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Stance against Reverse Payments in Schering-Plough v.
FTC/i>*

Steven W. Day

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NOTES

LEAVING ROOM FOR INNOVATION: REJECTING THE FTC'S STANCE AGAINST REVERSE PAYMENTS IN *SCHERING-PLOUGH V. FTC*[†]

INTRODUCTION

Patent infringement settlements in the Hatch-Waxman context¹ have reunited the yin and yang of economic development: patent and antitrust laws.² The problem is deceptively simple. A pharmaceutical company brings a patent infringement suit against a competitor who is planning to release a generic version of one of the pharmaceutical company's brand-name drugs. Before trial, the parties settle. As part of the settlement, the brand-name manufacturer agrees to pay the generic competitor a large sum of money (a "reverse payment") to concede that the generic drug was infringing a valid patent underlying the brand-name drug. Both parties are, ostensibly, better off. The brand-name keeps its patent and potential for market power. The generic receives more money from the brand-name than it would have earned

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¹ The "Hatch-Waxman context" refers to patent infringement suits brought under the Hatch-Waxman Act, 35 U.S.C. § 156 (2000), which will be explained in detail *infra* Part I.

² Patent and antitrust laws share a long history of conflict. See *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1217 (9th Cir. 1997) ("At the border of intellectual property monopolies and antitrust markets lies a field of dissonance yet to be harmonized by statute or the Supreme Court."); see also Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1815 (1984) ("The intersection of antitrust law and patent policy has proved to be a source of perpetual confusion and controversy since the passage of the Sherman Act nearly a century ago."); Aaron B. Rabinowitz, *When Does a Patent Right Become an Antitrust Wrong? Antitrust Liabilities for Refusals To Deal in Patented Goods*, 11 RICH. J.L. & TECH. 2 (2005) ("Congress, the courts, and government agencies have recognized the need to strike a reasonable balance between antitrust and patent law in determining how far a patentee may extend his right to exclude others from the use of his patented goods." (footnote omitted)).

by releasing its generic version.³ A blatant, naked restraint of trade, exclaim the critics.⁴ A company paying a competitor to stay out of the market is, clearly, an antitrust violation.⁵

Brand-name patent holders disagree.⁶ A patent, they argue, grants its owner a right to exclude others from using its invention.⁷ Moreover, courts encourage parties to settle.⁸ If both parties would rather settle their case, there is no reason to rake them over the “hot coals of antitrust litigation.”⁹ If both parties agree that the generic drug would infringe a valid patent, the patent holder has the right to settle the case and exclude the infringer. Courts presume a patent, granted by the Patent and Trademark Office (PTO) to the patent holder, is valid.¹⁰ A court will invalidate a patent through only “clear and convincing evidence.”¹¹ There is, therefore, little reason to doubt the validity of a litigated patent. So long as the settlement terms do not allow the patent holder to exceed the scope of the patent, a “reverse payment” is within the patent holder’s right to exclude.¹²

³ For a detailed explanation of a “reverse payment” settlement and the mathematics demonstrating how both parties may end up better off under the settlement compared to the release of the generic drug, see Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, in ANTITRUST LAW AND ECONOMICS 475, 479–80 (John B. Kirkwood ed., 2004); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 91–92 n.15 (2005).

⁴ See Leffler & Leffler, *supra* note 3, at 476; Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, ANTITRUST, Summer 2003, at 70 (“The danger to competition inherent in patent settlements between rivals should be self-evident.”).

⁵ See *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) (finding “horizontal” restraints on trade between competitors as per se violations of section 1 of the Sherman Act).

⁶ As do other commentators. E.g., Kevin McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L. J. 1033 (2004).

⁷ See *Zenith Radio Corp. v. Hazeltine Research Inc.*, 395 U.S. 100, 135 (1969) (“The heart of his legal monopoly is the right to invoke the State’s power to prevent others from utilizing his discovery without his consent.”); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 425 (1908) (“[W]henver this court has had occasion to speak it has decided that an inventor receives from a patent the right to exclude others from its use for the time prescribed in the statute.”).

⁸ *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (“The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”).

⁹ *Id.* at 992.

¹⁰ 35 U.S.C. § 282 (2000) (“A patent shall be presumed valid.”).

¹¹ *Neff Instrument Corp. v. Cohu Elecs., Inc.*, 298 F.2d 82, 86 (9th Cir. 1961) (“This presumption is based upon the expertness of the Patent Office.”).

¹² *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (“Unlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant.”).

The problem, however, is that only a court, during the litigation process, can conclusively determine the scope of a patent.¹³ The “metes and bounds” of a patent are defined with verbal boundaries, requiring a court to interpret the claims and decide whether a competing product infringes upon its territory. Likewise, parties must rely only on the litigation process to determine the validity of a patent. To be sure, a patent is presumed valid. Nevertheless, there is always the chance that a court may invalidate it. After a reverse payment, however, the parties never litigate the issues and, therefore, never thoroughly resolve them.

The critics’ concerns have not persuaded the courts.¹⁴ The majority of courts encountering antitrust suits over reverse payments have upheld the settlements on the basis that the antitrust plaintiffs failed to demonstrate that the settlements exceeded the scope of the underlying patent. Unless the antitrust plaintiff can show that the patent was invalid or not infringed, and that the settling parties knew it at the time of settlement,¹⁵ the courts presume that the settlement was within the patent holder’s right to exclude others from using its invention.¹⁶ Moreover, courts generally find that the settlement does not harm competition, because the patent holder merely retains the same patent rights (and any market power) it held before the commencement of litigation.¹⁷

Those wanting to use antitrust laws to challenge reverse payment settlements are stuck in a Catch-22. On the one hand, to show an antitrust violation, the plaintiff must show that the settlement exceeded the rights of the patent holder. On the other hand, one can determine the rights of a patent holder only through a trial on the merits of the patent, which of course, the settlement avoided. An

¹³ See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996) (“The duty of interpreting letters-patent has been committed to the courts.”) (quoting 2 W. ROBINSON, LAW OF PATENTS § 732, at 481–83 (1890)).

¹⁴ For an extensive review, see *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 524–30 (E.D.N.Y. 2005), which provides a detailed analysis of several holdings involving reverse payment settlements. For cases upholding reverse payment settlements, see *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *Valley Drug Co. v. Geneva Pharms., Inc.* 344 F.3d 1294 (11th Cir. 2003), and *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003).

¹⁵ In *Asahi Glass*, 289 F. Supp. 2d at 993, Judge Posner suggested an “objectively baseless” standard to determine whether settling parties knew, or should have known, at the time of settlement whether or not the patent was invalid or clearly not infringed by the generic drug.

¹⁶ *Id.*

¹⁷ *Id.*; *Valley Drug Co.*, 344 F.3d at 1309 (“If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit.”).

antitrust plaintiff can only win by litigating the case that the parties settled out of existence.

Necessity, of course, is the mother of invention. Critics of reverse payments have, accordingly, presented shortcuts to resolve the issue without requiring a trial on the merits of the patent. Some have argued for a presumption of illegality if the settlement price exceeds the anticipated cost of litigation.¹⁸ Others have argued that reverse payments, in and of themselves, create a strong presumption that the patent holder exceeded the scope of its patent.¹⁹ The courts, however, remain unmoved.²⁰

This issue recently took center stage, when the Supreme Court considered whether to grant certiorari in *Schering-Plough v. FTC*, a case in which the FTC brought antitrust charges against the parties to a reverse payment settlement.²¹ In *Schering-Plough*,²² the FTC charged Schering-Plough and two generic competitors with violating the Sherman Act²³ after the parties included a reverse payment as part of a patent infringement settlement. Schering-Plough and the generic companies negotiated settlements in which the generic companies could release their generic drugs at a later date (but before Schering-Plough's patent expired) and Schering-Plough paid a lump sum payment to the generic companies.²⁴ Although the FTC did not directly examine the merits of the underlying patent dispute, it concluded that the reverse payment, in and of itself, created a presumption that Schering-Plough exceeded its patent.²⁵ The FTC, relying on economic models,²⁶ argued that Schering-Plough would not have agreed to make the payment without getting something in return. They concluded that the settlement's quid pro quo was for Schering-Plough to pay money to the generics in exchange for the generics agreeing to a later entry date than they would have otherwise agreed to without the

¹⁸ Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

¹⁹ Shapiro, *Antitrust Analysis*, *supra* note 4, at 72; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (2003).

²⁰ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 531 (E.D.N.Y. 2005) (“There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle.”).

²¹ *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

²² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060–62 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

²³ 15 U.S.C. § 1 (2000) (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”).

²⁴ *Schering-Plough*, 402 F.3d at 1060–62.

²⁵ *Id.* at 1065.

²⁶ In particular, the FTC relied on economic arguments similar to those put forth by Professor Shapiro. See Shapiro, *Antitrust Limits*, *supra* note 19, at 407–08.

payment. The agreement, therefore, harmed consumers because it deprived them of the potential for lower (generic) prices at an earlier date.

The Eleventh Circuit rejected the FTC's conclusions and vacated their rulings against Schering-Plough.²⁷ The court maintained its insistence that plaintiffs alleging antitrust violations against settling parties must provide evidence that the settlement did, in fact, exceed the scope of the patent.²⁸ Although the FTC's inference may have intuitive appeal, the court would not presume that the agreement exceeded the patent's scope.

The Supreme Court recently denied the FTC's petition for a writ of certiorari,²⁹ based upon the Solicitor General's recommendation.³⁰ Although the Solicitor General recommended that the Court allow the Eleventh Circuit's decision to stand, his brief noted that the reverse payment controversy raises "important and complex issues concerning the antitrust treatment of settlements in patent cases,"³¹ but *Schering-Plough* did not "present an appropriate opportunity for [the] Court to determine the proper standards for distinguishing legitimate patent settlements."³² In other words, the Solicitor General left the door wide open by failing to take a position, one way or the other, on the legitimacy of reverse payments in patent settlements. Rather, the brief merely concluded that the facts presented in *Schering-Plough* were not an appropriate vehicle for determining whether courts should treat reverse payments as presumptively illegal under the antitrust laws. The controversy, therefore, continues.

In this Note, I examine the FTC's position that reverse payments are presumptively illegal and conclude that its argument fails on legal and practical grounds. I further propose that the rationale underlying Professor Michael Carrier's "common denominator" model for resolving patent/antitrust conflicts³³ is applicable in the reverse payment situation. Under Carrier's model, patent and antitrust laws share a

²⁷ *Schering-Plough*, 402 F.3d at 1076.

²⁸ *Id.* at 1075-76 ("We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.").

²⁹ *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

³⁰ Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2006 WL 1358441.

³¹ *Id.* at 8.

³² *Id.*

³³ Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761 (2002). Professor Carrier's article primarily addresses Sherman Act section 2 issues, in contrast to most reverse payment scenarios, which generally involve Sherman Act section 1 charges. Nevertheless, the underlying need to evaluate the impact on innovation when deciding between antitrust enforcement and patent protection remains in the reverse payment context.

common goal of promoting innovation (their “common denominator”).³⁴ Some industries require strong patent rights to foster innovation, when research and development is exceedingly expensive and products are easily replicable.³⁵ Other industries require high levels of competition for innovation, when products are relatively inexpensive to develop³⁶ and new products build upon technologies of older products.³⁷ The pharmaceutical industry is a quintessential example of an industry that relies heavily on strong patent rights for innovation.³⁸ I, therefore, conclude that, in the pharmaceutical industry, the presumption should rest in favor of the patent holders in order to promote innovation.

Part I provides further details about how the Hatch-Waxman Act gave rise to the reverse payment phenomenon. Part II addresses the main arguments for treating reverse payments as presumptively illegal, primarily the “probabilistic patent” model, upon which the FTC relied in *Schering-Plough*. Part III discusses the federal courts’ reasons for refusing to treat reverse payments as presumptively illegal. Part IV provides further examination of the FTC’s arguments in *Schering-Plough* and demonstrates its reliance on faulty assumptions and their impracticability. In Part V, I propose that courts and commentators should focus on the role of innovation when trying to resolve the reverse payment problem and that the burden should lie on those challenging the rights of patent holders in the Hatch-Waxman context.

I. THE REVERSE PAYMENT PHENOMENON

A. *The Hatch-Waxman Act*

In 1984, Congress passed the Drug Price Competition and Patent Restoration Act, commonly known as the Hatch-Waxman Act.³⁹ Through the Act, Congress sought to lower prices of prescription drugs by encouraging generic drug manufacturers to challenge patented brand-name drugs and enter the market.⁴⁰

Prior to the Hatch-Waxman Act, generic manufacturers hesitated in challenging the patents of brand-name drugs for two reasons. First, if

³⁴ *Id.* at 799–816.

³⁵ *Id.* at 820.

³⁶ *Id.* at 821.

³⁷ *Id.* at 829.

³⁸ *See id.* at 824–26 (providing an overview of the high costs involved in bringing a pharmaceutical product to the market).

³⁹ 21 U.S.C. § 355 (2000).

⁴⁰ H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48.

a generic manufacturer were to release a generic version of a patented drug and lose a patent infringement suit, it would be liable to the brand-name company for lost profits. Often, the damages to the patent holder would exceed the total revenues the generic stood to make.⁴¹

Second, even if a generic company were to successfully challenge the patent of a brand-name drug by winning a patent infringement suit, the generic company's competitors (i.e., other generic manufacturers) would also benefit from the lawsuit and release their own generic versions without incurring the costs that the challenger spent on litigation. Accordingly, a generic challenger, after losing its litigation costs, may find itself behind other generic companies who release their products without incurring the additional litigation costs.⁴²

The Hatch-Waxman Act aimed to remove the obstacles preventing generic companies from challenging brand-name patents. First, the Act established a procedure for the brand-name company and generic company to resolve any patent disputes before the generic releases its version of the drug into the market. Before gaining FDA approval for release, the generic must notify any patent holders of the brand-name drug and certify that either no patent is infringed or that the brand-name's patents are invalid.⁴³ If a patent holder wishes to challenge the generic drug for patent infringement, the Act creates a thirty-month stay to the FDA approval process. During the thirty-month stay, the parties litigate the infringement issue.⁴⁴ The issue of infringement is, therefore, resolved before the generic company releases its drug into the market and the patent holder does not suffer any damages in lost profits.

Second, the Act grants a one hundred and eighty day period of exclusive sales rights to the first generic company to successfully challenge a brand-name drug and enter the market.⁴⁵ The successful

⁴¹ See Lemley & Shapiro, *supra* note 3, at 91-92 (explaining how patent monopoly profits exceed potential profits for a generic entrant); McDonald, *supra* note 6, at 69 (“[T]he infringer’s profit on each sale is less than the damage the infringer will owe for that sale if the patent is upheld.”).

⁴² For a detailed explanation of the “public goods” phenomenon in challenging patents through litigation, see Joseph Farrell & Robert P. Merges, *Incentives To Challenge and Defend Patents: Why Litigation Won’t Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 952 (2004). See also Lemley & Shapiro, *supra* note 3, at 89.

⁴³ 21 U.S.C. § 355(j)(2)(B)(i) (2000) (“An applicant that makes a certification . . . shall include in the application a statement that the applicant will give notice as required by this subparagraph.”).

⁴⁴ *Id.* § 355(j)(5)(B)(iii) (“If [a patent infringement] action is brought [within 45 days], the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided . . .”). Prior to the Hatch-Waxman Act, a patent holder could hold liable a company developing a drug that infringed the patent.

⁴⁵ *Id.* § 355(j)(5)(B)(iv)(I) (“[I]f the application contains a certification . . . and is for a

challenger, therefore, has a brief amount of time to recoup its litigation costs while it shares duopoly prices with the brand-name drug.

B. The Reverse Payment as an Inevitable By-Product

The Hatch-Waxman context forces many patent holders, facing potentially substantial losses, to settle their infringement cases against generic challengers.⁴⁶ In a small number of these settlements, the patent holder agrees to pay the allegedly infringing generic company to stipulate to the validity and infringement of the patent and to delay releasing its generic drug.⁴⁷ Many have criticized these “reverse payments” or “exclusion payments,” claiming the payments are nothing more than a naked restraint of trade, as the patent holder pays a competitor to stay out of the market.⁴⁸ Others have argued that reverse payments are an inevitable by-product of the Hatch-Waxman context and so long as the settlement does not exceed the scope of the patent holder’s right to exclude, reverse payments are acceptable.⁴⁹

The following subsections explore the factors contributing to reverse payment settlements.

C. Pharmaceutical Patent Statistics

Pharmaceutical companies develop new drugs through an incredibly costly and lengthy process with no guarantee for success. Companies spend approximately \$800 million in research and development to bring a new drug to the market.⁵⁰ For every five thousand potential new drugs, only two hundred and fifty are tested in animals and only five will make it to human testing.⁵¹ Then, the FDA is likely to approve only one of the five drugs that make it to the human clinical

drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”)

⁴⁶ For a detailed analysis of Hatch-Waxman settlements up to 2002, see FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002).

⁴⁷ *Id.* at 25 (citing nine settlements in which a brand-name patent holder paid the generic challenger).

⁴⁸ *E.g.*, Leffler & Leffler, *supra* note 3, at 476.

⁴⁹ *See* Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1311 (“[T]he presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abbott’s potential exclusionary rights under the . . . patent.”); McDonald, *supra* note 6, at 69–70.

⁵⁰ PhRMA, *THE HATCH-WAXMAN ACT IN PERSPECTIVE: PHARMACEUTICAL INDUSTRY CONTEXT FOR THE FTC’S GENERIC DRUG STUDY 4*, FTC File No. V000014 (June 18, 2002).

⁵¹ *Id.* at 15 fig.1.

trials phase.⁵² Finally, when the one drug out of five thousand potential drugs enters the market, it faces competition from other patented drugs, in addition to the challenges from the generic companies under Hatch-Waxman.⁵³ Moreover, even before Congress enacted the Hatch-Waxman Act, only one in three drugs on the market recouped its research and development costs.⁵⁴

The pharmaceutical industry is, therefore, an incredibly risky enterprise. The threat of generic entry under Hatch-Waxman, and the subsequent loss of the brand-name's potential for market power, intensifies the risk. A patent holder would, therefore, clearly prefer to settle a Hatch-Waxman infringement case against a generic challenger rather than face even a small risk of losing at trial.

D. Bargaining Positions of the Parties

The Hatch-Waxman context also dramatically alters the bargaining positions of the parties in the infringement suit.⁵⁵ Normally, a patent holder sues an infringer after the infringer enters the market and damages the patent holder. The patent holder can potentially hold the infringer liable for its lost profits and for treble damages.⁵⁶ The patent holder, however, also faces the risk of losing any market powers it has if the court finds its patent invalid or noninfringed. Because both parties face a risk of loss, they are likely to compromise, with the alleged infringer paying the patent holder some portion of the potential damages based on the likely outcome of the trial. Alternatively, the parties might agree to a licensing arrangement, with the royalty structure reflecting the probability of the patent holder winning the case. In either case, the alleged infringer admits to infringing a valid patent and agrees not to compete directly with the patent holder.

The Hatch-Waxman context, however, places the risks solely on the patent holder.⁵⁷ Because the litigation takes place during the thirty-month stay before the release of the generic drug, the generic company is not at risk for any damages owed to the patent holder. Moreover, because the generic company did not spend millions of dollars to find the one safe and effective chemical out of five thousand candidates, its research and development costs are miniscule

⁵² *Id.*

⁵³ *Id.* at 14.

⁵⁴ *Id.* at 17. Generic entry, under the Hatch-Waxman Act, therefore, makes it even less likely that a pioneer brand-name will recoup its research and development costs.

⁵⁵ McDonald, *supra* note 6, at 69-70.

⁵⁶ *Id.*

⁵⁷ *Id.*

compared to the brand-name company's.⁵⁸ The generic company stands to lose only its litigation costs and its relatively small investment in developing the generic drug. The patent holder, on the other hand, stands to lose much more.

The United States District Court for the Eastern District of New York recognized this dramatic shift in bargaining position in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*⁵⁹ (*Cipro I*). There, the plaintiff argued that a reverse payment within a Hatch-Waxman settlement was a *per se* violation of the antitrust laws. The court noted, "Because of the Hatch-Waxman scheme, [generic company's] exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but has an enormous downside—losing its patent."⁶⁰ The court concluded:

[R]everse payments are a natural by-product of the Hatch-Waxman process, and—even if such payments were not contemplated or intended by the [Hatch-Waxman] amendments—plaintiffs have not shown that they are so nefarious in this case as to subject the challenged agreements, which provide for such payments, to *per se* treatment.⁶¹

One may disagree with the court's reasoning in *Cipro I* that the mere fact that reverse payments are the by-product of Hatch-Waxman litigation justifies their occurrence. After all, some clear antitrust violations might be the by-products of particular economic conditions. The question then becomes whether a patent holder can circumvent the risk asymmetry in a Hatch-Waxman infringement case and unilaterally enforce its patent rights by including a reverse payment in its settlement with an alleged infringer.

The following section outlines the dominant arguments against reverse payments, which rely heavily on the "probabilistic" approach to patent rights. These arguments conclude that the antitrust laws should prohibit a patent holder from unilaterally enforcing its patent rights in such a way that leaves the patent holder in a better position than it

⁵⁸ PhRMA, *supra* note 50, at 4 ("It typically costs only perhaps \$1 million or so for generic manufacturers to demonstrate bioequivalence, and otherwise prepare a regulatory application to [the] FDA . . ."). This would mean that releasing a generic version of a brand-name drug is approximately 1/800 of the cost to develop the brand-name drug.

⁵⁹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

⁶⁰ *Id.*

⁶¹ *Id.* at 252.

would have been had its infringement case gone through a complete trial.

II. PROBABILISTIC PATENTS

The “probabilistic patent” model underlies the strongest criticism of reverse payments in Hatch-Waxman settlements.⁶² Advocates of the probabilist model (“Probabilists”) stress that patent rights and litigation are inherently uncertain and only the federal court system can resolve the uncertainties.⁶³ The antitrust laws, they argue, should protect consumer welfare by prohibiting patent holders from “buying up” certainty and extending their monopoly powers.⁶⁴ This section outlines the Probabilist argument and illustrates why the Probabilists oppose reverse payments in patent settlements.

A. Four Underlying Principles

Economists endorsing the probabilistic patent model assume four underlying principles.⁶⁵

1. Market Power

In any antitrust case using the rule of reason, the plaintiff must demonstrate that the defendant had enough market power to disrupt competition through its behavior.⁶⁶ Although a patent does not necessarily create market power,⁶⁷ the Probabilists rely on economic studies and historical market activities that show a drop in prices when generic drugs enter the market.⁶⁸ They, therefore, assume that a patented brand-name drug has market power.

⁶² See Lemley & Shapiro, *supra* note 3.

⁶³ *Id.* at 85–87; see also Leffler & Leffler, *supra* note 3.

⁶⁴ Shapiro, *Antitrust Limits*, *supra* note 19, at 394–95.

⁶⁵ See Robert Kneuper, *Four Economic Principles Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements*, THE ANTITRUST SOURCE, January 2006, at 1.

⁶⁶ See *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 782 (1999) (Breyer, J., concurring in part and dissenting in part) (“[The] four classical, subsidiary antitrust questions: (1) What is the specific restraint at issue? (2) What are its likely anticompetitive effects? (3) Are there offsetting procompetitive justifications? (4) Do the parties have sufficient market power to make a difference?”).

⁶⁷ See *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281, 1293 (2006) (“Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.”); U.S. DEPT. OF JUSTICE AND FTC, *ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY* § 2.2 (1995) (“[We] will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner.”).

⁶⁸ Kneuper, *supra* note 65, at 2.

In the context of reverse payments, the Probabilists argue that the presumption of market power is even stronger. Critics of reverse payments, Leffler and Leffler suggest that the existence of a reverse payment is, itself, evidence of market power, because the patent holder would have no incentive to make the payment otherwise.⁶⁹

2. *Mutual Economic Incentives Between Settling Parties*

The Probabilists also point out that both the patent holder and the alleged infringer have economic incentives to delay market entry for the generic drug.⁷⁰ The patent holder's brand-name drug will lose more profits than the generic company stands to gain.⁷¹ Both parties, accordingly, are better off if the patent holder pays the generic company a sum of money that is more than what the generic company expects to gain but is less than what the brand-name company expects to lose.

3. *Patent Rights Are Inherently Uncertain*

The most prevalent criticism of reverse payments hinges on the idea that patent rights are "probabilistic" in nature.⁷² The PTO grants patents at an alarmingly high rate without the resources to ensure the validity of every issued patent.⁷³ Moreover, the "metes and bounds" of patents are verbally demarcated, leading to differences in interpretation.⁷⁴ These inherent weaknesses in the patent system lead to uncertainties over the true scope or validity of any given patent.

The Probabilists, therefore, argue that a patent holder does not have a "right to exclude," but rather a "right to *try* to exclude by asserting the patent in court."⁷⁵ Any patent holder bringing an infringement suit runs the risk of a court finding its patent invalid or that the

⁶⁹ Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 33 n.1 (2004) ("Of course, not all patents give the patent holder market or monopoly power. This is the case when, for example, the patented good faces many close substitutes at prices equal to its marginal costs or when there is little or no consumer value of the patented good. This Article does not consider cases where a patent gives no market power because in those cases there will be no gains from a payment settlement and therefore no economic incentive to engage in such settlements.").

⁷⁰ Kneuper, *supra* note 65, at 2.

⁷¹ Lemley & Shapiro, *supra* note 3, at 91–92 n.15; Leffler & Leffler, *supra* note 3, at 479–80.

⁷² See Lemley & Shapiro, *supra* note 3, at 75–76; Leffler & Leffler, *supra* note 3, at 486–89; Shapiro, *Antitrust Limits*, *supra* note 19, at 395.

⁷³ See Lemley & Shapiro, *supra* note 3, at 77–79 (discussing the rise in patent uncertainty due to the PTO's inefficient patent application process).

⁷⁴ See Lemley & Shapiro, *supra* note 3, at 85–87 (discussing the role of language's inherent ambiguity in patent uncertainty in litigation).

⁷⁵ Shapiro, *Antitrust Limits*, *supra* note 19, at 395.

allegedly infringing activity is outside of the scope of the patent. Accordingly, the patent holder always stands the chance to lose any market powers associated with its patent. A patent's "strength" is, therefore, calibrated to the patent holder's probability of winning any given infringement suit.⁷⁶

4. *The Role of Antitrust Laws*

Probabilists also assume that antitrust laws should protect consumer welfare.⁷⁷ The antitrust laws protect consumer welfare by prohibiting restraints on trade that negatively affect allocative or productive efficiencies.⁷⁸ Moreover, many courts have recently narrowed the focus of the antitrust laws to protect consumers, rather than competitors, by concentrating on the effects of anticompetitive restraints on consumer prices.⁷⁹

In the Hatch-Waxman context, the gains to society resulting from lower generic drug prices are arguably larger than the losses created by the costs of litigation. Economist Robert Kneuper has argued that consumer welfare losses from delayed generic entry are eighty-five times greater than the amount of expected losses from litigation.⁸⁰

B. *The Probabilists' Argument Against Reverse Payments*

The critics of reverse payments rely on a fundamental premise that patent settlements should leave consumers no worse off than what would be expected had the parties continued through a complete trial. Economics professor Carl Shapiro, for example, proposes that "consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts."⁸¹ Moreover, because patents are uncertain, the federal court system (and not the patent holder acting on its own) should resolve the uncertainties to guarantee that consumers receive the expected level of competition to which they are entitled. When a patent holder settles a claim against an alleged infringer by using a reverse payment, the patent holder is unilaterally buying

⁷⁶ *Id.*

⁷⁷ Leffler & Leffler, *supra* note 3, at 476; Shapiro, *supra* note 19, at 70.

⁷⁸ Carrier, *supra* note 33, at 810–11.

⁷⁹ See John B. Kirkwood, *Consumers, Economics, and Antitrust, in ANTITRUST LAW AND ECONOMICS* 1, 31–33 (John B. Kirkwood ed., 2004) (discussing the "primacy of consumer interests" in antitrust enforcement policies).

⁸⁰ Kneuper, *supra* note 65, at 4. This does not, however, factor in the social losses due to decreased innovation in the pharmaceutical industry. Rather, it balances only the gains from more generic drugs and the losses from increased patent litigation.

⁸¹ Shapiro, *Antitrust Limits*, *supra* note 19, at 396.

up certainty and circumventing the patent laws' inherent uncertainty at the expense of consumers.⁸²

The critics urge the courts to treat reverse payments as presumptively illegal violations of the antitrust laws.⁸³ Otherwise, they argue, parties in Hatch-Waxman suits will likely agree to delay generic entry, because both parties are economically better off with a settlement that includes a reverse payment.⁸⁴ Moreover, because delaying a generic drug's market entry is more costly to the overall consumer welfare than patent litigation costs, courts should tilt the balance towards protecting consumers instead of protecting an overburdened court system.

III. THE COURTS' RESPONSES TO THE PROBABILISTIC MODEL

The courts have been unreceptive to the Probabilists' plea for a presumption of illegality for settlements that include reverse payments.⁸⁵ In only one instance, the Sixth Circuit held a reverse payment to be a per se violation of the antitrust laws.⁸⁶ This case, however, is peculiar in its facts, because the parties agreed that the generic company would refrain from releasing *any* version of the drug, whether or not it infringed the brand-name's patent.⁸⁷ Other courts, however, have refused to treat reverse payment settlements as presumptive violations and have, instead, evaluated them under a "rule of reason" approach.⁸⁸

To put reverse payments in perspective, we can evaluate where these settlements fall on the spectrum that lies between those cases that all commentators are likely to agree are unlawful and those cases that all commentators are likely to agree are lawful. At the unlawful end of the spectrum, all parties would agree that if a patent holder is certain that the challenger is not infringing its patent, or that a court

⁸² *Id.*

⁸³ See Hovenkamp et al., *supra* note 18; Shapiro, *Antitrust Analysis*, *supra* note 4. And for an argument that supports a per se illegal treatment, see Leffler & Leffler, *supra* note 4.

⁸⁴ Leffler & Leffler, *supra* note 4, at 479–80; Lemley & Shapiro, *supra* note 3, at 91–92 n.15.

⁸⁵ See *infra* note 14 (listing cases upholding reverse payment settlements).

⁸⁶ *La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.* (*In re Cardizem CD Antitrust Litig.*), 332 F.3d 896, 907–08 (6th Cir. 2003).

⁸⁷ *Id.* at 902.

⁸⁸ *Joblove v. Barr Labs., Inc.* (*In re Tamoxifen Citrate Antitrust Litig.*), 429 F.3d 370 (2d Cir. 2005), amended by 2006 U.S. App. LEXIS 22154 (2d Cir. 2006); *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro III)*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied *sub nom.*, *Walgreen Co. v. Abbott Labs.*, 543 U.S. 939 (2004).

would certainly invalidate its patent, then the litigation would be “sham” litigation and a violation of the antitrust laws. On the other side of the spectrum, all parties would agree that a settlement including a licensing arrangement or a negotiated entry date would be lawful. The Probabilists argue that the market would drive the parties to agree to terms that reflect the strength of the patent. Others, who are not concerned with patent “strength,” see the settlement as a compromise that falls within the patent holder’s right to exclude or license its patent.

Between the two poles lies a reverse payment settlement, which may also include a licensing deal or a negotiated entry date in addition to the lump sum payment. The Probabilists argue that because there is no reason to believe that a reverse payment settlement adequately reflects a patent’s strength, courts should draw the line of legality at settlements including only a licensing deal or a negotiated entry date and presume that the parties agreed to terms that reflect the strength of the patent. Others, as explained below, feel that the probability of winning the patent infringement suit (outside of sham litigation) and the expected level of competition are not factors in the antitrust analysis. Accordingly, courts should draw the line at the point of sham litigation in which the patent holder is excluding competitors when it knows (or should know) that its patent does not warrant exclusion.

A. *Cipro III*

In a case commonly referred to as *Cipro III*, the Second Circuit recently provided the most thorough legal analysis rejecting the probabilist model and the “presumptively illegal” approach championed by many critics of reverse payment settlements.⁸⁹ The court, in *Cipro III*, determined whether a reverse payment, as part of a Hatch-Waxman settlement, violated the antitrust laws.⁹⁰ The antitrust plaintiffs, relying on the probabilist model, argued that the reverse payment was an illegal restraint of trade depriving consumers of the chance for lower drug prices.⁹¹ The court made the following detailed

⁸⁹ *Cipro III*, 363 F. Supp. 2d 514. This case is commonly referred to as *Cipro III*, since it is the third opinion generated from the same dispute.

⁹⁰ *Id.*

⁹¹ *Id.* at 531 (“The heart of plaintiffs’ argument is that there was at least a chance that the . . . [patent] was invalid and, therefore, the Agreements violated antitrust law because the patent rights they enforce derive from a potentially invalid patent. They argue that the potential invalidity of the patent translates into a potential for open competition (and, hence, lower prices), and that the possibility of realizing such open competition was unfairly foreclosed by the Agreements.”).

conclusions rebutting the plaintiffs' claims, and by extension, the probabilist model.⁹²

1. No Duty To Protect Consumer Surplus

The court first rebutted the premise that consumers have a property right in the outcome of private lawsuits, specifically the expected consumer surplus.⁹³ The court argued that holding parties accountable for a public interest, by threat of antitrust violations, would dissuade parties from settling and undermine the judicial system's preference for settlement.⁹⁴ If parties are unsure about the enforceability (and legality) of their settlement agreements, they are more likely to opt for a full trial, where the outcome is determinative and enforceable.

2. A Patent's "Strength" Is Impossible To Quantify

The court also argued that it is impossible for settling parties to objectively quantify the patent holder's "probability" of winning a case.⁹⁵ The plaintiffs argued that every patent has inherent uncertainties and cited data illustrating that courts have invalidated approximately 50% of patents litigated through trial.⁹⁶ The court rejected this argument, because it "undermin[es] the presumption of validity that Congress has afforded patents."⁹⁷ The court also concluded that the assumptions of the probabilist model would threaten valid licensing arrangements, because parties would worry about antitrust violations if their royalty schemes did not correspond to the "true" probability strength of the patent.⁹⁸

3. The Payment Amount Reflected the Patent Holder's Risk

The plaintiffs argued that the settlement was presumptively illegal, because the payment amount exceeded the expected costs of litiga-

⁹² The plaintiffs specifically cited Shapiro, *Antitrust Limits*, *supra* note 19, as authority in their motion for summary judgment. *Id.*

⁹³ *Id.* ("This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right.")

⁹⁴ *Id.* at 532 ("Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants 'to continue to litigate when they would prefer to settle' and 'to act as unwilling private attorneys general and to bear the various costs and risks of litigation.'" (quoting *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir.1985))).

⁹⁵ *Cipro III*, 363 F. Supp. 2d at 532.

⁹⁶ *Id.* at 532-33.

⁹⁷ *Id.* at 533.

⁹⁸ *Id.* ("To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.")

tion.⁹⁹ The plaintiffs assumed that if the patent holder was willing to pay more than its expected costs of litigation, it must have predicted the court would find its patent invalid or not infringed. The court rejected this argument, because the \$398 million payment accurately reflected the patent holder's belief that it had a 25% chance of losing the case.¹⁰⁰ That is, the payment amount equaled 25% of the patent holder's expected lost profits if it were to lose the trial. Whether or not the payment exceeded the expected costs of litigation was irrelevant. If courts were to use the "expected cost of litigation" as a benchmark for presuming a settlement as illegal, then it would force all patent holders to avoid settlement, because in generally all cases, the patents holders' expected loss of profits exceeds their costs of litigation.

4. *The Payment Is Not Evidence of a Quid Pro Quo To Delay Entry*

The court rejected the argument that reverse payments are evidence of a quid pro quo for the parties to agree to delay generic entry to the detriment of consumers.¹⁰¹ Relying on arguments put forth by Professor Shapiro,¹⁰² the plaintiffs concluded that without the reverse payment, the two parties would have settled on an earlier entry date for the generic drug.¹⁰³ The patent holder, they argued, used the payment to entice the generic company to release its drug at later a date, effectively sharing the brand-name's monopoly profits at the expense of the consumers.¹⁰⁴ The court rejected the notion that the parties would have otherwise agreed to another (earlier) entry date without the reverse payment: "The problem with this argument is that, due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger."¹⁰⁵

The court continued to attack the plaintiffs' quid pro quo argument on the grounds that there is no law requiring parties to agree to the "most competitive" arrangement.¹⁰⁶ In dismissing this "better settlement" argument, the court relied on the Supreme Court's recent hold-

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 533–34.

¹⁰¹ *Id.* at 535–36.

¹⁰² Shapiro, *Antitrust Limits*, *supra* note 19.

¹⁰³ *Cipro III*, 363 F. Supp. 2d at 535–36.

¹⁰⁴ *Id.* at 536.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* ("[I]f defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable.").

ing in *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*,¹⁰⁷ in which the Court stated: “The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.”¹⁰⁸ Accordingly, even if the patent holder did make a reverse payment in order to entice the generic to delay entry, there is no legal duty to garner the most competitive settlement, so long as both parties are settling within their rights (i.e., within the scope of the patent).¹⁰⁹

B. Schering-Plough and Scope of Patent

Despite the federal courts’ refusal to treat reverse payment settlements as presumptively illegal, the Federal Trade Commission recently adopted its own stance. In *Schering-Plough Corp. v. FTC*,¹¹⁰ the FTC relied on the Probabilists’ *quid pro quo* argument in bringing antitrust charges against parties involved in a Hatch-Waxman reverse payment settlement. The settlement involved Schering-Plough, owner of the patent for K-Dur,¹¹¹ and two generic manufacturers, ESI and Upsher-Smith, who were petitioning the FDA for the release of their generic versions of K-Dur under the Hatch-Waxman Act. In their settlement agreement, the parties agreed to allow both generic drugs to enter prior to the expiration of Schering-Plough’s patent. The parties also agreed to reverse payments.¹¹² The FTC charged Schering-

¹⁰⁷ 540 U.S. 398 (2004).

¹⁰⁸ *Id.* at 415–16.

¹⁰⁹ *Cipro III*, 363 F. Supp. 2d at 536 (“[Defendants] cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the . . . [p]atent.”).

¹¹⁰ 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

¹¹¹ Describing K-Dur 20, the court stated that:

[K-Dur 20 is] an extended-release microencapsulated potassium chloride product . . . which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering-Plough, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20

Id. at 1058.

¹¹² Upsher and Schering-Plough dispute whether or not Schering-Plough actually paid Upsher a reverse payment. Schering-Plough paid Upsher \$60 million for the licensing rights to market one of Upsher’s products, Niacor-SR. *Id.* at 1060. The parties argued to the FTC that the licensing deal was ancillary to the settlement agreement and within the normal range of similar licensing arrangements. The FTC disagreed and treated the payment as consideration for Upsher to stay out of the market with its generic version of K-Dur. *Id.* at 1061–62. For the purposes of this Note, I will treat the payment as if it were a reverse payment. As for the ESI settlement, Schering-Plough paid ESI \$5 million to settle the case and agreed to pay an additional \$10 million if the FDA approved ESI’s generic drug. *Id.* at 1060–61.

Plough, Upsher, and ESI with violations of the Sherman Act and the Commerce Act.¹¹³

At trial, the administrative law judge (ALJ) dismissed the charges against the parties, claiming the FTC's complaint counsel presented no evidence that the settlement exceeded the exclusionary scope of Schering-Plough's patent.¹¹⁴ Moreover, the ALJ determined that Schering-Plough did not possess a monopoly in the relevant potassium chloride supplement market and was sensitive to competitive prices from other potassium chloride supplements in the market.¹¹⁵

The Commission, however, reversed the ALJ's dismissal and found that the parties violated the antitrust laws.¹¹⁶ The Commission, relying on the arguments put forth by economists and critics of reverse payments, found that "it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."¹¹⁷

The Federal Court of Appeals for the Eleventh Circuit set aside and vacated the Commission's decision,¹¹⁸ agreeing with the ALJ that the FTC's complaint counsel provided no acceptable evidence that the settlement exceeded the exclusionary scope of Schering-Plough's patent.¹¹⁹ The FTC petitioned for, but was denied, an en banc review.¹²⁰ The Supreme Court also recently denied the FTC's petition to hear the case.¹²¹

¹¹³ *Id.* at 1061.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 1061–62. The ALJ, in its initial decision, reported that there were 23 potassium chloride supplements in the market, which were therapeutically similar and treated as interchangeable within the market. *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, ¶¶ 33–59 (F.T.C. June 27, 2002) (initial decision). The ALJ further determined that K-Dur competed with other substantially similar potassium chloride supplements in the market and was sensitive to competitive prices. *Id.* ¶¶ 60–113. For example, K-Dur was not the highest priced potassium chloride supplement in the market and Schering-Plough offered customers rebates on purchases of K-Dur, suggesting it was competing with other products. *Id.* ¶¶ 111–17. None of these factors support the FTC Commission's opinion that Schering-Plough had significant market power in the market for potassium chloride supplements.

¹¹⁶ *Schering-Plough*, 402 F.3d at 1062.

¹¹⁷ *In re Schering-Plough Corp.*, No. 9297, WL 22989651 (F.T.C. Dec. 8, 2003) (final order) (citing as support Shapiro, *Antitrust Limits*, *supra* note 19, and Hovenkamp et al., *supra* note 18).

¹¹⁸ *Schering-Plough*, 402 F.3d at 1076.

¹¹⁹ *Id.* at 1068–72.

¹²⁰ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *rehearing and rehearing en banc denied*, 147 Fed.App'x 156 (11th Cir. 2005) (unreported table decision).

¹²¹ *FTC v. Schering-Plough Corp.*, 126 S.Ct. 2929 (2006).

1. *The Commission's Decision*

In its decision to overturn the ALJ's findings, the FTC Commission did not evaluate Schering-Plough's market power. Instead, it relied on the *Indiana Federation of Dentists* exception that allows antitrust plaintiffs to avoid market power inquiries if they can show that the challenged conduct created a direct negative effect on the market.¹²² The Commission concluded that because generic entry normally lowers prices, an agreement to restrict generic entry necessarily has a direct effect on the market.¹²³ The Commission, therefore, ignored the ALJ's detailed factual findings on K-Dur's market power and its price sensitivity to the twenty-three other potassium chloride products, which included other generics, on the market at the time of the settlement.¹²⁴

Under the FTC's rule of reason analysis, once it showed the settlement's anticompetitive effects, the burden shifted to the settling parties to demonstrate pro-competitive reasons for their agreement.¹²⁵ The defendants proposed theoretical pro-competitive justifications for reverse payments, such as the need for the brand-name manufacturer to pay a "cash strapped" generic manufacturer in order to help it stay in business long enough to release its generic drug on the future negotiated entry date.¹²⁶ The Commission, however, found that neither of the generic companies was, in fact, cash strapped, and refused to accept any theoretical justifications for reverse payments not grounded in fact.¹²⁷ Reverse payments, according to the Commission's opinion, are presumptively illegal¹²⁸ and require a

¹²² *Schering-Plough*, 402 F.3d at 1065. ("Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986))).

¹²³ See *In re Schering-Plough Corp.*, No. 9297, WL 22989651, ¶¶ 16–20 (F.T.C. Dec. 8, 2003) (final order).

¹²⁴ See *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, ¶¶ 8–20 (F.T.C. June 27, 2002) (initial decision) (providing an extensive review of the market data showing that Schering-Plough's K-Dur was part of a competitive market).

¹²⁵ *In re Schering-Plough, Corp.*, No. 9297, WL 22989651, ¶¶ 36–39 (F.T.C. Dec. 8, 2003) (final order).

¹²⁶ *Id.* The defendant's argument was that a generic manufacturer may go out of business before the agreed upon entry date, so the reverse payment is necessary to keep it in business. Hence, in this sense, the reverse payment is pro-competitive since it ensures that the generic company is around long enough to release its drug and increase competition. See Sumanth Addanki, *Schering-Plough and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets*, ANTITRUST INSIGHTS, Spring 2005, at 1 (explaining the position that Addanki put forth in his expert testimony for the defendants).

¹²⁷ *In re Schering-Plough Corp.*, No. 9297, WL 22989651, ¶¶ 16–20 (F.T.C. Dec. 8, 2003) (final order).

¹²⁸ The Commission carefully avoids treating reverse payments as per se illegal. *Id.* ¶ 14. It

factual showing demonstrating pro-competitive benefits stemming from such payments.¹²⁹ Absent any actual pro-competitive showings, the FTC treats reverse payments as anticompetitive and a violation of the antitrust laws.¹³⁰

2. The Eleventh Circuit's Review

In reviewing the Commission's decision on appeal, the Federal Court of Appeals for the Eleventh Circuit conceded that the agreement was likely to create less competition than would have occurred if the generic drugs had entered the market earlier.¹³¹ The court, citing a previous decision,¹³² noted, "[a]lthough we acknowledged in *Valley Drug* that an agreement to allocate markets is 'clearly anticompetitive,' resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent."¹³³ The court, therefore, relied on its previous ruling in *Valley Drug* and determined that neither the per se approach nor the rule of reason approach applied in antitrust cases involving reverse payment settlements.¹³⁴ In rejecting both approaches, the court pointed out that patents, by their very nature, already "create an environment of exclusion, and consequently, cripple competition."¹³⁵

The court, accordingly, set forth a specific three step test for evaluating the antitrust implications of patent settlements. The court stated that, "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."¹³⁶ The court's analysis acknowledged the inherently anticompetitive effects of patents and requires an antitrust plaintiff to demonstrate that the alleged anticompetitive behavior exceeded the permissible exclusionary restraints embodied in the patent.¹³⁷

nevertheless puts the burden on the defendant to proffer pro-competitive justifications, supported by factual showings.

¹²⁹ *Id.* ¶ 39.

¹³⁰ *Id.*

¹³¹ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005).

¹³² *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

¹³³ *Schering-Plough*, 402 F.3d at 1064.

¹³⁴ *Id.* at 1065.

¹³⁵ *Id.* at 1065–66.

¹³⁶ *Id.* at 1066.

¹³⁷ The court concluded that its test reached "[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system." *Id.* at 1075 (quoting *Valley Drug*, 344 F.3d at 1307).

The court decided that, based on the evidence presented, neither of Schering-Plough's settlements exceeded the exclusionary scope of its patent.¹³⁸ Moreover, the court expressly rejected the FTC's quid pro quo argument that the existence of a reverse payment necessarily implies that the parties agreed "to defer [the] entry date beyond the date that represents an otherwise reasonable litigation compromise."¹³⁹ As the Second Circuit concluded in *Cipro III*,¹⁴⁰ the Eleventh Circuit found no reason to assume that the parties would have reached any other agreement¹⁴¹ without the reverse payment, considering the asymmetries of risk between the parties.¹⁴² The court further concluded that a bar on any settlements including consideration from the patent holder to the alleged infringer would effectively chill all settlements, because settlements, by their nature, require each party to give something to the other party.¹⁴³

The Eleventh Circuit's rule placed the burden back on the FTC. Under the court's rule, the FTC can no longer presume a reverse payment settlement harms competition. Instead, an antitrust plaintiff, such as the FTC, must first demonstrate that the settlement in question exceeded the exclusionary scope of the underlying patent and harmed competition to a greater degree than the patent permitted. Moreover, the court's use of the phrase "exclusionary potential" suggests an objective standard of "reasonableness," where the settlement does not have to fall within the strict, absolute confines of the patent. Rather, the settlement must fall into what the parties reasonably believed to be the patent's *potential* for exclusion. In more recent decisions involving reverse payments,¹⁴⁴ federal courts have applied the "objectively baseless" standard borrowed from *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*¹⁴⁵ Hence,

¹³⁸ *Schering-Plough*, 402 F.3d at 1072.

¹³⁹ *Id.* at 1073 (quoting *In re Schering-Plough Corp.*, No. 9297, WL 22989651 (F.T.C. Dec. 8, 2003) (final order)) (internal quotation marks omitted).

¹⁴⁰ *See supra* note 104.

¹⁴¹ Such as a compromised entry date for the generic drug.

¹⁴² *Schering-Plough*, 402 F.3d at 1073–74.

¹⁴³ *Id.* at 1074. The court cited Judge Posner's opinion in *Asahi Glass* in its reasoning: "[i]f any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (emphasis omitted).

¹⁴⁴ *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 429 F.3d 370 (2d Cir. 2005), *amended by* 2006 U.S. App. LEXIS 22154 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *see also Asahi Glass*, 289 F. Supp. 2d at 993 (applying the "objectively baseless" test to defendants' settlement agreement).

¹⁴⁵ 508 U.S. 49, 60 (1993) (defining an objectively baseless lawsuit as one in which "no reasonable litigant could realistically expect success on the merits").

not only must an antitrust plaintiff show that a settlement agreement exceeded the patent's scope, the plaintiff must also show that "no reasonable litigant" would have expected the patent holder to win the underlying patent infringement case.

IV. EVALUATING THE FTC'S POSITION

In its petition to the Supreme Court, the FTC remained steadfast in its belief that reverse payments should be presumptively illegal. The FTC argued that the Eleventh Circuit's ruling provided the exact opposite standard, making it presumptively *legal* for a patent holder to pay competitors to stay out of the market.¹⁴⁶ This section will provide an overview and criticism of the FTC's arguments for treating a reverse payment as presumptively illegal, ultimately concluding that the FTC's approach is neither legally, factually, nor practically valid.

A. *The Role of Patent Uncertainty*

The following subsections evaluate the FTC's first argument that criticizes a patent holder's ability to use its patent—unilaterally, without a court resolution—to exclude potential competitors.

1. *Excluding Potential Competitors*

The FTC first argued that antitrust laws prohibit companies from excluding competitors even when they are uncertain whether the competitor will enter the market.¹⁴⁷ The FTC cited cases in which courts held parties liable for entering into agreements that kept potential competitors out of the market.¹⁴⁸ These cases, however, are inapposite to the Hatch-Waxman scenario, because they were not patent cases nor did they involve patent holders exercising their rights to exclude competitors. It comes as little surprise that a company that does not possess any exclusionary rights cannot contract with a potential competitor to stay out the market, even if the competitor's entry is uncertain. The FTC's argument, however, obfuscated the issue by equating an agreement not to compete with an exercise of one's exclusionary rights under a patent.

¹⁴⁶Petition for a Writ of Certiorari at 12, *FTC v. Schering-Plough Corp.*, No. 05-273 (11th Cir. Aug. 29, 2005), 2005 WL 2105243 (claiming that the Eleventh Circuit's ruling makes it so that "a patentee is presumptively entitled to buy protection from all competition for the full patent term, even if such payments effectively augment the patent's actual exclusionary power").

¹⁴⁷*Id.* at 15.

¹⁴⁸*Id.* (citing *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49–50 (1990) (per curiam); *United States v. Griffith*, 334 U.S. 100, 107 (1948); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001)).

2. *The Inherent Weakness of Patents*

The FTC continued by arguing that the inherent uncertainties of patent litigation should prohibit patent holders from using settlements to unilaterally exclude potential infringers. In order to demonstrate the general “weakness” of patents, the FTC referred to an oft-cited Allison and Lemley study that found that courts invalidated approximately 46% of all patents challenged through litigation.¹⁴⁹ Many other commentators and critics of reverse payments have used the Allison and Lemley article and similar studies to highlight the ostensibly weak nature of patent rights. For example, Abbott and Michel claim:

As a matter of probabilities . . . it is clearly inappropriate to simply assume that a patentee could exclude a competitor from the market simply because he asserts that to be the case. Informed antitrust analysis will acknowledge this fact and recognize that exclusion payments cannot be justified on the basis of the patentee’s unproven assertion of its right to exclude.¹⁵⁰

Likewise, the Public Patent Foundation, in its amicus brief to the Supreme Court in support of the FTC’s petition, wrote:

Since roughly half of all asserted patents end up having no exclusionary power whatsoever, it was improper for the Court of Appeals to assume that Schering’s patent would have complete exclusionary power with respect to all generic products throughout its full term. Such an assumption was no more justified than assuming the patent will have no exclusionary power with respect to any product.¹⁵¹

These commentators are not-so-tacitly implying that reverse payments should be presumptively illegal, because it is unlikely that a patent holder could withstand any challenge in court. Or, at the very least, a patent holder is just as likely to lose as it is to win. A court

¹⁴⁹ *Id.* at 17 (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 *AJPLA Q.J.* 185, 205–206 (1998)). Some argue that the PTO’s inefficient procedures in granting patents leads to general uncertainty over whether a given patent is in fact valid. See Lemley & Shapiro, *supra* note 3.

¹⁵⁰ Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 *IDEA* 1, 12 (2005).

¹⁵¹ Motion of the Public Patent Foundation for Leave to File Brief as Amicus Curiae and Brief of Amicus Curiae in Support of Petitioner at 7, *FTC v. Schering-Plough Corp.*, No. 05-273 (11th Cir. Sept. 30, 2005), 2005 WL 2454837.

should, therefore, be reluctant to allow a patent holder to assert its right to exclude competitors.

These statements denigrating the strength of patents suffer from the logical fallacy of selection bias. The arguments rely only on cases that parties litigate through completion, which are unreliable data. In fact, it would be impossible to collect reliable data. Empirical methods require a random sampling of population groups.¹⁵² Patent infringement cases that are litigated to completion are not a random sampling of patents.¹⁵³ First, some patents may have certain factors that increase the likelihood that they will be challenged. Second, litigants settle the overwhelming majority of patent cases before trial.¹⁵⁴ Patent cases that are litigated through a complete trial are, therefore, likely to be non-representative of all patent cases.

Moreover, those relying on the Allison and Lemley data often overlook the fact that the authors broke the data into product types.¹⁵⁵ Pharmaceutical patents withstood validity challenges in over 72% of the sampled trials.¹⁵⁶ Even if the data could provide reliable inferences on the general "probabilities" of patents,¹⁵⁷ the Allison and Lemley data show that *pharmaceutical* patents, the patents underlying the Hatch-Waxman settlement controversy, have more than a mere fifty-fifty chance at excluding any competing product. In fact, the high success rate for pharmaceutical patent holders would be consistent with the patent laws' "clear and convincing" standard to invalidate a patent.

Nevertheless, the FTC continued to make similarly overreaching statements by alluding to other data collected in its own 2002 study.¹⁵⁸ The FTC, in its petition, claims that "the percentage of vulnerable patent claims appears to be even greater in the Hatch-Waxman context,"¹⁵⁹ because "generics prevailed in cases involving

¹⁵² See RICHARD P. RUNYON ET AL., *FUNDAMENTALS OF BEHAVIORAL STATISTICS* 18, 341 (9th ed. 2000) (explaining the necessity of random selection in empirical studies).

¹⁵³ See Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 374–75 (2000) ("Most scholars agree . . . that the small percentage of all legal disputes that reach trial is not a representative or random sampling of all cases.").

¹⁵⁴ Lemley & Shapiro, *supra* note 3, at 75 ("[O]nly 1.5 percent of patents are ever litigated, and only 0.1 percent of patents . . . are ever litigated to trial.").

¹⁵⁵ Allison & Lemley, *supra* note 149, at 199 (noting that the data were broken into groups of patents for mechanical, electrical, chemical, pharmaceutical, biotechnology, computer-related, or software).

¹⁵⁶ *Id.* at 217 tbl.5.

¹⁵⁷ Which it cannot, due to the study's selection bias.

¹⁵⁸ FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 19–20 (2002).

¹⁵⁹ Petition for a Writ of Certiorari at 17, *FTC v. Schering-Plough Corp.*, No. 05-273 (11th Cir. Aug. 29, 2005), 2005 WL 2105243.

73 percent of the challenged drug products.”¹⁶⁰ The FTC, however, failed to mention that in its own report, it broke data into patent validity and patent infringement cases. In the trials adjudicating patent validity, the patent holders prevailed 72% of the time.¹⁶¹ Hence, in the vast majority of cases in which the generic drug companies prevailed, they prevailed due to non-infringement. Because patent infringement is a case-specific issue that does not reflect the strength of patents in general, the data collected from infringement cases do not create an inference that pharmaceutical patents are generally weak and unlikely to withstand challenge.¹⁶²

Professors Landes and Posner offer data on patent validity that also belie the FTC and others’ misconstruction of general patent strength. The authors showed a remarkable increase in patent validity holdings since the inception of the Federal Circuit.¹⁶³ Immediately before the Federal Circuit, courts held patents as valid in approximately 45% of the cases.¹⁶⁴ The percentage has steadily increased to around the 65-70% range per year.¹⁶⁵ As Landes and Posner demonstrated in a series of statistical studies, the Federal Circuit has been strongly pro-patent.¹⁶⁶

The FTC overstates its claims about the general weakness of patents. Similar claims of “substantial uncertainty” that arise “when patents are litigated,”¹⁶⁷ are not supported when one scrutinizes the available data. In fact, in the pharmaceutical context, the data show that a court is *probably* going to uphold the validity of a challenged patent. To suggest that the antitrust laws should prohibit a patent holder from exercising its rights to exclude, based upon the purported findings of “substantial uncertainty” surrounding patent validity, is obscuring the data and drawing misleading conclusions. The Supreme

¹⁶⁰ *Id.* at 5.

¹⁶¹ The FTC found that in only 28% of the drug products that went to trial, the patent holder lost the trial due to an invalid patent (11/40). FEDERAL TRADE COMMISSION, *supra* note 158, at 20. The FTC even admits that its validity findings are consistent with the Allison and Lemley findings for pharmaceutical patents. *Id.* at 20 n.15. Nonetheless, the FTC neglected to mention this fact in its petition to the Supreme Court.

¹⁶² Moreover, one must not forget that these data are generally irrelevant to the *Schering-Plough* case, since many of the cases in the FTC study that reached a final resolution settled (20/53) and the cases that went through complete trials are unlikely to be representative statistical samples of patents as a population.

¹⁶³ WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 338–39 (2003).

¹⁶⁴ *Id.* at 338 tbl. 12.1.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 334–53; see also Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 25–30 (1989) (evaluating the criticism that the Federal Circuit demonstrates a greater pro-patent bias than the regional circuits).

¹⁶⁷ Lemley & Shapiro, *supra* note 3, at 80.

Court should, accordingly, disregard the FTC and others' attempts to persuade it that patent holders are using reverse payments to hide behind generally "weak" patents.

B. Preserving the Expected Level of Competition

The FTC continued by arguing that a patent's "strength"¹⁶⁸ should dictate the terms of the settlement agreement. That is, the settlement terms should ensure that consumers enjoy the expected level of competition had the parties resolved the issue through a complete trial. The FTC argued that reverse payments allow patent holders to garner a better settlement deal than their patents would have otherwise provided:

[I]f the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent. . . . If, however, the patent holder makes a substantial payment to the challenger as part of the deal, absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.¹⁶⁹

The FTC, relying on the probabilistic model, argued that parties should not agree to terms depriving consumers of their chance for possible competition.¹⁷⁰ Instead, the parties should agree to terms that adequately reflect the level of competition that otherwise would have occurred had the case gone through a complete trial.¹⁷¹ Licensing deals or negotiated generic entry dates would reflect the parties' collective assessment of the patent's strength. Reverse payments, on the other hand, allow the patent holder to buy certainty and deprive consumers of the level of competition that otherwise would have occurred under other settlement schemes.

¹⁶⁸ Meaning, the probability of the patent holder's success at trial. See Shapiro, *Antitrust Limits*, *supra* note 19, at 395.

¹⁶⁹ Petition for a Writ of Certiorari at 18, *FTC v. Schering-Plough Corp.*, No. 05-273 (11th Cir. Aug. 29, 2005), 2005 WL 2105243 (internal quotations omitted).

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 19 ("Where a patent holder makes a payment to a challenger in order to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.").

The FTC's "otherwise would have occurred" argument is the central tenet of the probabilistic model. For example, Leffler and Leffler argued that because Congress made patents presumptively valid rather than conclusively valid, then every patent has a chance to be found invalid.¹⁷² Moreover, by making patents merely presumptively valid, Congress intended to encourage competitors to challenge patents through the legal process.¹⁷³ The Lefflers conclude that patent holders who pay alleged infringers to settle are circumventing the patent laws and depriving consumers of competition that otherwise would have occurred.¹⁷⁴

Notwithstanding the fact that settling parties have no legal duty to agree to terms that provide consumers with the most competition,¹⁷⁵ the "otherwise would have occurred" argument fails for several practical reasons, as discussed in the following subsections.

1. The Difficulty in Determining the Patent's "Strength"

Patent litigation results are binary, not continuous. A patent holder either wins, and is able to continue excluding the challenger, or loses, and must allow the challenger to compete. The level of competition that otherwise would have occurred is, therefore, either all or none.¹⁷⁶

Understandably, the Probabilists ground their arguments in averages, i.e., competition that would occur in the aggregate. As Shapiro argues:

[A] patent settlement between rivals cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Effectively, antitrust gives consumers the right to the level of competition that would have prevailed, *on average*, had the two parties litigated the patent dispute to a resolution in the courts.¹⁷⁷

This approach, however, conveniently confuses two separate forms of probability. When a patent holder decides that it has a 75% chance of winning at trial, it uses a subjective probability or "betting odds" that have no mathematical or statistical verifiability. The Probabilists,

¹⁷² Leffler & Leffler, *supra* note 3, at 487; see also Keith Leffler & Cristofer Leffler, *The Probabilistic Nature of Patent Rights: In Response to Kevin McDonald*, ANTITRUST, Summer 2003, at 77.

¹⁷³ Leffler & Leffler, *supra* note 3, at 487.

¹⁷⁴ *Id.*

¹⁷⁵ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 531–32 (E.D.N.Y. 2005).

¹⁷⁶ See McDonald, *supra* note 6, at 74.

¹⁷⁷ Shapiro, *Antitrust Limits*, *supra* note 19, at 70 (emphasis added).

however, conveniently treat this 75% probability as if it were a frequency-based probability; if the patent holder tried its case in an infinite amount of universes, it would have prevailed in 75% of them.¹⁷⁸ By couching a patent holder's subjective probability in frequency-based probability terms, the Probabilists create the illusion that there is some objective and measurable (and, therefore, protectable) amount of competition that would have happened had the patent holder and the alleged infringer completed the trial.

One might argue that the two parties converge on the "real" probability through negotiation and compromise.¹⁷⁹ Accordingly, there is no need to consider an objective and measurable mathematical probability. The standard model of settlement, however, assumes that both parties substantially agree on the strength of the patent, or the patent holder's likelihood of success at trial.¹⁸⁰ As previously discussed, the assumption that both parties will converge on a "substantial agreement" over the patent's strength is diminished in the Hatch-Waxman context. The alleged infringer has not damaged the patent holder, nor has it sunk much cost into developing its generic. The alleged infringer has no constraints pushing it to a (reasonable) negotiable position. It is, therefore, difficult (if not impossible) to determine the "true" probability of the patent, because the parties are unlikely to come to a mutually agreed upon number.¹⁸¹

The Probabilists respond by saying "so be it." Congress enacted the Hatch-Waxman Act as part of the patent laws, so patent holders must accept their fate and accept the risk of having a patent that is vulnerable to such challenges.¹⁸² A patent holder with a pharmaceutical patent runs the risk of having to negotiate to a lower figure than it would have absent the Hatch-Waxman Act. A reverse payment, however, circumvents the balance and enforcement structure established by Congress and inherently extends the scope of the patent. Presuma-

¹⁷⁸ See Charles M. Yablon, *The Meaning of Probability Judgments: An Essay on the Use and Misuse of Behavioral Economics*, 2004 U. ILL. L. REV. 899, 906–20 (2005) (providing a comprehensive review of the different types of probability and their legal applications).

¹⁷⁹ See Shapiro, *Antitrust Analysis*, *supra* note 4, at 72 ("We may reasonably infer that the terms of the settlement, e.g., the royalty rate paid or field-of-use restrictions applied, reflect the assessments of the parties regarding their prospects in the patent litigation.").

¹⁸⁰ See Yablon, *supra* note 178, at 959 ("The standard economic model of settlement states that cases will settle whenever both parties to the litigation substantially agree as to the expected value of the claim.").

¹⁸¹ In licensing negotiations, outside of litigation, the licensor and licensee are still likely to agree to the patent's "strength," since the licensee would either gain no money, because the deal would not be made, or would face heavy infringement liability if it decided to release its own product without the license. In either case, the licensee has a reason to reach an agreement with the licensor about the patent's strength. In a Hatch-Waxman suit, there is much less incentive for the alleged infringer to agree to the patent holder's assessment of its patent strength.

¹⁸² See Leffler & Leffler, *supra* note 3, at 490–92.

bly, this means that in the likely event that the parties are unable to agree to the “strength” of the patent, the parties must continue on with the litigation.

But the argument overlooks the fact that Congress has structured the federal court system, the means of enforcing one’s patent rights, by passing laws to encourage settlement and manage judicial efficiency.¹⁸³ We are, therefore, left to assume that when Congress directed patent holders to the federal courts in order to enforce patent disputes, it also directed them to the underlying settlement provisions, as well. To say that reverse payments are outside of the federally prescribed enforcement structure and, therefore, illegal, simply assumes its own conclusion. There is, however, no evidence that the settlement laws explicitly bar reverse payments.¹⁸⁴ One cannot say that reverse payments break the rules of enforcing patents when there is no rule against reverse payments. Whether there should be a rule against reverse payments is precisely the issue at hand. We cannot assume that reverse payments lay outside of the scope of the settlement laws (a subset of the patent enforcement structure), just to conclude that reverse payments are illegal.

When a patent holder uses the federal court system, and its underlying settlement provisions, in a Hatch-Waxman suit, there is no guarantee that it and the alleged infringer will reach a mutual assessment of the patent’s “strength.” Forcing patent holder’s to lower their negotiating positions will lead more of them to choose trial over settlement. A law that prohibits reverse payments to resolve an impasse, especially when both parties are sure that the patent holder is more likely than not going to win (and therefore continue excluding the challenger), will waste judicial resources. Moreover, the level of competition that “otherwise would have occurred” is lost in the ether of subjective probability because the parties cannot come to a mutual conclusion.

¹⁸³ See Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991) (“There shall be implemented by each United States district court, in accordance with this chapter, a civil justice expense and delay reduction plan. The plan may be a plan developed by such district court or a model plan developed by the Judicial Conference of the United States. The purposes of each plan are to facilitate deliberate adjudication of civil cases on the merits, monitor discovery, improve litigation management, and ensure just, speedy, and inexpensive resolutions of civil disputes.”). This law is precisely the reason the judge forced the parties in Schering-Plough into settlement, including the reverse payment.

¹⁸⁴ Although Congress amended the Hatch-Waxman Act in 2003 and knew about the reverse payment phenomenon, it did not create an outright ban of reverse payments.

2. The Problem of Multiple Challengers

Even if both parties agree to a patent's "strength," we encounter another problem if we are to assume that settlements must protect the level of competition that otherwise would have occurred had the parties continued through trial. If a court invalidates a patent in one case, the patent holder can no longer use that patent to exclude others.¹⁸⁵ A finding of patent invalidity effectively puts the underlying invention into the public domain. This creates a problem for assessing a patent's strength when there are multiple challengers, as in *Schering-Plough*.

Suppose a patent holder has four competitors who are all independently, but simultaneously, challenging its patent's validity. Because the patent's strength as per validity will remain constant, the patent holder will face each challenger with an equal probability of success. Let us suppose all parties agree that the patent's strength is 75%. The strength of 75%, however, only applies to each individual trial (i.e., for each trial, the patent holder has a 75% chance of winning and a 25% chance of losing). Yet, if we were to calculate the patent holder's chances of winning *all four* trials, the patent's "strength" falls to 32%:

$$\begin{aligned} \text{Probability of winning all 4 trials} &= 0.75 * 0.75 * 0.75 * 0.75 \\ &= 0.316 \end{aligned}$$

Even if only two competitors were challenging the patent, its "strength" would fall to 56%:

$$\text{Probability of winning both trials} = 0.75 * 0.75 = 0.562$$

If we are to define a patent's strength by its ability to withstand challenge through litigation, *on average*,¹⁸⁶ it becomes more difficult to assess its strength when it faces multiple challengers, as Schering-Plough did when it faced challenges from both Upshaw and ESI. More importantly, if a patent holder has a duty to protect the expected consumer surplus by negotiating a settlement that adequately reflects the patent's strength,¹⁸⁷ multiple challengers make it more difficult to

¹⁸⁵ See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349–50 (1971) (allowing patent infringement defendants to assert a collateral estoppel defense against a plaintiff whose patent had previously been found invalid).

¹⁸⁶ Shapiro, *Antitrust Analysis*, *supra* note 4, at 70. Admittedly this argument treats subjective probabilities as frequency-based probabilities. But this is precisely how the Probabilists use the term probability when discussing its relation to the expected consumer surplus as they speak of the level of competition that would happen *on average*.

¹⁸⁷ Again, Shapiro argues that consumers have a *right* to the level of competition that would have occurred with a complete resolution at trial. *Id.* The argument implies that consumers have the same right to the level of competition that would have occurred if all trials from all

determine the level of expected surplus. What is the level of competition that “otherwise would have occurred” had each of the trials posed in the above hypothetical been completed through litigation? (1-0.75)? Or (1-0.32)?

If the courts adhere to an “otherwise would have occurred” policy when evaluating patent infringement settlements, they will run into the messy problem of combined probabilities. A patent with a 75% chance of winning any given challenge stands only a 32% chance of winning a combination of four independent challenges. Hence, a “strong” patent has become a “weak” patent through nothing more than an over-reliance on thinking of patents in probabilistic terms.

3. The Alleged Infringer's Incentive To Infringe and Hold Out

Another pragmatic problem with the “otherwise would have occurred” standard can best be described through a hypothetical: A company uses a competitor's patent to create an exact copy of the underlying product. The company makes no attempt to invent around the claims of the patent, and readily admits that it copied the patent's product as is. The patent holder sues the company for infringement. During settlement negotiations, the “alleged” infringer admits to infringing the patent and concedes to its validity. Both parties agree that the patent holder has a remarkably strong chance of prevailing at trial. The patent holder demands that the infringer stop wasting both parties' time and discontinue its infringing activity. The patent holder offers no payment, no licensing deal, no compromised entry date, or anything else to the infringer. The infringer agrees that the case is a waste of time and would like to walk away, but it cannot. Why? Because if the infringer admitted defeat and walked away, it would have violated the antitrust laws. After all, every patent has at least *some* probability of having a court invalidate it. Hence, there was a chance, albeit a small one, that the court would have invalidated the patent. If the parties settled, without a licensing deal or a negotiated entry date for the infringer, they would have robbed the consumers of the small expected increase in competition that otherwise would have occurred had the parties continued through trial.

This extreme, absurd result illustrates another problem with the “otherwise would have occurred” argument. The rule encourages

challengers were resolved in court. If a patent holder negotiates a deal reflecting a patent strength of 75% with all four challengers, then it is depriving consumers of a level of expected competition that would have occurred if all four trials were completed (a difference of 43% (75%-32%)).

patent infringement, because competitors would be enticed by the fact that patent holders must accept that their patents *may* be invalidated and negotiate a deal that adequately reflects the chance of that happening.

One might quibble with the absurdity of the example and claim that nobody is arguing that the alleged infringer should not be allowed to simply walk away without receiving anything. But consider the same set of facts, except the infringer refuses to walk away without some sort of deal. The patent holder has the statutorily prescribed right to refuse to license its product to the infringer.¹⁸⁸ Yet, if both parties agree that the patent holder has a 99% chance of winning and the expected lost profits, if litigated to judgment, are \$10 million (1% of expected profits after a win), the FTC's position prohibits the patent holder from paying the infringer \$10 million to go away, and forces it into a licensing deal or a negotiated entry date for the infringing product.¹⁸⁹ The only other alternative is for the parties to continue with the trial. We, therefore, have two parties, who both anticipate that the patent holder will decisively win, wasting the court's time and resources simply because the patent holder cannot pay the infringer to admit defeat and walk away.

Of course, in the Hatch-Waxman context, the parties' negotiation positions are reversed. Typically, the defendant makes an offer to the plaintiff that approximates the plaintiff's damages discounted by the probability of the defendant winning the case. In a Hatch-Waxman suit, however, the defendant generic company has not yet damaged the plaintiff patent holder and has nothing to lose other than litigation costs. The generic company, therefore, has no reason not to hold out and force the *plaintiff* to make an unrealistic offer. The generic would know that the patent holder must offer it a licensing deal or run the risk of losing its patent in court.¹⁹⁰

C. Settlements Without Reverse Payments Do Not Necessarily Preserve the Expected Level of Competition

The final pragmatic problem with the FTC's approach is that there is no guarantee that settlements without reverse payments will, in

¹⁸⁸ See U.S. Patent Act, 35 U.S.C. § 271(d)(4) (2000) ("No patent owner . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent.").

¹⁸⁹ The Probabilists may argue that this is precisely what *should* happen. The market should force patent holders into deals that adequately reflect the strength of their patents. But this completely undermines the patent holders' right to refuse licensing their products.

¹⁹⁰ In fact, this may be why more Hatch-Waxman infringement cases are litigated through trial than what would be expected in general patent infringement cases.

fact, promote more competition. As Professor Bulow illustrates, certain licensing arrangements generate the same effect as a reverse payment, such as when the royalties per unit increase over quantities sold.¹⁹¹ The licensee receives an ostensible discount in royalties for the first batch of products it sells. This discount effectively amounts to a payment to the licensee.

In *Brunswick Corp. v. Riegel Textile Corp.*,¹⁹² Judge Posner also noted how licensing agreements do not necessarily mean savings to consumers:

There would then be more manufacturers . . . than there are today, but there would not be more competition if the “competitors” were constrained by the terms of the patent license to charge the monopoly price. And they would be. As a rational profit-maximizer [patentee] would charge its licensees a royalty designed to extract from them all the monopoly profits that the patent made possible; and the licensees would raise their prices to consumers to cover the royalty expense. The price to the consumer would be the same as it is, today, with . . . only [one] seller in the market.¹⁹³

The Probabilists argue that the parties will negotiate a deal in which the royalty rate reflects the “strength” of the patent, or the probability that the patent holder would win in court.¹⁹⁴ The parties, however, could arrange for the licensee to pay a higher royalty rate in return for a “hidden” payment in the form of a discount on royalties at the beginning of the arrangement.¹⁹⁵ The licensee will, thus, increase its prices, by agreement, and the patent holder will reward it by granting a lower royalty rate in the first phase of the deal. The consumers, however, never see a lower price at any stage of the deal. Likewise, the parties could assign the licensee a region, such as outside of the United States, which would have little, if any, effect on the U.S. market prices.

Short of stepping in and reviewing all licensing arrangements so that settlement parties adequately reflect the expected consumer surplus,¹⁹⁶ there is no way for the courts to ensure that their licensing

¹⁹¹ Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in INNOVATION POLICY AND THE ECONOMY 145, 145–87 (Adam B. Jaffe et al., eds., vol. 4 2004).

¹⁹² 752 F.2d 261, 267 (7th Cir. 1984).

¹⁹³ *Id.* at 267.

¹⁹⁴ Shapiro, *Antitrust Analysis*, *supra* note 4, at 72.

¹⁹⁵ The price the licensee charges consumers remains constant in order to reap the benefit of the initial royalty discount (i.e., the hidden payment).

¹⁹⁶ Which is, in itself, impossible to calculate.

deals produce better consumer welfare than reverse payments coupled with negotiated early entry dates.

The FTC's approach requiring settling parties to preserve the level of competition that otherwise would have occurred had a court resolved the case is, therefore, untenable for several practical reasons. Treating reverse payments as presumptively illegal assumes that parties would have otherwise come to a mutual agreement on the patent's strength, which is not always likely in the Hatch-Waxman context. It also suffers from mathematical indeterminacy, especially if more than one competitor is challenging a patent. It encourages patent infringement and hold outs, because generic companies, who already have disproportionate leverage, can force patent holders into licensing agreements, against the patent holder's right to refuse to deal. Likewise, banning reverse payments does not necessarily protect any expected consumer surplus, because patent holders can hide payments in favorable licensing arrangements with generic companies.

Although the FTC's arguments fail for various reasons, there still remains the question of whether allowing patent holders to use reverse payments to settle infringement suits is good policy. In the next section, I propose reasons for allowing stronger patent protection in the Hatch-Waxman context at the possible expense of competition.

V. THE ROLE OF INNOVATION IN THE HATCH-WAXMAN CONTEXT

The reverse payment problem requires courts to balance three policy goals: a) encouraging innovation through the patent laws, b) keeping consumer prices at a competitive level through antitrust laws, and c) encouraging settlement to lower public costs to courts and private costs to the litigants. The trade-off between long-term economic gains and short-term economic efficiency lies at the heart of balancing patent and antitrust laws.¹⁹⁷ If the courts adopt a presumptively illegal standard for reverse payments, they will shift the balance away from long-term gains through innovation, and towards short-term gains through a more efficient allocation of resources. In this last section, I propose that courts and commentators should avoid narrowly focusing only on short-term efficiency losses in patent settlements.¹⁹⁸

¹⁹⁷ Leffler & Leffler, *supra* note 3, at 485.

¹⁹⁸ Leffler and Leffler suggest that we should presume that Congress has already struck the optimal balance between long-term and short-term efficiencies. *Id.* at 486. They argue that reverse payments should be *per se* illegal, since they are not part of the optimal system Congress established for patent enforcement. As noted above, this argument assumes its own conclusion, since it assumes that reverse payment settlements are not part of the patent enforcement structure, despite the fact that the very courts upon which the Lefflers' system relies explicitly state otherwise.

Rather, the focus should be on whether short-term or long-term efficiencies deserve more protection in the pharmaceutical context.

In his 2002 article, Professor Carrier took on the difficult task of resolving the recurring conflicts between patent and antitrust laws.¹⁹⁹ Carrier proposed a model that focuses on what he considers the “common denominator” of both the patent and antitrust laws: innovation.²⁰⁰ This section will explore the inherent conflicts between patent and antitrust laws as well as the common denominator of innovation underlying the seemingly contradictory laws. Then, the last part of this section argues that patent protection should trump antitrust protection in the Hatch-Waxman context.

A. *The Conflict Between Antitrust and Patent Laws*

Patent and antitrust laws have a longstanding inherent conflict. While both purport to enhance social welfare, they do so through often conflicting laws.²⁰¹

Patent laws protect an inventor from free-riding competitors by granting it a right to exclude others from using its invention.²⁰² The temporary right to exclude provides time for the inventor to recoup the costs of invention, thereby providing an incentive for investment in developing new technologies.²⁰³

Antitrust laws, on the other hand, aim to enhance social welfare by prohibiting restraints on competition.²⁰⁴ The underlying assumption is that competition produces lower prices, higher output, and more innovation. Antitrust laws, therefore, prohibit unreasonable restraints on price and output.

The conflict is obvious. Patent laws promote long-term consumer welfare by allowing patent owners to control output, and thus prices, and reap the benefits of their innovations.²⁰⁵ Antitrust laws promote short-term consumer welfare by precluding activities that aim to control output and harm consumers through higher prices.²⁰⁶ As Professor Carrier explains,

¹⁹⁹ Carrier, *supra* note 33.

²⁰⁰ *Id.* at 764.

²⁰¹ *Id.* at 766.

²⁰² See 35 U.S.C. § 271 (2000 & Supp. 2003).

²⁰³ Carrier, *supra* note 33, at 767.

²⁰⁴ *Id.* at 768.

²⁰⁵ Patent laws also require the patent holder to reveal the secrets of its invention, thereby promoting progress as others may build off the patented invention. See LANDES & POSNER, *supra* note 163, at 294–300 (discussing the economic logic of patent law).

²⁰⁶ See ROGER D. BLAIR & DAVID L. KASERMAN, ANTITRUST ECONOMICS 25–45 (1985) (providing a review of the economics supporting antitrust laws).

In interpreting antitrust law, courts have focused primarily on static efficiency—in other words, on increasing economic welfare through a reallocation of the existing supply of resources in a Pareto-optimal fashion (i.e., so that no individual's welfare could be improved by a resource reallocation without some other person's welfare being diminished). In particular, courts analyze allocative efficiency, striving for an optimal allocation of goods and services to customers. Patent law, on the other hand, attempts to increase dynamic efficiency, or the Pareto-optimal allocation of resources between the present and the future. The incentives underlying the patent system apply in the long term through the encouragement of future invention and innovation. Although courts that have analyzed the patent-antitrust intersection have not focused explicitly on the tradeoffs between static and dynamic efficiency, the disparate temporal perspectives provided by the distinct notions of efficiency further underscore the patent-antitrust conflict.²⁰⁷

B. Innovation as the Common Denominator

Professor Carrier attempts to resolve the inherent conflict between patent and antitrust laws by focusing on their common goal of promoting innovation.²⁰⁸ Patent laws promote innovation by rewarding inventors with the possibility of reaping financial rewards through temporary market powers.²⁰⁹ Antitrust laws promote innovation by increasing competition between firms, who will then invest in innovative technologies to gain a competitive edge.²¹⁰

With innovation as the common goal for both patent and antitrust laws, Professor Carrier proposes that when patent protections square off with antitrust protections, courts and lawmakers should determine whether patent protection or competition is more likely to foster innovation within the industry in question.²¹¹ Industries require more patent protection than antitrust protection to generate innovation

²⁰⁷ Carrier, *supra* note 33, at 770–71.

²⁰⁸ *Id.* at 799–803.

²⁰⁹ LANDES & POSNER, *supra* note 163, at 294–300.

²¹⁰ See BLAIR & KASERMAN, *supra* note 206, at 41–45 (discussing the traditional view of how competition can foster innovation, as well as some of its criticisms); see also Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609–25 (1962) (providing an economic account for how competition promotes innovation). But see Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1 (1969) (finding that the incentive to invent is greater under a monopoly than competition).

²¹¹ Carrier, *supra* note 33, at 815.

when their products have high development costs and are easy to replicate.²¹² On the other hand, industries with lower development costs and technologies that build off each other generate more innovation through competition than patent protection.²¹³ When courts and lawmakers balance the conflicts between patent protection and antitrust enforcement, they should consider the industry's source of innovation.

C. Stronger Patent Protection for Industries Dependent on Patents

The pharmaceutical industry typifies an industry that relies more on patent protections than competition to foster innovation.²¹⁴ The cost of development is extraordinarily high, as discussed in Part I. Likewise, the end products, pharmaceuticals, are easy to replicate.²¹⁵ The Hatch-Waxman Act, which permits generics to bypass the lengthy and expensive FDA requirements for safety and efficiency tests, makes it even easier for a competitor to avoid development costs and replicate a pharmaceutical product.²¹⁶ These factors indicate that the pharmaceutical industry relies heavily on patents for innovation, while increased competition, at the expense of patent protection, would likely do little to foster innovation.

D. Balancing Innovation with Allocation Efficiencies

As courts and commentators struggle with the appropriate balance between patent protection and antitrust protection in the Hatch-Waxman context, they should focus on the role of innovation. As Carrier notes, "The consensus among economists since [Joseph] Schumpeter is that the gains achieved from innovative efficiencies dwarf those derived from maximizing allocative efficiency and that innovation is the most important factor in the growth of the economy."²¹⁷ If innovation is the economy's primary goal, the balance

²¹² *Id.* at 815–16.

²¹³ *Id.*

²¹⁴ *Id.* at 824–25 ("[In the case of] pharmaceuticals . . . the cost of searching for the next breakthrough can be prohibitive. Biopharmaceutical companies often spend hundreds of millions of dollars and take ten to fourteen years to bring new drugs to market. These companies must pass through multiple stages of innovation, such as discovering the relevant molecules with therapeutic effects, undertaking thorough clinical testing, undergoing significant FDA review, and developing, manufacturing, and marketing the drug. Only one out of every four thousand discovered compounds tested in industry laboratories passes through each of the stages and reaches the marketplace.").

²¹⁵ *Id.* at 827–29.

²¹⁶ Especially considering patent laws require the patentee to disclose its invention.

²¹⁷ Carrier, *supra* note 33, at 813 (citing Joseph A. Schumpeter, CAPITALISM, SOCIALISM, AND DEMOCRACY (3d ed. 1950)).

should favor policies that will foster and protect innovation. In the case of pharmaceuticals, patent laws should trump antitrust laws.

The competition promoted under the Hatch-Waxman Act does nothing to promote innovation. In fact, precisely the opposite is true. The Hatch-Waxman provisions for generic drug entry are solely concerned with maximizing allocative efficiency by increasing output and lowering prices. Generic bioequivalents, by definition, are replicas of existing products and do nothing to promote new discoveries.

Not only does the Hatch-Waxman Act do nothing to promote innovation, it may actually have a negative effect. Brand-name manufactures may lose investors who doubt the company's ability to recoup its fixed costs of research and development. Lower investment in research and development means fewer discoveries.²¹⁸ In fact, Hughes and colleagues compared the consumer welfare gains from increasing allocative efficiencies to the consumer welfare losses from diminishing research and development.²¹⁹ They found that for every dollar saved by increasing access to generic drugs, consumers lose three dollars in health benefits due to losses in future innovation.²²⁰ Accordingly, an overzealous push for increasing competition through generic entry may eventually hurt consumers more than it helps.

Admittedly, if we presume that Congress struck the optimal balance between short-term and long-term tradeoffs with its patent laws, we must accept that the balance includes the Hatch-Waxman Act's bias towards short-term efficiencies. That does not, however, mean that we should accept that Congress meant to tip the balance so far away from patent protection as to force patent holders to protect the expected consumer surplus level through their settlements. Considering that the Hatch-Waxman Act provides generic challengers incentives to hold out to unreasonable degrees, there must be a check in place that keeps the balance from tipping too far towards short-term gains. Reverse payments, apparently, have become that check.

²¹⁸ Pharmaceutical companies may also turn away from patent protection, where disclosure is required, to more trade secret protection in order to gain a competitive advantage to protect its research and development costs.

²¹⁹ James W. Hughes, Michael J. Moore & Edward A. Snyder, *Napsterizing Pharmaceuticals: Access, Innovation, and Consumer Welfare* 28 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002) ("Thus, our analysis indicates that, while the static gains in consumer surplus are substantial, they are dwarfed by the dynamic losses in consumer surplus that would result from Napsterizing [i.e. an extreme scenario where patent protection is eliminated]. Comparing this figure to the static welfare gain of \$850 billion, the marginal benefit/marginal cost ratio for maintaining the status quo, conditional on our assumptions, is approximately 3 to 1.")

²²⁰ *Id.*

As the court in *Cipro III* noted,²²¹ there are market factors that also put a check on reverse payments. If a patent is inherently weak and encourages generic competitors, the patent holder is less likely to offer reverse payments because it would only encourage more competitors to challenge the patent and seek reverse payments. A patent holder is likely to settle with reverse payments only when it believes it has something worth protecting.

In addition, a ban on reverse payments may backfire and tip the balance away from generic entry. If courts adopt a presumptively illegal approach to reverse payments, more patent holders are likely to protect their inventions by litigating through a complete trial. When a patent holder wins a trial, it can continue excluding the challenger for the remaining life of the patent. Because reverse payments are often combined with negotiated entry dates,²²² if patent holders resolve their cases through complete litigation, consumers will miss out on the chances for earlier generic entry that might have occurred had the parties settled.²²³ A patent holder would still, however, have a net loss, because it had to bear its litigation costs. A ban on reverse payments would, therefore, deprive patent holders of some of the benefits of their innovation without providing comparable gains to the consumer surplus.

CONCLUSION

The Supreme Court decided to let the Eleventh Circuit's decision stand without making any formal decision on the legality of reverse payments in patent infringement settlements. The Court, however, based its denial of certiorari on the Solicitor General's opinion that the facts in *Schering-Plough* were inappropriate to adequately address

²²¹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 534–35 (E.D.N.Y. 2005) (“[W]hile 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 . . . Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. . . . It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.”).

²²² Such was the case in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1059–61 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

²²³ See Michael A. O’Shea, *Which School Are You in? Reverse Payments: The Patent School Versus the Antitrust School*, PATENT WORLD, Dec. 2005/Jan. 2006, at 29 (arguing that banning reverse payments may chill settlements and deprive consumers of competition that may have occurred under settlement); see also *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”).

the complex issue of reverse payment settlements. The Court's decision, therefore, does not resolve the issue and leaves the door open for other legal challenges to reverse payments.

Reverse payments are intuitively suspect given our general aversion to a company paying competitors to stay out of the market. This intuitive aversion must be tempered, however, by a respect for patent laws. Patents, in essence, permit patentees to temporarily circumvent the antitrust laws. The critical issue becomes whether or not the patent holder excludes more competition than the patent allows. Against the general position taken by the federal courts, the FTC would like to place the burden on the patent holder to show that it is justified in making a reverse payment to exclude an alleged infringer. The FTC's position, however, is grounded in unfounded assumptions about the general strength of patents and the ability for settling parties to reach an agreement that maintains an immeasurable level of "expected" competition. Moreover, the FTC's approach myopically focuses only on short-term gains, while ignoring the arguably more important role of patent rights in promoting innovation in the pharmaceutical industry.

STEVEN W. DAY[‡]

[‡] J.D. Candidate 2007, Case Western Reserve University School of Law. M.A. 2003, University of Illinois. I would like to thank Professors Dale A. Nance, Craig A. Nard and Jonathan L. Entin for their helpful guidance and discussions. I would also like to thank Greg Lewis and the Volume 57 Editorial Board for their comments along the way. My deepest gratitude goes to Beth Day, who made it all possible.

