenericDrug, Inc. finds itself in a better situation by the patent being found to be misused, it could side with the FTC. This may be ideal for the public, as GenericDrug, Inc. may have inside information which would benefit the FTC during the patent misuse hearing. Either way, GenericDrug, Inc. is not really benefiting from its collusion with GloboCorp because if the patent is found to not have been infringed, its money must be returned and other generics will have the ability to compete in the market, thus driving down GenericDrug, Inc.'s profits. Additionally, the period of exclusivity that GenericDrug, Inc. could have had will likely be gone.

With the monopoly busted, consumers would have a generic alternative that costs substantially less than GloboCorp's costly drug. GloboCorp can no longer hold its monopoly, which is equitable, since GenericDrug, Inc. was never infringing GloboCorp's patent.

D. ADVANTAGES IN UTILIZING THE PATENT MISUSE DOCTRINE

Advantages such as adherence to *stare decisis*, less confusion between antitrust and patent law, and equitable damages for the guilty patent owner would become apparent when adopting a misuse standard. First, a misuse-type test would allow a court to continue to hold that these agreements are not in violation of the antitrust laws, but are instead in violation of patent misuse. This would not conflict with the court's current treatment of the issue.²⁰⁰ *Stare decisis* could be maintained.²⁰¹

Second, the problem of a patent infringement trial within an antitrust trial would be somewhat subverted since no antitrust

²⁰⁰ See *supra* Part I.D.

²⁰¹ See *id.*

analysis is taking place. The patent misuse hearing would actually go on within a patent court. There would be no back and forth between antitrust law and patent law. This is more desirable because the laws of patent and antitrust will not be confused or intertwined. While a court examining a settlement under a misuse standard could rely on developed antitrust policy, its primary concern would be patent law and so it would seem perfectly appropriate to examine the scope of the claims and the validity of that patent within that examination.

Finally, the penalty of unenforceability would not be too extreme, as the patent's rights could be revived when the misuse stops. This is a benefit for the brand name drug maker because there is no risk that antitrust treble damages will have to be paid.

E. PROPELLING CHANGE IN PATENT MISUSE

A wide range of substantive and procedural changes in misuse would need to take place, but what can propel such a change? The first route to consider would be a completely court-developed misuse doctrine to apply to reverse payment settlements. With the rather flexible approach adopted by many courts in the development of the misuse doctrine, it would not be an unimaginable stretch to mold a new, misuse-rooted test to challenge the validity of suspicious reverse payment settlements. Admittedly though, this sort of step would be a substantial one, and it can only be speculated if an activist court would be prepared to make such a step.

A second option is to provide the court with a stimulus. Such a stimulus could come from new legislation which calls for such a change in the misuse doctrine to be developed. One such possibility would be an amendment to the Hatch-Waxman Act. Such an amendment could demand that a court be open to a misuse-type proceeding described above to analyze the fairness of a reverse payment settlement. This would allow a patent court to analyze the patent, completely unrelated to any antitrust claim. The legislation approach is probably more realistic, and could even be embedded within the Hatch-Waxman Act.²⁰²

V. CONCLUSIONS

In conclusion, the doctrine of patent misuse could be a potential tool in targeting reverse payment settlements. Patent policy is in favor

²⁰² 21 U.S.C. § 355 (2006).

of limiting suspicious reverse payment settlements and a misuse analysis would take that patent policy into account when determining the legality of a reverse payment settlement. While substantial procedural and substantive changes in patent misuse would be required, its close ties to antitrust analysis and its concern with defending the public good make it a feasible alternative to the antitrust rule of reason analysis of reverse payment settlements.