REVERSE PAYMENTS, PERVERSE INCENTIVES

Murat C. Mungan†

ABSTRACT

Issuing and enforcing prescription drug patents requires courts and legislatures to strike a delicate balance. A patent gives drug manufacturers a legal, if temporary, monopoly on sales of a drug; this encourages manufacturers to engage in costly research and development of new medicines. But not all patents issued by the Patent Office are ultimately deemed valid –generic drug manufacturers can infringe the patent, and, when sued, attack its validity in court on a variety of grounds, including obviousness. In recent years, patent holders have begun to settle these suits (which they initiated) by paying the alleged infringer. Not surprisingly, these reverse payment settlements ("RPSs") have been challenged on antitrust grounds. The federal courts of appeals split over whether this practice is presumptively an illegal restraint of trade, and in December 2012 the Supreme Court agreed to decide the issue, granting a writ of certiorari in FTC v. Watson Pharmaceuticals. In light of the importance of the issue to both drug consumers and manufacturers, it is crucial to understand the economic effects of RPSs. Many courts, including the Second Circuit and the Eleventh Circuit, commentators and scholars have suggested that restricting RPSs would necessarily retard technological progress, by reducing the expected returns of becoming a patentee. In this Article, I show, with the help of a game-theoretical model, that this conclusion is unwarranted. Restricting RPSs has the effect of chilling generic entry when—and only when—the underlying patent is strong, or likely to be held valid and infringed. Therefore, restricting RPSs increases the expected returns of holding a strong

† Visiting Assistant Professor of Law, Florida State University College of Law; beginning Fall 2013, Assistant Professor, Florida State College of Law E-mail: mmungan@law.fsu.edu. I would like to thank Mark Lemley, Mark Seidenfeld, Joshua Wright, Jake Linford, Samuel Wiseman, David Landau, Bruce Kobayashi, and David Orozco for useful comments and suggestions, and Nick Horner, Kristan Rivers and Pouyan Bohloul for excellent research and editing assistance.

patent by eliminating potential payments to generic entrants, while at the same time eliminating the possibility of monopoly profit-splitting between branded and generic manufacturers when the patent is weak. This reward shifting effect implies that restricting the use of RPSs is likely to foster more revolutionary innovations, which lead to stronger patents, while lowering R&D towards relatively obvious inventions, which lead to weaker patents. This reward shifting effect of restrictive rules on RPSs has gone unnoticed in the past, and it should play an important role in the Supreme Court's cost benefit analysis.

TABLE OF CONTE0NTS

INTRODUCTION

The Supreme Court granted *certiorari* in *FTC v. Watson Pharmaceuticals* on December 7, 2012[1] in response to the petition by the Federal Trade Commission ("FTC") on the following question:

> Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).[2]

A reverse payment agreement or settlement ("RPS") typically occurs when a patented drug manufacturer "agrees to pay a large sum of money to an accused infringer (its would-be competitor), and the competitor agrees that it will no longer challenge the patent and will not enter the market for a specified period of time."[3] As pointed out by the FTC in its petition, there is an important and recent split among courts regarding the desirability and legality of RPSs,[4] and this split is paralleled by an academic debate among law and economics scholars.[5]

---

[1] *F.T.C. v. Watson Pharmaceuticals, Inc.*, 12-416, 2012 WL 4758105 (U.S. Dec. 7, 2012).

[2] Petition for Writ of Certiorari at I, *F.T.C. v. Watson Pharmaceuticals, Inc.*, 2012 WL 4750283 (U.S.).

[3] *Id.* at II.

[4] *Id.* at 10-11. *See also* Part I. C., *infra*, discussing antitrust litigation involving reverse payment settlements, and the recent split among courts.

[5] Beyond a split in the circuits on the validity of such agreements, a quick search of law review articles on WestLaw using the search term "reverse payment settlements" will produce over 150 articles on the subject. Articles that point out the anticompetitive or welfare reducing potential of RPS include Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, TEX. L. REV. (forthcoming). On the other hand, other articles that discuss the dangers associated with using restrictive rules that make RPS presumptively or per se illegal include Sumanth Addanki and Alan J. Duskin, Patent Settlement Agreements in Issues in Competition Law and Policy, Volume 1 (American Bar Association, 2008); Roger Blair & Thomas Cotter, *Are settlements of patent disputes illegal per se?*, 47 ANTITRUST BULL. 491 (2002); Henry Butler & Jeffrey Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57 (2010); Bret Dickey & Daniel Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. COMPETITION L. & ECON. 615 (2012); james Langenfel & Wnqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J. 777 (2003); Robert

In light of the Supreme Court's decision to grant *certiorari* and the importance of the issue to both the industry and consumers, it is crucial that we properly understand the costs and benefits of RPSs and the effects of restricting their use.

This Article furthers this goal by demonstrating that both judges and academics have erroneously associated a particular dynamic cost with illegalizing RPSs. Specifically, many courts, including the Second and Eleventh Circuits, and legal scholars have argued or assumed that illegalizing RPSs is likely to retard technological progress by making it difficult to maintain monopoly profits on a contested patent, and therefore reducing the reward to becoming a patentee.[6] In this Article, I demonstrate that this conclusion is unwarranted by using a formal game theoretical model to prove that under a range of conditions, restricting RPS increases firms' incentives to engage in research and

D. Willig & John Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

[6] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 256 (E.D.N.Y.2003) ("Moreover, a rule that makes it per se illegal to settle a Hatch-Waxman lawsuit, like the Bayer/Barr patent litigation, limits the options available to both generic and brand-name manufacturers. If brand-name manufacturers are unable to control or limit their risk by settling Hatch-Waxman litigation, they, like generic manufacturers, may be less inclined to invest the research and development ("R & D") costs associated with bringing new drugs to the market. The pharmaceutical industry depends greatly on R & D and the economic returns to intellectual property created when a successful new drug is brought to market."); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003) aff'd, 466 F.3d 187 (2d Cir. 2006), 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), 1308 ("Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. (...) By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation."); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 760 ("A rule prohibiting exit payments may have the unintended effect of increasing the risks of engaging in inventive activity, and therefore lead to a sub-optimal amount of innovation. (...) the patentee would not have created the invention at issue had it not been for her ex ante expectation of legal protection from free-riding"); Dickey & Rubinfeld, *supra* note 5, at 622 ("A settlement makes the brand manufacturer better off (or the brand manufacturer would not have agreed to such a settlement) and as a result increases the incentive to invest in R&D relative to a world in which such settlements are outlawed."); Langfeld & Li, *supra* note 5, at 778 ("These settlements can increase firms' incentive to undertake R&D investment and thus lead to more innovations in the long run. Consequently, there is a consumer welfare trade-off between the tendency of these agreements to increase the prices that consumers pay for existing products and the agreements' ability to stimulate the introduction of new products for future consumption. In many circumstances, a strict per se illegal treatment of such payments would unduly limit the patent holder's ability to protect its intellectual property rights, reducing total consumer welfare in the long run.").

development ("R&D") for a variety of technologies. More specifically, RPSs channel pharmaceutical companies' investment in R&D toward relatively obvious and weak inventions. This channeling or reward-shifting effect, which, to the best of my knowledge, has so far been unnoticed, converts what scholars have previously identified as a dynamic cost[7] of illegalizing RPSs into a potential benefit, and may therefore tip the cost-benefit analysis in favor of making RPSs presumptively illegal, as suggested by the Third Circuit.[8]

The reward shifting is, however, only one of the many ramifications associated with allowing RPSs. To better understand the various effects of RPSs, one must appreciate the circumstances under which such agreements take place.[9] RPSs occur under the peculiar framework structured by the Hatch-Waxman Act ("HWA"),[10] which regulates entry by generic drug manufacturers (hereinafter "*G*") into the patented drug market. The HWA lowers the cost of entry to *G* by allowing him to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA").[11] By submitting an ANDA, *G* essentially skips new and costly clinical trials, which would otherwise be necessary, by demonstrating that its drug is the bioequivalent of a previously approved[12] branded drug. If that branded

[7] *See, e.g.,* Crane, *supra* note 5, 759-762, characterizing this incentive effect as an "Innovation Cost" and stating that "The option to settle patent lawsuits, then, is a valuable right that will make a risk-averse inventor more likely to commit capital to patentable research and development projects. Conversely, the absence of that option will make risk-averse firms somewhat less likely to commit capital to research and development projects. The absence of a non-entry settlement right, therefore, imposes a social cost: some firms will be less likely to commit capital to potentially productive research and development, which is the goal of the patent laws."

[8] *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) ("we will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties. Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.").

[9] *See* Part I.C. *infra*, for brief summaries of the regulatory framework structutred by the Hatch-Waxman Act. *See also* Scott Hemphill & Mark Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L. J. 947 (2011), 951-958; Butler & Jarosch, *supra* note 5; David Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEORGETOWN L. J. 1303 (2010); for other great reviews of the relevant aspects of the Hatch-Waxman Act.

[10] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282).

[11] *See, e.g.,* Butler and Jarosch, *supra* note 5, 63-64 (making a similar observation).

[12] 21 U.S.C. § 355(j)(8)(B) defines bioequivalency.

drug is also patented, and *G* seeks to enter the market prior to patent expiration, then *G* must include a "Paragraph IV" certification in its ANDA stating that the relevant patent is either invalid or will not be infringed by the marketing of the proposed generic drug.[13] This act constitutes patent infringement,[14] which allows the branded drug manufacturer (hereinafter "*P*") to sue *G* for infringement. It is only after this process that the parties (i.e., *P* and *G*) ordinarily agree on a RPS.

In the typical RPS *G* agrees to delay entry in exchange for a large sum of money from *P*.[15] The parties' incentives to reach a RPS can be understood by focusing on the surplus generated by such agreements. When *G*'s entry is delayed, *P* preserves its monopoly or its ability to charge supra-competitive prices for its branded drug. The profit made by *P* alone is greater than the combined profit *G* and *P* would make if they competed against each other.[16] Furthermore, the parties can avoid litigation costs by settling.[17] Therefore, an RPS generates a surplus equal to the difference between monopoly profits and duopoly profits plus litigation costs.[18] A simple application of the Coase Theorem reveals that *P* and *G* have the necessary incentives to reach a settlement to capture and share the surplus generated through this option.[19]

Whether RPSs are pro-competitive, i.e. promote social welfare, or anti-competitive, i.e. detract from social welfare, is a very complex

[13] 21 U.S.C. § 355(j)(2)(A)(vii)(IV). *See,* Part I.B., *infra*, for a brief review of the three other certifications, namely Paragraphs I, II, and III, that a generic entrant may file. This Article is mainly concerned with Paragraph IV certifications.
[14] 35 U.S.C. § 271(e)(2)(A).
[15] The reverse payment in *In Re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), for instance, was $21 million plus a non-exclusive license.
[16] This follows from the simple, and reasonable assumption that mopoly profits are greater than combined duopoly profits. If this assumption were not true, the monopolist could increase its profits simply by dividing itself into two entities, and having them compete against eachother. This would be a violation of the assumption that the monopolist was making monopoly profits.
[17] *See* Part III, infra, for a review of the law and economics literature on settlements. The primary social benefit of settlements is their elimination of litigation costs.
[18] This statement assumes that *G* may enter with certainty. If its likelihood of entry is smaller than unity, then the surplus generated through settlement is proportional to that likelihood. Parts III andIV, *infra*, analyze cases where *G*'s likelihood of entry depends on patent strength, and consider all probabilities of entry.
[19] *See* Part III.B.I., *infra*, formally deriving this result by using an economic model of settlement. This result relies on parties not being relatively over-optimistic. Relative over-optimism is considered in detail in Part IV.D., *infra*.

question and has drawn enormous attention from law and economics scholars in recent years.[20] The literature has generally been quite successful in identifying costs and benefits associated with RPSs and conditions under which such costs or benefits are likely to be significant. Scholars critical of RPSs have pointed out the collusive effect of these arrangements.[21] According to these scholars, RPSs allow *P* to preserve its monopoly, which shrinks the sales volume and increases deadweight loss.[22] On the other hand, other scholars have suggested that some RPSs can have pro-competitive virtues that should be weighed against such costs.[23] These include reducing litigation costs and [24]uncertainty,[25] and allowing liquidity-constrained generic manufacturers to survive until market entry.[26] Furthermore, a line of case law and some prominent scholars have suggested that another cost of illegalizing RPSs is its effect of retarding technological progress by reducing the rewards to becoming a patentee.[27] However, quite surprisingly, there is neither empirical[28] nor sound theoretical

[20] *See, e.g.,* the references cited in note 5, *supra*.
[21] *See, e.g.,* Janis, Hovenkamp & Lemley; Shapiro; Elhauge & Krueger, *supra* note 5.
[22] *See, e.g.* Janis, Hovenkamp & Lemley, *supra* note 5, 1722 ("the parties to an IP dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest with respect to either competition or innovation. Parties to an IP dispute, like parties to a cartel agreement or joint venture, are more interested in maximizing their own profits than enhancing the public welfare."); Elhauge & Krueger, *supra* note 5, 11-12 ("But-for ex post consumer welfare reflects the level of expected consumerwelfare that would have resulted had the particular patents at issue been litigated rather than settled. (...) Because the patentholder can charge a significantly higher price while the potential entrant is excluded from the market, a settlement reduces ex post consumer welfare below but-for levels if the settlement excludes the entrant from the market for a larger portion of the patent's remaining life than one would have expected to result from litigation.")
[23] *See, e.g.,* Blair & Cotter; Butler & Jarosch; Dickey & Rubinfeld, *supra* note 5, and Crane, *supra* note 6.
[24] Crane, *supra* note 6, 749 ("A rule strictly prohibiting payments to settle patent litigation may mean that firms must engage in expensive and inefficient litigation to resolve a patent dispute even though they might be able to avoid the cost of protracted litigation through a settlement. The cost of patent litigation, which may frequently amount to many millions of dollars, will be passed on to consumers like any other cost").
[25] *See, e.g.,* Addanki & Duskin; Butler & Jarosch, supra note 5, and Crane supra note 6, discussing the effects of risk-aversion, and settlements' effects of reducing uncertainty.
[26] *See, e.g.,* Butler & Jarosch, *supra* note 5, 98 ("A reverse payment could solve the problems faced by cash-poor generic drug manufactures by providing an immediate payment that allows the company to survive until it enters the market. To the extent that a given reverse payment allows a generic drug manufacturer to survive and to later market a generic drug when it otherwise would not have been able to do so, reverse payments may have procompetitive rather than anticompetitive effects. A prohibition of reverse payments in such situations would stifle generic entry.")
[27] *See* note 6 *supra*.
[28] There is an "absence of meaningful empirical evidence on the aggregate effects that reverse payments have on competition or output." Butler & Jarosch, *supra* note 5.

support[29] for this last proposition. In fact, as I demonstrate in this Article, illegalizing RPSs may increase rather than reduce the rewards to becoming a patentee for less obvious and more revolutionary inventions, and thereby foster rather than retard technological progress.[30] Thus, there is a fallacy, although subtle, in the reasoning that has lead scholars to conclude that illegalizing RPS is likely to retard technological progress.

To illustrate this subtle fallacy, it is best to start by describing the accurate and correct observations in the literature. Previous commentary and articles on RPSs have correctly identified two points: (i) illegalizing RPSs removes an option which would otherwise be available to *G* and *P*, and (ii) a simple application of the Coase Theorem reveals that the removal of this option reduces the ex-post expected return to *G* and *P*.[31] At first glance, these two observations seem to imply that illegalizing RPSs has the effect of reducing the reward to becoming a patentee by reducing the ex-post expected return.[32]

This deduction contains a subtle error, though. It implicitly assumes that *G*'s decision to challenge *P*s patent is exogenous to the legal regime. However, illegalizing RPSs reduces the ex-post return not only to *P*, but also to *G*.[33] Therefore, when RPSs are illegalized, *G* is expected to challenge *P*'s patent under fewer circumstances. Specifically, *G* is expected to lack the incentives to challenge *P*s patent when *P*s patent is relatively strong, i.e., when *P*s patent is less likely to be invalidated and more likely to be found infringed.[34] Since *P*

[29] Crane, *supra* note 6, and Langenfeld & Li, *supra* note 5, consider some theporetical implications, but they commit the fallacy that I outline in the next paragraph.
[30] Part IV, *infra*, formalizes this result by using a game throretical model.
[31] *See, e.g., Asahi Glass Co. v. Pentech Pharm., 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."); Dickey & Rubinfeld, *supra* note 5, 622 ("settlement makes the brand manufacturer better off (or the brand manufacturer would not have agreed to such a settlement) (...) If the generic does opt to settle rather than litigate, it is clearly better off (otherwise it would not have chosen to settle)").
[32] *See* note 6, *supra*.
[33] This point is also made by Dickey & Rubinfeld, *supra* note 5, and Linda Gratz, *Economic Analysis of Pay-for-Delay Settlements and Their Legal Ruling*, (Working Paper Series, Jan. 4, 2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1979699.
[34] *See* Part II.C., *infra*, and the references cited therein, for a more detailed discussion of patent strength and probabilistic patents.

expects to face fewer challenges when RPSs are illegalized, it expects to save an amount equal to settlement payments that it would otherwise make to *G*. This increases *P*s rewards for becoming an inventor. Therefore, contrary to what has been argued or assumed in court opinions and previous literature, illegalizing RPSs does not reduce the rewards to holding a relatively strong patent; it increases them.

This observation implies that per se legality may not provide the dynamic benefits that scholars have taken for granted. Furthermore, the same observation does not affect the static benefits associated with presumptive illegality previously identified by scholars.[35] Under presumptive illegality, once the parties' ability to make monetary transfers through RPSs is removed, *G* cannot be compensated for delaying entry until patent expiration. Thus, the parties are *forced* into a simple delayed entry settlement ("DES") instead, where *G* enters the market *prior* to patent expiration and no monetary payments are made between parties.[36] This shortens the amount of time in which *P* can charge monopoly or supra-competitive prices, and therefore increases consumer welfare. Moreover, since the parties can avoid litigation through DESs even when RPSs are restricted, the illegality of RPSs has no impact on litigation costs.[37]

Therefore, absent "rare circumstances,"[38] restricting RPSs leads to static benefits without increasing expected litigation costs, and dynamic benefits in the form of increased R&D for relatively stronger inventions. However, in some instances there may be deviations from the standard assumptions used to derive these results, which may make some RPSs pro-competitive.[39] When *G* is liquidity-constrained, for instance, RPSs may be necessary for it to financially survive until it

[35] *See* note 22, supra, and the references cited therein.
[36] *See* Gratz, *supra* note 33; Lemley, Janis, Hovenkamp, supra note 5, making similar observations.
[37] This is true as long as parties are not relatively over-otpmistic. Part IV.D. discusses the effect of relative over-optimism in detail. Lemley, Janis, Hovenkamp, *supra* note 5, 1760-1761, makes a similar point.
[38] I am following the Third Circuit in labeling these circumstances as *rare*. *See In re K-Dur Antitrust Litig., supra* note 8, at 218. Whether or not these circumstances are in fact rare as an empirical matter, is not a question that I attempt to answer in this Article. Therefore, for purposes of this Article *rare circumstances* could be interpreted as instances where there are important deviations from the standard assumptions that are used in this article to derive results.
[39] *See* notes 23-26, *supra*, and accompanying text.

enters the market.[40] The straightforward implication of these observations is that RPSs ought to be prevented absent deviations from circumstances embodied by standard assumptions in the literature, and that the legal use of RPSs ought to be confined to limited circumstances. This can be achieved by a structured rule of reason, similar to that proposed by the Third Circuit in *K-Dur*, which creates a rebuttable presumption of illegality when RPSs are present, and where rebuttal can be achieved by a showing that the RPS furthers some pro-competitive goal.[41]

It should be noted that, just like any economic model, the game-theoretic model presented in Parts III and IV abstracts from potentially relevant issues.[42] Thus this Article does not purport to address every relevant aspect of restricting RPSs. It serves a less ambitious goal, namely to identify a previously unnoticed and positive effect of restricting RPSs. Because circuit courts have assumed or concluded that restricting RPSs are likely to have the contrary effect, it is important to report the findings of this Article before the issue is addressed by the Supreme Court.

The remaining parts of this Article are devoted to more precisely presenting the arguments briefly outlined above, particularly through the use of a game-theoretical model. Part I presents the legal

[40] *See* note 26, *supra*, and accompanying text.

[41] The Third Circuit advocates a quick look rule of reason which makes RPS presumptively illegal. Figuring out the precise quickness with which the rule of reason ought to be applied is not an easy task. As the Supreme Court has "there is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment... What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." California Dental Ass'n v. FTC 526 U.S. 756 (1999), 780-781. Although a single article, including the instant one, cannot provide a complete answer as to how quickly the rule of reason ought to be applied, one can identify factors that ought to go into determining the appropriate quickness. This Article shows that what used to be previously interpreted by courts and scholars as a dynamic cost may, in fact, be a dynamic benefit. The obvious implication is that courts ought to be allowed to demonstrate anticompetitive effects of RPS more quickly than they would be allowed to absent the observations in this Article.

[42] It abstracts for instance, from the issue of at-risk entry, recently addressed by Elhauge & Krueger *supra* note 5, the incentive distortion effect of the 180-day exclusivity period addressed by Hemphill & Lemley *supra* note 9, and it focuses on the interactions between a patentee and a single generic entrant. There is no reason to believe, *a priori*, that the inclusion of these frictions in the model presented in Parts III and IV, *infra*, is likely to diminish the magnitude of the reward shifting effect, they may on the contrary magnify the effect. The one natural extension of the model studied in this Article, for instance, analyzes the effect of parties' imperfect information regarding trial outcomes, and reveals that the reward shifting effect is likely to be magnified. Further research is necessary to determine the effects of these factors.

developments and regulatory framework, which has led the Supreme Court to recently grant *certiorari* on the issue of RPSs. Part II reviews reward theory, the dominant utilitarian approach to studying patent law, and introduces and defines the concept of "probabilistic patents". Reward theory and an understanding of probabilistic patents provide the necessary tools to conjecture how a change in relevant laws is likely to affect potential inventors' incentives to engage in R&D. Part III reviews the economics literature on settlements, which provides the necessary analytical framework to evaluate the relevant parties' incentives to engage in DESs. Part IV uses the insights and analytical tools introduced in Parts II and III to structure a game theoretical model of R&D and settlement. This part demonstrates that illegalizing RPSs can foster technological progress by giving potential inventors' greater incentives to engage in strong R&D, and later discusses the effect of relaxing some of the assumptions employed in the game theoretical model. Part V consists of an appendix containing derivations necessary to prove a few claims.

I. REVERSE PAYMENT SETTLEMENTS AND EXISTING LAW

A. Reverse Payment Settlements

A reverse payment settlement is an agreement between a patent owner and alleged patent infringer. The agreement has the patent owner paying the alleged infringer to stay out of a particular market until the patent owner's patent expires or, at the very least, delay entry. The atypical direction of the settlement payment, namely from patentee to infringer, rather than infringer to patentee, is why the word 'reverse' is used to describe the settlement.[43] After reading this brief description of RPS, two questions should immediately emerge. First, if the patent holder is the legitimate patent owner why would she settle with an alleged infringer – instead of enforcing the legitimacy of a patent through ligation? And the inverse, if the alleged patent infringer believes that the patent owner's patent is invalid, why would

[43] *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 205 (2d Cir. 2006), petition for cert. filed, 75 U.S.L.W. 3333 (U.S. Dec. 16, 2006) (No. 06-830) (explaining why the word 'reverse' is used to describe such payments)

she forego profits by settling – instead of entering the market, providing a cheaper alternative, and reaping the benefits from consumers?

Nowhere are these questions more relevant, and debated, than in the use of reverse payment settlements with pharmaceuticals. In fact, the majority of antitrust challenges to reverse payment settlements are in the context of generic drug companies' challenges of branded drug patents. "Because of the huge drop in drug prices that occurs when such patent challenges succeed and the atypical direction of payment flow, these settlements have garnered much interest from the FTC and others."[44] To put the discussion of reverse payment settlements and pharmaceuticals into context, it will be helpful to understand the regulatory and statutory framework that is the impetus for such agreements, the Hatch-Waxman Act, and its relation to the Food and Drug Administration's process of approving new pharmaceutical's patent.[45]

B. The Hatch-Waxman Act and ANDAs

Under the Federal Food, Drug, and Cosmetic Act, no prescription drug can be marketed prior to gaining approval from the Food and Drug Administration (FDA).[46] The applicant seeking approval files a New Drug Application (NDA),[47] which requires the applicant to go through multiple phases of clinical trials.[48] The process is time intensive and extremely costly.[49] If the FDA approves the NDA, it

[44] Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494 (2007).
[45] Opderbeck, *supra* note 9, contains an excellent review of the regulatory framework generated by the Hatch-Waxman Act, which I have extensively referred to while writing Part I.B., *infra*.
[46] 21 U.S.C. § 355(a)
[47] The NDA must contain detailed information about the drug, including its "composition", "full reports of investigations" about its safety and effectiveness, "full descriptions" of its production and packing processes, and "specimens of the labeling proposed to be used". *Id.* § 355(b) (1).
[48] *See* Gerald J. Mossinghoff, *Overview of the Hatch Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187 (1999); *see also* Dickey, Orszag & Tyson, supra note **Error! Bookmark not defined.**, at 369 ("[r]ecent studies estimate that the average new drug ook 10 to 15 years and cost over $1.3 billion (including both direct costs and opportunity costs) to develop." (notes omitted))
[49] *Id. See also* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151 (2003) (estimating the costs at $802 million) and Salomeh Keyhami, Marie Diener-West & Neil Powe, *Are Development Times for Pharmaceuticals Increasing or Decreasing?*, 25 Health Aff. 461, 463 (2006) (finding the median time for drug development is 6.4 years).

publishes the drug and patent information in a book commonly referred to as the "Orange Book." [50] After all of this, a drug usually reaches the market with a short period of time left on the original patent.[51] However, generic competitors of these branded pharmaceuticals do not have the ability to "pounce" on the market and capitalize on the brief shelf life of these patents. Rather, these generic drug companies are prevented from marketing a competing product unless they meet a statutory exception to the Patent Act.[52]

The Hatch-Waxman Act (HWA) has altered the regulatory context of these policies to pharmaceuticals. Specifically, HWA provided an extension for up to five years on drug patents that were subject to regulatory delay.[53] Additionally, the Act helps generic competitors by exempting them from patent liability for activities associated with regulatory approval and, more importantly, allows for an Abbreviated New Drug Application (ANDA) to show that a generic drug was a "bioequivalent" of a patented drug.[54]

The ANDA allows an applicant to piggyback on the safety and efficacy studies of a patented drug.[55] The ability of a generic company to gain approval of its drug by using an ANDA reduces its regulatory costs.[56] An ANDA that piggybacks on a drug must make one of four "paragraph certifications."[57] Under "Paragraph I," the generic company must certify that no patent information for the brand name drug has been filed with the FDA.[58] For a "Paragraph II" certification, the generic company must show that the patent for the branded drug expired.[59] Under Paragraph I and II, the FDA merely reviews the

[50] 21 U.S.C. § 355 (j)(7)(A); *see also* Hemphill & Lemley, *supra* note 9, at 952 ("Those patents are listed by the brand-name firm in an FDA document commonly known as the Orange Book.")
[51] *See Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study* 4 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf) (last visited December 26, 2012) ("[T]he effective terms of many patents were shortened due to the time required for the FDA to ensure the safety and efficacy of the brand-name company's drug product.")
[52] 35 U.S.C. § 271.
[53] 35 U.S.C. §156(c)(3), (g)(6)(A).
[54] *See* 21 U.S.C §355(j)(2)(A).
[55] *Id.*
[56] Opderbeck, *supra* note 9, at 1307.
[57] *F.T.C. v. Watson Pharmaceuticals*, 677 F.3d 1298, 1303 (11th Cir. 2012).
[58] 21 U.S.C. §355(j)(2)(A)(vii)(i).
[59] *Id.* §355 (j)(2)(A)(vii)(ii).

ANDA and makes its approval or denial decision.[60] Under "Paragraph III," the applicant must demonstrate that a patent will terminate on a certain date and the FDA places the application on hold until that expiration date. [61] Of greater import is the incentives for potential generic competitors to challenge drug patents before they expire, which happens under a "Paragraph IV" certification. If the ANDA applicant files a Paragraph IV certification, he "certifies that the challenged patent is invalid or will not be infringed by the generic version. The first filer of a Paragraph IV certification receives a 180-day period of generic market exclusivity."[62]

Under Paragraph IV, there are many moving parts. The applicant must provide notice to the pharmaceutical company of its challenge of the branded drugs patent.[63] After the notice, the challenged pharmaceutical company has 45 days to respond by filing an infringement lawsuit against the ANDA applicant.[64] If the patent holder fails to sue, the FDA proceeds with its approval of the generic drug.[65] However, if the suit is timely filed the FDA delays approval for 30 months to allow resolution through litigation or settlement.[66]

The typical RPS under Hatch-Waxman occurs after the generic manufacturer files a Paragraph IV certification ANDA, and involves an agreement by the generic company not to market a generic version of a branded pharmaceutical in exchange for a monetary payment from the branded manufacturer.[67]

---

[60] *Id.* §355(j)(5)(B)(i) ("If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.")

[61] *Id.* §355 (j) (5)(B)(ii), (2)(A)(vii)(ii).

[62] *Id. See also* Hemphill & Lemley, *supra* note 9 (discussing the incentives provided to generic manufacturers through the 180-day exclusivity period).The model in Parts III and IV, *infra*, does not formally incorporate the 180-day exclusivity period to focus on the 'reward shifting effect' of illegalizing RPS, which is discussed in Part I.V., *infra*.. The effects of this exclusivity period, and potential reforms are discussed in detail in Hemphill & Lemley, *supra* note 9.

[63] 21 U.S.C. §355(j)(2)(B).

[64] *Id.* §355(j)(5)(B)(iii).

[65] Id.

[66] *Id.*

[67] See Matthew Avery, Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments, 60 Hastings L.J. 171, 191-194 (2008); and Christopher M. Holman, Do Reverse Payment Settlements Violate the Antitrust Laws?, Santa Clara Computer & High Tec. L.J. 489, 494-500 (2007).

C. Litigation Involving Reverse Payment Settlements

The circuit courts of appeals produced conflicting opinions on the implications and potential violations of antitrust laws. The Federal,[68] Second,[69] and Eleventh[70] Circuits adopted permissive tests, which do not consider the existence or amount of reverse payment as a factor in determining the legality of a settlement agreement. The Sixth Circuit, found that a RPS that did not settle the underlying patent litigation was per se illegal.[71] And finally, the Third Circuit adopted a test making RPS presumptively illegal.[72]

1. The Second Circuit

The patent *In Re Tamoxifen Citrate Antitrust Litigation* covered a "block-buster cancer drug"[73] by Zeneca and the original infringement litigation was based on generic manufacturer Barr's Paragraph IV filing, in which the patent was found invalid because the patent holder withheld testing information from the patent office.[74] "[W]hile the appeal was pending, the parties entered into a confidential settlement agreement … where Zeneca … and Barr agreed that in return for $21 million and a non-exclusive license … Barr would … [agree to] not market its own generic version of tamoxifen until Zeneca's patent expired in 2002."[75]

The Second Circuit, in review of the district court's dismissal of plaintiff's complaint, noted their "longstanding adherence to the principle that courts are bound to encourage the settlement of litigation."[76] The court also stated *that settlements promote certainty, which in turn sparks innovation* – the ultimate goal of patent law and regulation.[77] Focusing on the risks generated for patented drug

[68] *In Re Ciprofloxacin*, 544 F.3d 1323, 1328-1332 (Fed. Cir. 2008).
[69] *In Re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006);
[70] *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005).
[71] *In Re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 902 (6th Cir. 2003).
[72] *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012)
[73] Opderbeck, *supra* note 9, at 1308.
[74] *In Re Tamoxifen Citrate Antitrust Litig.*, *supra* note 69 at 193.
[75] *Id.* at 202 (internal quotation marks and citation omitted).
[76] *Id.* 197-199
[77] *Id.* at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.")

manufacturers under the HWA regulatory framework, the court claimed that it is natural to observe RPSs resolving litigation arising from Paragraph IV certifications.[78] The court refused to find RPSs presumptively illegal, even in situations where the amount of the reverse payment is "excessive",[79] and agreed with the Eleventh Circuit's conclusion in *Valley Drug Co. v. Geneva Pharms., Inc.*[80] that a payment from the branded manufacturer to a generic competitor "cannot be the sole basis for a violation of antitrust law".[81]

After noting that the existence of a reverse payment and its amount are irrelevant for purposes of determining the legality of a settlement the court agreed with the statement in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*[82] that an RPS is legal "absent an extension of the monopoly beyond the patent's scope",[83] "absent fraud", [84] and as long as the "lawsuit was [not] objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits".[85] Applying this test to the particular case, the court noted that fraud was not alleged, and that "the plaintiffs do not contend that they can … establish that Zeneca's claim was baseless."[86] Thus, the only remaining question was whether there was "an extension of the monopoly beyond the patent's scope".[87] In finding that there was no such extension, the court focused on three things: (i) that the RPS "did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products,"[88] (ii) that the RPS "ended all litigation between Zeneca and Barr,"[89] and (iii) that "they did not entirely foreclose competition because they allowed Barr to market Zeneca's version of Tamoxifen". [90]

[78] *Id.* at 206-207.
[79] *Id.* at 208-213.
[80] *Valley Drug*, *supra* note 6.
[81] *In Re Tamoxifen Citrate Antitrust Litig.*, *supra* note 69 at 212.
[82] In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F.Supp.2d 514 (E.D.N.Y.2005).
[83] *In Re Tamoxifen Citrate Antitrust Litig.*, *supra* note 69 at 213.
[84] *Id.*
[85] *Id.*
[86] Id.
[87] *In Re Tamoxifen Citrate Antitrust Litig.*, *supra* note 69 at 213.
[88] Id.
[89] *Id.* at 215.
[90] *Id.* at 223 (Judge Pooler summarizing the third factor analyzed by the majority in determining that the scope of the patent was not extended through the settlement).

The Tamoxifen test was later applied, despite being criticized, by the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*.[91] The court stated: "Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud. Thus, the only reasonable basis for distinguishing Tamoxifen would be if plaintiffs demonstrated that the settlement agreement here, unlike in Tamoxifen, exceeded the scope of the Cipro patent. Plaintiffs cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent." [92] The court refused to address the defendants' policy arguments because they were "bound by *Tamoxifen* absent a change in law by higher authority or by way of an in banc proceeding."[93] Nevertheless, the court explicitly voiced its concerns regarding the *Tamoxifen* rule: "[W]e believe there are compelling reasons to revisit Tamoxifen with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc."[94] Following the court's suggestion the plaintiffs petitioned for hearing in banc, but their petition was denied.[95]

In crafting the *Tamoxifen* rule, which was subsequently criticized, the court relied heavily on the assumption that RPSs would foster. This is revealed by the court's lengthy discussion of the need to, as Judge Pooler, the only dissenter in the case, states, "balance the interests at stake in this litigation. These interests include, *on one side, the encouragement of innovation fostered by the patent laws*, the public and private interest in amicable settlements, and judicial economy; and, *on the other side, an interest in vigorous competition protected* by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated."[96]

[91] Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010).
[92] *Id.* at 106.
[93] *Id.* at 108.
[94] *Id.* at 111.
[95] Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir. 2010).
[96] *Id.* at 221 (emphasis added).

2. The Federal Circuit

In Re Ciprofloxacin, pharmaceutical companies, Barr and Bayer, entered into a RPS, which included a delay to enter the market until six months before Bayer's patent expired and provided a supply of the drug to Barr for resale.[97] Bayer successfully defended against other Paragraph IV litigation by other generic drug manufacturers post the agreement with Barr.[98] Subsequently, consumers and advocacy groups challenged the settlement between the two companies on antitrust grounds.[99]

In reviewing the district court's finding that the RPS did not violate the Sherman Act, the court characterized the district court's analysis as one using the full rule of reason, and approved its use.[100] Furthermore, the court noted it was proper for the district court to conclude "that the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent"[101] because "there was no evidence that the Agreements created a bottleneck on challenges to the … patent or otherwise restrained competition outside the exclusionary zone of the patent."[102] Accordingly, the court concluded that any anti-competitive effects that are within the "exclusionary zone" of the patent cannot be taken into consideration while conducting a rule of reason analysis.

3. The Eleventh Circuit

In *Schering-Plough Corp. v. F.T.C.*, [103] the court reviewed the FTC's invalidation order of two settlement agreements between Schering-Plough and two generic manufacturers. The FTC's order required the parties to "cease and desist from being parties to any agreement

[97] *In Re Ciprofloxacin*, 544 F.3d 1323, 1328-1332 (Fed. Cir. 2008).
[98] *Id.* at 1329.
[99] *Id.* at 1329-1330.
[100] *Id.* at 1332
[101] *Id.*
[102] *Id.* (internal quotation marks omitted)
[103] *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005). In a later case in the same year, namely, *Andrx Pharmaceuticals v. Elan Corp.*, 421 F.3d 1227, 1230-31 (11th Cir. 2005), the Eleventh Circuit agreed that the plaintiff supplied enough facts to get past the pleading stage for an antitrust claim. *See* Opderbeck, *supra* note 11 at 1315 (briefly summarizing *Andrx Pharmaceuticals v. Elan Corp.*).

settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time."[104] The FTC deemed any agreement satisfying these two prongs to be an unlawful restraint on trade, unless "payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement."[105]

The Eleventh Circuit rejected the FTC's approach, and noted that "neither the rule of reason nor the *per se* analysis is appropriate"[106] in analyzing RPS cases. Instead the court applied a test focusing on three factors to determine whether a settlement agreement was anticompetitive; "(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."[107]

In applying this test, the court initially focused on the patent in question, and concluded that "without any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product."[108] The court then turned to the second prong of the test, and found that the agreements do not exceed the scope of the patent's exclusionary power, which ultimately led to the conclusion that they do not violate antitrust laws.[109]

The court's decision to apply this test was guided to an important extent by its concern that "antitrust liability might undermine the encouragement of innovation."[110] According to the court, "a rule that forecloses a patentee's ability to settle its infringement claim … may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research,

[104] *Schering-Plough Corp. v. F.T.C., supra* note *103* at 1058.
[105] *Id.* at 1062.
[106] *Id.* at 1065.
[107] *Id.* at 1066 (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003)).
[108] *Id.* at 1068
[109] *Id.* at 1076 ("Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.")
[110] *Id.* (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003))

develop, and market the patented product or allegedly infringing product."[111]

4. The Sixth Circuit

In Re Cardizem CD Antitrust Litigation, Andrx entered an agreement in which it would refrain from marketing a generic version of a branded drug while the underlying patent infringement litigation was pending in exchange for quarterly payments "beginning on the date Andrx received final FDA approval."[112] The infringement litigation settled after two years, and was accompanied by a termination of the initial agreement.[113] Two weeks later, Andrx began to market a generic version, at which time its 180-day exclusivity period began to run.[114] To summarize briefly, the initial agreement did not settle the underlying infringement claim, enabled Andrx to preserve its 180-day exclusivity rights, and eliminated competition for the branded manufacturer until the parties eventually settled.

The Sixth Circuit agreed with the district court that the agreement was a per se illegal horizontal restraint of trade;

> [t]here is simply no escaping the conclusion that the agreement… was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade… It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.[115]

It is very important to note that the agreement analyzed by the Sixth Circuit cannot be characterized as a typical RPS, because it does not settle the underlying patent infringement case. The court made

[111] *Id.* 1075
[112] 332 F.3d 896, 902 (6th Cir. 2003).
[113] *Id.* at 903.
[114] *Id.*
[115] *Id.* at 908.

the same observation when it stated that "the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation."[116] Therefore, the *per se* illegality approach –when the agreement does not settle the underlying litigation— of the Sixth Circuit should not be interpreted as being in tension with the relatively permissive approaches adopted by the Federal, Second, and Eleventh Circuits. To the contrary, the agreement *In Re Cardizem CD Antitrust Litigation* can be thought of as one involving an agreement beyond the exclusionary zone or the scope of the patent, and would presumably be found illegal also under the tests applied by these circuit courts.

5. The Third Circuit

In re K-Dur Antitrust Litig., the Third Circuit addressed a series of reverse payment settlements between Schering-Plough and generic drug manufacturers, Upsher and ESI, for a controlled release potassium chloride drug.[117] The significance of the decision had less to do with the particulars of the actual agreements between the parties and more on how the Third Circuit evaluated reverse payment settlements in light of antitrust implications versus other circuits. The court argued that those circuits that relied upon the scope of the patent to uphold reverse payment settlements between drug manufacturers improperly restricted the application of antitrust law.[118] The argument focused on the process of patenting a drug and the strength of patents in general.[119] The court highlighted that a number of "patents issued by the [Patent Trademark Office (PTO)] [were] later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch–Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time."[120]

[116] *Id.* 908.
[117] *In re K-Dur Antitrust Litig.,* 686 F.3d 197, 202 (3d Cir. 2012)
[118] *Id.* at 214.
[119] *Id.*
[120] *Id.* at 214-25. See FTC, Generic Drug Entry Prior to Patent Expiration 16 (2002), available at http://www.ftc.gov/os/2002/07/genericdrug study.pdf; Kimberly A. Moore, Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box, 99 Mich. L. Rev. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial).

Additionally, the court countered the secondary argument from these circuits, which placed undue weight on the ability of subsequent challengers to weed out weak patents as a legitimizing factor for these agreements. The court reasoned that the first challenger had the greatest incentive to attack a weak patent because of the 180-day exclusivity and that the reverse payment settlement eliminated that advantage to the detriment of subsequent challengers.[121] Further, any arguments that a monopolist could not "buy off" subsequent challengers with its high profit margins from the branded pharmaceutical were untenable.[122]

For these reasons, the court rejected the scope of the patent test in favor of a quick look rule of reason analysis. Using the quick look analysis, "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[123] The court remanded the case back to the district court for the application of this analysis.[124]

6. The Supreme Court

On December 7, 2012, the U.S. Supreme Court granted a *writ of certiorari* on the question of "whether reverse-payment agreements are per se lawful, unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are they presumptively anticompetitive and unlawful."[125] The FTC, appealing the decision against it by the Eleventh Circuit Court of Appeals in *FTC v. Watson Pharmaceuticals*, filed the petition.[126] The Eleventh Circuit, applying the Exclusionary Zone Test from *Schering-Plough Corp. v. FTC*, held

[121] *Id.* at 215.
[122] *Id. See King Drug Co. of Florence, Inc.,* 702 F.Supp.2d at 521–22 (drug manufacturer settled infringement suits by four generic firms, which agreed to delay market entry "in exchange for significant payments ... for various licensing agreements, supply agreements and research and development deals")
[123] *Id.* at 218.
[124] *Id.*
[125] *F.T.C. v. Watson Pharmaceuticals, Inc.,* 12-416, 2012 WL 4758105 (U.S. Dec. 7, 2012).
[126] F.T.C. v. Watson Pharmaceuticals, Inc., 677 F.3d 1298 (11th Cir. 2012).

that absent sham litigation or fraud in obtaining a patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the patent.[127] The FTC claimed that the settlement between three manufacturers was simply a tool to avoid judgment that the challenged patent was either invalid or would not be infringed upon by a generic equivalent, allowing the companies to divvy up the profits from an unlawful monopoly.[128]

II. UTILITY OF PATENTS, REWARD THEORY AND ITS APPLICATION IN THE PHARMACEUTICAL SECTOR, AND PROBABILISTIC PATENTS

This Article focuses upon the "most common"[129] utilitarian theory of patents, namely reward theory. [130] Aside from its known properties as a moral theory,[131] utilitarianism is the dominant approach courts use to evaluate the social desirability of competing antitrust rules[132] and is the "most popular"[133] approach or "the principal philosophical theory"[134] to studying intellectual property rights.[135]

---

[127] *Id.* at 1311.
[128] *Id.* at 1305.
[129] See William Fisher, *Theories of Intellectual Property*, in New Essays in the Legal and Political Theory of Property 178 (2001)
[130] *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 310-313 (1992) (providing a brief review of the historical developments in reward theory, and distinguishing between the strong and weak forms of reward theory).
[131] Unlike non-welfarist assessments, Utilitarianism satisfies the Pareto principle, meaning that if there are two potential outcomes A and B, where A provides greater utility to each individual in society, it ranks A higher than B. *See* Louis Kaplow and Steven Shavell, *Any Non-Welfarist Method of Policy Assessment Violates the Pareto Principle*, 109 J. POL. ECON. 281 (2001) ("show[ing] … that any non-welfarist method of policy assessment violates the Pareto principle"). For a lengthy and technical discussion of utilitarianism as a theory of distributive justice, *see*, John Roemer, THEORIES OF DISTRIBUTIVE JUSTICE 127-162 (1996).
[132] *See, e.g. Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) ("Congress designed the Sherman Act as a "consumer welfare prescription"").
[133] Fisher, *supra* note 129, at 169. *See also* Peter S. Menell, *Intellectual Property: General Theories*, in ENCYCLOPEDIA OF LAW AND ECONOMICS 129 (Bouckaert, Boudewijn and De Geest, Gerrit eds., 2000), available at http://encyclo.findlaw.com/tablebib.html (stating "Not surprisingly, the principal philosophical theory applied to the protection of utilitarian works - that is, technological inventions - has been utilitarianism").
[134] *Id.*
[135] Other, non-utilitarian, theories of intellectual property described in Fisher, *supra* note 129, include: (i) the Lockean approach, which stems from the idea that people who add value, through their labor, to previously unclaimed resources are entitled to the products of their labor, (ii) the Kantian/Hegelian approach, which suggests that property rights ought to be allocated to enable individuals to fulfill primary human needs, including creativity, and (iii) a version of legal

Within the utilitarian approach to intellectual property, there are several competing and complementary approaches.[136] The most prominent theories are (i) reward theory, (ii) prospect theory, and (iii) commercialization theory. These theories have in common the normative goal of maximizing social welfare. The utilitarian theories diverge, however, in their assessment of how to achieve this normative goal, which economic tradeoffs are fundamental, and which of the various patent functions are to be given the greatest emphasis. Among these three theories, the reward theory is the "most common one",[137] and is applied frequently, either explicitly or implicitly, to study the desirability of various features of the patent system. Its intuitive appeal is most likely the reason for its popularity among law and economics scholars. In Section II.A., I briefly describe the main features of reward theory, consider its critiques, and discuss the applicability of these critiques when reward theory is specifically applied to R&D in the pharmaceutical sector. Section II.B. very briefly discusses other utilitarian theories and comments on why it is relatively harmless to focus exclusively on reward theory. In Section III.C. I explain how patents do not confer a right to exclude with certainty, but only probabilistically. The higher the probability of exclusion the 'stronger' is the patent. The fact that patents have varying degrees of strength has important consequences in the application of reward theory to studying reverse payments settlements.

A. Reward Theory

Reward theory posits the primary benefit of issuing patents is to provide incentives to potential inventors to engage in R&D activity. Without patents, the fundamental economic problem is that, as Posner observes, "the manufacturer will not make the invention in the first place; he won't sow if he won't be able to reap."[138] The benefits of the patent from this perspective are the dynamic incentive to innovate that, in turn, fuels economic growth.

realism, which focuses on "foster[ing] the achievement of a just and attractive culture" (Fisher, supra note 129 at p. 172)

[136]See Mark A. Lemley, *The Myth of the Sole Inventor* (Stanford Public Law Working Paper, No. 1856610, July 21,2011) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1856610 for another review of competing utilitarian theories.

[137]Fisher, *supra* note 129, at 178.

[138] Richard A. Poser, ECONOMIC ANALYSIS OF LAW, 48 (8th ed. 2011).

There are also well-known social costs associated with the patent system. The primary cost arises from the patentees' ability to prevent others from legally making, using or selling the patented product. This confers patentees a degree of market power by limiting competition, which leads to deadweight loss. Economists and legal scholars have long recognized the competing goals of reducing such costs and increasing overall R&D activity.[139]

Early works focusing on these competing goals have identified various instruments which can influence these costs and benefits. Most obviously, increasing the duration of patents from twenty years to twenty one years, for instance, is hypothesized to increase R&D activity by making the prize for potential patentees larger. Lengthening patent duration also comes at the cost of conferring additional market power to patentees. This use-creation tradeoff[140] is the focal point of a great deal of patent research.[141] It has been applied to study the optimal duration[142] and breadth of patents,[143] as well as the desirability of various aspects of patent regimes, including the

[139] *See, e.g.,* William D. Nordhaus, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969); Richard Gilbert and Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON 106 (2010) (studying the optimal patent duration, and more generally optimal patent structure, by focusing on similar trade-offs).

[140] The use-creation trade-off refers to the "the inevitable production of dead-weight loss in the ex-post market for the invention for the purpose of fostering technological progress." Murat C. Mungan, *Less Protection, More Innovation?* (Supreme Court Economic Review, Forthcoming; FSU College of Law, Public Law Research Paper No.507, March 27, 2012) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1865949. *See also* Michelle Burtis & Bruce Kobayashi, *Intellectual Property & Antitrust Limitations on Contract*, in DYNAMIC COMPETITION AND PUBLIC POLICY: TECHNOLOGY, INNOVATION AND ANTITRUST ISSUES 229, (J. Ellig, ed., Cambridge University Press (2001)) (using the same phrase, *i.e.* "use-creation", to refer to this trade-off").

[141] See, e.g., Stephen Maurer & Suzanne Scotchmer. Independent Invention Defence in Intellectual Property, 69 ECONOMICA 535 (2002); Samson Vermont Independent Invention as a Defense to Patent Infringement, 105 MICH. L. REV. 475 (2006); Mark Lemley, Should Patent Infringement Require Proof of Copying?, 105 MICH. L. REV. 1525 (2007); Economics of the Independent Invention Defense Under Incomplete Information, 20 SUP. CT. ECON. REV. 183 (2012); Carl Shapiro, Prior User Rights, 96 AM. ECON. REV. 92 (2006); Emerick Henry. Runner-up Patents: Is Monopoly Inevitable?, 112 SCANDINAVIAN J. ECON. 417 (2010);

[142] *See, e.g.* Nordhaus, *supra* note 139; Gilbert & Shapiro, *supra* note 139.

[143] *See, e.g.* Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113 (1990); ; Gilbert & Shapiro, *supra* note 139.

independent invention defense,[144] runner-up patents,[145] prior user rights,[146] and probabilistic enforcement of patents.[147]

This framework highlights a second and important cost that fits well within the framework of reward theory. Stronger patents, by increasing the expected value of the patent to patentees, may encourage more firms to incur duplicative R&D costs,[148] which can in turn be interpreted as a species of rent-seeking activity.[149] The mere presence of rent-seeking activity, however, need not dramatically alter the main implications of reward theory. Rent seeking costs can simply be regarded as costs in addition to 'use' costs that increase in the strength of the patent. As such, the main question identified in reward theory is preserved: How much rent-seeking plus 'use' costs must be incurred to incentivize the creation of new products and ideas?

The reward theory is the "most common"[150] utilitarian approach to studying patents, but has been criticized for drawing an incomplete picture of the patent system. The simplest form of the reward theory does not account for the fact that broad patents on complementary technologies, each of which is necessary for a new product, may lead to hold-up problems.[151] Moreover, there is some empirical evidence

[144] *See, e.g.,* Mungan, *supra* note 140; Mungan *supra* note 141; Maurer & Scotchmer *supra* note 141; Vermont *supra* note 141.
[145] *See, e.g.,* Henry *supra* note 141.
[146] *See, e.g.,* Shapiro *supra* note 141.
[147] *See, e.g.,* Mark Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75 (2005).
[148] *But see*, Mungan, *supra* note 140 (providing a proof that greater expected rewards need not foster innovation).
[149] On rent-seeking, *see* Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft,* 5 W. ECON. J. 224, 231 (1967). *See also*, Yoram Barzel, *Optimal Timing of Innovations*, 50 REV ECON. & STATISTICS 348 (1968) (arguing that rent-seeking may lead to sub-optimally early invention efforts in addition to duplicative research costs).
[150] Fisher *supra* note 129, at 178.
[151] *See, e.g.,* Nancy Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. ECON. PERSPECTIVES, 131, 132 (2002); ("This [disclosure] benefit of patents must be balanced against the social costs that arise because the disclosed inventions are not freely available during the patent term: patented inventions will be used too little, may hold up subsequent research on related inventions and may generate substantial transaction costs from costly legal challenges about possible infringement.")Joseph Farrell, John Hayes, Carl Shapiro & Theresa Sullivan, *Standard Setting, Patents, and Hold-Up*, 74 ANTITRUST L. J. 603, 604 (2007) ("We discuss the risk of hold-up when standard-setting organizations (SSOs) include patented technology in standards. We focus on the mechanism of, and techniques for avoiding, inefficient patent hold-up"). Similarly broad patents can retard technological progress by blocking secondary inventors from using the patented technology for the invention of a newer technology. The cumulative invention framework, proposed by Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative*

contradicting the implications of reward theory. The theory suggests that increasing the reward associated with becoming a patentee necessarily leads to faster technological progress.[152] There are recent empirical studies suggesting otherwise, namely that stronger patent protections do not necessarily lead to more innovation.[153]

However, a more detailed survey of the existing empirical work on patents and innovation highlights a peculiar characteristic of R&D in the pharmaceutical sector. Specifically, decision makers in the pharmaceutical sector appear to be affected by the availability and strength of patents the most,[154] and many have stated that they would not have developed a new product if patent protections were not available.

This interesting fact is explained by the 'discrete'[155] nature of most technologies in the pharmaceutical sector. This aspect of the pharmaceutical sector is best described by the well-known study by Cohen, Nelson and Walsh:[156]

> [T]he key difference between a complex and a discrete technology is whether a new, commercializable product or process is comprised of numerous separately

Research and the Patent Law, 5 J. ECON. PERSPECTIVES 29 (1991) can be used to account for this possibility.

[152] *See,* Adam Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RES. POL'Y 531, 545 (2000) ("a generalized increase in patent breadth or scope, holding all else equal, unambiguously increases the innovation rate, because it does not affect the incentives of subsequent potentially infringing inventors"). *But see*, Mungan *supra* note 139 (showing that if coordination effects are considered, theoretically, more protection can lead to less innovation).

[153] *See, e.g.,* Lee Branstetter & Mariko Sakakibara, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms*, 32 RAND J. ECON. 77 (2001) ("Interviews with practitioners and professional documents for patent agents suggest the reforms significantly expanded the scope of patent rights. However, econometric analysis using both Japanese and U.S. patent data on 307 Japanese firms finds no evidence of an increase in either R&D spending or innovative output which could be plausibly attributed to patent reform").

[154] Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* (Nat'l Bureau of Econ. Research, Working Paper No. 7552, February 2000) available at http://www.nber.org/papers/w7552.

[155] *Id.* at 19. *See also* Ken Kusunoki, Ikujiro Nonaka, and Akiya Nagata, *Organizational Capabilities in Product Development of Japanese Firms: A Conceptual Framework and Empirical Findings*, in 9 ORGANIZATION SCIENCE 699 (1998); Don Kash and William Kingson, *Patents in a World of Complex Technologies*, 28 SCI. & PUB. POL'Y 11 (2001) (distinguishing between complex and discrete technologies).

[156] *Id.*

> patentable elements versus relatively few. New drugs or chemicals typically are comprised of a relatively discrete number of patentable elements. In contrast, electronic products tend to be comprised of a larger number — often hundreds— of patentable elements and, hence, may be characterized as complex.

Given the discrete nature of most products in the pharmaceutical industry, the application of the reward theory appears to be less problematic than in other industries. This is perhaps why most studies analyzing the desirability of reverse payment settlements focus, implicitly or explicitly, on the reward theory of patents.

B. Other Utilitarian Theories of Patents

1. Prospect Theory

Prospect theory was first developed by Edmund Kitch in 1977.[157] This theory "conceives of the process of technological innovation as one in which resources are brought to bear upon an array of prospects".[158] According to Kitch, granting broad patent rights to patentees enables them to coordinate research efforts that build upon the initially patented technology, and therefore provides incentives to "further develop the field".[159] Aside from increasing overall output, such coordination is socially desirable, as it eliminates rent-seeking and therefore potentially excessive development costs by third parties.[160]

To structure his arguments, Kitch analogizes the patent system to the mineral claim system, which "permitted one who found mineralization on the public land to file a claim which gave him the exclusive right to develop the claim."[161] According to Kitch, this system had the effect of incentivizing "prospectors to pack their burros and

[157] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).
[158] *Id. at* 266.
[159] Lemley, *supra* note **Error! Bookmark not defined.**, at 60.
[160] *See also* Posner, supra note **Error! Bookmark not defined.**, at 49 (providing a brief review of his theory).
[161] Kitch, *supra* note 157, at 271.

walk off into the desert in search of mineralization," but it also had the effect of increasing mineral output.[162]

Mark Lemley contests the empirical accuracy of this analogy. Lemley contends that one of the primary purported benefits identified by prospect theory does not exist. Unlike the analogized mineral claims case, the historical "evidence suggests that strong patent control significantly impedes both commercialization and improvement of new technologies."[163] Furthermore, there are well known costs to having strong patents that are ignored in Kitch's framework. In particular, granting strong patents runs the risk of retarding technological progress by preventing other firms from working on development of technologies that build on the patented invention.[164] Furthermore, although strong patents may eliminate rent-seeking efforts for such secondary inventions, they may increase rent-seeking activity for the initial invention. In light of these observations, scholars have heavily criticized prospect theory,[165] and discounted its ability to provide a rationale for why we have a patent system.[166]

The dispute on whether Kitch's analogy is misplaced or whether it is appropriate is one that is unlikely to be settled by a single article. It appears, however, that the applicability of prospect theory, assuming it is a valid theory, depends on the inventive process being relatively complex, rather than discrete, because it relies on R&D resources to be "brought to bear upon an array of prospects".[167] Given that the pharmaceutical industry involves relatively discrete technologies,[168] abstracting from issues related to prospect theory appears to be less harmful than in other sectors.

---

[162] *Id.* at 274.
[163] Lemley, *supra* note **Error! Bookmark not defined.**, at 74.
[164] Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 871-878 (1990).
[165] *See, e.g.,* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005); Merges & Nelson, *supra* note 164.
[166] *See, e.g.,* Lemley, *supra* note **Error! Bookmark not defined.**.
[167] Kitch, *supra* note 157, at 266.
[168] *See* note **Error! Bookmark not defined.** *supra* and accompanying text.

2. Commercialization Theory

Commercialization "refer[s] to the transformation of an innovative or creative idea or design (be it patentable or copyrightable) into a commercially viable product or method that some end-user can actually put into practice".[169] Theories focusing upon commercialization stress that individuals' incentives to invent may diverge from their incentives to commercialize their inventions. As evidence for such divergence, these scholars point out that an important proportion of patented inventions are not commercialized.[170]

Michael Abramowicz suggests that patentees may choose not to exert the appropriate effort to commercialize their inventions if their patents are sufficiently close to expiring at the time commercializing the invention becomes "potentially attractive".[171] Similarly, there is some empirical evidence to suggest that "being refused a patent reduces the likelihood of commercialization".[172] To solve such problems, commercialization scholars have proposed somewhat unorthodox methods. Abramowicz and Duffy, for instance, that commercialization difficulty ought to be a factor in determining patentability.[173] Similarly, Ted Sichelman suggests that "commercialization patents," in addition to traditional patents, ought to be awarded to incentivize interested parties to develop existing inventions further.[174]

Mark Lemley, on the other hand, suggests that "commercialization theory [does not] offer a reason to grant broad patent rights to an inventor even though the patent wasn't necessary to induce the invention."[175] Lemley's criticism focuses upon the empirical observation that "[o]rdinary economic rents, coupled with non-patent advantages such as first-mover benefits and brand reputation, have long proved

[169] Ted M. Sichelman, *Taking Commercialisation Seriously*, 33 EUR. INTELL. PROP. REV. 200 (2011)
[170] Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, (2010) ("About half, probably more, of all patented inventions in the United States are never commercially exploited.")
[171] Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065 (2007).
[172] Elizabeth Webster & Paul H. Jensen, *Do Patents Matter for Commercialization?*, 54 J.L. ECON. 431, 447 (2011).
[173] Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. Rev. 337 (2008).
[174] Sichelman, *supra* note 170, at 346.
[175] Lemley, *supra* note **Error! Bookmark not defined.**, at 62.

sufficient to encourage entry into new markets even in the absence of patent protection."[176]

Unsurprisingly, there is no consensus as to whether under-commercialization is a real and significant problem in general.[177] Fortunately, for purposes of studying reverse payment settlements, an answer to a much narrower question is required: Is under-commercialization a significant problem in the pharmaceutical sector? The answer to this question appears to be negative. There is empirical evidence suggesting that there is very little variation, less than 8%, between the proportion of inventions that would not have been developed and the proportion of inventions which would not have been commercialized if patent protection could not have been obtained.[178] Given this fact, abstracting from commercialization theory and focusing on reward theory appears to be less problematic in the pharmaceutical sector than in other sectors.

C. Probabilistic Patents: Weak Patents v. Strong Patents

Many scholars tend to consider a hypothetical and idealized patent when discussing the optimality of various policies. The hypothetical "idealized" or "ironclad" patent[179] gives the patentee the right and ability to stop others from making, using or selling the patentee's invention with certainty. A real patent, however, is a far less valuable object than the ironclad patent.[180] The likelihood that an ordinary patent, once challenged, will be found to be partially or entirely invalid

[176] *Id.* at 63.

[177] A very recent article, Webster & Jensen, *supra* note 172, asks whether patents have an effect on commercialization. Their results are summarized as follows: "being refused a patent reduces the likelihood of commercialization by about 13 percentage points. However, we cannot rule out the fact that unobserved differences in the underlying value of the invention may partly explain this result. If these are positively correlated with a patent grant, then the true effect will be less than our estimates. Second, invention owners get some spillover protection from complementary patents embodied in the final product or process. The presence of copatents boosts the probability of commercialization by an additional 3–5 percentage points. Third, we find that many unpatented inventions (with refused and pending applications) continue along the commercialization path. Thus, we conclude that patents are neither a necessary nor a sufficient condition for commercialization. Finally, we find no support for the view that the marginal effect of a patent is greater for PROs, SMEs, and individuals, who lack manufacturing capabilities, or for inventions in the highly codified areas of chemical and pharmaceutical technology." (Webster & Jensen, *supra* note 172, at 447).

[178] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986).

[179] Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003).

[180] *Id.* at 395 ("[A]ll real patents are less strong than the idealized patent grant usually imagined in economic theory.")

is far from zero. In fact, "[o]f patents litigated to a final determination (appeal, trial, or summary judgment), 46 percent are held invalid."[181]

In applying reward theory to study the desirability of reverse payment settlements it is crucially important to realize that patents confer a "right to *try* to exclude" rather than "the right to exclude".[182] To incorporate this fact I consider "probabilistic patents" [183] rather than ironclad patents. When a patentee who holds a probabilistic patent sues another party for infringement, the court may determine that the patent is either invalid or not infringed. I call the patent 'weak' ['strong'] if the probability of [both] either event[s] is high ['low'].

The strength of the patent not only affects the patentee's incentives to sue or settle, but also provides information on the social value of the invention for which the patent was granted.[184] A rational patentee holding a weak patent, *ceteris paribus*, ought to be willing to pay a much greater price to avoid litigation, which may eventually reveal the invalidity or non-infringement of its patent.[185] Furthermore, patents granted for relatively more obvious or relatively less novel inventions are weaker because there is a greater likelihood that such patents may be invalidated later. These inventions, everything else equal, contribute less to social welfare, because they constitute a smaller technological advance. Therefore, it plausible to assume that a legal regime that induces less R&D in weakly patentable inventions and more R&D in strongly patentable inventions will tend to increase social welfare.

In short, recognizing that not all patents have the same strength is crucial for revealing that restrictions on reverse payment settlements may (i) affect parties' litigation and settlement incentives differently based on the strength of the relevant patent, (ii) affect potential

[181] Mark A. Lemley & Carl Shapiro, *Probablistic Patents*, 19 J. ECON. PERSPECTIVES 75, 80 (2005). But it should be noted that this number may not very accurately reflect the probability with which the average patent will be found to be invalid. It only demonstrates that invalidity is a real possibility.

[182] *See* Shapiro *supra* note 179, at 395 (emphasis original).

[183] This refers to the title of Lemley & Shapiro, *supra* note 181.

[184] *See* Shapiro, supra note 179, at 395 (making a similar observation: "In my view, the patentholder is not "entitled" to obtain the same level of profits, or the same rights to exclude rivals, as would the owner of the fictionalized ironclad patent")

[185] *See* Part III.C.3. and Part IV, *infra*, where this result is derived.

inventor's R&D efforts differently depending on the obviousness or novelty of the potential invention, and (iii) increase the aggregate value of inventions obtained through R&D by shifting rewards from weakly patentable to strongly patentable inventions. Next, I review the economics literature on settlements to later formally analyze these effects by using a game theoretical model involving settlements.

III. THE ECONOMICS OF SETTLEMENT

It is commonly believed that at least 90% of civil suits are settled in the United States.[186] This fact alone stresses the importance of settlements as a tool to resolve disputes. Therefore, it is not surprising that there is a broad literature on the economics of settlements. This section reviews three important settlement models, namely (i) the basic, (ii) the injunctive, and (iii) the delayed entry settlement models. This review not only demonstrates how settlement models have evolved to account for the peculiar dynamics one encounters in infringement cases in the pharmaceutical sector, but it also highlights important observations made in each model that are directly relevant to discussing the effects of restricting RPS. After reviewing these models, in Part III.C., I use the delayed entry settlement model to study the incentives of a patentee (P) and a generic manufacturer (G), and to estimate their expected pay-offs after settling.

[186] *See, e.g.,* Kevin C. McMunigal, The Costs of Settlement: The Impact of Scarcity of Adjudication on Litigating Lawyers, 37 UCLA L. Rev. 833, 835-38 (1990); Marc S. Galanter, The Day After the Litigation Explosion, 46 Md. L. Rev. 3, 8 (1986); David M. Trubek, Austin Sarat, William L.F. Felstiner, Herbert & M. Kritzer, and Joel B. Grossman , The Costs of Ordinary Litigation, 31 UCLA L. Rev. 72, 86 (1983). Those who cite such numbers typically rely on data on the percentage of cases that are resolved without a trial, but point out that such statistics may understate or overstate the settlement rates. *See, e.g.,* David Rosenberg & Steven Shavell, A Simple Proposal to Halve Litigation Costs, 91 Va. L. Rev. 1721, 1725 (2005) ("Recent data on state courts show that about 96% of civil cases are resolved without trial. See Nat'l Ctr. for State Courts, Examining the Work of State Courts, 1999-2000: A National Perspective from the Court Statistics Project 29 (Brian J. Ostrom et al. eds., 2001). Similarly, recent data on federal courts demonstrate that approximately 98% of civil cases are resolved short of trial. Leonidas Ralph Mecham, Judicial Business of the United States Courts: 2001 Annual Report of the Director 154 (2001). These percentages, however, may overstate or understate the settlement rate. Because cases that are resolved without trial may have been dismissed or abandoned, 96% or 98% may overstate the settlement rate. But because disputes may be settled before complaints are filed, 96% or 98% may understate the settlement rate.")

First, I review the basic settlement model pioneered by Landes,[187] Gould[188] and Posner[189]. The basic model provides insights on many important issues, including why an overwhelming majority of cases settle, and why we ought to care about designing laws and standards that govern legal disputes given that an overwhelming majority of cases are simply settled. Briefly stated, parties settle, because it is cheaper compared to continuing with trial,[190] and laws and standards matter even if most parties settle, because they affect parties' expectations from proceeding with legal disputes, and therefore their bargaining positions in settlement negotiations.[191] Early extensions of the basic settlement model also explain how differences in expectations can cause a small proportion of cases to be litigated, even though settlement is the cheaper option.[192] This final observation is particularly important for identifying the effect of illegalizing RPS on the frequency of litigation.

The standard settlement model is not without its problems. Most importantly –for purposes of analyzing RPS— it assumes that parties can only transfer wealth through settlements, and that they cannot affect the *status quo* right allocations among the parties involved. This assumption is clearly violated, and in an important way, when settlements contain injunctive clauses.[193] A clear indication of this is that reverse payments are unlikely to be observed unless the settlement agreement contains an injunctive clause.[194]

---

[187] William M. Landes, *An Economic Analysis of the Courts*, 14 J. LAW & ECON. 61 (1971).
[188] John P. Gould, *The Economics of Legal Conflicts*, 2 J. LEGAL STUD. 279 (1973).
[189] Richard A. Posner, An Economic Approach to Legal Procedure and Judicial Administration, 2 J. LEGAL STUD. 399 (1973).
[190] This is a standard assumption in the literature. *See, e.g.,* George Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1, 13 (1984) ("We assume that litigation costs to the parties are greater than settlement costs").
[191] *See* Robert Cooter & Thomas Ulen, LAW AND ECONOMICS 414 (4th ed. 2003). ("Bargaining is more important than trials for the resolution of most disputes. However, bargaining occurs *in the shadow of the law*. In other words, expectations about trials determine the outcomes of bargains.")
[192] *Id.* at 406 ("Game theory explains why rational bargainers sometimes fail to settle their disputes and end up in trial. Although there are several strands of the argument, the simplest explanation is that trials occur because the parties have different expectations about the value of the trial.") *See also* Priest & Klein, *supra* note 190, at 4 (presenting "a model of the litigation process that clarifies the relationship between the set of disputes settled and the set litigated" while assuming settlement is cheaper than litigation)
[193] *See* Part III.A., *infra*.
[194] Part III.A., *infra,* explains that parties are unlikely to have RPS under the simple model, unless the plaintiff is somehow forced to sue the defendant.

The injunctive settlement model, proposed by Professors Hylton and Cho, provides a model whereby parties' incentives can be analyzed when they have the ability to craft injunctive settlement agreements.[195] This model is particularly useful for studying the way patentees and generic manufacturers are likely to craft settlement agreements when reverse payments are legal. Under a wide range of circumstances, the patentee has an incentive to offer the generic manufacturer a reverse payment in exchange for delaying entry until the expiration of its patent.[196]

When reverse payments are legal, as demonstrated in Part III.C.1., the parties do not possess the necessary incentives to delay entry to a date that is earlier than the expiration of the branded manufacturer's patent. Therefore, it is not necessary to go beyond the injunctive settlement model to analyze parties' incentives. But, when RPS are illegal, *P* can no longer (legally) offer a sum of money to *G* in exchange for delaying entry until its patent expires. In these cases, the parties can negotiate over the date of entry, which typically is before the expiration of the patent, to settle their dispute and avoid litigation costs. Formalizing this type of settlement requires extending the simple injunctive model to allow the parties to negotiate over the date of entry rather than a monetary settlement amount to be transferred from one party to another. This model, which I call the delayed entry model, is reviewed in Part III.C.

After reviewing the delayed entry model, I use it to study the settlement incentives and decisions of *P* and *G* under different legal regimes. The results obtained from this analysis, in turn, are directly relevant to *G*'s and P's investment decisions in earlier stages, which are studied in section IV.

A. The Basic Model

The simple economic model of settlement assumes plaintiffs and defendants, who compare the relative costs and benefits of going to

[195] Keith N. Hylton & Sungjoon Cho, *The Economics of Injunctive and Reverse Settlements*, 12 AM. L. ECON. REV. 181 (2010).

[196] Part III.B.2., *infra,* demonstrates that parties are likely to have RPS if (i) they have similar bargaining powers, (ii) they have asymmetric bargaining powers but the patent is weak, *or* (iii) *G*'s litigation costs are small in comparison to his expected return from litigation.

trial and settling a legal dispute. Each party is willing to settle only if the net benefit from doing so is greater than the net expected benefit from going to trial. Furthermore, they are assumed to know three things:[197] the monetary value of a favorable judgment for the plaintiff (J),[198] and the cost of litigation for each party (L_p and L_d, for the plaintiff and defendant respectively). Moreover, each party is assumed to estimate the probability that the plaintiff will obtain a favorable judgment in trial (P_p and P_d, respectively refer to the plaintiff's and defendant's estimate).

Using this notation, a plaintiff expects a pay-off of $(P_p \times J) - L_p$ by going to trial. The plaintiff is willing to settle, if his pay-off from settling is greater than his expected pay-off from going to trial, or in symbols, if

$$S > (P_p \times J) - L_p \qquad (1)$$

where S is the settlement offer.

Similarly, the defendant expects to incur a loss of $(P_d \times J) + L_d$ by going to trial. Accordingly, for the defendant the cost of settlement is less than the expected cost of going to trial if:

$$(P_d \times J) + L_d > S \qquad (2)$$

(1) and (2) summarize the intuitive result that the plaintiff is only willing to accept settlement offers that are relatively large and that the defendant is only willing to make settlement offers that are relatively small. Whether the parties can eventually agree on settlement terms that are mutually acceptable depends on whether the highest settlement offer the defendant is willing to make exceeds the lowest settlement offer the plaintiff is willing to accept. This condition can be

[197] I am assuming away settlement costs for the sake of brevity, because the inclusion of such costs which do not exceed litigation costs does not alter my main results. It is common in the literature to assume that settlement costs less than litigation. *See* note 190 *supra*.

[198] In the simple model of settlement, the plaintiff's gains are the defendant's losses. As such, the cost of a negative judgment to the defendant equals J. this assumption is relaxed in Part III.B., *infra*.

expressed in symbols by combining (1) and (2): $(P_d \times J) + L_d > (P_p \times J) - L_p$. Re-arranging, we have:[199]

$$L/J > (P_p - P_d) \quad (3)$$

where L denotes the sum of litigation expenses (i.e. $(L_p + L_d)$).

(3) describes the conditions under which rational parties decide to settle. Specifically, they are likely to settle if: (i) the costs that can be avoided through settlement (i.e. litigation costs of L) are large, and (ii) the plaintiff is not much more optimistic than the defendant regarding his likelihood of securing a favorable judgment (P_p is not much larger than P_d).

When would one expect the parties to have greatly diverging beliefs concerning the likelihood of a favorable judgment for the plaintiff in trial? Priest and Klein answer this question in their seminal article.[200] Under reasonable assumptions, parties are more likely to have diverging beliefs if the case is a close one. In other words, the harder it is to determine whether the plaintiff is entitled to a favorable judgment, the more likely it is for the parties to have divergent beliefs concerning the outcome of a case, and therefore proceed with litigation.[201] This observation plays a key role in determining the likely effects of illegalizing reverse payment settlements on the frequency of litigation, and therefore I will refer to it in Part IV when I consider the issue of relative over-optimism and litigation frequency.

Although the basic model provides strong insights as to when and why parties may wish to settle, it is incapable of explaining why parties would ever engage in reverse payment settlements unless the plaintiff is somehow forced to bring a claim in the first place[202] and litigation costs exceed the plaintiff's expected gains from trial. This is because (i) it assumes that the settlement's only function is to facilitate

[199] This condition is equivalent to the condition expressed in inequality (6) in Priest & Klein, *supra* note 190, at 13.
[200] *Id.*
[201] *Id.* at 17 ("Where either the plaintiff or defendant has a "powerful" case, settlement is more likely because the parties are less likely to disagree about the outcome.")
[202] One might think that the Hatch-Waxman Act does exactly this. But it does not. It gives the patentee a choice: either allow generic companies to enter the market or sue. If injunctive settlements were not possible, a patentee would choose to not sue the generic manufacturer if he expected to later make reverse payments to avoid litigation costs.

a wealth transfer from one party to the other without generating anything of further value for either party, and (ii) the plaintiff would not bring a claim if he expected to make payments to the defendant to avoid proceeding with trial.[203]

In some contexts, including patent infringement cases, however, the first assumption is violated. A recent paper by Professors Hylton and Cho recognizes this point and describes the problem as follows:

> The economics of settlement in injunctive litigation are not fully explained by the traditional Landes–Posner–Gould model because it ignores settlements that implement the injunction sought by the plaintiff. For example, in the patent infringement context, a settlement implementing the terms of the injunction sought by the plaintiff involves the defendant exiting the market to let the plaintiff firm sell at the monopoly price.[204]

Stated differently, settlements can be used to allow the plaintiff to purchase outcomes that are valuable to the plaintiff. Therefore, injunctions can be used for generating monetary surplus through a legal dispute. In these cases, the 'reverse payment' can be interpreted as the mutually agreed upon price for the outcome desired by the plaintiff, namely the injunction. Next, I consider the economics of injunctive settlements in more detail, since it allows the identification of conditions under which parties choose to engage in RPS.

B. The Economics of Injunctive Settlements

Hylton and Cho extend the standard settlement model to study injunctive settlements.[205] To be precise, injunctive settlements refer to cases where the parties settle on terms which require the defendant to

[203] In a Subgame Perfect Nash Equilibrium (SPNE), the most common solution concept in the literature on the economics of settlements, parties must have no way to unilaterally increase their pay-offs. In this simple settlement model, a situation in which the plaintiff initiates a case against the defendant only to later make a reverse payment cannot be a SPNE, because the plaintiff can increase his pay-off from –S to 0 by simply not suing the defendant in the first place.
[204] Hylton and Cho, *supra* note 195, at 186.
[205] *Id.*

cease an activity complained of by the plaintiff. The patent infringement case can be characterized as a situation where the producer of a patented drug (*P*) seeks to enjoin the producer of a generic drug (*G*) from selling drugs, which perform the same function as the patented drug.

One may wonder why the standard settlement model cannot completely explain the interactions between *P* and *G*. In particular, why can one not simply assume that *P* values the injunction more than *G*, incorporate this assumption in the standard settlement model, and repeat the analysis? To answer this question, consider the four states of the world and the resources to be allocated between the two adversary parties under each state.

State of the World	Resources to be Allocated Between P and G
No-Legal Dispute	Duopoly Profits
Proceed with Trial	Monopoly or Duopoly Profits
Standard Settlement	Duopoly Profits
Injunctive Settlement	Monopoly Profits

Unless *P* initiates a legal dispute, *G* will be able to enter the market and sell generic versions of *P*s drugs. In this case, *G* and *P* each expect to make duopoly profits, denoted by π_d, in the market for drugs.[206]

On the other hand, if *P* sues *G*, and the parties do not settle, the court eventually makes a decision, which *de facto* determines the total producer surplus to be allocated among *P* and *G*. If the court enjoins *G* from operating in the market, it eliminates competition for *P*. For simplicity, we may assume that *G* is the only competitor of *P*, and that therefore enjoining him amounts to *P* having a monopoly. In this case, *P*s monopoly profits are denoted by π_m and *G*'s profits are zero. This implies an increase in the joint profits of *G* and *P*, because $\pi_m > 2\pi_d$.[207] If the court decides not to enjoin *G*, then it is entitled to enter the market,

[206] Assuming asymmetric profits does not change qualitative results.

[207] This inequality reflects a standard assumption in the literature, *see, e.g.* Carl Shapiro, *Prior User Rights*, 96 AM. ECON. REV. PAPERS AND PROCEEDINGS 92, (2006) ("Assume combined duopoly profits are less than monopoly profits, $2\pi_D < \pi_M$"). If this assumption were violated, the patentee (who is a monopolist) could increase its profits by creating a subsidiary and competing with it, which would contradict the initial supposition that the patentee is a monopolist.

and the parties are again expected to make duopoly profits of Π_d. Therefore, a court decision leads to an allocation of monopoly profits to *P* or duopoly profits to each of the two parties, depending on whether or not it involves an injunction.

When the parties settle through a standard settlement they are allocating pre-dispute resources among themselves. This follows, because a standard settlement, by definition, is incapable of enjoining *G* from operating in the market in the future. This implies that the settlement will involve some monetary transfer between *G* and *P*, that *G* and *P* will later compete against each other in the market for drugs, and that they will therefore obtain duopoly profits.

An injunctive settlement, on the other hand, is one where *G*, in exchange for the other terms of the settlement, agrees to exit the market. In this case, the joint profits of the parties are increased from $2\Pi_d$ to Π_m.

The most important thing that this brief analysis highlights is that standard settlements and injunctive settlements lead to different total profits to be shared among *G* and *P*. This being the case, it is only natural to expect that the possibility of enjoining *G* in a settlement may change the dynamics of settlement negotiations. How exactly does the availability of injunctive settlements, assuming of course that they are legal, give *P* an incentive to make "reverse payments"? This is described next.

3. When do Parties Settle?

If the parties litigate, *P*s patent will be found valid and infringed with a probability of *X*, which reflects the strength of the patent: the closer *X* is to one, the stronger the patent.[208] *P* and *G*, however, are not necessarily perfectly informed about this probability. They have estimates of this probability, denoted by X_p and X_g, where the subscript denotes the party possessing the estimate. Their estimates are subject

[208] *See* Part II.C., *supra*, which discusses probabilistic patents in further detail.

to error, so that X_p and X_g need not necessarily equal each other or X.[209] Parties base their decisions on these estimates.

Accordingly, *G*'s expected return from litigation is $(1\text{-}X_g)\Pi_d$. *G* also faces litigation costs of L_g, making its expected pay-off from litigation $(1\text{-}P_g)\Pi_d\text{-}L_g$. Therefore, if it receives an injunctive settlement offer of S from *P*, it will accept it only if

$$(1\text{-}X_g)\Pi_d\text{-}L_g<S \qquad (4)$$

P, on the other hand, expects to make monopoly profits of Π_m with a probability of X_p, and duopoly profits of Π_d with a probability of $(1\text{-}\ X_p)$. Therefore, *P*s expected pay-off from litigation is $X_p\Pi_m+(1\text{-}\ X_p)\Pi_d\text{-}\ L_p$, where L_p denotes *P*s litigation costs. An injunctive settlement on the other hand, confers *P* monopoly profits, because it requires *G* to refrain from entering the market, but involves a payment of S to *G*. Hence, *P*s expected pay-off from settlement is Π_m-S. Accordingly, P's expected pay-off from settlement exceeds its pay-off from litigation when: Π_m-S $>X_p\Pi_m+(1\text{-}\ X_p)\Pi_d\text{-}\ L_p$, which can alternatively be expressed as:

$$(1\text{-}\ X_p)(\Pi_m\text{-}\ \Pi_d)\ +L_p>S \qquad (5)$$

(4) and (5) imply that an injunctive settlement will take place as long as: $(1\text{-}\ X_p)(\Pi_m\text{-}\ \Pi_d)+L_p>(1\text{-}X_g)\Pi_d\text{-}L_g$. Expressed in a slightly simpler way:

$$(1\text{-}X_p)(\Pi_m\text{-}2\Pi_d)+2L>(X_p\text{-}X_g)\Pi_d \qquad (6)$$

where 2L is the sum of litigation costs.

(6) demonstrates that injunctive settlements will take place, as long as parties are not relatively over-optimistic[210] regarding their prospects

[209] Following Priest and Klein, *supra* note 190, I am assuming that X_g and X_p are random variables with $X_g=X+\varepsilon_x$, where ε_x, the error term, is symmetrically distributed around zero, and its variance is greater when X is intermediate. This assumption will be useful in discussing relative over-optimism in Part IV.D.

[210] Over optimism can be defined with greater precision. The parties are over optimistic if *P*s estimate of the likelihood of securing a favorable judgment for himself exceeds *G*'s estimate of the same by a margin of $\frac{(1-X_p)(\pi_m-2\pi_d)+L}{\pi_d}$. This condition is more likely to hold when (i) litigation costs are small, and (ii) π_d is large in comparison to the surplus generated from the injunction *i.e.*$\pi_m - 2\pi_d$. An increase in patent strength affects the likelihood with which parties will become over-optimistic and litigate in two separate ways: (i) it affects the distribution of X_p, which appears in the threshold margin identified above, and (ii) it affects the distribution of $X_p\text{-}X_g$. For weak patents an increase in patent strength will lower the expected value of the margin identified above and increase the likelihood with which $X_p\text{-}X_g$ takes on large values. Therefore, intermediately strong

of obtaining a beneficial judgment through litigation. This follows because $\Pi_m > 2\Pi_d$, which makes the left hand side of (6) positive. This implies that the inequality holds as long as $X_p \leq X_g$. Assuming that the parties have good estimates of the strength of the patent, the gap between X_g and X_p is likely to be small, and the parties will end up reaching an injunctive settlement. Until I consider the impact of over optimism in Part IV.D., I will abstract from issues related to over optimism by assuming that the parties have perfect information regarding the strength of the patent, *i.e.* that $X_g=X_p=X$.

4. When do Parties Agree on Reverse Payment Settlements?

Given that parties are not overly optimistic an injunctive settlement will occur, but will it necessarily involve a reverse payment? That is, must S be positive? Stated differently, is it always in the plaintiff's best interest to buy the injunction from the defendant, or can it insist on proceeding to trial and obtaining an injunction through litigation, unless the defendant compensates him? To answer this question, note that (4) and (5) imply that the settlement offer, S, must be within the following range:

$$S \in [(1-X)\Pi_d - L_g;\ (1-X)(\Pi_m - \Pi_d) + L_p] \qquad (7)$$

Therefore, as long as the lower bound for the settlement, *i.e.* $(1-X)\Pi_d - L_g$, is positive, S will be positive. This condition is likely to hold when (i) X is small, *i.e.* the patent is weak, and/or (ii) Π_d is large in comparison to litigation costs. Furthermore, if the parties have similar bargaining powers, they will split the surplus that they generate through an injunctive settlement close to evenly. In those cases, S, the settlement offer will be close to the mid-point of the settlement range expressed in (7). When the parties' litigation costs are equal, this midpoint can easily be calculated as: $\frac{(1-X)\pi_m}{2}$ which is positive.[211]

To summarize, when allowed, the parties will reach an injunctive settlement involving reverse payments as long as: (i) they have similar

patents are more likely to generate legal disputes than weak patents. This observation and its implications are discussed in Part IV.D., *infra*.

[211] When the parties litigation costs are not equal, the mid-point of the settlement range is positive as long as: $(1-X)\Pi_m > (L_g - L_p)$. That is, as long as *G*'s litigation costs do not exceed *P*s litigation costs by a large margin.

bargaining powers, or (ii) when they have asymmetric bargaining powers but the patent is weak, or G's litigation costs are small in comparison to his expected return from litigation. Moreover, for the second condition above to hold, it is sufficient for the patent to be weak enough to off-set the difference in the parties bargaining powers. The smaller the difference between the parties' bargaining powers, the stronger the patent is allowed to be without violating condition (ii).

Although dynamic effects will be considered to a greater extent in Part IV, it is worth noting a simple and important point that relates to *G*'s ex-ante incentives. As the above analysis demonstrates, *G* has no incentive to make the necessary arrangements, such as filing an ANDA to enter the market[212] unless he expects to receive a reverse payment from *P*. If S is negative, entry induces a pay-off of –S, whereas doing nothing induces a pay-off of 0.[213] Therefore, a generic company is likely to attempt entry only when he expects reverse payments, and this, as demonstrated above, happens under a very wide variety of circumstances.

C. Delayed Entry Settlements

Although the model of injunctive settlements provides insights regarding settling parties' incentives, it needs to be modified to capture one of the most prevalent features of reverse payment settlements. Reverse payment settlements require the entrant to postpone entry. This is the method through which the settling parties can increase their expected joint profits by increasing the (expected) amount of time in which the patentee enjoys monopoly profits. What the injunctive settlement model abstracts from is the fact that the parties can negotiate over the exact time of entry, enabling *P* to preserve his monopoly power over a proportion of the remaining patent life before *G* enters the market. Simply stated, the injunctive settlement model does not allow the parties to choose the length of the injunction.

[212] *See* Part I.A., *supra*, explaining how the Hatch-Waxman Act structures entry for generics.. A stylized version of the interactions between *P* and *G* is presented as a sequential game in Part IV, *infra*. Filing an ANDA corresponds to *G*'s strategy in the second period of the drug game.

[213] In other words, a strategy profile where *G* is entering and later settling cannot be a Subgame Perfect Nash Equilibrium (*see* note 203, *supra*, on Subgame Perfect Nash Equilibria) because *G* can increase its pay-off from –S to zero by not entering in the first place.

The model can easily be extended to account for this possibility. In particular, one can consider a new variable, α, which denotes the ratio between the time remaining until the agreed upon entry and the remaining patent life (*e.g.* if the parties agree on entry in 3 years, and the remaining patent life is 10 years, then α=0.3). Using α, one can calculate *P*s pay-off from settling as, $\alpha\pi_m+(1-\alpha)\pi_d$, and *G*'s expected pay-off as $(1-\alpha)\pi_d$. How does this modification affect parties' settlement strategies? Do the parties have an incentive to delay entry as much as they can? The answer to this question depends on whether or not the parties are allowed to have settlements involving reverse payments as decribed in the previous sub-section.

1. Parties' incentives when reverse payment settlements are per-se legal

As can be inferred from the discussion of injunctive settlements, absent legal restrictions, *P* and *G* have incentives to delay *G*'s entry as much as possible (*i.e.* until the patent expires)[214] in exchange for a reverse payment that compensates *G* for his forgone expected profits.

To see this, first note that when α=1, *P*s and *G*'s pay-offs from settlement are identical to the corresponding values in Part III.B., namely, π_m-S and S, respectively. This is not a coincidence. The simple injunctive settlement model simply assumes that through a settlement *P* can either enjoin *G* for the entirety of the remaining patent term, or not at all. In symbols, it assumes that the settlement must select between α=0 or α=1. Therefore, the conditions under which it is preferable for *P* and *G* to have a reverse payment settlement with α=1, rather than no settlement at all, corresponds to the conditions discussed in Part III.B..

Next, note that for the settling parties a settlement with α=1 is strictly preferable to a settlement with α<1. This is because by increasing α, the parties increase their joint profits from settlement from $\alpha\pi_m+2(1-\alpha)\pi_d$ to simply π_m. Since joint profits are increased, the parties can engage in simple Coasean bargaining to move from a settlement with α<1 to one with α=1. Due to these reasons, whenever

[214] This assumption implicitly incorporates the fact that the parties cannot legally delay entry beyond the patent expiration date.

reverse payments are legal, assuming that the parties are not overly optimistic,[215] P and G have incentives to agree on a reverse payment settlement that delays entry until the patent expires.

2. Parties incentives when reverse payment settlements are restricted

When reverse payments are illegal, the parties lose the mechanism through which P can transfer some of the surplus created by G's delayed entry –which is in the form of greater profits for P due to lack of competition minus what G loses by not entering early. However, assuming that litigation is costly, the parties still have incentives to settle and avoid litigation due to reasons described in Part III.A. In particular, the parties can settle on a date of entry, α, which off-sets expected pay-off's to each party from litigation, which is costly.

The entry date, described by α, must satisfy two conditions for both parties to be willing to enter the settlement: P's and G's settlement pay-offs must exceed the corresponding expected pay-offs from litigation. Or, in symbols, it must be true that:

$$\alpha\Pi_m+(1-\alpha)\Pi_d>X\Pi_m+(1-X)\Pi_d-L_p \quad (8)$$

and

$$(1-\alpha)\Pi_d>(1-X)\Pi_d-L_g \quad (9)$$

Without information on parties' litigation costs and bargaining power it is impossible to pin-point the exact date of entry in a DES. But, if for simplicity the parties are assumed to have equal bargaining power and litigation costs (of L for each party), they will settle on an entry date of:[216]

$$\alpha^I = x + L\frac{\pi_m-2\pi_d}{2\pi_d(\pi_m-\pi_d)} \quad (10)$$

[215] Over optimism is studied in detail in Part IV.D., *infra*.

[216] This expected entry date corresponds to the *Nash bargaining solution* that P and G reach when they have equal bargaining power. See Nolan McCary & Adam Meirowitz, POLITICAL GAME THEORY: AN INTRODUCTION 275-80 (2007) (providing a brief introduction to bargaining theory, a definition of the Nash Bargaining Solution, and the axiomatic foundations of this solution concept).The calculations necessary to derive this result are relegated to Appendix A, *infra*.

In other words, when reverse payments are not allowed, we should expect parties to settle on an entry date that sets the pay-off from settlement greater than the expected return from litigation for both parties.

An important corollary is that as long as the parties do not believe that the patent is almost ironclad,[217] they will not reach a settlement where the generic company promises to delay entry until the patent expires, *i.e.* $\alpha<1$. This implies that for patents that are not close to being ironclad, restricting RPS induces earlier generic entry compared to per-se legality, since, as shown in Part III.C.1., $\alpha=1$ when reverse payment settlements are per-se legal.[218]

D. Parties settlement decisions and ex-post pay-offs across regimes as a function of patent strength

Given the observations in Parts III.B.-C., parties' ex-post pay-offs, that is pay-offs excluding any costs that may have been incurred prior to their settlement decisions, can be calculated across legal regimes and as a function of patent strength. Identifying parties' ex-post pay-offs will be useful for studying generic companies' entry decisions and dynamic R&D decisions in Part IV..

1. When Reverse Payments are Legal

As discussed in section III.B., when reverse payments are legal, the parties reach a settlement where *P* makes a payment of $S=\frac{1}{2}(1-X)\Pi_m$ to *G*, and *G* delays entry until the end of the patent term. Given that *G* does not enter during the patent term, *P* expects to collect monopoly profits of Π_m over the patent term. Therefore, its ex-post pay-off is monopoly profits net of settlement payments:

$$\Pi_m-\tfrac{1}{2}(1-X)\Pi_m=\tfrac{1}{2}(1+X)\Pi_m \qquad (11)$$

Since *G* agrees to exit the market, its only gains consist of settlement payments from *P*, which is

[217] More specifically, as long as the parties do not believe that the patent has a strength exceeding $1-L\frac{\pi_m-2\pi_d}{2(\pi_m-\pi_d)\pi_d}\equiv X^C<1$.

[218] For patents with strength exceeding X^C, a settlement would induce the same result, i.e. entry at $\alpha=1$.

$$½(1\text{-}X)\Pi_m \quad (12)$$

2. When Reverse Payments are Illegal

As discussed in Part III.C., when reverse payments are illegal, the parties structure a DES where *G* agrees to enter at date α^I, which is expressed in (10). Because there are no settlement payments from one party to the other, the parties' ex-post pay-offs consist only of profits they collect in the market. Therefore, *P*s and *G*s ex-post pay-offs are respectively given by (13) and (14) below:

$$\alpha^I\Pi_m+(1\text{-}\alpha^I)\Pi_d \quad (13)$$

and

$$(1\text{-}\alpha^I)\Pi_d \quad (14)$$

where α^I is the entry date described in (10).[219]

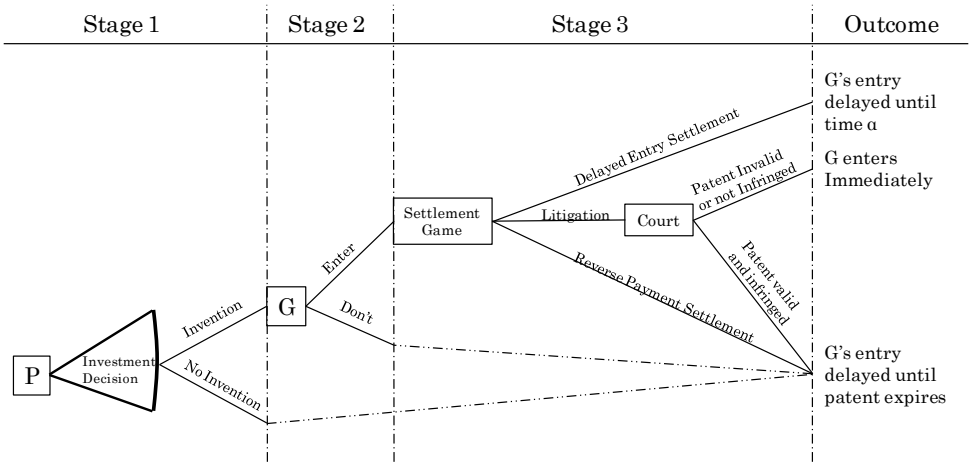
IV. REWARD SHIFTING

Section III summarizes parties' incentives and pay-offs under per-se legality and illegality of reverse payment settlements. That analysis assumes, first that a patentee, *P*, engages in R&D and comes up with a new invention, and second that another party, *G*, decides to incure entry costs to put itself in a position to market a generic version of that invention.

The particular legal regime, however, may have an effect on whether *P* invests in R&D in the first place, and whether *G* makes the necessary investment to enter the market if *P* comes up with a new invention. This section incorporates these ex-ante effects by using a stylized model which is best summarized by the following game tree.

[219] This assumes that the patent is not stronger than x^C, as defined in note 217, *supra,* however, as will be revealed in Part IV, one need not focus on patents with $x>x^C$, because in those cases *G* does not have an incentive to enter (because it would be making net-losses), and therefore settlements never take place.

Figure I: Game Tree



As reflected in the game tree, in stage 1, *P* makes R&D decisions, which have a direct effect on the likelihood with which it succeds in inventing a new product or process. If an invention results, *P* obtains a patent on it, and in stage 2, *G* chooses whether or not it makes the necessary investment to enter the market. When the generic company doesn't make the necessary investment, *P* remains the only supplier, and collects monopoly profits in the market for the invention. If the generic company makes the necessary investment to enter, *P* and *G* play the 'settlement game' which is described at length in Parts III.C. and D. To highlight the main effects of illegalizing reverse payment settlements, I will assume, as in Parts III.C. and D., that the parties have accurate estimates regarding the strength of *P*s patent.[220]

To solve this 'game' I use the most common method among law and economics scholars to study settlements, namely backward induction.[221] This method requires a player to predict what she and other players will do in the future under various circumstances. She then chooses the action that will lead to those circumstances under which the other players act in a way that is most favorable to her. For

[220] Part IV.D. discusses the effects of relaxing this assumption.

[221] *See, e.g.,* Lucian A. Bebchuk, *A New Theory Concerning the Credibility and Success of Threats to Sue*, 25 J. LEGAL STUD. 1, 6 (1996) ("In analyzing this case, as well as subsequent cases, we are going to apply "backward induction." This approach is the standard method used by economists for analyzing strategic interactions in which parties make decisions over several time periods.")

instance, when making a decision in stage 1, *P* will consider whether or not *G* will enter in the second period, if *P* in fact comes up with an invention. If *P* believes that *G* is likely to enter in stage 2, then he has to predict the outcome of the settlement game in stage 3. If he thinks that the future benefits associated with these outcomes outweigh the cost of R&D, he will engage in R&D, otherwise, he will not.

To make the example even more concrete, consider the following unrealistic yet simple scenario. In stage 1, *P* has a choice between investing $5M, in which case an invention results with certainty, and not investing. Furthermore, assume that *P* predicts that if an invention results, *G* will make the necessary investments to enter the market in stage 2, and that in stage 3 it will enter a settlement with *G*, where *G* agrees to exit the market in exchange for a payment of $3M. In this scenario, if *P* expects to make more than $8M from the sales of its invention, it will make the necessary investment, otherwise it will not.

G's decision making process will be similar to that of *P*s, but will require fewer predictions. *G* only needs to compare the cost of the investment necessary to enter, with what he expects to gain as a result of the 'settlement game'. Fortunately, the 'settlement game' was already solved in Part III.D.. Therefore, *G*'s entry decision can be analyzed by comparing its expected pay-off expressed in (12) or (14) – depending on the legal regime– minus the cost of investing for entry, denoted as *F*, and its outside option of not investing, which results in a pay-off of zero. *G*'s entry decision is analyzed next.

A. Generic Manufacturer's Investment Decision

When reverse payments are legal, by investing in entry, *G* expects to obtain a settlement offer from *P* in the amount of ½(1-X)Π_m in exchange for delaying entry until *P*s patent expires. *G*'s expected pay-off from entry is therefore his expected gains from settlement minus the cost of investing in entry, namely ½(1-X)Π_m-F. Since *G*'s outside option is to not invest, which results in a pay-off of zero, *G* enters only when:

$$\frac{(1-X)\pi_m}{2} > F \qquad (15)$$

When reverse payment settlements are not allowed, *G* expects to reach a DES with *P*, by investing in entry. This option has a value of $(1- \alpha^I)\pi_d$-F, and therefore *G* invests only when:

$$(1-\alpha^I)\pi_d > F \qquad (16)$$

Plugging in the value for α^I described in (10), this condition can be expressed as:

$$\left(1-\mathrm{X}-L\frac{\pi_m-2\pi_d}{2(\pi_m-\pi_d)\pi_d}\right)\pi_d > F \qquad (17)$$

Simply by comparing conditions under which *G* enters under the two legal regimes, one can see that entry is more likely to occur when reverse payments are legal.[222] This is because $\frac{1}{2}(1-X)\pi_m$, the expected ex-post pay-off to *G* under per-se legality, exceeds $\left(1-\mathrm{X}-L\frac{\pi_m-2\pi_d}{2(\pi_m-\pi_d)\pi_d}\right)\pi_d$, the ex-post expected pay-off when reverse payments are illegal. A closer look at these conditions reveals even more about *G*'s decision to enter: *illegalizing reverse payment settlements effects G's decision to enter only if the patent is sufficiently strong*.

The best way to make this observation is to identify the conditions under which *G* enters as a function of patent strength. Manipulating (15) reveals that *G* makes the necessary investment to enter only if the patent strength is below a certain threshold value. In particular, *G* invests only if:

$$X < 1-\frac{2F}{\pi_m} \equiv X^L \qquad (18)$$

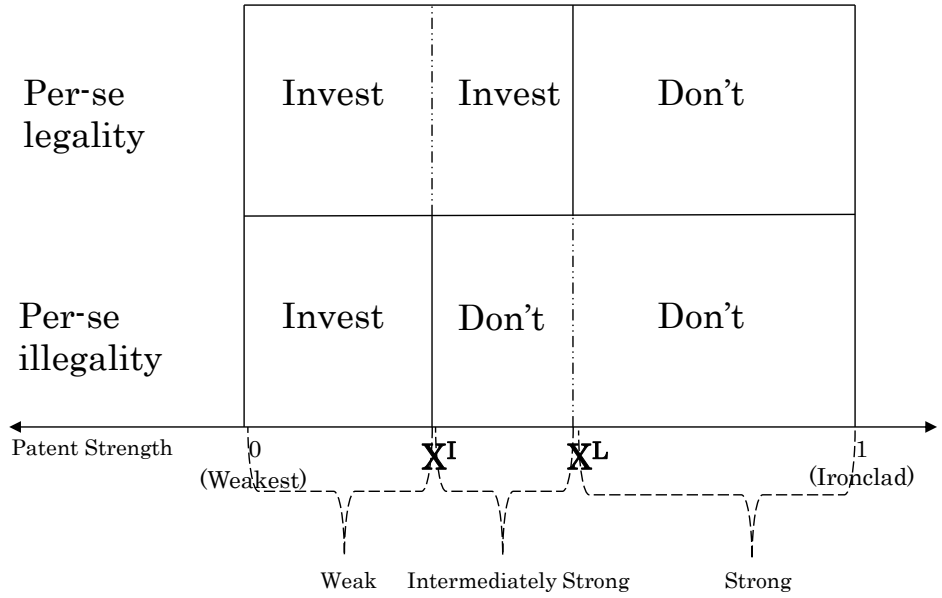
where X^L denotes the threshold patent strength under per-se legality. A similar exercise reveals that when reverse payments are not allowed, *G* is willing to enter when:

$$X < 1-L\frac{\pi_m-2\pi_d}{2(\pi_m-\pi_d)\pi_d}-\frac{F}{\pi_d} \equiv X^I \qquad (19)$$

[222] Assuming of course that the drug has been invented in period 1.

where X^I denotes the threshold patent strength under per-se illegality. It is easy to verify that $X^I<X^L$,[223] which implies that illegalizing reverse eliminates investment in entry only when the patent is stronger than X^I. This observation can be better illustrated by a simple figure:

Figure 2:
G's incentives to invest as a function of patent strength and legal regime



As can be inferred from figure 2, a switch from per-se legality to illegality eliminates investments by G to enter when X is between X^L and X^I. This observation reflects the concerns voiced by Richard Posner in Asahi Glass:

> 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.

[223] To see this, simply note that $X^I \equiv 1 - L\frac{\pi_m - 2\pi_d}{2(\pi_m - \pi_d)\pi_d} - \frac{F}{\pi_d} < 1 - \frac{F}{\pi_d} < 1 - \frac{2F}{\pi_m} \equiv X^L$, where the second inequality follows from the fact that $2\pi_d < \pi_m$.

If, however, investment in entry is motivated by the prospect of extracting favorable settlements in the future, such investments do not really generate additional welfare.[224] This is explained next.

B. Effects on Entry

Illegalizing reverse payment settlements has the effect of eliminating investment in entry by generic companies for intermediately strong patents, but it also has the effect of inducing earlier entry by *G*, when *G* decides to invest in entry. This is because entry happens at time 1 when reverse payments are legal, but at time $\alpha<1$ under per-se illegality.[225]

When $X<X^I$ both regimes induce investment by *G*. *G* enters at time 1 under per-se legality, but at time *X* under per-se illegality. This means that per-se legality protects *P*s ability to charge supra-competitive prices for its drug for a longer duration, which results in reduction in consumer welfare and deadweight loss.

If the patent is intermediate, so that $X^I<X<X^L$, then *G* invests in entry only if there is a rule of per-se legality. However, the parties decide to settle, and therefore *G* delays entry until the end of the patent expiration period. Therefore, *G*'s investment in entry does not reduce the length of time in which *P* is able to charge supra-competitive prices –the two regimes produce the same effect.

G has no incentive to invest in entry under either rule when $X> X^L$, because investment costs exceed the potential gains from a settlement. Therefore, both regimes have the same effect on ex-post social welfare.

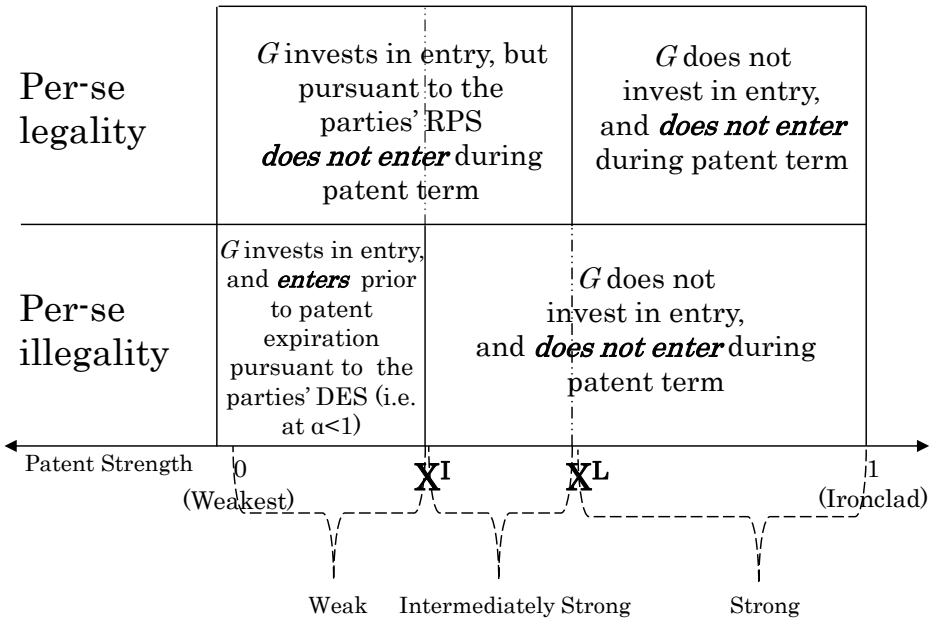
These observations are combined and summarized in figure 3 below. An important result that is highlighted by figure 3 is that

[224] Entry can occur earlier under per-se legality, if parties suffer from over-optimisim and therefore are unable to reach a settlement *and* the patent is found to be invalid and infringed. In these cases, whether per-se legality leads to an increase in welfare depends on the magnitudes of (i) deadweight loss prevented from early entry, (ii) strength of the patent, and (iii) the reduction in *P*s incentives to innovate in the first place. This case is discussed in section IV.D., after all necessary effects are introduced and discussed in section III.B. and III.C..

[225] *See*, Part III.C.2. and notes 217 and 218, *supra*, which demonstrate that the settlement date is prior to patent expiration (i.e. $\alpha<1$), unless the patent strength exceeds $1- L\frac{\pi_m-2\pi_d}{2(\pi_m-\pi_d)\pi_d} \equiv X^C$. Since *G* invests only when $X< X^I< X^C$, it follows that whenever there is a delayed entry settlement entry occurs prior to patent expiration.

illegalizing reverse payments induces earlier entry when patents are weak, but has not effect on the entry date otherwise.

Figure 3: *G*'s time of entry as a function of patent strength and legal regime



C. The Reward Shifting Effect and Implications

Figure 3 describes *G*'s decision to invest in entry as a function of patent strength and the conditions under which the parties enter a reverse payment or delayed entry settlement. Using these conditions and the observations in Part III the expected reward to *P* from becoming a patentee can be calculated.

When $X<X^I$, *G* invests in entry regardless of the legal regime. The parties reach a RPS under per-se legality and a DES under per-se illegality. As explained in Part III.D. *P*s expected reward from becoming a patentee corresponds to the ex-post pay-offs expressed in (11) and (13), *i.e.* $\frac{1}{2}(1+X)\Pi_m$ under per-se legality, and $\alpha^I\Pi_m+(1-\alpha^I)\Pi_d$ under per-se illegality. A comparison of these two values suggests that per-se legality always provides greater expected rewards for very weak

patents, and that it provides greater expected returns for patents close to strength X^I under a very wide range of conditions.[226]

For intermediately strong inventions, *i.e.* when $X^I<X<X^L$, *G* invests in entry under per-se legality, but refrains from investment under per-se illegality. Accordingly, under per-se legality, the reward from being a patentee corresponds, as in the weak invention case, to (11), namely $\frac{1}{2}(1+X)\pi_m$. Under per-se illegality, however, entry does not occur, and therefore the reward associated with being a patentee is π_m.

When $X^L<X$, the reward associated with becoming a patentee is the same under per-se legality and illegality, namely π_m, because there is no potential entry by G. These results are summarized in Figure 4, below.

Figure IV: *P*s reward as a function of patent strength and legal regime

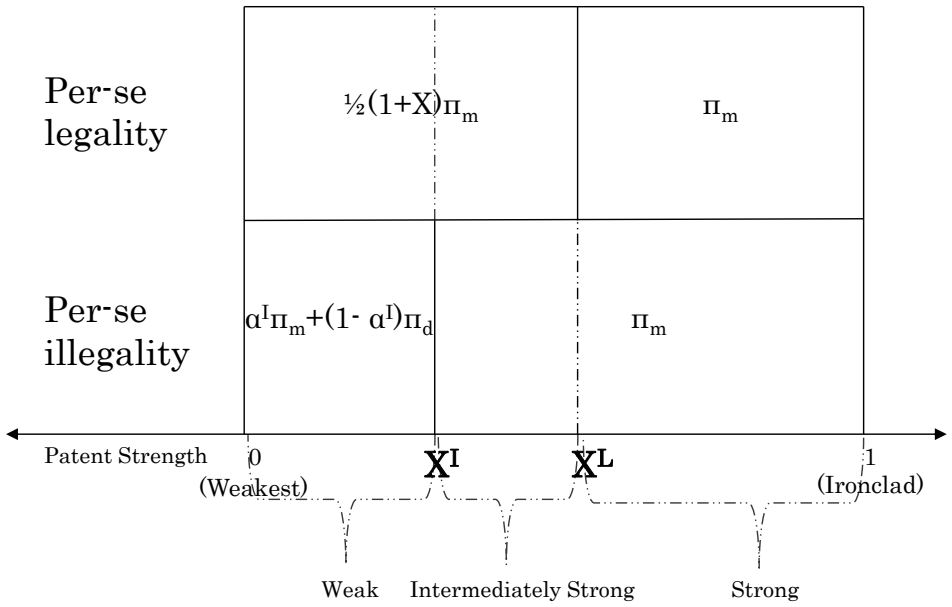


Figure 4 highlights an important result: illegalizing reverse payments reduces the reward to holding a weak patent, but also increases the

[226] More specifically, 1.5F>L is a sufficient, but not necessary condition, for per-se legality to generate greater expected rewards to holding a weak patent. The derivation of this result is relegated to Appendix B., *infra*.

reward to holding an intermediately strong patent. In other words, illegalizing RPS shifts the reward from weak inventions towards stronger inventions. The implications of this observation are revealed by simple applications of reward theory.

First, a pharmaceutical company which has a research lead on a relatively strong project may be induced to abandon R&D efforts when RPS is per-se legal, but be induced to carry on with R&D under per-se illegality. In particular, if the cost of continuing with R&D is C, and the probability of successfully completing R&D and obtaining a patent is q, such that $\frac{1}{2}(1+X)\Pi_m < C/q < \alpha^I\Pi_m + (1-\alpha^I)\Pi_d$, the pharmaceutical company will find it in its best interest to continue with R&D only if RPS are illegal.

Second, another budget-constrained pharmaceutical company, which has the choice between choosing to engage in R&D for a project which will potentially result in a weak invention versus a strong project may be induced to choose the weak project when RPS is legal, but the strong project when RPS is illegal. This follows, because switching from a per-se legality regime to a per-se illegality regime increases the rewards for the strong project while at the same time reducing the rewards for the weak project.

In sum, the reward shifting effect of per-se illegality has the effect of shifting pharmaceutical R&D efforts from weak projects towards stronger projects. As long as the social value of projects correspond to the strength of the project, illegalizing RPS will increase social welfare through this reward shifting effect.

D. The Exacerbating Effect of Relative Over-Optimism

Throughout the preceding analyses I assumed that parties do not suffer from relative over-optimism. Relative over-optimism refers to cases where *P* and *G* have diverging beliefs regarding the probability with which *P*'s patent will be found valid and infringed in case they choose not to settle and proceed with litigation. In particular, if *P*s estimate of this probability sufficiently exceeds *G*'s estimate, the parties will be said to be relatively over-optimistic and proceed with litigation.

To analyze the effects of potential relative over-optimism, it should first be noted that parties are more likely to litigate due to divergences in their estimates of *P*s probability of securing a favorable judgment under per-se illegality. This follows because the surplus that the parties can generate through settlement is lowered under per-se illegality, because an option, namely preserving P's monopoly profits through *RPS* arrangements, is taken away from the parties. The consequence is that the gains from settling are reduced, making the option less desirable to both parties. Appendix C, *infra*, formalizes this point with more precision by providing an algebraic proof.

The effects of this observation, namely that relative over-optimism occurs more frequently under per-se illegality, are better understood by focusing on parties' incentives to settle as a function patent strength,

When the relevant patent is weak, entry occurs in both regimes.[227] In these cases settlement negotiations are more likely to breakdown under per-se illegality. Because the patent is weak, the patent is likely to be declared invalid through litigation. This generates a second benefit associated with per-se illegality: once the patent is declared invalid, the generic company can enter the market and sell a generic version of the drug, which produces static benefits in the form of reduced deadweight loss.

When the patent is intermediately strong, *G* will not attempt entry under per-se illegality, but will under per-se legality. Therefore, under per-se legality, *G* and *P* will, even if rarely, litigate to determine the validity of the patent. This will lead to some of the patents being found invalid. This will generate static benefits, in the form of reduced deadweight loss, but at the expense of a dynamic cost: a reduction in *P*s incentive to engage in R&D for intermediately strong projects.

Finally, when the patent is close to being ironclad, entry will not occur under either regime. Therefore, divergences in parties' beliefs regarding patent strength will not affect parties' incentives.

[227] The threshold X's will change in response to incorporating the possibility of litigation, but this does not change the fact that there will be a new threshold such that weak patents will be challenged under both.

In sum, per-se illegality is likely to increase litigation of weak patents creating additional static benefits at the expense of litigation, and reducing the reward associated with weak patents even further. On the other hand, per-se legality will tend to increase litigation for intermediately strong patents, increasing potential static gains, but at the cost of reducing the *P*s rewards to becoming a patentee. Therefore, potential relative over-optimism appears to magnify the reward shifting effect of per-se illegality: it reduces both the comparative reward to holding a weak patent under per-se illegality and the comparative reward to holding an intermediately strong patent under per-se illegality.

V. APPENDIX

A. Nash Bargaining Solution in Delayed Entry Settlements When Parties Have Equal Bargaining Power

As explained in Part III.C.2., the parties will be willing settle if two conditions hold:

$$\alpha\pi_m + (1-\alpha)\pi_d > X\pi_m + (1-X)\pi_d - L \qquad \text{(A.1.)}$$

and

$$(1-\alpha)\pi_d > (1-X)\pi_d - L \qquad \text{(A.2.)}$$

Given the patent strength, the *Nash bargaining solution* involves choosing an entry date (α) which maximizes the product of the differences in the parties' settlement pay-offs and expected litigation pay-offs.[228] Or, in symbols:

$$\max_{\alpha}[(\alpha - X)\pi_m - (\alpha - X)\pi_d + L][L - (\alpha - X)\pi_d] \qquad \text{(A.3.)}$$

$$\text{s. t. } (\alpha - X)\pi_m - (\alpha - X)\pi_d + L \geq 0 \text{ and } L - (\alpha - X)\pi_d \geq 0 \qquad \text{(A.4.)}$$

(A.3.) can alternatively be expressed as:

[228] *See* Nolan McCary & Adam Meirowitz, POLITICAL GAME THEORY: AN INTRODUCTION, 275-80 (2007) (providing a brief introduction to bargaining theory, a definition of the Nash Bargaining Solution, and the axiomatic foundations of this solution concept).

$$-(\alpha - X)^2\left(\pi_d(\pi_m - \pi_d)\right) + (\alpha - X)\left(L(\pi_m - 2\pi_d)\right) + L^2 \qquad \text{(A.5.)}$$

This expression generates the following first order condition:

$$\alpha^I = x + L\frac{\pi_m - 2\pi_d}{2(\pi_m - \pi_d)\pi_d} \qquad \text{(A.6.)}$$

That α^Imaximizes (A.3.) is guaranteed by the concavity of the expression in (A.5).

B. Comparing P's Expected Rewards for Holding a Weak Patent Across Legal Regimes

P's expected rewards from holding a weak patent under per-se legality and illegality, are respectively expressed in (11) and (13) as:

$$A(X) = \frac{(1+X)\pi_m}{2} \qquad \text{(A.7)}$$

and

$$B(X) = \alpha^I(X)\pi_m + (1 - \alpha^I(X))\pi_d \qquad \text{(A.8)}$$

where $\alpha^I(X)$, defined in (10), is the expected entry date under a DES between P and G as a function of the strength of the patent. Since, A(0)>B(0), and since both A and B are increasing and linear functions of patent strength, it follows that if $A(X^I)>B(X^I)$, then per-se legality results in greater expected rewards to P for all weak patents. Plugging in the expression for α^Iin (10) into (A.8.), and evaluating (A.8.) and (A.7.) at $X=X^I$ reveals that:

$$A(X^I) = \pi_m\left(1 - L\frac{\pi_m - 2\pi_d}{4\pi_d(\pi_m - \pi_d)} - \frac{F}{2\pi_d}\right) \qquad \text{(A.9.)}$$

and

$$B(X^I) = \left(1 - \frac{F}{\pi_d}\right)\pi_m + F \qquad \text{(A.10.)}$$

Therefore, $A(X^I) > B(X^I)$ if

$$\pi_m\left(1 - L\frac{\pi_m - 2\pi_d}{4\pi_d(\pi_m - \pi_d)} - \frac{F}{2\pi_d}\right) > \left(1 - \frac{F}{\pi_d}\right)\pi_m + F \qquad \text{(A.11.)}$$

Manipulating this inequality reveals that it is equivalent to the following condition:

$$L < \left(2 - \frac{\pi_d}{\pi_m}\right)F \qquad \text{(A.12.)}$$

The minimum value $\left(2-\frac{\pi_d}{\pi_m}\right)$ can take is 1.5, since $2\pi_d < \pi_m$. Therefore, $A(X^I) > B(X^I)$ whenever $L < 1.5F$, in which case per-se legality generates greater expected pay-offs to P for all weak patents.

C. Relative Over-Optimism Leads to Litigation More Frequently Under Per-se Illegality

Under per-se legality, the condition for litigation is as expressed in (6):

$$\frac{(1-X_p)(\pi_m-2\pi_d)}{\pi_d}+\frac{2L}{\pi_d} < X_p - X_g \qquad \text{(A.13.)}$$

And the condition for litigation under per-se illegality is obtained by combining (8) and (9), *supra*:

$$L\left(\frac{1}{\pi_d}+\frac{1}{\pi_m-\pi_d}\right) < X_p - X_g \qquad \text{(A.14.)}$$

The left hand side of (A.13.) is greater than the left hand side of (A.14.), since $\frac{2L}{\pi_d} > L\left(\frac{1}{\pi_d}+\frac{1}{\pi_m-\pi_d}\right)$. This implies that the divergence between the two parties' beliefs (i.e. $X_p - X_g$) must be greater under per-se legality than under per-se illegality for relative over-optimism to lead to litigation. Therefore, per-se illegality is likely to lead to more litigation conditional on G filing an ANDA.