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Reverse Payments, Perverse Incentives

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REVERSE PAYMENTS, PERVERSE INCENTIVES

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I. INTRODUCTION

In July 2013 the Supreme Court held in *FTC v. Actavis* that courts ought to apply the rule of reason[1] when deciding whether a particular reverse payment settlement ("RPS") constitutes an illegal restraint on trade. The Supreme Court had granted certiorari[2] 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).[3]

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."[4] As the FTC pointed out in its petition, there was an important and recent split among courts regarding the desirability and legality of RPSs,[5] and this

1. *See* FTC v. Actavis, Inc., No. 12-416, slip op. at 20–21 (U.S. June 17, 2013).
2. FTC v. Watson Pharm., Inc., 133 S. Ct. 787 (2012).
3. Petition for Writ of Certiorari at I, FTC v. Actavis, Inc., No. 12-416 (U.S. June 17, 2013).
4. *Id.* at 2.
5. *Id.* at 10–11; *see also infra* Part II.C (discussing antitrust litigation involving reverse payment settlements and the recent split among courts).

split is paralleled by an academic debate among law and economics scholars.[6] In light of the Supreme Court's recent decision and the importance of the issue to both the pharmaceutical 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 demonstrates 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 would likely retard technological progress by making it difficult to maintain monopoly profits on a contested patent, thereby reducing the reward for becoming a patentee.[7] This Article illustrates that this

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6. 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" produced over 150 articles on the subject. Various articles point out the anticompetitive or welfare-reducing potential of RPSs. *See, e.g.*, David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003). On the other hand, other articles discuss the dangers associated with using restrictive rules that make RPSs presumptively or per se illegal. *See, e.g.*, Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, *in* 3 ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY 2127 (Wayne Dale Collins et al. eds., 2008); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002); Henry N. Butler & Jeffrey Paul 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 M. Dickey & Daniel L. Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. COMPETITION L. & ECON. 615 (2012); James Langenfeld & Wenqing 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 D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

7. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006) ("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."); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (noting that "a rule that forecloses a patentee's ability to settle its infringement claim" increases the duration of uncertain litigation, and thereby may decrease the parties' "ability to research, develop, and market" their drugs); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003) ("[E]xposing 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."); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (explaining that "a rule that makes it per se illegal to settle a Hatch-Waxman lawsuit" may prevent brand from controlling or limiting and make them "less inclined to invest the research and development ('R & D') costs associated with bringing new drugs to the market"); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 760 (2002) ("A rule prohibiting exit payments may . . . increas[e] the risks of engaging in inventive activity, and therefore lead to a suboptimal amount of innovation . . . [T]he patentee would not have created the invention at

conclusion is unwarranted by using a formal game-theoretical model to prove that, under a range of conditions, restricting RPSs increases firms' incentives to engage in research and development ("R&D") for a variety of technologies. Specifically, RPSs channel pharmaceutical companies' investment in R&D toward relatively obvious and weak inventions. This channeling or reward shifting effect, which so far has gone unnoticed, converts what scholars have previously identified as a dynamic cost[8] of illegalizing RPSs into a potential benefit. The reward shifting effect may therefore tip the cost-benefit analysis in favor of more frequently disallowing RPS arrangements, as suggested by the Third Circuit,[9] especially since the Second and Eleventh Circuits, as well as a number of district courts, have relied on the erroneous assumption that RPSs foster innovation when justifying their permissive treatment of RPSs.[10]

The reward shifting effect, however, is 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.[11] RPSs occur under the peculiar

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issue had it not been for her *ex ante* expectation of legal protection from free-riding."); Dickey & Rubinfeld, *supra* note 6, at 622 (observing that "[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"); Langenfeld & Li, *supra* note 6, at 778 ("These settlements can increase firms' incentive to undertake R&D investment . . . . [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.").

8. *See, e.g.*, Crane, *supra* note 7, at 759–62, (The author characterized this incentive effect as an "Innovation Cost" and stated, "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.").

9. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *vacated* ("[W]e 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.").

10. *See supra* note 7 and accompanying text; *infra* Part II (demonstrating how courts have relied on this erroneous assumption).

11. See *infra* Part II.B, for a brief summary of the regulatory framework under the Hatch-Waxman Act; *see also* Butler & Jarosch, *supra* note 6, at 63–66; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 951–58 (2011); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1306–07 (2010) (reviewing the relevant aspects of the Hatch-Waxman Act).

framework structured by the Hatch-Waxman Act ("HWA"),[12] which regulates entry of a generic drug manufacturer ("*G*") into the patented drug market. The HWA lowers the cost of entry to *G* by allowing it to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA").[13] By submitting an ANDA, *G* essentially skips new and costly clinical trials by demonstrating that its drug is the bioequivalent[14] of a previously-approved branded drug. If that branded 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.[15] This act constitutes patent infringement,[16] which allows the branded drug manufacturer ("*P*") to sue *G* for infringement. Only after this process would the parties agree to an RPS.

In the typical RPS, *G* agrees to delay entry in exchange for a large sum of money from *P*.[17] The parties' incentives to reach an RPS can be understood by focusing on the surplus generated by such agreements. When *G*'s entry is delayed, *P* preserves its monopoly — i.e., its ability to charge supra-competitive prices for its branded drug. The profit made by *P* alone is greater than the combined profit *P* and *G* would make if they competed against each other.[18] Furthermore, the parties can avoid litigation costs by settling.[19] Therefore, an RPS generates a surplus equal to the difference between monopoly profits and duopoly profits plus litigation costs.[20] A simple application of the Coase Theorem reveals that *P* and *G* have the necessary incentives to

12. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections at 21 U.S.C. (2012); 28 U.S.C. (2006); 35 U.S.C. (2006)).

13. *See* Butler & Jarosch, *supra* note 6, at 63–64.

14. 21 U.S.C. § 355(j)(8)(B) (2012) (defining "bioequivalent").

15. § 355(j)(2)(A)(vii)(IV). See *infra* Part II.B, 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.

16. 35 U.S.C. § 271(e)(2)(A) (2006).

17. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 193–94 (2d Cir. 2006) (considering a generic challenger's agreement to delay entry in exchange for $21 million RPS and a non-exclusive license).

18. This follows from the reasonable assumption that monopoly profits are greater than combined duopoly profits. *See, e.g.*, Carl Shapiro, *Prior User Rights*, 96 AM. ECON. REV. 92, 92 (2006) (assuming that "combined duopoly profits are less than monopoly profits, $2\pi_D < \pi_M$"). If this assumption were not true, the monopolist could increase its profits simply by dividing itself into two entities, and have them compete against each other. This would be a violation of the assumption that the monopolist was making monopoly profits.

19. See *infra* Part IV, for a review of the law and economics literature on settlements. The primary social benefit of settlements is the reduction of litigation costs.

20. This statement assumes that *G* may enter with certainty. If its likelihood of entry is less than 100%, then the surplus generated through settlement is proportional to that likelihood. See *infra* Parts IV and V, for an analysis of cases where *G*'s likelihood of entry depends on patent strength, and consider all probabilities of entry.

reach a settlement to capture and share the surplus generated through this option.[21]

Whether RPSs are pro-competitive (promote social welfare) or anti-competitive (detract from social welfare) is a very complex question and has drawn enormous attention from law and economics scholars in recent years.[22] 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.[23] According to these scholars, RPSs allow *P* to preserve its monopoly, which shrinks sales volume and increases deadweight loss.[24] Other scholars have suggested that certain RPSs can have pro-competitive virtues that should be weighed against such costs.[25] These benefits include reducing litigation costs[26] and uncertainty,[27] and allowing liquidity-constrained generic manufacturers to survive until market entry.[28] 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 of becoming a patentee.[29] However, there is no empirical support for this last proposition.[30] In fact, as this Article demonstrates, illegalizing RPSs may increase, rather than reduce, the rewards of

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21. See *infra* Part IV.B.I, for a formal derivation of this result through an economic model of settlement. This result relies on parties not being relatively over-optimistic. See *infra* Part V.D, for a detailed consideration of relative over-optimism.

22. *See supra* note 6 and accompanying text.

23. *See, e.g.*, Elhauge & Krueger, *supra* note 6, at 284–85; Hovenkamp, Janis & Lemley, *supra* note 6, at 1722; Shapiro, *supra* note 6, at 392–93.

24. *See, e.g.*, Elhauge & Krueger, *supra* note 6, at 293 (noting that because the patent holder can charge monopoly prices, settlements reduce consumer welfare "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"); Hovenkamp, Janis & Lemley, *supra* note 6, at 1722 (observing that "parties to an IP dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest" by "maximizing their own profits" instead of "enhancing the public welfare").

25. *See, e.g.*, Blair & Cotter, *supra* note 6, at 525–26; Butler & Jarosch, *supra* note 6, at 62–63; Crane, *supra* note 7, at 749–50; Dickey & Rubinfeld, *supra* note 6, at 618–19.

26. *See, e.g.*, Crane, *supra* note 7, at 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.").

27. *See, e.g.*, Addanki & Daskin, *supra* note 6, at 2133–34; Butler & Jarosch, *supra* note 6, at 95–97; and Crane, *supra* note 7, at 772 (discussing risk-aversion and the role of settlements in reducing uncertainty).

28. *See, e.g.*, Butler & Jarosch, *supra* note 6, at 98 (noting that a reverse payment could be pro-competitive if it allows a cash-poor generic drug manufacturer to survive until it enters the market).

29. *See supra* note 7 and accompanying text.

30. *See, e.g.*, Butler & Jarosch, *supra* note 6, at 113 (stating there is an "absence of meaningful empirical evidence on the aggregate effects that reverse payments have on competition or output").

becoming a patentee for less obvious and more revolutionary inventions.[31] Thus, there is a fallacy, albeit a subtle one, in the reasoning that has led judges and scholars to conclude that illegalizing RPSs is likely to retard technological progress.

To illustrate this subtle fallacy, it is best to start by describing the correct observations in the literature. Previous commentary and articles on RPSs have correctly identified two points: (1) illegalizing RPSs removes an option which would otherwise be available to *P* and *G*, and (2) a simple application of the Coase Theorem reveals that the removal of this option reduces the ex-post expected return to *P* and *G*.[32] At first glance, these two observations seem to imply that illegalizing RPSs has the effect of reducing the reward of becoming a patentee by reducing the ex-post expected return.

This deduction contains a subtle error. 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 the patent is relatively strong, i.e., when a court is less likely to invalidate *P*'s patent and more likely find it infringed.[34] If RPSs are illegalized, a *P* holding strong patents would expect to face fewer challenges, saving an amount equal to settlement payments that it would have otherwise paid to *G*. This increases strong-patent *P*'s rewards to 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 trans-

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31. See *infra* Part V, where this result is formalized using a game-theoretical model.

32. *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 6, at 622 ("[S]ettlement 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).").

33. *See, e.g.*, Dickey & Rubinfeld, *supra* note 6, at 618–19; Linda Gratz, Economic Analysis of Pay-for-Delay Settlements and Their Legal Ruling 2–5 (Jan. 4, 2012) (working paper), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1979699.

34. See *infra* Part III.C and the references cited therein, for a more detailed discussion of patent strength and probabilistic patents.

35. *See, e.g.*, Elhauge & Krueger, *supra* note 6, at 293; Hovenkamp, Janis & Lemley, *supra* note 6, at 1722.

fers through RPSs is removed, *G* cannot be compensated for delaying entry until patent expiration. Thus, the parties are forced into either litigation or a delayed entry settlement ("DES"),[36] where *G* enters the market *prior* to patent expiration and no monetary payments are made between the parties.[37] This shortens the amount of time in which *P* can charge monopoly or supra-competitive prices, and therefore increases consumer welfare.[38] Moreover, unless the parties are relatively over-optimistic, they can avoid litigation through DESs even when RPSs are restricted, and the illegality of RPSs should have no impact on litigation costs.[39]

Therefore, absent "probably rare"[40] circumstances, restricting RPSs leads to static benefits without increasing expected litigation costs[41] and dynamic benefits in the form of increased R&D for relatively stronger inventions.[42] However, in some instances there may be deviations from the standard assumptions used to derive these results, which could make some RPSs pro-competitive.[43] For instance, when *G* is liquidity-constrained, an RPS may be necessary for the firm to survive financially until it enters the market.[44] Absent such deviations from standard assumptions, RPSs ought to be prevented. Appropriate restriction can be achieved by applying the rule of reason to allow RPSs only when there is clear indication that the settlement would further pro-competitive goals.[45]

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36. See *infra* Part IV.C, for a model of delayed entry settlements.

37. *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 217–18 (3d Cir. 2012) *vacated*; Gratz, *supra* note 33, at 9.

38. *See infra* Part V.C.

39. Hovenkamp, Janis & Lemley make a similar point. *Supra* note 6, at 1760–61. See *infra*, Part V.D, for a detailed discussion of the effect of relative over-optimism. It demonstrates that accounting for potential over-optimism magnifies the reward shifting effect of illegalizing RPSs by increasing litigation costs for weak patents and reducing litigation costs for strong patents.

40. *K-Dur*, 686 F.3d at 218. This Article follows the Third Circuit in labeling these circumstances as *probably rare*. *Id.* (labeling as "probably rare" the "situations where a reverse payment increases competition"). Whether or not these circumstances are in fact rare, as an empirical matter, is not a question that this Article addresses.

41. This is true as long as parties are not over-optimistic. Over-optimism might lead to increased litigation costs, but it also strengthens the reward shifting result presented in the Article. *See supra* note 39 and accompanying text; *infra* Part V.D.

42. *See infra* Part V.

43. *See supra* notes 25–28 and accompanying text.

44. *See supra* note 28 and accompanying text.

45. In *K-Dur*, the Third Circuit advocated a "quick look rule of reason analysis," which makes RPSs presumptively illegal. 686 F.3d at 218. Figuring out the precise quickness with which the rule of reason ought to be applied is not an easy task. As the Supreme Court stated, "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 . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 780–81 (1999). Although a single article cannot provide a complete answer as to how quickly the rule of reason ought to be applied, one can identify relevant factors. This Article shows that what

It should be noted that, just like any economic model, the game-theoretic model presented in Parts IV and V abstracts from potentially relevant issues.[46] Thus, this Article does not purport to address every relevant aspect of restricting RPSs. Instead, it serves a less ambitious goal, namely to identify a previously unnoticed and positive effect of restricting RPSs.

The remaining parts of this Article are devoted to more precisely presenting the arguments outlined above, particularly through the use of a game-theoretical model. Part II presents the regulatory framework under which RPSs take place and explains the tests used by each of the five circuit courts that have decided RPS cases in the past. It also examines how the circuit courts that have treated RPSs permissively relied on the assumption that RPSs foster innovation. Finally, it briefly reviews the Supreme Court's decision in *FTC v. Actavis*. Part III reviews reward theory, the dominant utilitarian approach to studying patent law, and introduces and defines the concept of "probabilistic patents." It also documents the peculiar features of the pharmaceutical sector and describes why these features may make reward theory particularly suitable for analyzing companies' incentives in this sector. Part IV reviews the economics literature on settlements, which provides the necessary analytical framework to evaluate the relevant parties' incentives to engage in DESs. Part V uses the insights and analytical tools introduced in Parts III and IV to structure a game-theoretical model of R&D and settlement.

Part V further 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 VI concludes by discussing directions for future research.

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courts and scholars previously interpreted as a dynamic cost may in fact be a dynamic benefit.

46. For instance, the model abstracts from the issue of at-risk entry recently addressed by Elhauge & Krueger, *supra* note 6, the incentive distortion effect of the 180-day exclusivity period addressed by Hemphill & Lemley, *supra* note 11. Rather it focuses on the interactions between a patentee and a single generic entrant. There is no reason to believe, *a priori*, that including these details in the model presented in Parts IV and V is likely to diminish the magnitude of the reward shifting effect; to the contrary, it may magnify the effect. *See infra* Parts IV, V. 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.

II. REVERSE PAYMENT SETTLEMENTS AND EXISTING LAW

A. Reverse Payment Settlements

An RPS is an agreement between a patentee and an alleged patent infringer, whereby the patentee pays the alleged infringer to delay entry into the market for a certain period of time. The atypical direction of the settlement payment, namely from patentee to infringer rather than from infringer to patentee, is why the word "reverse" is used to describe the settlement.[47] Two questions should immediately come to mind: If the patentee is the owner of a legitimate patent, why would it settle with an alleged infringer instead of enforcing the legitimacy of its patent through ligation? Conversely, if the alleged patent infringer believes that the patent is invalid, why would it forego profits by settling instead of entering the market?

These questions are most relevant and thoroughly debated regarding the use of RPSs in the pharmaceutical sector. The majority of antitrust challenges to RPSs occur in the context of generic drug companies' challenges of branded drug patents.[48] To put the discussion of RPSs and pharmaceuticals into perspective, it will be helpful to understand the regulatory and statutory framework that is the impetus for such agreements, i.e., the Hatch-Waxman Act, and its relation to the Food and Drug Administration's process of approving generic drugs.[49]

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 FDA.[50] The applicant seeking drug approval files a New Drug Application ("NDA"),[51] which requires the applicant undergo multiple phases of

47. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 205 (2d Cir. 2006) (explaining why the word "reverse" is used to describe such payments).

48. *See, e.g.*, Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494 (2007) ("Because of the huge drop in drug price 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.").

49. Opderbeck, *supra* note 11, contains an excellent review of the regulatory framework generated by the Hatch-Waxman Act, to which the Author extensively referred. *See* discussion *infra* Part II.B.

50. 21 U.S.C. § 355(a) (2012).

51. *Id.* § 355(b)(1). The NDA must contain detailed information about the drug, including its "composition," "full reports of investigations" about its safety and effectiveness, "a full description" of its production and packing processes, and "specimens of the labeling proposed to be used." *Id.*

clinical trials,[52] a process that is both time-intensive and extremely costly.[53] If the FDA approves the NDA, it publishes the drug and patent information in a book[54] commonly referred to as the "Orange Book."[55]

Before the HWA, the end result of the approval process was usually for the drug to reach the market with a short period of time left on the original patent.[56] However, potential competitors could not legally develop generic versions of branded pharmaceuticals to be launched upon patent expiration unless they met a statutory exception to the Patent Act.[57]

The HWA altered the regulatory context of these policies for pharmaceuticals. Specifically, the HWA provided an extension for up to five years on drug patents that were subject to regulatory delay.[58] The Act helps generic competitors as well, however, by allowing them to seek regulatory approval without incurring patent liability.[59] More importantly, the Act also allows a generic competitor to seek an ANDA if it can be shown that the generic drug is the "bioequivalent" of a patented drug.[60] The ANDA allows an applicant to piggyback on the safety and efficacy studies of a patented drug, thereby reducing regulatory costs to generic competitors.[61]

An ANDA "must make one of four 'paragraph certifications'" regarding the patent for the branded drug.[62] Under "Paragraph I," the generic company certifies that no patent information for the brand name drug has been filed with the FDA.[63] For a "Paragraph II" certifi-

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52. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 192–93 (1999).

53. *See* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 369 (2010) (noting evidence that, on average, new drugs take between ten and fifteen years and cost more than $1.3 billion to develop); Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (estimating the "fully capitalized" cost of developing a new drug at $802 million); Salomeh Keyhani, Marie Diener-West & Neil Powe, *Are Development Times for Pharmaceuticals Increasing or Decreasing?*, 25 HEALTH AFF. 461, 463 (2006) (finding that the median clinical trial phase for drug development is 5.1 years).

54. 21 U.S.C. § 355(j)(7)(A) (2012).

55. Hemphill & Lemley, *supra* note 11, at 951–52 ("Those patents are listed by the brand-name firm in an FDA document commonly known as the Orange Book.").

56. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4 (July 2002), http://permanent.access.gpo.gov/websites/www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("[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.").

57. Opderbeck, *supra* note 11, at 1306.

58. 35 U.S.C. §§ 156(c)(3), (g)(6)(A) (2006 & Supp. V 2011).

59. Opderbeck, *supra* note 11, at 1307.

60. *See* 21 U.S.C § 355(j)(2)(A) (2012).

61. Opderbeck, *supra* note 11, at 1307.

62. *FTC v. Watson Pharm.*, 677 F.3d 1298, 1303 (11th Cir. 2012).

63. 21 U.S.C. § 355(j)(2)(A)(vii)(I) (2012).

cation, the generic company must show that the patent for the branded drug has expired.[64] Under "Paragraph III," the applicant must demonstrate that a patent will terminate on a certain date,[65] and the FDA then places the application on hold until that expiration date.[66] Of greatest import, however, are the incentives for potential generic competitors to challenge drug patents *before* they expire, which happens under a "Paragraph IV" certification. Under Paragraph IV, an applicant certifies that the challenged patent "is invalid or will not be infringed by" the generic version of the drug.[67] The first filer of a Paragraph IV certification receives a 180-day period of generic market exclusivity.[68]

Under Paragraph IV, the applicant must provide notice to the pharmaceutical company of its challenge to the branded drug's patent,[69] after which the challenged pharmaceutical company has 45 days to respond by filing an infringement lawsuit against the ANDA applicant.[70] If the patent holder fails to sue, the FDA proceeds with its approval of the generic drug.[71] However, if the suit is timely filed, the FDA delays approval for 30 months to allow resolution through litigation or settlement.[72]

The typical RPS under Hatch-Waxman occurs when a generic manufacturer files an ANDA with a Paragraph IV certification, and settles the subsequent lawsuit by agreeing to delay marketing a generic version of the drug in exchange for a monetary payment from the branded manufacturer.[73]

C. Litigation Involving Reverse Payment Settlements

The circuit courts of appeals have applied different sets of rules to determine the legality of RPSs, which has led to conflicting results. Six circuit courts have evaluated various types of RPSs: the Second,

64. *Id.* § 355(j)(2)(A)(vii)(II).
65. *Id.* § 355(j)(2)(A)(vii)(III).
66. *Id.* § 355(j)(5)(B)(ii).
67. *Id.* § 355(j)(2)(A)(vii)(IV).
68. Hemphill & Lemley, *supra* note 11, at 953. The model in Parts IV and V does not formally incorporate the 180-day exclusivity period to focus on the reward shifting effect of illegalizing RPSs, which is discussed in Part V. *See infra* Parts IV, V. The effects of this exclusivity period, and potential reforms, are discussed in detail in Hemphill & Lemley, *supra* note 11.
69. § 355(j)(2)(B) (2012).
70. *Id.* § 355(j)(5)(B)(iii).
71. *Id.*
72. *Id.*
73. *See, e.g.*, 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 (2008); Holman, *supra* note 48, at 494–500.

Third, Sixth, Eleventh, Federal, and D.C. Circuits.[74] Only four of these circuits analyzed typical RPSs, where the agreement settles the underlying infringement case.[75] Among these circuits, only the Third Circuit's rule can fairly be characterized as one that restricts the use of typical RPSs.[76] The three circuits that applied permissive rules to evaluate RPSs — the Eleventh Circuit, the Second Circuit, and, indirectly and to a lesser extent, the Federal Circuit — relied on the assumption that allowing RPSs would foster innovation.[77] The divergence between these Circuits' approaches and the Third Circuit's approach led the Supreme Court to grant certiorari in an Eleventh Circuit case, and subsequently to decide that courts must apply the rule of reason when considering antitrust challenges to RPSs.[78] To highlight how the assumption that RPSs increase R&D incentives have contributed to these developments, and to describe the split between the circuit courts in further detail, this Article briefly reviews important aspects of the Second, Third, Eleventh, and Federal Circuits' decisions. Then, this Article describes the recent Supreme Court decision in *FTC v. Actavis*.

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74. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 209–14 (3d Cir. 2012) (listing prior circuit court decisions concerning RPSs).

75. *Id.* at 210–11 (explaining that the D.C. Circuit and the Sixth Circuit analyzed the same RPS, and that the RPS did not settle the underlying patent infringement).

76. *See id.* at 218.

77. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006) ("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."); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (noting that restricting RPSs "may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product"). The Federal Circuit relied on the district court's analysis of the "tension between the antitrust laws and the patent laws" in concluding that only anti-competitive effects outside "the exclusionary zone" ought to be taken into account when applying the rule of reason. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008). The district court, in turn, referred to a previous case where the court pointed out that illegalizing RPS may retard innovation. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 532 (E.D.N.Y. 2005) (citing *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.").

78. FTC v. Actavis, Inc., No. 12-416, slip op. at 20–21 (U.S. June 17, 2013).

1. Reliance by the Second, Eleventh, and Federal Circuits on the Assumption that RPSs Increase R&D Incentives

The Second, Eleventh, and Federal Circuit courts all applied permissive rules when evaluating the legality of RPSs, as the existence and amount of the reverse payment played no role in their analysis of RPSs. In fact, according to *K-Dur*, "[a]s a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial."[79] All three courts relied on the assumption that allowing RPSs fosters innovation. Though the Federal Circuit's reliance was rather indirect, the Second and Eleventh Circuits' reliance on this assumption was very explicit.

In In re *Tamoxifen Citrate Antitrust Litigation*, the Second Circuit reasoned that restricting RPSs would generate "uncertainty surrounding patents and might delay innovation."[80] Similarly, in *Schering-Plough Corp. v. FTC*, the Eleventh Circuit suggested that "the caustic environment of patent litigation may actually decrease product innovation."[81] The Federal Circuit, on the other hand, relied on the lower court's analysis of the "tension between the antitrust laws and the patent laws" in concluding that only anti-competitive effects outside "the exclusionary zone" ought to be taken into account when applying the rule of reason.[82] Yet the lower court, in turn, had relied on the reasoning that illegalizing RPSs would "limit[] the options available to both generic and brand-name manufacturers," and that this would induce branded and generic manufacturers alike to "be less inclined to invest the research and development ('R & D') costs associated with bringing new drugs to the market."[83]

It is impossible to ascertain how much these courts relied on the alleged R&D-reducing effect of illegalizing RPSs, or whether they would have decided differently had they observed the reward shifting effect of illegalizing RPSs. It is certain, however, that one cannot lend as much credibility to their opinions after observing the reward shifting effect, since any analysis purporting to address the "tension between the antitrust laws and the patent laws"[84] must carefully consider how various rules affect the expected rewards to potential patentees. This is true not only because "the constitutional provision upon which the copyright and patent statutes rest indicates that the purpose of

79. *K-Dur*, 686 F.3d at 214.
80. *Tamoxifen*, 466 F.3d at 203.
81. *Schering-Plough*, 402 F.3d at 1075.
82. *Ciprofloxacin*, 544 F.3d at 1333.
83. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 532 (E.D.N.Y. 2005).
84. *Ciprofloxacin*, 544 F.3d at 1333.

those laws is to provide incentives for creative intellectual efforts that will benefit the society at large,"[85] but also because courts display a desire to provide proper R&D incentives.[86]

2. The Third Circuit

In In re *K-Dur Antitrust Litigation*, the Third Circuit considered the RPSs between Schering-Plough and two generic drug manufacturers, Upsher and ESI.[87] Those two agreements had been reviewed previously by the Eleventh Circuit in *Schering-Plough Corp. v. FTC*.[88]

After reviewing previous RPS cases decided by other circuit courts, the court refused to apply the "scope of the patent test"[89] previously used by the Eleventh and Second Circuits because the "test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition."[90] The Third Circuit emphasized that the scope of the patent test creates an "almost unrebuttable presumption of patent validity."[91] After citing studies that provide empirical support for the proposition that "[m]any patents issued by the PTO are later found to be invalid or not infringed,"[92] the court focused on the dangers and costs associated with enforcing weak patents, and concluded that "the public interest supports judicial testing and elimination of weak patents."[93] Finally, the court supported this conclusion by turning to Supreme Court precedent on the issue. Specifically, the court cited to *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, a case in which the Supreme Court emphasized "the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents."[94]

After rejecting the scope of the patent test, the court adopted a quick look rule of reason test, which creates a rebuttable presumption of illegality upon a showing that the patentee made a payment to the

85. William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 173 (Stephen R. Munzer ed., 2001).

86. *See supra* note 7; *Schering-Plough*, 402 F.3d at 1075 ("[W]e must recognize '[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system.'" (quoting Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1307 (11th Cir. 2003))).

87. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 202 (3d Cir. 2012).

88. *Schering-Plough*, 402 F.3d at 1058.

89. *K-Dur*, 686 F.3d at 212.

90. *Id.* at 214.

91. *Id.*

92. *Id.* at 215.

93. *Id.*

94. 329 U.S. 394, 400 (1947).

generic manufacturer who agreed to delay entry.[95] The court supported its decision by emphasizing that parties' incentives to settle would be preserved to a great extent because they could still agree on settlements that only involve delayed entry by the generic manufacturer but no reverse payment.[96] This rule, according to the court, would eliminate anticompetitive behavior without threatening most settlements.[97]

3. The Supreme Court

In *FTC v. Watson Pharmaceuticals*, the Eleventh Circuit did not depart from the test it previously promulgated in *Schering-Plough Corp. v. FTC*, explaining that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[98] After applying this test to the RPSs between branded manufacturer Solvay and its generic competitors, the Eleventh Circuit affirmed the lower court's decision to dismiss the FTC's claim.[99] The FTC appealed the decision and the Supreme Court granted certiorari on the question of "[w]hether 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)."[100]

In *FTC v. Actavis*, the Supreme Court reversed the judgment of the Eleventh Circuit and held that the rule-of-reason must be applied to determine the validity of RPSs.[101] In coming to the conclusion that it should not grant "near-automatic antitrust immunity to [RPSs]," the Supreme Court made a number of observations, summarized as follows:

> [An RPS] can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the pa-

95. *K-Dur*, 686 F.3d at 218.
96. *Id.* at 217–18.
97. *Id.* at 218.
98. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012).
99. *Id.* at 1315.
100. Petition for Writ of Certiorari, *supra* note 3, at (I).
101. FTC v. Actavis, Inc., No. 12-416, slip op. at 21 (U.S. June 17, 2013).

> tent; and parties may well find ways to settle patent disputes without the use of reverse payments.[102]

The Court similarly refused "to hold that reverse payment settlement agreements are presumptively unlawful,"[103] because this would be appropriate only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[104]

Most relatedly to the observations made in this Article, in explaining its rationale, the Supreme Court noted that an issued patent "may or may not be valid," and similarly that it "may or may not be infringed."[105] Therefore, "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[106] Hence, just like the Second and Eleventh Circuits, the Supreme Court focused on striking a balance between the dynamic efficiency objectives of patent law and static efficiency objectives of antitrust law.

Contrary to claims by the Second and Eleventh Circuits, this Article demonstrates that RPSs may be retarding, rather than promoting, technological progress by shifting rewards from strong inventions towards weak inventions. Therefore, to serve the Supreme Court's stated objective of balancing static benefits and dynamic costs, lower courts must hesitate to draw broad conclusions regarding the costs of precluding RPSs when applying the rule of reason in the future.

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

This Article focuses on utilitarian theories of patents.[107] Known as a moral theory,[108] utilitarianism is the dominant approach courts

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102. *Id.* at 19–20.

103. *Id.* at 20.

104. *Id.* (citing Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999)).

105. *Id.* at 8.

106. *Id.* at 8–9.

107. For a discussion of utilitarian theories of patents, see Fisher, *supra* note 85, at 177.

108. 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 & Steven Shavell, *Any Non-Welfarist Method of Policy Assessment Violates the Pareto Principle*, 109 J. POL. ECON. 281 (2001). For a lengthy and technical discussion of utilitarianism as a theory of distributive justice, see JOHN ROEMER, THEORIES OF DISTRIBUTIVE JUSTICE 127–62 (1996).

use to evaluate the social desirability of competing antitrust rules[109] and is "the principal philosophical theory"[110] used to study intellectual property rights.[111]

Within the utilitarian approach to intellectual property, there are several competing and complementary theories.[112] The most prominent are reward theory,[113] prospect theory,[114] and commercialization theory.[115] These theories have in common the normative goal of maximizing social welfare. However, they diverge in their assessments of how to achieve this normative goal, which economic tradeoffs are fundamental, and which patent functions deserve the greatest emphasis. Of these three theories, reward theory is the most commonly applied,[116] either explicitly or implicitly, to study the desirability of various features of the patent system. For instance, the Eleventh Circuit, in *FTC v. Watson Pharm., Inc.*,[117] which eventually reached the Supreme Court, appeared to be applying reward theory in its opening paragraph.[118] The remainder of this Part discusses the details of various utilitarian theories as well as the probabilistic nature of patents' ability to exclude.

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109. *See, e.g.*, Reiter v. Sonotone Corp., 442 U.S. 330, 343 (1979) ("Congress designed the Sherman Act as a 'consumer welfare prescription.'").

110. Peter S. Menell, *Intellectual Property: General Theories*, in ENCYCLOPEDIA OF LAW AND ECONOMICS 129, 130 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000) ("Not surprisingly, the principal philosophical theory applied to the protection of utilitarian works — that is, technological inventions — has been utilitarianism.") (citation omitted); s*ee also* Fisher, *supra* note 85, at 169.

111. Other, non-utilitarian theories of intellectual property described in Fisher, *supra* note 85, at 170–72, include: (1) 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, (2) the Kantian/Hegelian approach, which suggests that property rights ought to be allocated to enable individuals to fulfill primary human needs, including creativity, and (3) a version of legal realism, which focuses on "foster[ing] the achievement of a just and attractive culture."

112. *See* Mark A. Lemley, *The Myth of the Sole Inventor* 2 (Stanford Public Law Working Paper, No. 1856610, July 21, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1856610 (reviewing competing utilitarian theories).

113. *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 310–13 (1992) (providing a brief review of the historical developments in reward theory, and distinguishing between the strong and weak forms of reward theory); *infra* Part III.A.

114. *See infra* Part III.B.1 (discussing prospect theory in further detail).

115. *See infra* Part III.B.2 (discussing commercialization theory in further detail).

116. Fisher, *supra* note 85, at 178.

117. 677 F.3d 1298 (11th Cir. 2012).

118. *Id.* at 1300 "Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than $1.3 billion. No rational actor would take that kind of a risk over that period of time without the prospect of a big reward. The reward, if any, comes when the drug is approved and patented, giving the pioneer or 'brand name' company that developed it a monopoly over the sale of the new drug for the life of the patent. The pioneer company can then exploit the patent monopoly by charging higher prices than it could if competitors were allowed to sell bioequivalent or 'generic' versions of the drug.") (footnote omitted).

A. Reward Theory

Reward theory posits that the primary reason for issuing patents is to provide incentives to potential inventors to engage in R&D activity. Without patents, as Judge Posner observes, the fundamental economic problem is that "the manufacturer will not make the invention in the first place; he won't sow if he won't be able to reap."[119] The benefit of a patent from this perspective, then, is the dynamic incentive to innovate, which in turn fuels economic growth.

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 a degree of market power on patentees by limiting competition, which increases deadweight loss. Economists and legal scholars have long struggled to strike a balance between the competing goals of reducing such costs and increasing overall R&D activity.[120]

Early works focusing on these competing goals have identified various instruments that can influence the associated costs and benefits. Most notably, increasing the duration of patents is hypothesized to increase R&D activity by making the prize to potential patentees larger. Lengthening patent duration, however, also comes at the previously mentioned social cost of conferring additional market power to the patentees. This use-creation tradeoff[121] is the focal point of a great deal of patent research.[122] It has been applied to study the optimal duration[123] and breadth of patents,[124] as well as the desirability of various aspects of patent regimes, including the independent invention

119. RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 48 (8th ed. 2011).

120. *See, e.g.*, WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 88–89 (1969); Richard Gilbert & 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 the tradeoffs between innovation and deadweight loss).

121. The use-creation tradeoff refers to "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?*, 21 SUP. CT. ECON. REV. (forthcoming) (manuscript at 10), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1865949.

122. *See, e.g.*, Emeric Henry, *Runner-up Patents: Is Monopoly Inevitable?*, 112 SCANDINAVIAN J. ECON. 417 (2010); Mark A. Lemley, *Should Patent Infringement Require Proof of Copying?*, 105 MICH. L. REV. 1525 (2007); Murat C. Mungan, *Economics of the Independent Invention Defense Under Incomplete Information*, 20 SUP. CT. ECON. REV. 183 (2012); Shapiro, *supra* note 18.

123. *See, e.g.*, Gilbert & Shapiro, *supra* note 120; Nordhaus, *supra* note 120, at 76–86.

124. *See, e.g.*, Gilbert & Shapiro, *supra* note 120; Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113 (1990).

defense,[125] runner-up patents,[126] prior user rights,[127] and probabilistic enforcement of patents.[128]

Reward theory has been criticized for drawing an incomplete picture of the patent system. The simplest form of reward theory does not account for the fact that broad patents on complementary technologies, each necessary for a new product, may lead to hold-up problems.[129] Moreover, while reward theory suggests that increasing the reward to becoming a patentee necessarily leads to faster technological progress,[130] there are some recent empirical studies that suggest otherwise: namely that stronger patent protection may not stimulate innovation.[131]

A more detailed survey of the existing empirical work on patents and innovation reveals a peculiar characteristic of R&D in the pharmaceutical sector. Specifically, decision makers in the pharmaceutical sector appear to be most affected by the availability and strength of patents, with many claiming that they would not have developed a new product if patent protections were not available.[132]

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125. *See, e.g.*, Stephen M. Maurer & Suzanne Scotchmer, *The Independent Invention Defence in Intellectual Property*, 69 ECONOMICA 535 (2002); Mungan, *supra* note 121, at 2; Mungan *supra* note 122; Samson Vermont, *Independent Invention as a Defense to Patent Infringement*, 105 MICH. L. REV. 475 (2006).

126. *See, e.g.*, Henry, *supra* note 122.

127. *See, e.g.*, Shapiro, *supra* note 18.

128. *See, e.g.*, Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75 (2005).

129. *See, e.g.*, 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. A cumulative invention framework can be used to account for this possibility. *See* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

130. *See* Adam B. 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 121 (showing that if coordination effects are considered, theoretically, more protection can lead to less innovation).

131. *See, e.g.*, Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473, 499–500, 502 (2005) (reviewing empirical studies to support the proposition that "patent law may not stimulate R&D as directly as assumed by conventional incentive theories"); Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms*, 32 RAND J. ECON. 77, 77 (2001) (finding "no evidence of an increase in either R&D spending or innovative output" attributable to increased patent scope).

132. Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, Feb. 2000), *available at* http://www.nber.org/papers/w7552.

This interesting fact can be explained by the "discrete"[133] nature of most technologies in the pharmaceutical sector, which is described by the well-known study by Cohen, Nelson, and Walsh[134]:

> [T]he key difference between a complex and a discrete technology is whether a new, commercializable product or process is comprised of numerous separately 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, applying reward theory in this context appears to be less problematic than applying it in other industries. This is likely why most studies and court opinions analyzing the desirability of RPSs focus, either implicitly or explicitly, on the reward theory of patents.

B. Other Utilitarian Theories of Patents

1. Prospect Theory

Edmund Kitch first developed the prospect theory in 1977.[135] This theory "conceives of the process of technological innovation as one in which resources are brought to bear upon an array of prospects."[136] According to Kitch, granting broad patent rights enables patentees to coordinate research efforts that build upon the initially patented technology, incentivizing them to "further develop the field."[137] In addition to increasing overall output, such coordination is socially desirable because it eliminates rent-seeking and thus, potentially excessive development costs by third parties.[138]

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133. *Id.* at 19; *see also* Don E. Kash & William Kingston, *Patents in a World of Complex Technologies*, 28 SCI. & PUB. POL'Y 11, 12 (2001) (distinguishing between complex and simple technologies); Ken Kusunoki et al., *Organizational Capabilities in Product Development of Japanese Firms: A Conceptual Framework and Empirical Findings*, 9 Org. Sci. 699 (1998).

134. Cohen, Nelson & Walsh, *supra* note 132, at 19.

135. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

136. *Id.* at 266.

137. Lemley, *supra* note 112, at 60.

138. *See* POSNER, *supra* note 119, at 48–49 (providing a brief review of how patent law mitigates rent-seeking).

Kitch supports his arguments by analogizing the patent system to the mineral claims 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."[139] According to Kitch, this system increased mineral output by incentivizing "prospectors to pack their burros and walk off into the desert in search of mineralization."[140]

Mark Lemley contests the empirical accuracy of Kitch's analogy.[141] Lemley contends that one of the primary purported benefits identified by prospect theory does not exist. Unlike the mineral claims case, the historical "evidence suggests that strong patent control significantly impedes both commercialization and improvement of new technologies."[142] Kitch's framework also fails to recognize well-known costs associated with strong patents. In particular, granting strong patents runs the risk of retarding technological progress by discouraging other firms from developing technologies that build on the patented invention.[143] While this may eliminate rent-seeking efforts for such secondary inventions, it may increase rent-seeking activity for the initial invention. In light of these observations, scholars have criticized prospect theory as inconsistent with the realities of innovation.[144]

The dispute over whether Kitch's mineral claims analogy is misplaced is unlikely to be settled by a single article. It appears that the applicability of prospect 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."[145] Given that the pharmaceutical industry involves relatively discrete technologies,[146] abstracting from issues related to prospect theory may be less harmful than it would be in other industries. However, because there are not sufficient empirical analyses focusing on the topic, it is impossible to make definite statements about the importance and relevance of prospect theory related considerations in the pharmaceutical sector.

2. Commercialization Theory

Commercialization is "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

139. Kitch, *supra* note 135, at 271.
140. *Id.* at 274.
141. *See* Lemley, *supra* note 112, at 59–74.
142. *Id.* at 73–74.
143. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 871–79 (1990).
144. *See, e.g.*, Lemley, *supra* note 112, at 2; Merges & Nelson, *supra* note 143, at 872.
145. Kitch, *supra* note 135, at 266.
146. *See* Kash & Kingston, *supra* note 133, at 13 and accompanying text.

into practice."[147] Theories focusing on commercialization stress that an individual's incentive to invent may diverge from her incentive to commercialize the invention. As evidence of such divergence, scholars point out that a large number of patented inventions are not commercialized.[148]

Michael Abramowicz asserts that patentees may choose not to commercialize their inventions if their patents are sufficiently close to expiring at the time commercialization becomes "potentially attractive."[149] Likewise, empirical evidence suggests that "being refused a patent reduces the likelihood of commercialization."[150] Thus, undercommercialization and underdevelopment of products may emerge as potential problems, which essentially eliminate products from the market. To solve such problems, commercialization scholars have proposed somewhat unorthodox methods. Abramowicz and Duffy, for instance, argue that commercialization difficulty ought to be a factor in determining patentability.[151] 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.[152]

Mark Lemley, on the other hand, suggests that "commercialization theory [does not] offer a reason to grant broad patent rights to an inventor [when] the patent wasn't necessary to induce the invention."[153] 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 sufficient to encourage entry into new markets even in the absence of patent protection."[154]

Unsurprisingly, there is no consensus as to whether undercommercialization is a real and significant problem in general and it is unclear whether Lemley's criticisms are particularly relevant in the pharmaceutical sector.[155] Fortunately, for purposes of studying RPSs, an answer to a much narrower question is required: Is under-

147. Ted Sichelman, *Taking Commercialisation Seriously*, 33 EUR. INTELL. PROP. REV. 200, 200 (2011).

148. Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 341 (2010) ("About half, probably more, of all patented inventions in the United States are never commercially exploited.").

149. Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1065 (2007).

150. Elizabeth Webster & Paul H. Jensen, *Do Patents Matter for Commercialization?*, 54 J.L. ECON. 431, 447 (2011).

151. Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. Rev. 337, 395–408 (2008).

152. Sichelman, *supra* note 148, at 346.

153. Lemley, *supra* note 112, at 62.

154. *Id.* at 63.

155. See Webster & Jensen, *supra* note 150, at 447, for an empirical discussion of whether patents have an effect on commercialization.

commercialization a significant problem in the pharmaceutical sector? There is at least some empirical evidence that supports a negative answer. At least one study found that in the pharmaceutical sector there is little variation between the proportion of inventions that would not have been developed and the proportion of inventions that would not have been commercialized if patent protection could not have been obtained.[156]

Given the lack of sophisticated and comprehensive studies on the relevance of commercialization theory or prospect theory, it is currently not possible to determine the precise importance of exclusively focusing on reward theory. Therefore, this Article must be interpreted as providing a benchmark model focusing on reward theory, which can in future research be extended to include considerations of commercialization and prospect theories.

C. Probabilistic Patents: Weak Patents v. Strong Patents

Many scholars tend to consider only hypothetical and idealized patents when discussing the optimality of competing patent policies. An idealized "ironclad" patent[157] gives the patentee the right and ability to stop others from making, using, or selling the patentee's invention with certainty. Real-world patents, however, are far less valuable than ironclad patents.[158] The likelihood that an ordinary patent, once challenged, will be found to be partially or entirely invalid is far from zero. In fact, "[o]f patents litigated to a final determination (appeal, trial, or summary judgment), 46 percent are held invalid."[159]

In applying reward theory to study the desirability of RPSs, it is crucial to realize that patents confer the "right to *try* to exclude," rather than "the [absolute] right to exclude,"[160] because a patentee's confidence in settlement negotiations will crucially depend on how likely it thinks it *will be able* to exclude. To incorporate this aspect, this Article considers "probabilistic patents"[161] rather than ironclad patents. When a patentee who holds a probabilistic patent sues another

156. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986) (reporting that of all developed or commercially introduced inventions in the pharmaceuticals industry between 1981 and 1983, 65% would not have been commercially introduced, and 60% would not have been developed, if patent protection could not be obtained).

157. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003).

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

159. Lemley & Shapiro, *supra* note 128, at 80 (2005) (internal citation omitted). It should be noted that this number may not accurately reflect the probability with which the average patent would be found invalid. It only demonstrates that invalidity is a real possibility for litigated patents.

160. *See* Shapiro, *supra* note 157, at 395.

161. This refers to the title of Lemley & Shapiro's article, *supra* note 128.

party for infringement, the court may determine that the patent is invalid or not infringed. This Article refers to a patent as "weak" if the probability of either event is high and "strong" if the probability of both is low.

The strength of a patent not only affects the patentee's incentives to sue or settle, it also provides information as to the social value of the invention for which the patent was granted. A rational patentee holding a weak patent, *ceteris paribus*, would be willing to pay a great price to avoid revealing the invalidity or non-infringement of its patent through litigation.[162] Moreover, patents granted for relatively obvious or relatively less novel inventions are weaker because they are more likely to be found invalid if challenged. These inventions, *ceteris paribus*, contribute less to social welfare than those protected by strong patents because they represent smaller technological advances. Therefore, it is 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 imperative to understanding that restrictions on RPSs may (1) affect parties' litigation and settlement incentives differently based on the strength of the patent, (2) affect potential inventors' R&D efforts differently depending on the obviousness or novelty of the potential invention, and (3) affect the aggregate value of inventions obtained through R&D by shifting rewards from weakly patentable to strongly patentable inventions. Next, this Article reviews the economics literature on settlements to analyze formally these effects using a game theoretical model.

IV. THE ECONOMICS OF SETTLEMENT

It is believed that at least 90 percent of civil suits are settled in the United States.[163] Therefore, it is not surprising that there exists a broad literature on the economics of settlements. This Part reviews

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162. *See infra* Parts IV.C.3, V (showing derivation of this result).

163. *See, e.g.*, Marc Galanter, *The Day After the Litigation Explosion*, 46 MD. L. REV. 3, 8 (1986); Kevin C. McMunigal, *The Costs of Settlement: The Impact of Scarcity of Adjudication on Litigating Lawyers*, 37 UCLA L. REV. 833, 836 (1990); David M. Trubek et al., *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 not accurately reflect settlement rates. *See, e.g.*, David Rosenberg & Steven Shavell, *A Simple Proposal to Halve Litigation Costs*, 91 VA. L. REV. 1721, 1725 n.6 (2005) ("Recent data on state courts show that about 96% of civil cases are resolved without trial. Similarly, recent data on federal courts demonstrate that approximately 98% of civil cases are resolved short of trial. 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.") (citations omitted).

three important settlement models: the basic, the injunctive, and the delayed entry settlement models. This review not only demonstrates how settlement models have evolved to account for the peculiar dynamics encountered in infringement cases in the pharmaceutical sector, it also highlights important observations that are directly relevant to discussing the effects of restricting RPSs. After reviewing these models, in Part IV.C, this Article uses the delayed entry settlement model to study the incentives of a patentee ("*P*") and a generic manufacturer ("*G*"), and to estimate their expected payoffs after settling.

First, this Article reviews the basic settlement model pioneered by Landes,[164] Gould,[165] and Posner.[166] 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 settle. Briefly stated, parties settle because it is cheaper than continuing with litigation,[167] and we care because laws and standards shape parties' bargaining positions in settlement negotiations.[168] Early extensions of the basic settlement model also explain how differences in expectations can cause a small proportion of cases to be litigated despite the availability of a cheaper option, i.e., settling.[169] This final observation is particularly important for identifying the effect of illegalizing RPSs on the frequency of litigation.

Nonetheless, the basic settlement model is not perfect. For instance, it assumes that parties can only transfer wealth through settlements, and that they cannot affect their future rights. This assumption is clearly violated when settlements contain injunctive clauses.[170] Therefore, it is important to relax this assumption in order to incorpo-

164. William M. Landes, *An Economic Analysis of the Courts*, 14 J.L. & ECON. 61 (1971).

165. John P. Gould, *The Economics of Legal Conflicts*, 2 J. LEGAL STUD. 279 (1973).

166. Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEGAL STUD. 399 (1973).

167. This is a standard assumption in the literature. *See, e.g.*, George L. 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 . . . .").

168. *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.").

169. *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 167, 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).

170. *See infra* Part IV.A.

rate injunctive settlements, because reverse payments are unlikely to occur unless the settlement agreement contains an injunctive clause.[171]

The injunctive settlement model, proposed by Professors Hylton and Cho, provides a framework for analyzing parties' incentives when they have the ability to craft injunctive settlement agreements.[172] This model is particularly useful for studying the way patentees and generic manufacturers are likely to structure settlement agreements when reverse payments are legal. Later, this Article shows that a patentee has an incentive to offer a generic manufacturer a reverse payment in exchange for delaying entry until the expiration of its patent under a wide range of circumstances.[173]

When reverse payments are legal, as demonstrated in Part IV.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 RPSs are illegal, the patentee can no longer offer a sum of money to the generic company in exchange for delaying entry until its patent expires. In these cases, the parties can only 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 Article develops such a model, the "delayed entry model," in Part IV.C.

After developing the delayed entry model, this Article uses 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 *P*'s and *G*'s investment decisions in earlier stages, which are studied in Part V.

A. The Basic Model

The basic economic model of settlement involves plaintiffs and defendants who compare the relative costs and benefits of going to 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

171. *See infra* Part IV.A (explaining that parties are unlikely to have RPSs under the simple model, unless the plaintiff is somehow forced to sue the defendant).

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

173. *See infra* Part IV.B.2, (demonstrating that parties are likely to have RPSs if (1) they have similar bargaining powers, (2) they have asymmetric bargaining powers but the patent is weak, or (3) the generic manufacturer's litigation costs are small in comparison to its expected return from litigation).

from going to trial. Further, they are assumed to know three things[174]: the monetary value ("J") of a favorable judgment for the plaintiff,[175] and the cost of litigation for each party (L_p and L_d for the plaintiff and defendant, respectively). Moreover, it is assumed that each party estimates the probability that the plaintiff will obtain a favorable judgment at trial (P_p and P_d refer to the plaintiff's and defendant's estimates, respectively).

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

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

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, the cost of settlement for the defendant is less than the expected cost of going to trial if:

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

(1) and (2) summarize the intuitive result that the plaintiff is only willing to accept settlement offers that are sufficiently large and that the defendant is only willing to make settlement offers that are sufficiently small. Whether the parties can eventually agree on mutually acceptable settlement terms 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 expressed in symbols by combining (1) and (2): $(P_d \times J) + L_d > (P_p \times J) - L_p$. Rearranging this inequality, we have[176]:

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

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

Inequality (3) describes the conditions under which rational parties decide to settle. Specifically, they are likely to settle if: (1) the costs ("L") that can be avoided through settlement are large, and

174. This Article assumes no settlement costs for the sake of brevity, because the inclusion of costs, which do not exceed litigation costs, does not alter this Article's conclusions. It is common in the literature to assume that settlement costs are less than litigation costs. *See supra* note 167.

175. 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 IV.B, *infra*.

176. This condition is equivalent to another. *See* Priest & Klein, *supra* note 167, at 13 (condition expressed in inequality (6)).

(2) the plaintiff is not much more optimistic than the defendant regarding his likelihood of securing a favorable judgment, i.e., P_p is not much larger than P_d.[177]

Although the basic model provides strong insights as to when and why parties may wish to settle, it cannot explain why parties would ever engage in RPSs, unless the plaintiff were somehow forced to bring a claim in the first place[178] and litigation costs exceeded the plaintiff's expected gains from trial. This is because the basic model assumes that (1) the settlement's only function is to facilitate a wealth transfer from one party to the other without generating anything of further value for either party, and (2) the plaintiff would not bring a claim if he expected to make payments to the defendant to avoid proceeding with trial.[179]

However, in some contexts, including patent infringement cases, 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 [basic] 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.[180]

Stated differently, settlements can be used to allow the plaintiff to purchase outcomes that are valuable to the plaintiff. Therefore, injunctions generate monetary surplus through legal disputes. 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.

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177. For the purposes of this Article, a meticulous inquiry into what leads parties to have diverging beliefs is not necessary. For more on this subject, see Priest & Klein, *supra* note 167, at 17 (demonstrating that under simple hypothesis, parties are more likely to have diverging beliefs if the case is a close one).

178. One might think that the Hatch-Waxman Act does exactly this. 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 not to sue the generic manufacturer if it expected later to make reverse payments to avoid litigation costs.

179. 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 payoffs. *See generally* ROBERT GIBBONS, GAME THEORY FOR APPLIED ECONOMISTS 55–141 (1992) (explaining dynamic games and the concept of SPNE). In this simple settlement model, a situation in which the plaintiff initiates a case against the defendant only later to make a reverse payment cannot be an SPNE, because the plaintiff can increase his payoff from −S to 0 by simply not suing in the first place.

180. Hylton & Cho, *supra* note 172, at 186.

The next Part considers the economics of injunctive settlements in more detail, identifying conditions under which parties choose to engage in RPSs.

B. The Economics of Injunctive Settlements

To study injunctive settlements, Hylton and Cho extended the basic model to incorporate the possibility of parties allocating future rights through settlements.[181] To be precise, injunctive settlements refer to cases where the parties settle on terms that require the defendant to cease an activity complained of by the plaintiff. In the typical pharmaceutical patent infringement case, the producer of a patented drug seeks to enjoin the producer of a generic version from entering the market.

One may wonder why the basic settlement model does not fully 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 parties under each state.

Table 1

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

Unless *P* initiates a legal dispute, *G* will be able to enter the market and sell the generic version of *P*'s drug. For simplicity, we may assume that *G* is the only competitor of *P*,[182] in which case *G* and *P*

181. *Id.*

182. There are some empirical and theoretical reasons to think that this assumption is harmless. As an empirical matter, "the FTC (2002) reports that at most two generic companies challenged probabilistic patents in the past." Gratz, *supra* note 33, at 5 n.5. Moreover, as noted in *K-Dur*, "the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period." *In re* K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012), *vacated*. Nevertheless, it is hard to know the exact impact of relaxing this assumption on the reward shifting effect without further research.

would split duopoly profits, denoted by $2\pi_d$, evenly in the market for *P*'s drug.[183]

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 between *P* and *G*. If the court enjoins *G* from operating in the market, it eliminates competition for *P*. 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 $\pi_m > 2\pi_d$.[184] If the court decides not to enjoin *G*, then *G* is entitled to enter the market, and the parties are again expected to make duopoly profits of $2\pi_d$, collectively. Therefore, a court decision leads either to an allocation of monopoly profits to *P*, or to duopoly profits to be split between the two parties.

When the parties settle through a standard settlement, they are incapable of reaching an agreement where *G* is enjoined from operating in the market in the future. This implies that the settlement will involve some monetary transfer between *G* and *P* and that *G* and *P* will later compete against each other in the market, at which point they will therefore obtain duopoly profits.

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

The most important thing this brief analysis highlights is that standard settlements and injunctive settlements lead to different total profits to be shared between *P* and *G*. 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. The next Part describes how the availability of injunctive settlements, if legal, give *P* an incentive to make reverse payments.

1. When Do Parties Settle?

If the parties litigate, *P*'s patent will be found valid and infringed with a probability, X, which reflects the strength of the patent: the closer X is to one, the stronger the patent.[185] *P* and *G*, however, are not perfectly informed about this probability. Instead, they only have estimates of this probability, denoted by X_p and X_g respectively. Their estimates are subject to error, so that X_p and X_g need not necessarily equal each other or X. Parties base their decisions on these estimates.

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183. Even if profits are asymmetric, the qualitative results do not change.

184. This inequality reflects a standard assumption in the literature. *See, e.g.*, Shapiro, *supra* note 18, at 92 (assuming that "combined duopoly profits are less than monopoly profits, $2\pi_D < \pi_M$"). If this assumption were violated, the monopolist patentee could increase its profits by creating a subsidiary and competing with it, which would contradict the initial supposition that the patentee is a monopolist.

185. *See supra* Part III.C (discussing probabilistic patents in further detail).

Accordingly, *G*'s expected return from litigation is $(1 - X_g)\pi_d$.[186] In this Section, all settlement offers will require *G* to exit the market for the duration of *P*'s patent. *G* also faces litigation costs of L_g, making its expected payoff from litigation $(1 - X_g)\pi_d - L_g$. Therefore, if *G* receives an injunctive settlement offer of S from *P*, *G* will accept it only if:

$$(1 - X_g)\pi_d - L_g < S \tag{4}$$

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 $(1 - X_p)$. Therefore, *P*'s expected payoff from litigation is $X_p\pi_m + (1 - X_p)\pi_d - L_p$, where L_p denotes *P*'s litigation costs. An injunctive settlement prohibiting *G* from entering the market enables *P* to earn monopoly profits at the cost of a payment of S to *G*. Hence, *P*'s expected payoff from settlement is $\pi_m - S$. Accordingly, *P*'s expected payoff from settlement exceeds its payoff from litigation when $\pi_m - S > X_p\pi_m + (1 - X_p)\pi_d - L_p$, which can alternatively be expressed as:

$$(1 - X_p)(\pi_m - \pi_d) + L_p > S. \tag{5}$$

Inequalities (4) and (5) imply that an injunctive settlement will take place as long as $(1 - X_p)(\pi_m - \pi_d) + L_p > (1 - X_g)\pi_d - L_g$, which is equivalent to:

$$(1 - X_p)(\pi_m - 2\pi_d) + 2L > (X_p - X_g)\pi_d \tag{6}$$

where 2L is the sum of litigation costs.

Inequality (6) demonstrates that injunctive settlements will take place as long as parties are not relatively over-optimistic[187] regarding their prospects of obtaining a beneficial judgment through litigation. In particular, parties will reach an injunctive settlement if $X_p \leq X_g$. In such cases, the right hand side of (6) is not positive. As the left hand side of (6) is always positive (because $\pi_m > 2\pi_d$), the inequality will hold.

When 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

186. This Article does not consider complications such as the 180-day exclusivity for the first moving generic. *See infra* Part VI.

187. Relative 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 $\frac{(1-X_p)(\pi_m-2\pi_d)+2L}{\pi_d}$. This condition is more likely to hold when (1) litigation costs are small, and (2) π_d is large in comparison to the surplus $\pi_m - 2\pi_d$ generated from the injunction.

will end up reaching an injunctive settlement. For expositional purposes this Article assumes that parties have perfect information regarding the strength of the patent, i.e., that $X_g = X_p = X$. In Part V.D, this Article revisits the issue of relative over-optimism and shows that incorporating it only strengthens the results.[188]

2. When Do Parties Agree on Reverse Payment Settlements?

If parties are not overly optimistic, an injunctive settlement will occur. The question still arises: will it necessarily involve a reverse payment? Stated differently, is it in the plaintiff's best interest to *buy* the injunction from the defendant, or to proceed to trial and obtain an injunction through litigation? To answer this question, note that inequalities (4) and (5) imply that a successful settlement, S, must be within the following range:

$$S \in [(1 - X)\pi_d - L_g, (1 - X)(\pi_m - \pi_d) + L_p] \quad (7)$$

The lower bound for the settlement range is likely to be positive when (1) X is small, i.e., the patent is weak, or (2) π_d is large in comparison to litigation costs. Furthermore, if the parties have similar bargaining power, they will split the surplus that they generate through an injunctive settlement close to evenly. In those cases, S will be close to the midpoint of the settlement range expressed in (7). When the parties' litigation costs are equal, this midpoint is $\frac{(1-X)\pi_m}{2}$, which is positive.[189]

To summarize, when allowed, the parties will reach an injunctive settlement involving reverse payments as long as one of the following conditions is met: (1) they have similar bargaining power, (2) the patent is weak enough to offset any imbalance in bargaining power, or (3) *G*'s litigation costs are small in comparison to his expected return from litigation.

Although dynamic effects will be considered to a greater extent in Part V, it is worth noting a simple and important point that relates to *G*'s ex ante incentives. As the above analysis demonstrates, when payments are the only mode of compensation,[190] *G* has no incentive to enter the market unless it expects to receive a reverse payment.[191] If S

188. See *infra* Part V, for a discussion.

189. When the parties' litigation costs are not equal, the midpoint of the settlement range is positive as long as $(1 - X)\pi_m > (Lg - Lp)$, that is, as long as *G*'s litigation costs do not exceed *P*'s litigation costs by a large margin.

190. If DESs are possible, then *G* may still have an incentive to invest in entry, even if it does not expect a payment from *P*. *See supra* Part IV.B (introducing DESs and illustrating this point).

191. *See supra* Part II.A (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

is negative, entry induces a payoff of −S, whereas doing nothing induces a payoff of zero.[192] Therefore, a generic company is likely to attempt entry only when it 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, increasing expected joint profits by increasing the amount of time during which the patentee enjoys monopoly profits. The injunctive settlement model does not incorporate the fact that parties can negotiate over the exact time of entry, continuing *P*'s monopoly power over a portion of the remaining patent life. Simply stated, the injunctive settlement model does not allow the parties to choose the length of the injunction: it must be the remaining duration of the patent.

The model can easily be extended to account for variable length injunctions. 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 seven years, and the remaining patent life is ten years, then $\alpha = 0.7$). One can then calculate *P*'s payoff from settling as $\alpha\pi_m + (1 - \alpha)\pi_d$ and *G*'s expected payoff as $(1 - \alpha)\pi_d$. The effect of this modification on parties' settlement strategies depends on whether or not reverse payment settlements are possible.

1. Parties' Incentives When Reverse Payment Settlements Are Per Se Legal

As can be inferred from the discussion regarding 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)[193] in exchange for a reverse payment that compensates *G* for his forgone expected profits. When $\alpha = 1$, *P*'s and *G*'s payoffs from settlement are identical to the corresponding values in Part IV.B, namely $\pi_m - S$ and

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game. *See infra* Part V. Filing an ANDA corresponds to *G*'s strategy in the second period of the drug game.

192. In other words, a strategy profile where *G* is entering and later settling cannot be a Subgame Perfect Nash Equilibrium because *G* can increase its payoff from −S to zero by not entering in the first place. *See supra* note 179.

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

S, respectively. This result is not a coincidence. The 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 $\alpha = 0$ or $\alpha = 1$. Therefore, the conditions under which it is preferable for *P* and *G* to have a reverse payment settlement with $\alpha = 1$, rather than no settlement at all, correspond to the conditions discussed in Part IV.B.

Next, note that for the settling parties, a settlement with $\alpha = 1$ is preferable to a settlement with $\alpha < 1$. By increasing α, i.e., the duration of *P*'s monopoly, 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 $\alpha < 1$ to a settlement with $\alpha = 1$. If reverse payments are legal and the parties are not overly optimistic,[194] then *P* and *G* have the incentive to agree on a reverse payment settlement that delays entry until the patent expires.

2. Parties' Incentives When Reverse Payment Settlements Are Restricted

When RPSs are illegal, the parties lose the mechanism through which *P* can transfer some of the surplus created by *G*'s delayed entry, i.e., *P*'s profits due to the lack of competition less what *G* loses by not entering early. Absent this mechanism, the cost of litigation still gives parties incentives to settle due to reasons described in Part IV.A. In particular, the parties can settle on a date of entry that offsets the expected payoffs to each party from litigation.

In order for both parties to accept a settlement with entry date described by α, both parties' settlement payoffs must exceed their corresponding expected litigation payoffs. 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

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

where X represents the parties' accurate belief that the patent will be found valid and infringed in litigation.

Without information on parties' litigation costs and bargaining power, it is impossible to pinpoint the exact date of entry in a delayed entry settlement. But, if for simplicity the parties are assumed to have

194. See *infra* Part V.D, for a detailed study of over-optimism.

equal bargaining power and litigation costs they will settle on an entry date described by[195]

$$\alpha^I = \mathrm{X} + L\frac{\pi_\mathrm{m} - 2\pi_\mathrm{d}}{2\pi_\mathrm{d}(\pi_\mathrm{m} - \pi_\mathrm{d})}. \quad (10)$$

In other words, when reverse payments are not allowed, we should expect parties to settle on an entry date that sets the payoff 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,[196] they will reach a settlement with $\alpha < 1$, i.e., *G* promises to delay entry until some date *prior* to the expiration of the patent. Thus, for patents that are not close to being ironclad, restricting RPSs induces earlier generic entry than under per se legality, since, as shown in Part IV.C.1, $\alpha = 1$ when reverse payment settlements are per se legal.[197]

D. Parties' Settlement Decisions and Ex Post Payoffs Across Regimes as a Function of Patent Strength

Given the observations in Parts IV.B and IV.C, parties' ex post payoffs, i.e., payoffs 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 payoffs will be useful for studying generic companies' entry decisions and dynamic R&D decisions in Part V.

1. When Reverse Payments are Legal

As discussed in Part IV.B, when reverse payments are legal, the parties reach a settlement where *P* makes a payment of $\mathrm{S} = \frac{1}{2}(1 - \mathrm{X})\pi_\mathrm{m}$ 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 for the duration of the patent's life.

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195. This expected entry date corresponds to the Nash bargaining solution that *P* and *G* reach when they have equal bargaining power. *See generally* NOLAN MCCARTY & 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). See *infra*, Appendix A, for the calculations necessary to derive this result.

196. More specifically, as long as the parties do not believe that the patent has strength exceeding $1 - L\frac{\pi_m - 2\pi_d}{2(\pi_m - \pi_d)\pi_d}$, denoted X^C, they will reach a settlement with $\alpha < 1$. Note that since $\pi_m - 2\pi_d > 0$, $\mathrm{X}^\mathrm{C} < 1$.

197. For patents with strength exceeding X^C, *see supra* note 196, a settlement would induce the same result, i.e., entry at $\alpha = 1$.

Therefore, *P*'s ex post payoff is monopoly profits less settlement payments, or

$$\pi_m - \tfrac{1}{2}(1 - X)\pi_m = \tfrac{1}{2}(1 + X)\pi_m. \quad (11)$$

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

$$\tfrac{1}{2}(1 - X)\pi_m. \quad (12)$$

2. When Reverse Payments are Illegal

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

$$\alpha^I\pi_m + (1 - \alpha^I)\pi_d \quad (13)$$

and

$$(1 - \alpha^I)\pi_d, \quad (14)$$

where α^I is the entry date described in (10).[198]

V. REWARD SHIFTING

Part IV summarizes parties' incentives and payoffs under per se legality and illegality of reverse payment settlements. That analysis assumes two things: (1) that a patentee *P* engages in R&D and comes up with a new invention; and (2) that another party *G* decides to incur entry costs to market a generic version of that invention.

That may not always be the case, however, as the legal regime 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 Part incorporates these ex ante effects by using a stylized model which is best summarized by the following game tree.[199]

198. This assumes that the patent is not stronger than X^C. *See supra*, note 197. However, if $X > X^C$, *G* does not have an incentive to enter because it would incur net losses, and therefore there would be no settlement. *See infra* Part V.

199. *See generally* GIBBONS, *supra* note 179, at 57–61 (explaining how to structure game trees and how to use them to compute the backwards-induction outcomes of games).

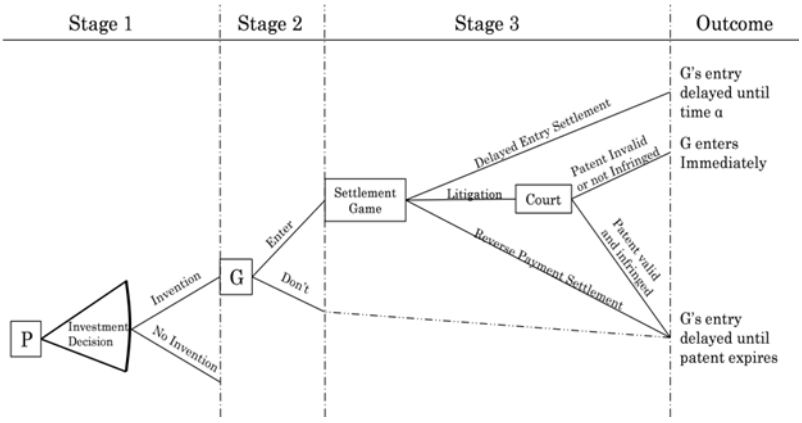

Figure 1: Game Tree

As reflected in the game tree in Stage 1, *P* makes R&D decisions that have a direct effect on the likelihood with which it succeeds in inventing a new product or process, which it subsequently patents. In stage 2, *G* chooses whether or not to make the necessary investment to enter the market. When *G* does not invest, *P* remains the only supplier and therefore retains its monopoly on the invention for the duration of the patent. When *G* does invest, *P* and *G* play the "settlement game" which is described at length in Parts IV.C and IV.D. To highlight how illegalizing RPSs would affect parties' decisions to invest, this Part will assume, as in Parts IV.C and IV.D, that the parties have accurate estimates regarding the strength of *P*'s patent. This is a simplifying assumption, and as demonstrated in Part V.D, the reward shifting effect presented in this Part increases when this assumption is relaxed.

To solve this "game," this Article uses backward induction, the most common method used among scholars to study settlements.[200] This method requires a player to predict what she and other players will do in the future under various circumstances.[201] She then chooses the action leading to those circumstances under which the other players act in a way that is most favorable to her.[202] For instance, when making a decision in Stage 1, *P* will consider whether *G* will enter in

200. *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."). *See generally* GIBBONS, *supra* note 179, at 57–61 (explaining backward induction).

201. For a more detailed description of how backward induction is applied to solve dynamic games, see GIBBONS, *supra* note 179, at 57–61.

202. Here the game is deterministic, and therefore no uncertainty is involved. Part V.D considers the effects of uncertainty and assumes that actors seek to maximize expected values.

Stage 2 if *P* in fact comes up with an invention. If *P* believes that *G* is likely to enter in Stage 2, then *P* has to predict the outcome of the settlement game in Stage 3. *P* will only engage in R&D if it believes the future benefits associated with that outcome outweigh the cost of R&D.

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 it expects to gain from the settlement game. Fortunately, the settlement game was already solved in Part IV.D. Therefore, *G*'s entry decision can be analyzed by comparing its expected payoff expressed in expressions (12) or (14), depending on the legal regime, to the cost F of investing for entry. Choosing not to invest results in a payoff of zero. *G*'s entry decision is analyzed next, because *P*'s decision in Stage 1, as explained in the preceding paragraph, depends on *G*'s decision in Stage 2.

A. Generic Manufacturer's Investment Decision

When reverse payments are legal, *G* expects to obtain an RPS from *P* in the amount of $\frac{1}{2}(1 - X)\pi_m$, in exchange for delaying entry until *P*'s patent expires. *G*'s expected payoff from entry is therefore its expected gains from settlement minus the cost of investing in entry, namely $\frac{1}{2}(1 - X)\pi_m - F$. Since *G*'s outside option is not to invest, which results in a payoff of zero, *G* enters only when

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

When reverse payments are illegal, *G* expects to reach a DES with *P*. This option has a value of $(1 - \alpha^I)\pi_d - F$, and therefore *G* invests only when

$$(1 - \alpha^I)\pi_d > F. \tag{16}$$

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

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

Simply by comparing the conditions under which *G* enters in each legal regime, one can see that entry is more likely to occur when reverse payments are legal.[203] This is because the expected ex post payoff to *G* under per se legality, $\frac{1}{2}(1 - X)\pi_m$, exceeds the expected ex

203. This assumes, of course, that the drug has been invented in Stage 1.

post payoff when reverse payments are illegal, $\left(1 - X - L\frac{\pi_m - 2\pi_d}{2(\pi_m - \pi_d)\pi_d}\right)\pi_d$. A closer look at these conditions reveals even more about *G*'s decision to enter: illegalizing RPSs affects *G*'s decision to enter only if the patent is sufficiently strong.

To observe this consequence, 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:

$$X < 1 - \frac{2F}{\pi_m} \equiv X^L, \tag{18}$$

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

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

where X^I denotes the threshold patent strength under per se illegality. It is easy to verify that $X^I < X^L$,[204] which implies that illegalizing reverse payments eliminates investment in entry only when the patent is stronger than X^I. This observation can be better illustrated by a simple figure:

204. To see this, 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 $2\pi_d < \pi_m$.

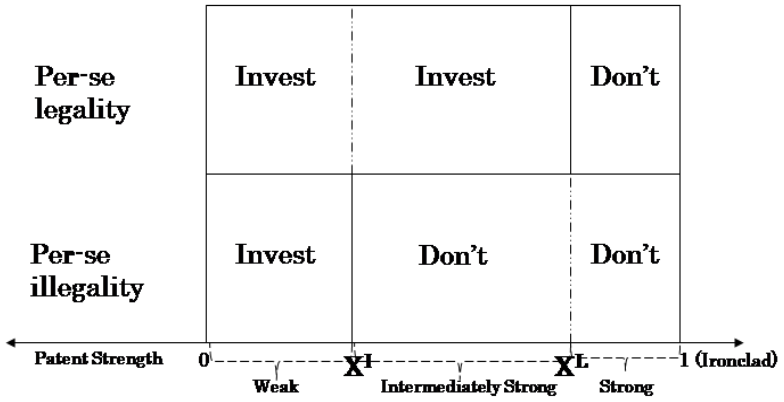

Figure 2: *G*'s Incentives to Invest as a Function of Patent Strength and Legal Regime

As shown in Figure 2, a switch from per se legality to illegality eliminates investment by *G* to enter when X is between X^I and X^L. This observation reflects the concerns voiced by Richard Posner in *Asahi Glass*[205]: "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."[206]

If, however, investment in entry is motivated by the prospect of extracting favorable settlements in the future, such investments do not in fact generate additional welfare.[207] This notion is explained next.

B. Effects on G's Entry Date

Illegalizing RPSs 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 when *G* does decide to invest in entry. This is because entry occurs at patent expiration ($\alpha = 1$) when reverse payments are legal, but at some time before patent expiration ($\alpha < 1$) under per se illegality.[208]

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205. Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986 (N.D. Ill. 2003).

206. *Id.* at 994.

207. Entry can occur earlier under per se legality if (1) the patent is intermediately strong, (2) the parties suffer from over-optimism, (3) the parties are unable to reach a settlement, and (4) subsequently the patent is found to be invalid or not infringed. This implies that the value of holding an intermediately strong patent is even lower under per se legality. Part V.D discusses this case after Parts IV.B and IV.C introduce and discuss all necessary effects.

208. See Part IV.C.2 and *supra* notes 197 and 198, which demonstrate that the settlement date is prior to patent expiration ($\alpha < 1$), unless the patent strength exceeds $1 -$

If the patent is weak, $X < X^I$, both regimes induce investment by *G*, which enters at time $\alpha = 1$ under per se legality, but at time $\alpha < 1$ under per se illegality. Thus, 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 increased deadweight loss.

If the patent is intermediately strong, 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, delaying *G*'s entry until the end of the patent expiration period ($\alpha = 1$). Therefore, *G*'s investment in entry does not reduce the length of time during 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 legal regime when $X > X^L$ because investment costs exceed the potential gains from settlement. Therefore, both regimes have the same effect on ex post social welfare.

These observations are combined and summarized in Figure 3. An important result highlighted by Figure 3 is that illegalizing reverse payments induces earlier entry when patents are weak, but has no effect on the entry date otherwise.

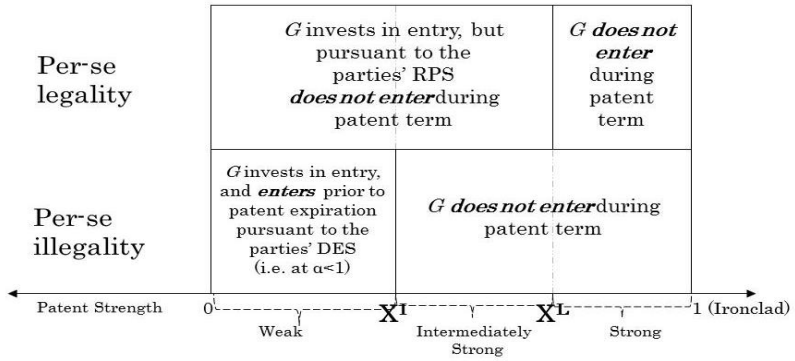

Figure 3: *G*' Time of Entry as a Function of Patent Strength and Legal Regime

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. Applying these conditions

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$L\frac{\pi_m - 2\pi_d}{2(\pi_m - \pi_d)\pi_d} \equiv X^C$. 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.

to the observations in Part IV, 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 an RPS under per se legality and a DES under per se illegality. As explained in Part IV.D, *P*'s expected reward from becoming a patentee corresponds to the ex post payoffs 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 greater expected returns for patents whose strength is close to X^I under a range of conditions.[209]

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, the reward for being a patentee under per se legality is, as in the weak invention case, given by expression (11), $\frac{1}{2}(1 + X)\pi_m$. Under per se illegality, however, entry does not occur, and therefore the reward associated with being a patentee is π_m.

When $X > X^L$, 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.

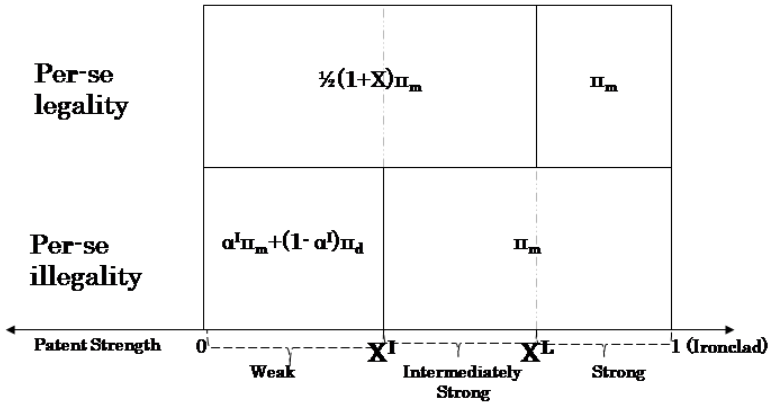

Figure 4: *P*'s Reward as a Function of Patent Strength and Legal Regime

Figure 4 highlights an important result: illegalizing reverse payments reduces the reward for holding a weak patent while simultaneously increasing the reward for holding an intermediately strong

209. More specifically, F > L is a sufficient but not necessary condition for per se legality to generate greater expected rewards for holding a weak patent. See *infra* Appendix B, for the derivation of this result.

patent. In other words, illegalizing RPSs shifts the reward from weak inventions to stronger inventions. The implications of this observation can be revealed by a simple application of reward theory.

First, a pharmaceutical company with a relatively strong project may abandon the project when RPSs are per se legal, but be induced to carry on with the project 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, and $\frac{1}{2}(1 + X)\pi_m < C/Q < \alpha^I\pi_m + (1 - \alpha^I)\pi_d$, the pharmaceutical company will be incentivized to continue with R&D only when RPSs are illegal.

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

In sum, per se illegality may shift pharmaceutical R&D efforts from weak projects towards stronger projects.

D. The Exacerbating Effect of Relative Over-Optimism

Throughout the preceding analyses, this Article 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 that *P*'s patent will be found valid and infringed if they 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 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. The surplus that the parties can generate through settlement is lower under per se illegality due to the fact that the option of preserving *P*'s monopoly profits through an RPS is not available. The consequence is that the gains from settling are reduced, making the option less desirable to both parties. Appendix C, *infra*, formalizes this point by providing an algebraic proof.

The effect that relative over-optimism occurs more frequently under per se illegality is better understood by focusing on parties' incentives to settle as a function of patent strength.

When the relevant patent is weak, settlement negotiations are more likely to break down under per se illegality, though entry still

occurs under both legal regimes.[210] Because the patent is weak, it is likely to be declared invalid through litigation, generating a second benefit: 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, *P* and *G* may occasionally litigate to determine the validity of the patent, sometimes leading to the patent being found invalid. This scenario 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 to enter.

In sum, per se illegality is likely to increase litigation for weak patents, creating additional static benefits at the expense of litigation, thereby 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 *P*'s rewards to becoming a patentee. Therefore, potential relative over-optimism appears to magnify the reward shifting effect of per se illegality by reducing the comparative reward for holding a weak patent and increasing the comparative reward for holding an intermediately strong patent.

VI. CONCLUSION

This Article identifies a previously overlooked impact of RPSs: the reward shifting effect. Contrary to an assumption underlying the circuit courts' decisions that found RPSs essentially per se legal,[211] RPSs likely hinder technological progress by incentivizing R&D investment in safe but incremental innovations and discouraging investment in risky but potentially revolutionary projects. Post *FTC v. Actavis*, it is imperative that courts consider the reward shifting effect in applying the rule of reason, as the existence of a patent should not justify anticompetitive agreements if they systematically blunt, rather than promote, technological progress. In particular, if shifting rewards from weak inventions towards stronger ones is deemed to be a social

210. The threshold X's will change in response to incorporating the possibility of litigation, but this does not alter the fact that there will be new threshold patent strengths, serving the same function as X^I and X^L.

211. *See supra* Part II.C (reviewing circuit court decisions).

benefit, courts ought to weigh it in favor of prohibiting a given RPS when applying the rule of reason.

The main claims in this Article, although quite intuitive, are supported by and formally derived in a game-theoretical model that captures the interactions between (potential) patentees and generic manufacturers.[212] One of the important benefits of using a formal model is the possibility of testing the robustness of claims and determining whether results continue to hold under more general or alternative sets of assumptions. This Article conducted one such robustness check by extending the model to incorporate situations where parties may have incorrect beliefs about the patentee's likelihood of obtaining a favorable judgment in an infringement suit, and demonstrated that the results are only enhanced when this possibility is considered.[213] Unfortunately, it is impossible to consider all potentially useful extensions in a single article. But it is possible to identify potentially fruitful directions for future research. For instance, models investigating how the reward shifting is affected by the incentive distortions that presumably arise out of the 180-day exclusivity period and at-risk entry by generic manufacturers are likely to be of value. Although these issues were independently studied by law and economics scholars,[214] how they interact with the reward shifting effect remains unknown.

APPENDICES

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

As explained in Part IV.C.2, the parties will be willing to 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 X, the Nash bargaining solution involves choosing an entry date (α) which maximizes the product of the

212. *See supra* Parts III, IV.

213. *See supra* Part V.D.

214. *See* Elhauge & Krueger, *supra* note 6 (considering at-risk entry in the context of RPSs); Hemphill & Lemley, *supra* note 11 at 949 (proposing that "the first generic . . . be entitled to the 180-day exclusivity period only if it successfully defeats the patent owner . . . , obtains a settlement that permits entry without delay, or can enter the market without delay because the patent holder does not sue for infringement").

differences in the parties' settlement payoffs and expected litigation payoffs.[215] Or, in symbols:

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

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

The expression in (A.3) can alternatively be expressed as

$$-(\alpha - X)^2\big(\pi_d(\pi_m - \pi_d)\big) + (\alpha - X)\big(L(\pi_m - 2\pi_d)\big) + L^2. \quad \text{(A.5)}$$

The problem (A.3) generates the following first order condition:

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

That α^I maximizes (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

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

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

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 the expression for α^I in (10) into (A.8), and evaluating (A.8) and (A.7) at $X = X^I$ reveals that

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

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

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215. *See generally* MCCARTY & MEIROWITZ, *supra* note 195, at 275–80 (providing a brief introduction to bargaining theory, a definition of the Nash bargaining solution, and the axiomatic foundations of this solution concept).

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

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

Manipulating this inequality reveals that it is equivalent to the condition

$$L < 2\left(1 - \frac{\pi_d}{\pi_m}\right)F. \quad \text{(A.12)}$$

The minimum value $2\left(1 - \frac{\pi_d}{\pi_m}\right)$ can take is 1, since $2\pi_d < \pi_m$. Therefore, $A(X^I) > B(X^I)$ whenever $L < F$, in which case per se legality generates greater expected payoffs 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):

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

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

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

The left hand side of (A.13) is greater than the left hand side of (A.14), since $\frac{2L}{\pi_d} > L\left(\frac{1}{\pi_d} + \frac{1}{\pi_m - \pi_d}\right)$. Thus 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.