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Michael Owens

COMMENT

A Cure for Collusive Settlements: The Case for a *Per Se* Prohibition on Pay-for-Delay Agreements in Pharmaceutical Patent Litigation

MICHAEL OWENS*

I. INTRODUCTION

The legal standard for evaluating reverse payments in pharmaceutical infringement settlements (or "pay-for-delay" settlements) has become a highly controversial issue over the past decade and a half.[1] Under a pay-for-delay agreement, a manufacturer of a brand-name pharmaceutical will settle patent infringement litigation by making payments to a defendant generic manufacturer in exchange for the generic manufacturer refraining from entering the market.[2] These agreements have important implications for both patent law and antitrust law because they can allow a potentially invalid patent to remain in effect and restrain competition.[3] Judges, commentators and antitrust enforcement bodies have all reached widely divergent conclusions regarding the appropriate antitrust treatment for these settlements, and while academic disagreement is certain to persist, a single legal standard has been established in *FTC v. Actavis*[4] (previously *FTC v. Watson Pharmaceuticals*), which resolved a circuit split created by the United States Court of Appeals for the Third Circuit's July 2012 decision, *In re K-Dur Antitrust Litigation*.[5] The *K-Dur* decision brought to head the conflict over of pay-for-delay settlements and, in holding such agreements to be presumptively illegal, rejected precedent established by three separate courts of appeals.[6] The Supreme Court's

* B.A. Economics, University of Missouri, 2007; J.D. Candidate, University of Missouri School of Law, 2014; Associate Member, *Missouri Law Review*, 2012-2013. Many thanks to Professor Thom Lambert for his guidance and encouragement throughout this process.

1. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2230 (2013), *rev'g* FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012).

2. *See id.* at 2231, 2234-35.

3. *See id.* at 2234.

4. *Id.* at 2237.

5. 686 F.3d 197 (3d Cir. 2012).

6. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); *In re* Cardizem CD

decision in *Actavis* announced the "rule of reason" as the controlling liability rule for what some commentators have called "one of the most important business decisions that the court will have issued in quite some time."[7]

This Comment will examine how the particulars of the Hatch-Waxman Act, the regulatory scheme that governs generic competition in pharmaceutical industry, gives rise to reverse settlements in infringement litigation;[8] review existing analysis of the pay for delay problem in judicial decisions, in academic commentary, and amongst antitrust enforcement bodies;[9] and finally, draw upon a decision theoretic framework to propose per se illegality as the appropriate antitrust rule for pay-for-delay settlements.[10]

II. THE RECIPE FOR REVERSE PAYMENTS: OVERLAP OF ANTITRUST, PATENT LAW, AND PHARMACEUTICAL REGULATION

A. Antitrust Law and the Prohibition on Agreements to Restrain Competition

Reverse payments raise problems under Section 1 of the Sherman Act (Section 1), which prohibits "[e]very contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations."[11] The rationale for antitrust enforcement is to promote "unfettered competition as the [fundamental] rule of trade."[12] This rationale

> rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.[13]

Justice Hugo Black has emphasized that "even were that premise open to question, the policy unequivocally laid down by the Act is competition."[14] The most commonly accepted policy goal underlying antitrust law's reverence for competition is protecting consumers from artificially reduced

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Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).

7. Jonathan Stempel, *Supreme Court to Hear "Pay-for-Delay" Drug Case*, REUTERS (Dec. 7, 2012, 6:18 PM), http://www.reuters.com/article/2012/ 12/07/us-usa-court-drugs-payfordelay-idUSBRE8B617T20121207?%20irpc=932.

8. *See infra* Part II.C.

9. *See infra* Part III.

10. *See infra* Part IV.

11. 15 U.S.C. § 1 (2006).

12. *See* N. Pac. Ry. Co. v. United States, 356 U.S. 1, 4 (1958).

13. *Id.*

14. *Id.*

output and the resulting artificial price increases.[15] Proposed goals that have received less judicial recognition include: protecting small business from larger firms, preventing transfer of wealth from consumers to producers, and promoting innovation.[16] Though these goals are frequently in harmony with each other, these secondary goals will generally yield to the question of whether a given practice tends to increase or decrease output in a given market.[17]

To this end, the Supreme Court has interpreted this broad language to apply only to "unreasonable" restraints on trade, rather than any agreement that literally restrains trade.[18] In applying Section 1, courts have developed three methods of inquiry: a "per se" rule of illegality for restraints that are blatantly anticompetitive; a "quick-look" analysis for restraints that appear anticompetitive but have plausible pro-competitive justifications; and a wide open "rule-of-reason" analysis for restraints that have ambiguous effects on competition and require a more extensive balancing of pro and anticompetitive effects.[19] As applied, these categories are not as rigid as they may initially appear, and "are best viewed, as a continuum on which the amount and range of information needed to evaluate a restraint varies depending on how highly suspicious and how unique the restraint is."[20]

The harshest form of antitrust condemnation, "per se illegality," is reserved for practices so blatantly injurious to competition that further inquiry is unnecessary, even with respect to actual harm caused.[21] These generally include horizontal agreements between direct competitors in the same market,[22] horizontal market allocation,[23] and horizontal refusals to deal.[24] Hori-

15. *See, e.g.*, Frank H. Easterbrook, *Workable Antitrust Policy*, 84 MICH. L. REV. 1696, 1703 (1986).

16. *See id.* at 1704-05.

17. *See, e.g.*, Chi. Prof'l Sports Ltd. P'ship v. Nat'l Basketball Ass'n, 95 F.3d 593, 597 (7th Cir. 1996) ("The core question in antitrust is output. Unless a contract reduces output in some market, to the detriment of consumers, there is no antitrust problem.").

18. *See, e.g.*, State Oil Co. v. Khan, 522 U.S. 3, 10 (1997); Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 343 (1982).

19. *See In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1310-11 (S.D. Fla. 2005) (citing Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1728 (2003)).

20. Cont'l Airlines, Inc. v. United Airlines, Inc., 277 F.3d 499, 508-09 (4th Cir. 2002) (internal quotation marks omitted).

21. *See* Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984).

22. *See, e.g.*, United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940); United States v. Trenton Potteries Co., 273 U.S. 392 (1927).

23. *See, e.g.*, Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990); United States v. Topco Assocs., 405 U.S. 596 (1972); Timken Roller Bearing Co. v. United States, 341 U.S. 593 (1951).

zontal restraints receive harsher treatment because they turn what would otherwise be a competitive relationship into a cooperative one, leading to higher prices and lower output without any offsetting consumer benefit.[25] Because pay-for-delay settlements constitute an agreement not to compete between would-be competitors, there is no question that these agreements meet the categorical criteria for per se illegality.[26] The question becomes whether the lawful right to exclude conferred by the patents underlying these disputes warrants a departure from per se illegality, and if so, to what extent.

B. Patent Law and Its Unique Role in the Pharmaceutical Industry

Despite the obvious antitrust concerns, reverse payments are plausibly a legal exercise of the exclusionary rights granted under the system of patent laws authorized by Article I of the U.S. Constitution.[27] This clause grants Congress the power to pass laws that "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[28] There are two primary objectives of the patent system: to promote public disclosure of inventions and to encourage innovation by rewarding inventors with the time-limited right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[29] By rewarding a patentee with monopoly power (i.e., the power to charge prices appreciably above the costs of production without incurring dramatic losses in sales),[30] the patentee realizes a level of return on its innovation greater than it would have absent patent protection. Simple economic theory predicts that a greater expected return on innovation will result in a higher level of innovative activities, such as research, development, and testing.[31] Economic theory also predicts that the availability of patent protection will result in lower output and higher prices than would occur in competitive markets.[32] Because the inventor enjoys this reward at the ex-

24. *See, e.g.*, Klor's, Inc. v. Broadway-Hale Stores, Inc., 359 U.S. 207 (1959); Fashion Originators' Guild of Am. v. FTC, 312 U.S. 457 (1941).

25. *See Topco Assocs.*, 405 U.S. at 608.

26. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) ("[W]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike." (quoting *Socony-Vacuum Oil Co.*, 310 U.S. at 222)).

27. U.S. CONST. art I, § 8, cl. 8.

28. *Id.*

29. 35 U.S.C. §154(a)(1) (2006).

30. *Id.*

31. *See* F.M. Scherer, *The Pharmaceutical Industry – Prices and Progress*, 351 NEW ENG. J. MED. 927, 929 (2004).

32. *See* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 80 (2005).

pense of efficient allocation of the patented subject matter, the inventor is required to disclose how to make and use the invention, enabling the public to have unrestricted access to the patent after the term expires.[33] The underlying rationale for granting patents to protect new innovations is simple enough: by conferring a legally protected monopoly for those who bring innovations into existence, the system encourages innovation-producing activities.[34] Patent policy therefore encompasses a set of legislative judgments about the proper long run balance between competition and innovation.[35]

Patent prosecution begins with a prospective patentee filing an application with the United States Patent and Trademark office (USPTO).[36] There, patent examiners evaluate whether the claimed invention is novel and non-obvious as compared to relevant prior art.[37] The invention is patentable if it is a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[38] The scope of the exclusionary right conferred by a patent is defined by the "claims" of the patent, each of which must independently be novel,[39] non-obvious,[40] and described "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the [invention]."[41] If successful in prosecuting a patent, the applicant will be awarded a twenty-year right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States,"[42] which will generally commence on the date of the earliest filing of an application.[43]

Perhaps more so than in any other industry, patents are recognized as a necessary driver of innovation within the pharmaceutical industry.[44] A new drug is best understood as an information good – a commodity that derives its main value from the information it contains.[45] It can take several hundred million dollars to discover, develop, and gain regulatory approval for a new drug.[46] Without patent protection, rival firms could simp-

33. *See* § 154.
34. *See* Scherer, *supra* note 31, at 928.
35. *See* Hovenkamp et al., *supra* note 19, at 1729.
36. *See* § 153.
37. *See* §§ 102-03.
38. § 101.
39. *See* § 102.
40. § 103.
41. § 112.
42. § 154(a)(1).
43. § 154(a)(2).
44. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1562-63 (2006).
45. *See* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT'L ECON. L. 849 (2002).
46. *See id.*

ly free-ride off of the innovator's research, development, and FDA approval and offer the compound without the tremendous expenses incurred by the innovator to bring the drug into existence.[47] Because duplication costs for pharmaceuticals are extremely low relative to the innovator's costs of discovering and developing a new compound, the free rider problem threatens to drive research and development far below socially optimal levels.[48] Studies have estimated that, while 86% of innovations across all industries would have been developed even without patent protection, only 40% of pharmaceutical innovations would have been developed absent patent protection.[49] Even commentators skeptical of patent policy's role in stimulating research and development often note an exception in the context of pharmaceutical innovation.[50]

One recurring problem in evaluating the pay-for-delay dilemma is the relatively cursory nature of the inspection that that the USPTO gives an application when considering whether to grant a patent.[51] There are several reasons why the USPTO conducts "surprisingly little actual assessment of whether a patent should issue."[52] First, patent prosecution is conducted *ex parte*, meaning that the only parties involved in the application process are the applicant and the patent examiner.[53] There is little incentive for extensive discovery of information that would be adverse to the issuance of the patent, and as a result, such information is unlikely to come to light during the application process. For example, applicants are required to submit only the relevant prior art "of which they are aware."[54] Applicants "are under no obligation to search for prior art, and most do not."[55] The patent examiner then has the sole burden of considering "the application, searching for and identifying the relevant prior art, . . . deciding whether the application should be allowed by comparing the claims to the prior art, and writing an 'Office Action' explaining the reasons why any claims were rejected."[56] The appli-

47. *See id.*

48. *See id.*

49. FTC, ANTICIPATING THE 21ST CENTURY: COMPETITION IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE 6-6 to 6-8 (1996), *available at* http://www.ftc.gov/opp/global/report/gc_vl.pdf.

50. *See, e.g.*, Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 795-96, 819 (discussing a survey commenced in 1981 that shows that pharmaceutical and other chemical manufacturers valued patents particularly highly as means of appropriation).

51. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1499-1500 (2001).

52. *Id.* at 1499.

53. *Id.*

54. *Id.* at 1499-1500; *see also* 37 C.F.R. § 1.56 (2012).

55. Lemley, *supra* note 51, at 1500.

56. *Id.*

cant will usually submit a response to the Office Action, and the process can repeat itself many times for a single application.[57] The average time spent examining a patent ends up totaling about eighteen hours and costing about $20,000.[58] This may not seem like inadequate examination, but in the patent litigation context, "lawyers and technical experts will spend hundreds and perhaps even thousands of hours" analyzing prior art and reexamining the claims and prosecution history to assess precisely the same validity issues that are decided with a fraction of the resources and incentives for accurate determination at the USPTO.[59] It therefore should be unsurprising that the USPTO issues many patents that it would otherwise not issue if the examiners possessed better information.[60] Much for this reason, of patent challenges that are litigated to conclusion, the patent at issue is held invalid forty-six percent of the time.[61]

Although patent examiners make validity determinations while operating under a considerable degree of ignorance as to material information, the system is a likely sensible arrangement.[62] This ignorance is rational because the benefits from patent examiners discovering additional information relevant to initial validity determinations would not be justified by the costs.[63] First, "the overwhelming majority of patents are never litigated or even licensed."[64] Nearly two thirds of all patents issued lapse for failure to pay maintenance fees, half of which do so even before the first half of the patent term has passed.[65] A very small percentage is licensed,[66] and an even smaller percentage is litigated.[67] With the benefit of hindsight, it is clear that a vast

57. *Id.*
58. *Id.* at 1499-1500.
59. *Id.* at 1502.
60. *Id.* at 1500.
61. *Id.*
62. *See id.* at 1514.
63. *See id.* at 1497.
64. *Id.*
65. *Id.* at 1503 n.34 ("Maintenance fees are due in increasing amounts at periods of three and a half years, seven and a half years, and eleven and a half years after the patent issues." (citation omitted)).
66. *Id.* at 1503 ("Obviously, though, many patents that do remain in force never get litigated. Some of these patents are licensed for royalties without litigation. Surprisingly, it does not appear that anyone knows precisely how many patents are licensed for royalties. There are reasons to believe, however, that the number is not large.").
67. *Id.* at 1501 ("Of the roughly two million patents currently in force, only a tiny number are the basis for lawsuits each year. About 1,600 patent lawsuits are filed each year, involving at most perhaps 2,000 different patents. The overwhelming majority of these lawsuits settle or are abandoned before trial. Only about one hundred cases per year (and 125 patents) actually make it to trial. Based on these numbers, it is reasonable to estimate that at most only about two percent of

number of patents did not justify the initial costs of determining validity and certainly would not have justified any additional costs.[68] As a result, the most efficient way to determine patent validity is to tolerate a necessarily cursory initial inspection by the USPTO and, if it later turns out that there is sufficient commercial stake in determining the validity of a patent, rely on the courts to conduct a more costly and extensive reevaluation of validity in the course of litigation.[69] While this is a reasonable approach to administering a remarkably ambitious system, an inevitable result is that a large number of objectively invalid patents will issue.[70] This result reveals the importance of courts' ability to conduct *ex poste* reevaluations of patent validity.[71] One of the fundamental problems with pay-for-delay settlements is permitting parties to avert this reevaluation.[72]

This present analysis will draw heavily upon the "probabilistic" nature of patents as described by Lemley and Shapiro, which emphasizes that patents are not so much rights to exclude as they are rights to *try to exclude* rivals by asserting patent rights in court.[73] Lemley and Shapiro explain: "When a patent holder asserts its patent against an alleged infringer, the patent holder is rolling the dice. If the patent is found invalid, the property right will have evaporated."[74] This understanding of patent rights demonstrates the inadequacy of looking to the formal scope of a patent to excuse or condemn exclusionary conduct because the only time when the status of the patent rights is conclusively known is upon a final judgment.[75] Part of the appeal of deferring to the formal scope of the patent is the statutory presumption of validity afforded to patent rights,[76] which challengers can only rebut by "clear and convincing evidence."[77] This presumption is factually unwarranted based on how the USPTO actually makes validity determinations.[78] But even if the

all patents are ever litigated, and less than two-tenths of one percent of all issued patents actually go to court.").

68. *See* Lemley & Shapiro, *supra* note 32, at 82 (discussing the reasons why inventors file many patents that turn out to have little or no value, including "a failure to understand the value of patents; the use of patents to obtain financing and boost market valuation; the use of patents as signaling mechanisms; and the 'defensive' use of patents to deter others from suing. Even individually weak patents might have value as part of a large patent portfolio, because the portfolio can be licensed as a block or can serve to deter lawsuits." (citations omitted)).

69. *See* Lemley, *supra* note 51, at 1531.

70. *Id.* at 1532.

71. *See id.*

72. *See infra* Part III.D.

73. *See* Lemley & Shapiro, *supra* note 32, at 75.

74. *Id.*

75. *See id.*

76. *See* 35 U.S.C. § 282(a) (2006).

77. Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011).

78. *See supra* notes 51-61 and accompanying text.

presumption is generally defensible on judicial economy grounds,[79] relying on this presumption in the context of pay-for-delay settlements is not. In this context, the general presumption effectively transforms into a conclusive one because settlement precludes the opportunity for challenge to the patent's presumed validity.[80] Exclusionary rights that are really only probabilistic are transformed into certain rights for reasons unrelated to the substantive merits of the patent.[81] Examining the regulatory quirks of the Hatch-Waxman Act will help reveal why seemingly adversarial parties are united in their desire to avert challenges to the validity of brand-name manufacturers' patents.

C. The Hatch-Waxman Act and the Regulation of Generic Entry

Pay-for-delay settlements are a unique product of the regulatory scheme created under the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman),[82] which amended the Federal Food, Drug, and Cosmetic Act.[83] The Act created a regulatory scheme governing the approval of generic drugs by the FDA.[84] The law sought to help jumpstart generic competition with brand-name pharmaceuticals[85] and has been tremendously successful in this regard. Since the passage of Hatch-Waxman, the number of total prescriptions written for generic drugs has increased from fifteen percent to seventy percent.[86] In furtherance of this goal, Hatch-Waxman enacted two key features that are responsible for the proliferation of pay-for-delay agreements in the industry: the availability of Abbreviated New Drug Applications (ANDAs), and 180-day exclusivity bounty for the first generic entrant to successfully challenge the patent.[87]

79. *See, e.g.*, Meredith Norris, Note, *Clear and Convincing Evidence as Proper Standard of Proof for a Patent Invalidity Defense Under § 282 of the Patent Act of 1952:* Microsoft Corp. v. I4i Ltd. Partn., 14 DUQ. BUS. L.J. 335, 352 (2012).

80. *See* Lemley & Shapiro, *supra* note 51, at 1529-30.

81. *See id.* at 1530.

82. *See* Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 179 (2008).

83. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006), 35 U.S.C. §§ 156, 271(e) (2006)).

84. *See* Avery, *supra* note 82, at 175-76.

85. Colleen Kelly, Comment, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

86. *Id.* at 418.

87. *See* § 355(j)(5)(B)(iv).

1. Abbreviated New Drug Applications

The FDA approval process for generic entry is greatly expedited by the ANDAs.[88] Prior to Hatch-Waxman, generic firms had to submit lengthy pre-clinical and clinical data demonstrating the drug's safety and efficacy to FDA, just as if they were applying for a New Drug Application (NDA) and the compound was coming onto the market for the very first time.[89] After Hatch-Waxman, the generic manufacturer need only show the FDA its data that the drug is "bioequivalent" to a previously approved compound.[90]

When a generic manufacturer files an ANDA, it is also required to file a certification that, "in the opinion of the applicant and to the best of his knowledge," the generic drug does not infringe on any patent for that drug listed with the FDA.[91] The generic manufacturer may meet this requirement by certifying one of four options with respect to the patent for the listed drug: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) [by certifying] the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[92] A Paragraph IV certification constitutes a constructive act of patent infringement.[93] Upon a Paragraph IV filing, the ANDA applicant must notify both the patent owner and the NDA holder of the certification, along with "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[94] A patent holder then has forty-five days after receiving notice of the Paragraph IV certification to file an infringement suit against the ANDA applicant or the ANDA will automatically be approved.[95] However, if the patent holder brings an infringement action against the ANDA applicant within forty-five days, the FDA may not approve ANDA for another thirty months.[96]

In a typical patent infringement case, a rival firm will spend substantial sums on the manufacturing, marketing, and distribution of the potentially infringing product, and therefore must carefully consider the risks that these expenditures will be wasted, as well as the risk of incurring infringement damages.[97] In Paragraph IV infringement, the generic firm has not yet in-

88. *See* Kelly, *supra* note 85, at 426.
89. *See id.* at 423.
90. *Id.*
91. § 355(j)(2)(A)(vii).
92. *Id.*
93. § 271(e)(2)(A).
94. § 355(j)(2)(B)(iv)(II).
95. § 355(j)(5)(B)(iii).
96. *Id.* (providing that the court may increase or decrease the thirty-month period if either party "failed to reasonably cooperate in expediting the action.").
97. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206-07 (2d Cir. 2006) (comparing Paragraph IV infringement with typical patent infringement cases

curred any of these manufacture, marketing, or distribution expenses.[98] Further, there are usually no infringement damages for the patent holder to recover, so the generic entrant risks only litigation costs against the opportunity for future profits from selling the generic drug.[99] The goal of this process is to resolve litigation before the generic hits the market so that these costs are avoided altogether.[100] While this declaratory judgment provision is a useful tool in helping firms clarify and resolve "lurking legal issues,"[101] the availability of Paragraph IV certification disproportionately benefits generic firms by providing a low risk and high reward method for infringing pharmaceutical patents.[102] Some view this arrangement as embodying a congressional judgment in favor of litigated challenges, which is defeated by pay-for-delay settlements,[103] while others feel the risk asymmetry created by this regulation necessitates the use of reverse payments in order to level the playing field.[104]

2. The 180-Day Exclusivity Bounty and the "Approval Bottleneck"

The drafters of Hatch-Waxman were concerned that free-rider problems might give generic firms insufficient incentive to challenge the validity of patents.[105] Generic firms would have inadequate incentive to incur litigation risks and expenses if other firms could simply free ride off a favorable judgment, thereby inviting competition into the market and eroding profits to the point that the original challenger might not recover its litigation costs.[106] To remedy this problem, Hatch-Waxman establishes an additional

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and noting that "[b]y contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed – *before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.").

98. *Id.* at 206.

99. *Id.* at 206-07.

100. *See* Kelly, *supra* note 85, at 424.

101. Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"*, 78 FORDHAM L. REV. 1075, 1091 (2009).

102. *See id.* at 1096-97.

103. *See, e.g.*, Hemphill, *supra* note 44, at 1597.

104. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 207.

105. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA 389, 423-24 (1999).

106. *See id.* at 423.

incentive for the first ANDA that contains a Paragraph IV certification.[107] This incentive comes in the form of a 180-day exclusivity period for the first Paragraph IV ANDA filer, during which the FDA will not approve any subsequent Paragraph IV ANDA until the earlier of: "(1) the date of the first commercial marketing of the drug under the first-to-file ANDA; or (2) the date a court holds the challenged patent(s) invalid or not infringed by the first ANDA applicant."[108] This essentially creates a duopoly in the market for a particular drug for the period of the exclusivity, potentially worth hundreds of millions of dollars for a major drug.[109] Whether this provision was necessary to motivate patent challenges presents an interesting question,[110] but this Comment will focus instead on the unintended consequences of the exclusivity provision.

Prior to the 2003 Medicare Prescription Drug Modernization Act (MMA), a second generic company could not enter the market until the first ANDA filer had exhausted the 180-day exclusivity period.[111] This meant that the first-to-file ANDA applicant could prevent all other generic competitors from entering the market by refraining from marketing the drug itself.[112] The MMA corrected this explicit "statutory bottleneck" by providing that certain conduct would result in the first ANDA filer's forfeiture of the exclusivity period.[113] Such conduct included failure to market the generic[114] and entering an agreement with another applicant, the listed drug application holder, or a patent owner.[115] In addition, a subsequent ANDA applicant may file for a declaratory judgment that the relevant "patent is invalid or will not be infringed by the drug for which the applicant seeks approval."[116] If the subsequent ANDA filer prevails in its declaratory action, the "failure to market" provision is triggered, thereby defeating what was previously a potentially

107. Patel, *supra* note 101, at 1082-83.

108. Anne-Marie C. Yvon, Note, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1895 (2006).

109. Hemphill, *supra* note 44, at 1560.

110. *See* Engelberg, *supra* note 105, at 423-24 (noting that free rider problems are unlikely to occur when the Paragraph IV claim is noninfringment, that "the cost and risk of patent validity challenges turned out to be far less than expected, . . . [and] that potential profit from a successful challenge generally far exceeds the cost of litigation.").

111. Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 11 (2005).

112. *See id.*

113. *See* 21 U.S.C. § 355(j)(5)(D) (2006).

114. § 355(j)(5)(D)(i)(I).

115. § 355(j)(5)(D)(i)(V).

116. § 355(j)(5)(C)(i)(II).

indefinite bottleneck for subsequent filers.[117] Post MMA, it appears that the brand-name manufacturer's ability to utilize the exclusivity period as an absolute bar to subsequent generic entry has been corrected.[118]

But overreliance on an explicit bottleneck to demonstrate feasibility of an anticompetitive settlement gives insufficient weight to the incentive effects of a generic's eligibility for the exclusivity bounty.[119] The exclusivity period is not available to subsequent filers, even in the event of forfeiture by the first filer.[120] Further, in order for a subsequent filer to force forfeiture under the "failure to market" provision, there must be "a nonappealable court decision that all of the patents, which the First Paragraph IV ANDA filer made a Paragraph IV certification against, are invalid or not infringed."[121] This can come from a patent infringement suit involving any ANDA filer or a declaratory judgment action by any ANDA filer, but given the presence of a settlement, it will almost certainly have to come from the latter.[122] The adequacy of the amendments to solve the problem of settlements excluding additional generic entry depends not only on whether it is possible for potential subsequent filers to get around the bottleneck, but whether it is plausible in light of their incentives to litigate infringement.[123] Many commentators believe that it is not.[124] Indeed, casual observation seems to support this concern. If subsequent entry were easy, then there would be an endless number of generic firms lining up to collect their settlement payments or, alternatively, choosing to litigate, thus subjecting the brand-name firm to the very same litigation risks it made the initial payments to avoid. Reverse payments, therefore, make very little sense to brand-name manufacturers unless the payments tend to exclude subsequent generics in some nontrivial way.

117. *See* Williams, *supra* note 111, at 60-61.

118. *See id.*

119. Hemphill, *supra* note 44, at 1588 ("The approval bottleneck is sufficient but not necessary to demonstrate the feasibility of pay-for-delay settlement or the presence of allocative harm.").

120. Patel, *supra* note 101, at 1112.

121. *Id.* at 1100.

122. *Id.* This is the most common situation where failure to market forfeiture will be triggered. Other events include parties reaching a settlement which includes a judicial finding that all Paragraph IV certified patents, by the First Paragraph IV ANDA Filer, are invalid or not infringed, or the brand-name manufacturer removes from the Orange Book all patents subject to the Paragraph IV certification by the First Paragraph IV ANDA Filer. *Id.*

123. *See id.* at 1101.

124. *See, e.g.*, Hemphill, *supra* note 44, at 1587.

III. THE SPLIT: DISPARATE APPROACHES IN EVALUATING THE ANTITRUST IMPLICATIONS OF PAY-FOR-DELAY AGREEMENTS

Several policy tensions explain the disagreement amongst courts, commentators and enforcement bodies over the appropriate antitrust treatment of pay-for-delay settlements. The task has most commonly been characterized as ascertaining the appropriate boundaries between intellectual property law and antitrust law.[125] Others have characterized the problem as determining the appropriate relationship between antitrust law and firm behavior within regulated industries.[126] Analyses of pay-for-delay settlements also draw upon the general judicial preference for settlements,[127] as well as the legislature's encouragement of litigated patent challenges that arguably underlies the Hatch-Waxman Act.[128] These policy tensions have resulted in a wide range of proposed approaches to determining the legality of pay-for-delay settlements: per se illegality,[129] traditional rule of reason analysis,[130] quasi-per se illegality or "quick look" rule of reason analysis,[131] and per se legality so long as the settlement restrains competition only within the apparent scope of the brand-name manufacturer's patent.[132]

A. Per Se Illegality: The Sixth Circuit – In re Cardizem CD Antitrust Litigation

The leading case giving pay-for-delay settlements per se treatment is the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation.*[133] *Cardizem* was the first time that a federal court of appeals considered the legality of a reverse settlement.[134] The case involved a challenge to an agreement under which a brand-name firm, Hoechst Marion Roussel, Inc. (HMR), paid a generic company, Andrx Pharmaceuticals, Inc. (Andrx), quarterly payments to refrain from producing a generic version of the drug Cardizem CD,[135]

125. *See* Yvon, *supra* note 108, at 1886; Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 2 (2005).

126. *See* Hemphill, *supra* note 44, at 1556-57.

127. *See supra* Part III.A-D.

128. *See, e.g.*, Hemphill, *supra* note 44, at 1605-06.

129. *See infra* Part III.A.

130. *See infra* Part III.D.

131. *See infra* Part III.C.

132. *See infra* Part III.B.

133. 332 F.3d 896, 899-900 (6th Cir. 2003).

134. *See* Yvon, *supra* note 108, at 1899.

135. *In re Cardizem CD Antitrust Litig.*, 332 F.3d. at 900.

which is used to treat angina and hypertension and for the prevention of heart attacks and strokes.[136]

The settlement agreement was struck nine days after the FDA gave partial approval to Andrx's ANDA for marking a generic version of Cardizem,[137] with full approval to be given upon the expiration of the thirty-month waiting period or upon a declaration of non-infringement in the Paragraph IV litigation.[138] The agreement provided that Andrx would refrain from marketing a generic version of Cardizem CD in the United States until the earliest of: "(1) Andrx obtaining a favorable, final and nonappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; *or* (3) HMR entering into a license agreement with a third party."[139] When the thirty-month waiting period expired in July of 1998, the FDA issued its final approval of Andrx's ANDA.[140] In compliance with the agreement, "HMR began making quarterly payments of $10 million . . . , and Andrx did not bring its generic product to market."[141] The parties ultimately terminated the agreement, and Andrx began marketing a reformulated version of the generic in June of 1999.[142] The generic sold for a much lower price than the patented Cardizem CD and has captured a substantial portion of the market.[143]

The plaintiffs in *Cardizem* alleged that but for the settlement agreement, Andrx would have marketed its generic version of Cardizem immediately upon the 1998 FDA approval and at a lower price than the patented Cardizem CD.[144] Therefore, from the first FDA approval in July of 1998 through introduction of the reformulated generic in 1999, the plaintiffs were deprived of the cost savings that generic competition in the market for Cardizem CD equivalent compounds would have brought consumers.[145] The Sixth Circuit was persuaded that the settlement agreement was "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."[146] The court rejected the HRM's attempts to characterize the agreement as "merely an attempt to enforce patent rights or an interim settlement of the patent litigation," pointing out that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to

136. *Id.* at 901.
137. *Id.* at 902.
138. *Id.* at 901.
139. *Id.* at 902.
140. *Id.* at 903.
141. *Id.*
142. *Id.*
143. *Id.*
144. *Id.* at 904.
145. *See id.* at 907.
146. *Id.* at 908.

bolster the patent's effectiveness."[147] The court also rejected HRM's contention that the novelty of the legal issue presented should preclude per se treatment, relying on *Arizona v. Maricopa County Medical Society*,[148] which held that that once a practice is determined to constitute horizontal price-fixing, antitrust law will not entertain any arguments that the practice is justified by the nature or particulars of the industry at issue.[149]

The *Cardizem* decision is notable for its analysis of the approval bottleneck in deciding to condemn the settlement as a per se unlawful restraint on trade.[150] The court found it particularly troubling that as part of the settlement agreement, Andrx agreed not to "relinquish or otherwise compromise . . . [the] 180-day period of exclusivity."[151] The court observed, "[b]y delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer."[152] "By agreeing . . . not to end the underlying patent dispute and not to market a generic drug product in the relevant domestic market, [the settlement] effectively precluded" any commercial marketing of the generic.[153] The settlement even contained an express provision that Andrx could not relinquish or transfer its exclusivity.[154] However, it is not clear the extent to which the settlement's utilization of the statutory bottleneck was essential to the holding in *Cardizem* because settlement was struck prior to the implementation of the forfeiture provisions of the MMA.[155]

147. *Id.* The court further noted that "[w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation . . . . Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem." *Id.* at 908 n.13 (citing *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 242 (E.D.N.Y. 2003)).

148. 457 U.S. 332 (1982).

149. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908-09; *see also* United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 221 (1940) (discussing modern definition of horizontal price fixing and defining price fixing broadly as "[a]ny combination which tampers with price structures," and not just agreements that literally fix price).

150. *See* In re *Cardizem CD Antitrust Litig.*, 332 F.3d at 907.

151. *Id.* at 902.

152. *Id.* at 907.

153. *Id.* at 907 n.12; *see In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp.2d 188 (E.D.N.Y. 2003) (detailing the process and distinguishing that case from the district court's opinion in *In re Cardizem CD Antitrust Litig*., 105 F. Supp. 2d 682 (E.D. Mich. 2000)).

154. In re *Cardizem CD Antitrust Litig.*, 332 F.3d at 907.

155. *See id.* at 896; *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-172, 117 Stat. 2066.

B. Scope of Patent Test

1. The Eleventh Circuit – *Valley Drug*, *Schering-Plough*, and *Watson*

Prior to the Third Circuit's ruling in *K-Dur*,[156] the clear trend amongst courts was to apply a formal scope of patent test.[157] Some commentators have also described this test as a straightforward rule of reason analysis, with the question of whether the settlement impermissibly expands the scope of the patent as a part of the rule of reason inquiry.[158] *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*[159] involved a civil antitrust challenge to two settlement agreements: one between Abbott Labs (Abbot) and Geneva Pharmaceuticals (Geneva), and another between Abbot and Zenith Goldline Pharmaceuticals (Zenith).[160] Abbott entered into "interim settlement" agreements with Zenith and Geneva during the course of patent litigation stemming from those companies' Paragraph IV certifications with respect to Abbott's patents for the drug Hytrin, used to treat hypertension and enlarged prostate conditions.[161] In the Zenith settlement, Zenith agreed not to sell or distribute any generic version of Hytrin until another firm introduced a generic Hytrin, or until Abbott's patent expired.[162] Zenith further agreed not to sell or transfer its rights under any ANDA application relating to a Hyrin generic, including its right to the 180-day exclusivity period.[163] In return, Abbott agreed to pay Zenith $3 million up front, another $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the agreement expired.[164] The agreement allowed Abbot to continue its infringement litigation in the district court,[165] and it provided that the payments would only terminate if Abbot prevailed on appeal.[166] Abbot eventually obtained a ruling of

156. *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012), *vacated sub nom.* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., Inc. 133 S. Ct. 2849 (2013).

157. *See* Yvon, *supra* note 108, at 1900-02 (discussing the Eastern District of New York's decision in *In re Ciprofloxcin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("Cipro II"), and the Second Circuit's decision in *In re Tamoxifen Citrate Antitrust Litigation*, 429 F.3d 370 (2d Cir. 2005)).

158. *See, e.g.*, *id.* at 1900.

159. 344 F.3d 1294 (11th Cir. 2003).

160. *Id.* at 1295-96.

161. *Id.* at 1298-99.

162. *Id.* at 1300.

163. *Id.*

164. *Id.* The agreement also provided that "if another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired." *Id.*

165. *See* Abbott Labs. v. Geneva Pharm., Inc., Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998).

166. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1300 (11th Cir. 2003).

invalidity "because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent."[167] The district court in *Valley Drug* found this subsequent judgment of invalidity dispositive on the antitrust questions because it meant that Geneva never had any patent rights in the first place.[168] In reversing, the Eleventh Circuit held that a court "must judge the antitrust implications of a reverse payment settlement as of the time that the settlement was executed."[169] Moreover, at the time of the settlement, the patent conferred "*potential* exclusionary power" with respect to the generic, and this potential exclusionary power should be treated as equivalent to actual exclusionary power for antitrust purposes.[170] The Eleventh Circuit articulated a highly deferential scope of patent test that considers "(1) the scope of the exclusionary *potential* of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[171]

In *Schering-Plough Corp. v. FTC*, the Eleventh Circuit reviewed an FTC determination that the settlement between Schering-Plough (Schering) and Upsher-Smith Laboratories (Upsher) was an unlawful restraint on trade.[172] The litigation resulted from Upsher's submission of a Paragraph IV ANDA, which certified that Upsher's proposed generic potassium-chloride compound, Klor Con M20 (Klor Con), did not infringe upon Schering's patented K-Dur 20 compound.[173] In 1997, Schering and Upsher began settlement discussions, but Schering was reluctant to pay Upsher to stay out of the market.[174] The parties eventually reached an agreement under which Upsher would delay entry until September 2001, and in exchange, Schering would enter into a separate agreement to license five of Upsher's cholesterol products for "(1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales."[175] Schering also entered into a similar agreement in 1997 with Lederle, Inc. (ESI), another pharmaceutical manufacturer who sought FDA approval to market its own generic version of K-Dur 20 called "Micro-K 20."[176] The agreement divided

167. *Id.* at 1301.

168. *Id.* at 1306.

169. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1308 (11th Cir. 2012) (citing *Valley Drug*, 344 F.3d at 1306).

170. *Id.* (quoting *Valley Drug*, 344 F.3d at 1311).

171. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing *Valley Drug*, 344 F.3d at 1312) (emphasis added).

172. 402 F.3d at 1063.

173. *Id.* at 1058, 1058 n.2. Potassium chloride compounds are used to high blood pressure and congestive heart disease. *Id.* at 1058. Potassium chloride commonly used and is not patentable. *Id.* Schering's K-Dur 20 formula includes a patented extended-release coating that surrounds the potassium chloride. *Id.*

174. *Id.* at 1059.

175. *Id.* at 1059-60.

176. *Id.* at 1060-61.

the remaining patent life of K-Dur 20 and promised payments of $5-15 million[177] if ESI would wait until January of 2004 to enter the market.[178] The FTC believed these royalty payments exceeded the true value of the license and were simply "reverse payments" in disguise.[179]

The Eleventh Circuit adhered to the framework devised in *Valley Drug*, emphasizing that traditional antitrust was "ill-suited" for evaluating patent settlements because it seeks to "determine whether the challenged conduct had an anticompetitive effect on the market" and because "[b]y their nature, patents create an environment of exclusion, and . . . [t]he anticompetitive effect is already present."[180] While both cases utilize the same framework, it is useful to parse the court's analysis in *Schering-Plough* because, while the *Valley Drug* decision resulted in remand for factual findings within the scope of patent analysis framework prescribed by the court of appeals,[181] the court in *Schering-Plough* was able to make its own factual determinations in applying the test.[182]

The court began by acknowledging the presumption of patent validity and noting that there was nothing in the record that would allow the court to depart from this presumption.[183] The existence of a valid patent gave Schering the lawful right to exclude infringing products from the market and to license the patent.[184] Absent any evidence to rebut the presumed legitimacy of the patent,[185] Schering's exclusionary conduct was a lawful means of excluding infringing conduct.[186]

The court then applied the next prong of the test: whether the record supported a finding that the agreements restricted competition beyond the exclusionary effects of patent.[187] The court defined the potential exclusionary scope of the K–Dur 20 patent as the right to exclude both of the generic com-

177. *Id.* Schering offered to pay $5 million, which it attributed to legal fees. *Id.* at 1060. When ESI insisted upon another $10 million, the parties devised a settlement whereby Schering would pay ESI up to $10 million if ESI received FDA approval by a certain date. *Id.* at 1060-61.

178. *Id.* at 1060.

179. *Id.* at 1068.

180. *Id.* at 1065-66 (citation omitted).

181. *See* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312-13 (11th Cir. 2003).

182. *See Schering-Plough*, 402 F.3d at 1062 ("We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. The FTC's findings of fact, 'if supported by evidence, shall be conclusive.' This standard applies regardless whether the FTC agrees with the ALJ. We may, however, examine the FTC's findings more closely where they differ from those of the ALJ." (citations omitted) (quoting 15 U.S.C. § 45(c) (2000)).

183. *See id.* at 1066.

184. *Id.* at 1067.

185. *Id.* at 1068.

186. *Id.*

187. *Id.*

panies from the K–Dur 20 market, and the "right to grant licenses, if it so chooses."[188] Because the agreement excluded generic competition against a compound apparently within the patent's objective scope, and for a shorter period of time than the remaining patent term, the court concluded that the agreement did not impermissibly extend Schering's patent monopoly.[189] The court then went on to describe that the agreements actually had a number of pro-competitive benefits.[190] For example, the provision of the settlement under which Upsher's licensed some of its own patents to Schering "may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation."[191] The agreement also allowed Upsher and ESI to enter the market prior to the expiration of Schering's patent.[192] The court concluded its analysis by considering the public policy arguments in favor of settling litigation and found that the benefits of settlement outweighed any ancillary competitive restraints contained in the agreements.[193]

The Eleventh Circuit reiterated its adherence to the scope of patent analysis in *FTC v. Watson Pharmaceuticals, Inc.*[194] The case involved facts very similar to *Valley-Drug*.[195] Watson Pharmaceuticals, Inc. (Watson) filed a Paragraph IV certified ANDA seeking approval to market a generic version of Solvay Pharmaceuticals' (Solvay) patented AndroGel, a topical gel that treats the symptoms of low testosterone in men.[196] Just prior to the district court's ruling on Watson's motion for summary judgment, the parties entered into a reverse payment agreement.[197] Under the agreement, Watson would not market generic versions of AndroGel until August 31, 2015, unless another manufacturer did so before then.[198] In exchange, Solvay agreed to share some of its AndroGel profits with Watson, projecting payments of $19 million and $30 million through 2015.[199]

The core of the FTC's argument was that Solvay probably would have lost the underlying patent infringement litigation,[200] thus warranting heightened antitrust scrutiny of the settlement.[201] The court adamantly reject-

188. *Id.* at 1066-67.
189. *Id.* at 1076.
190. *Id.* at 1075.
191. *Id.*
192. *Id.* at 1060.
193. *Id.* at 1075.
194. 677 F.3d 1298, 1312-13 (11th Cir. 2012).
195. *Id.* at 1306-07 (noting the similarity between the two cases).
196. *Id.* at 1303-04.
197. *Id.* at 1305.
198. *Id.*
199. *Id.*
200. *Id.*
201. *Id.* at 1312. The court also noted that "Watson agreed to promote branded AndroGel to urologists, and Par agreed to promote it to primary care doctors. Par also

ed the "FTC's retrospective predict-the-likely-outcome-that-never-came approach."[202] Instead, the court emphasized that the high stakes and uncertain outcomes inherent in patent litigation,[203] the difficulty in retroactively determining the parties' probabilities of success at trial,[204] and the burdens such an inquiry would impose on the courts counsel in favor of simply deferring to the formal scope of the patent.[205] The court also felt that the risk of such agreements being used to prop up suspect patents was mitigated by the presence of numerous other generic firms not bound by the settlement agreement who could subsequently challenge the patent,[206] indicating that the Eleventh Circuit's approach relies to some extent on the notion that other generics are sufficiently able and motivated to pursue subsequent challenges.[207] Indeed, even under its deferential test, the Eleventh Circuit conceded that reverse payments could violate antitrust laws if the terms of the agreement created a bottleneck that blocked other generic competition.[208] Ultimately, the *Watson* decision tracked the analysis in *Valley Drug* and *Schering-Plough* and reaffirmed the highly deferential scope of patent test as the controlling liability rule in the Eleventh Circuit.[209]

2. Second Circuit - *In re Tamoxifen Citrate Antitrust Litigation*

The Second Circuit also opted to use a scope of patent analysis in deciding *In re Tamoxifen Citrate Antitrust Litigation.*[210] Imperial Chemical Industries, PLC, (ICI) obtained a patent for the breast cancer drug Tamoxifen, which went on to become the most prescribed cancer drug in the world.[211] Barr Labs (Barr) sought to manufacture a generic version of Tamoxifen and filed a Paragraph IV certified ANDA with the FDA in September of 1987.[212]

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agreed to serve as a backup manufacturer for branded AndroGel but assigned that part of the agreement to Paddock." *Id.* at 1305.

202. *Id*. at 1314.

203. *Id*. at 1313.

204. *Id*. at 1313-14.

205. *Id*. at 1312, 1314.

206. *Id*. at 1315.

207. *See id.*

208. *See* Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that because the manufacturer had agreed "to refrain from *ever* marketing a generic" version of the patented drug, the settlement agreement blocked generic competition *after* the patent expired, and in that way excluded competition beyond the scope of the patent) (emphasis added).

209. *Watson Pharm., Inc.*, 677 F.3d at 1312.

210. 466 F.3d 187 (2d Cir. 2006).

211. *Id*. at 193.

212. *Id*. ("On April 20, 1992, the district court (Vincent L. Broderick, Judge) declared ICI's tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld 'crucial information' from the Patent and Trademark Office

Barr claimed that ICI's Tamoxifen patent was invalid because ICI had withheld "crucial information" regarding the safety and efficacy of the drug from the USPTO during the patent application process.[213] The United States District Court for the Southern District of New York agreed with Barr in the infringement suit and declared ICI's Tamoxifen patent invalid.[214] ICI appealed the ruling to the Federal Circuit.[215] While the appeal was pending, the parties entered into a settlement under which Zeneca (which had succeeded ICI's ownership rights of the patent) would pay $21 million and grant Barr a non-exclusive license to sell Zeneca-manufactured Tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex.[216] In exchange, Barr would change its ANDA from a Paragraph IV certification to a Paragraph III certification,[217] thereby delaying entry until the expiration of Zeneca's patent in 2002.[218]

The case is illustrative of the use of an *implicit* bottlenecking agreement to forestall other generic entry.[219] As part of the settlement, Barr "understood" that it was to prevent the subsequent generic manufacturers from producing generic Tamoxifen by asserting the 180-day exclusivity right possessed by the first Paragraph IV filer.[220] The parties' efforts to bottleneck entry was aided by the invalidation of the FDA's "successful defense" rule, which previously required that a generic entrant must successfully defend its Paragraph IV certification in the infringement litigation in order to obtain the 180-day exclusivity right because a settlement would not have constituted a "successful defense."[221] The successful defense rule has since been struck

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regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. Those tests had revealed hormonal effects 'opposite to those sought in humans,' which, the court found, could have 'unpredictable and at times disastrous consequences.'" (citations omitted)).

213. *Id.*

214. *Id.*

215. *Id.*

216. *Id.*

217. Recall that a Paragraph III certification acknowledges the validity of the patent, and merely certifies "the date on which such patent will expire." 21 U.S.C. § 355(j)(2)(A)(vii)(III) (2006); *see also supra* notes 91-96 and accompanying text.

218. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 194.

219. *See id.*

220. *Id.* The 180-day exclusivity period would only commence when Barr begins marketing its own generic version of the drug. *Id.* Because Barr was able to market Zeneca's version of tamoxifen pursuant to the settlement agreement, it had no incentive to begin marketing until its own version (and thus trigger the exclusivity period) until after the settlement expired. *See id.*

221. *See* Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130-32 (D.D.C. 1997); *see also* Granutec, Inc. v. Shalala, 139 F.3d 889, Nos. 97-1973, 97-1874, 1998 WL 153410, at *7 (4th Cir. Apr. 3, 1998).

down.[222] Though challenged, Barr's exclusivity rights ultimately helped the settlement agreement effectively forestall all generic entry until the expiration of Zeneca's Tamoxifen patent in August of 2002.[223]

A class of consumers and consumer groups challenged the legality of the 1993 settlement between Zeneca and Barr on antitrust grounds,[224] alleging that the reverse payment enabled Zeneca and Barr "to circumvent the district court's invalidation of Zeneca's tamoxifen patent . . . , which . . . would have been affirmed" on appeal.[225] The district court granted the defendant's motion to dismiss, emphasizing that: (1) although a patent holder is "prohibited from acting in bad faith 'beyond the limits of the patent monopoly' to restrain or monopolize trade," a patent holder is permitted to enter into a licensing agreement with the alleged infringer without violating the Sherman Act, (2) defendants could not be held liable for Barr's assertion of the 180-day exclusivity period to block additional generic entry even if this was an express term of the settlement because the "successful defense" rule was still valid in 1993 when the settlement was struck, and (3) while the vacatur of initial rul-

222. *Mova Pharm. Corp.*, 140 F.3d at 1076 ("We find that the FDA exceeded its statutory authority in imposing the successful-defense requirement as a prerequisite to the invocation of the 180–day exclusivity rule by a first applicant under section 355(j)(5)(B)(iv).").

223. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 196.

> Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than "successfully defended" against, Zeneca's lawsuit. . . . Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in *Mylan Pharmaceuticals*, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. It concluded that, although Judge Broderick's ruling of invalidity in *Tamoxifen I* had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180-day exclusivity period, which therefore had already expired. . . . On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. The court noted that subsequent to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. Thus, even if, as the district court held in *Mylan*, Barr's 180-day exclusivity period had run, Pharmachemie and Mylan were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired.

Id. (citations omitted).

224. *See id.* Plantiffs alleged a number of antitrust violations, including:

> [T]he Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; *and (5) prevented competition from other generic manufacturers of tamoxifen.*

Id. (emphasis added).

225. *Id.* at 197.

ing of invalidity deprived future generic filers of collaterally estopping Zeneca's claims of patent validity, thereby forcing future generic entrants to litigate the validity of the patent, such inconvenience did not constitute an "injury to competition" recognized under antitrust laws.[226]

On appeal, the Second Circuit rejected a per se rule in evaluating patent infringement settlements involving reverse payments.[227] Consistent with the Eleventh Circuit, the test employed by the Second Circuit is whether the "exclusionary effects of the agreement exceed the scope of the patents."[228] The Second Circuit also declined to consider the likelihood of the patentee's success at trial.[229] This insistence again came despite that fact the present settlement was struck during the appeal of a finding of patent invalidity, an appeal which would have proceeded with considerable deference to the district court's initial holding.[230] The Second Circuit found the mere fact that "appellants prevail with some frequency" was sufficient to adhere to the general rule that courts should refrain from guessing at what another court would have held.[231] The court further declined to consider the size of the reverse payment in its analysis.[232] The decision tracked the analysis in *In re Ciprofloxacin*,[233] so it appears that rule of reason is the law in the Second Circuit for evaluating reverse payment settlements.[234]

3. The Federal Circuit – *In re Ciprofloxacin Hydrochloride Antitrust Litigation*

The Federal Circuit applied the scope of the patent test in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* stating, "The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."[235] The court further "agree[d] with the Second and

226. *Id.* at 197-98.

227. *Id.* at 198, 206.

228. *Id.* at 213 (quoting Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005)) (internal quotation marks omitted).

229. *Id.* at 204.

230. *Id.*

231. *Id.* The court also noted that federal district courts concluding in later lawsuits seeking to enforce the Tamoxifen patent that the patent was, in fact, valid provided additional reason not to inquire into the chances that the patent would or would not have been invalidated. *Id.* ("While we do not think that these results enable us to estimate the chances that the Federal Circuit would have reversed the judgment of the district court in *Tamoxifen* I, they at least suggest the extent to which the outcome of such proceedings may be unpredictable.").

232. *See id.* at 208-13.

233. In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008).

234. *See* Yvon, *supra* note 108, at 1902.

235. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1336.

Eleventh Circuits . . . that, in the absence of evidence of fraud . . . or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."[236] Judge Posner gives the following example of what is meant by a "sham" patent litigation:

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices – masks – for fixing prices, in violation of antitrust law.[237]

C. Quasi Per Se or "Quick Look" Analysis – In re K-Dur Antitrust Litigation

The Third Circuit's decision in *In re K-Dur Antitrust Litigation*[238] rejected the trend toward the scope of patent test, creating a circuit split regarding the legality of reverse payments in patent settlements.[239] In its place, the Third Circuit devised a "quick look" rule of reason analysis under which reverse payments in exchange for delayed market entry are prima facie evidence of an unreasonable restraint on trade.[240] Defendants may rebut this presumption of illegality by showing that the agreement "(1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[241] The case arose out of the same settlements as the agreement as *Schering.*[242]

The Third Circuit identified three problems with the scope of patent test.[243] First, the court took issue with effectively irrebuttable presumption of patent validity, arguing that the scope of patent test inappropriately regarded the presumption of patent validity as a substantive right rather than a procedural device.[244] The court cited empirical data that showed that the generic challenger prevailed 73% of the time in Paragraph IV litigation from 1983 to

236. *Id.*

237. Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

238. 686 F.3d 197 (3d Cir. 2012).

239. *See id.* at 218.

240. *Id.*

241. *Id.*

242. *Id.* at 211; *see supra* notes 171-179 and accompanying text.

243. *In re* K-Dur Antitrust Litig., 686 F.3d at 214.

244. *Id.* at 214 ("While persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural device and is not a substantive right of the patent holder.").

1999.[245] Second, contrary to the Eleventh Circuit in *Watson*, the court doubted the assumption that "subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger"[246] because the 180–day exclusivity bounty was only available to the initial Paragraph IV filer.[247] The court worried that pay-for-delay agreements will therefore eliminate the most motivated generic challenger.[248] The court also noted that the monopoly over the drug at issue is often valuable enough to justify reverse payments to keep out multiple challengers.[249] Finally, the court relied on a series of Supreme Court cases that emphasized the strong policy interest in ensuring that the free exploitation of ideas is not repressed by invalid patents.[250]

D. The Supreme Court – FTC v. Actavis

The Supreme Court resolved the circuit split in June of 2013 in *FTC v. Actavis*, holding 5-3 that antitrust challenges to reverse settlements should be evaluated under a rule of reason standard.[251] In doing so, the court rejected the Eleventh Circuit's holding in *FTC v. Watson*, that as long as the anticompetitive effects of a settlement fell within the objective scope of the patent, the settlement was immune from antitrust challenge.[252]

The Supreme Court questioned whether the presumption of patent validity should hold as much weight as it does under the scope of patent test.[253] "[T]o refer, as the [Eleventh] Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed."[254] Because the settlement ends the litigation that would determine the validity of the patent, the legality of the settlement may not be determined solely on what constitutes appropriate exclusion for a holder of a valid patent.[255] As a result, the Court required legality of the settlement to be determined by "traditional antitrust factors."[256] The Court found additional support for its posi-

245. *Id*. (citing FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrug study.pdf; Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000)).

246. *Id*. at 215.

247. *Id*.

248. *Id*.

249. *Id*.

250. *Id*. at 215-16.

251. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2226 (2013).

252. *Id*. at 2227.

253. *Id*. at 2230-31.

254. *Id*.

255. *Id*.

256. *Id*. at 2231.

tion in the "general procompetitive thrust" of the Hatch-Waxman Act, which contains specific provisions for facilitating challenges to patent validity.[257]

The Court also found that the general judicial policy of favoring settlement was insufficient to warrant complete abandonment of antitrust limitations on settlements.[258] The Court identified five factors that weighed in favor of permitting antitrust challenges: these settlements have the potential for "genuine adverse effects on competition";[259] the anticompetitive effects will at least sometimes be unjustified;[260] the patentee has the power to bring about these anticompetitive effects;[261] antitrust action against these settlements is feasible;[262] and the risk of antitrust liability does not preclude the possibility of settlement.[263]

The Court also declined to adopt a "quick-look" rule of reason approach adopted by the Third Circuit and advocated by the FTC.[264] The Court believed that the anticompetitive effects of these settlements were far too dependent on particular circumstances of each case to justify a presumption of anticompetitiveness.[265] The Court did acknowledge that "[t]here is always something of a sliding scale in appraising reasonableness, and as such the quality of proof required should vary with the circumstances."[266] However, the decision did not go as far as to discuss what this inquiry would be, and the Court instead left to lower courts the task of structuring the appropriate rule of reason inquiry for these cases.[267] This leaves considerable uncertainty regarding how the antitrust analysis will proceed. This uncertainty will create an environment where courts and firms are likely to commit costly errors when making and reviewing settlements that include reverse payments.

IV. DEVELOPING AN OPTIMAL LIABILITY RULE

A. Decision Theory: Basic Insights

Antitrust doctrine has consciously evolved in accordance with developments in economic thinking about the competitive effects of certain business

257. *Id.* at 2234.
258. *Id.* at 2235.
259. *Id.* at 2234.
260. *Id.* at 2235-36.
261. *Id.* at 2226.
262. *Id.*
263. *Id.* at 2237.
264. *Id.*
265. *Id.*
266. *Id.* at 2237-38 (alteration in original) (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 780 (1999)) (internal quotation marks omitted).
267. *Id.* at 2238.

practices.[268] More recently, the idea of incorporating a branch of economic analysis called "decision theory" to evaluate the rules and processes for making antitrust liability determinations has gained favor.[269] The basic proposition is this: when devising and applying legal rules, courts and other lawmaking bodies must make a determination about the underlying factual realties in the realm they seek to regulate.[270] In a world of perfect information, whether a certain activity should be permitted or enjoined would depend on a straightforward application of appropriate law to the facts of a given case.[271] Of course, courts do not operate in a world of perfect information, and instead operate in a reality where crucial facts may be costly or unattainable.[272] In light of this uncertainty, courts must form presumptions, impose burdens of proof, collect and process information, make relevant findings of fact, and apply the relevant legal standards to those findings.[273] The process of obtaining and deliberating upon the information upon the information necessary to make liability determinations is called "decision costs"[274] and will be the first cost considered in this analysis. The more intensive the process of gathering and using additional information, the more likely a court can reach a correct liability determination.[275] The desirability of discovering additional infor-

268. *See, e.g.*, Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 878 (2007) (finding that the "economics literature is replete with procompetitive justifications for a manufacturer's use of resale price maintenance, and the few recent studies on the subject also cast doubt on the conclusion that the practice meets the criteria for a *per se* rule."); Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 575 (1986) (drawing upon emerging consensus in the economics field regarding the implausibility of predatory pricing schemes to constrain the action).

269. *See* C. Frederick Beckner, III & Steven C. Salop, *Decision Theory and Antitrust Rules*, 67 ANTITRUST L.J. 41, 41-42 (1999).

270. *See id.* at 43.

271. *See id.*

272. *See id.*

273. Judge Marshall gives the following justification of per se rules under this framework:

> Per se rules always contain a degree of arbitrariness. They are justified on the assumption that the gains from imposition of the rule will far outweigh the losses and that the significant administrative advantages will result. In other words, the potential competitive harms plus the administrative costs of determining in what particular situations the practice may be harmful must far outweigh the benefits that may result. If the potential benefits in the aggregate are outweighed to this degree, then they are simply not worth identifying in individual cases.

United States v. Container Corp. of Am., 393 U.S. 333, 341 (1969) (Marshall, J., dissenting).

274. *See* Thomas A. Lambert, *The Roberts Court and the Limits of Antitrust*, 52 B.C. L. REV. 871, 877 (2011).

275. *See* Beckner, *supra* note 269, at 46.

mation then depends on the costs of obtaining that information relative to the benefits of considering it.[276]

In addition to the costs of adjudication under a given liability rule, decision theory also considers the costs of erroneous decisions ("error costs").[277] Some errors are inevitable given the court's task of resolving complex issues based on imperfect information.[278] These errors come in two forms. First, courts may wrongly convict beneficial practices (also termed "false positives" or "Type I errors").[279] Alternately, courts may wrongly acquit harmful practices (also termed "false negatives" or "Type II errors").[280] In devising optimal decision rules, courts must consider the relative frequencies with which a given liability regime will tend to generate Type I and Type II errors.[281] The total error costs of a liability regime equals the magnitude of loss occasioned by each respective error type weighted by the probability that the regime tends to produce each type of error.[282] The costs of a liability rule that tends to generate Type I errors are "not just the costs associated with the parties before the court (or agency), but also the loss of procompetitive conduct by other actors that, . . . are deterred from undertaking such conduct by a fear of litigation."[283] Likewise, the cost of a regime that generates a high number of Type II errors is not only the cost of failure to enjoin anticompetitive behavior in the case at bar but also the cost of inadequately deterring future anticompetitive behavior of nonparties whose behavior will be influenced by litigation risks.[284]

Given these considerations, the framework posits that an optimal rule is one that minimizes the sum of decision and error costs.[285] The general framework can be expressed as:

> ∑[decision Costs + Prob (Type I) x Magn (Type I) + Prob (Type II) x Magn (Type II)][286]

In the context of reverse payments, appropriate antitrust rules should minimize sum of the probability weighted sum of the costs associated with

276. *See id.*
277. *See id.*
278. *See id.* at 45.
279. *See* Lambert, *supra* note 2745, at 878.
280. *See id.*
281. *See* U.S. DEP'T OF JUSTICE, COMPETITION AND MONOPOLY: SINGLE-FIRM CONDUCT UNDER SECTION 2 OF THE SHERMAN ACT 16 (2008) [hereinafter D.O.J. REPORT], *available at* http://www.justice.gov/atr/public/reports/236681.pdf.
282. *See* Beckner *supra* note 269, at 45.
283. D.O.J. REPORT, *supra* note 281, at 16.
284. *See id.* at 162.
285. *See* Beckner, *supra* note 269, at 61.
286. *See id.* at 41.

condemning unlawful exclusion, acquitting lawful exclusion, and the cost of determining the lawfulness of the patent holder's exclusionary conduct.

B. Caveat – Amenability of the Pay-for-Delay Problem to Decision Theory Analysis

There may be some doubt about whether the question of the appropriate liability rule for patent settlements involving reverse payments is even an appropriate candidate for decision theoretic analysis.[287] On one hand, the disagreement is fundamentally about how to make a liability decision in the absence critical information, namely, whether the generic compound in fact infringes on a valid patent.[288] Knowledge that the underlying patent is not valid or is not infringed would render the agreements unlawful horizontal market allocations,[289] while knowledge that the underlying patent is valid and infringed would render the settlements lawful.[290] Disagreement exists about what the appropriate presumptions are in a world where this decisive information is costly to obtain.[291]

On the other hand, the often-divergent goals promoted by patent law and antitrust law[292] create a sort of apples-to-oranges comparison that may render the issue of reverse settlements resistant to decision theoretic analysis. If this issue presented questions of pure of antitrust law, then the effects of a given liability rule could be measured against a single benchmark – i.e., whether the rule, accounting for decision and error costs, tends to increase or decrease output in the relevant market.[293] Because both erroneous and proper enforcements of patent rights will result in short-term price increases and output restrictions that are inconsistent antitrust goals, an output-focused analysis would necessarily overemphasize the antitrust goals and undervalue the innovation incentives encouraged by patent rights. But ultimately, even though this problem prevents the analysis from being as quantitatively rigorous as we would like, it is still useful to estimate the relative likelihood of false positives and false negatives under competing liability rules, cost of each error, and the administrative costs of sorting one from the other.

287. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 37 (2009).

288. *See id.* at 73.

289. *See id.* at 72.

290. *See id.*

291. *See* Beckner, *supra* note 269, at 41-42.

292. *See supra* Part II; *see also* Carrier, *supra* note 287, at 73.

293. *See* HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE: PRINCIPLES AND EXECUTION 2-5 (2005) (justifiying equating effects on competition with output).

C. Decision Costs: The Costs of Determining Underlying Infringement

The cost of obtaining information is a key component which factors into the overall costs of a given liability rule.[294] In the case of reverse patent settlements, the validly of such settlement will turn on whether the generic compound actually infringes on a valid patent held by the brand-name manufacturer.[295] The main justification for permitting these agreements rests on the judicial policy favoring settlement as a way to avoid the costs associated with discovering the information necessary to determine infringement in a fully litigated case.[296] Indeed, settlements have particular appeal in patent infringement litigation, as the costs of fully litigating a high stakes infringement case can range from three to ten million dollars.[297] The upper bound of an estimate of decision costs averted by a regime that permits reverse payments will therefore be the total cost of infringement litigation times the number of infringement cases that would have been fully litigated but for the availability or reverse payments to settle the litigation.

The amount of litigation expense actually saved in the event of settlement will almost certainly be less, and maybe considerably so. For one, the settlements are frequently struck at late stages of the infringement litigation, after some portion of litigation expenses are already incurred.[298] There is also reason to believe that the net decision costs saved by permitting reverse payments will not be that great compared to a regime that prohibits reverse payments. First, a scope of patent regime would inevitably retain some potential for an antitrust challenge to the legality of the settlement, such as whether the settlement unlawfully expands even the presumed formal scope of the patent, whether the underlying infringement litigation was fraudulent or a sham, or by considering the strength of the underlying patent as part of the antitrust inquiry.[299] Under a per se rule, costs of prosecuting and defending subsequent antitrust suits likely vanish because firms would respond to the prohibi-

294. *See* Beckner, *supra* note 269, at 45-46.

295. *See* FTC v. Watson, 677 F.3d 1298, 1301 (11th Cir. 2012).

296. *See id.* at 1314.

297. AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 2007 25 (2007). In 2007, in patent cases with more than $25 million at risk, each party faced a median expense of $5 million. *Id.*; *see also* AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 2009 29 (2009) (reporting that patent litigation suits with over $1 million at stake cost roughly between $3 million and $6 million).

298. *See, e.g.*, *Watson*, 677 F.3d at 1305 (noting that Watson's and Par/Paddock settled the case just prior to the district court deciding motions for summary judgment); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 193-94 (2d Cir. 2006) (noting that Zenecca and Barr reached settlement after a full trial in the district court and during the pendency of an appeal.).

299. *See supra* Parts III.B, III.C.

tion by not entering such settlements.[300] Generic firms might also be more judicious in initiating Paragraph IV litigation in the first place because they could no longer expect to be bought off with a generous settlement.[301] Finally, it is not obvious that prohibiting reverse payments would take settlements off the table.[302] Many settlements of Paragraph IV litigation do not require reverse payments, meaning that litigation costs can still be avoided under less problematic agreements.[303]

D. Probability of a Type II Error is High Under the Scope of Patent Test

The definition of a Type II error in the pay-for-delay context differs slightly from existing antirust commentary utilizing a decision theoretic framework. Generally, this framework is employed to analyze practices which have ambiguous effects on competition.[304] This is not the case for reverse payments, which are universally understood to have anticompetitive effects, and are rescued only by the presence of a presumptively valid patent.[305] Therefore, the a Type II decision error arises when a patentee is permitted to exclude a generic entrant from the market, even though the underlying patent at issue is in fact invalid or not infringed.

The tendency to produce a high number of Type II errors is the single most concerning feature of the scope of patent test and regimes that are highly deferential to settlement decisions of the parties. This tendency can be explained by the way that parties' settlement incentives in Hatch-Waxman litigation differs from those faced by adversaries in typical litigation settings.[306] In a settlement where plaintiff and defendant are aligned as adversaries, the parties' willingness to settle will mainly depend upon their confidence in prevailing at litigation.[307] For example, if $10 million in damages is

300. *See supra* Parts III.B, III.C.

301. *See* Ian Hastings, *Dynamic Innovative Inefficiency in Pharmaceutical Patent Settlements*, 13 N.C. J. L. & TECH. 31, 54 (2011) ("This is the rent that Lemley and Hemphill identified as being sought by generic challengers, and the reason why challenges are so common. A generic need not win a patent invalidity case; it need only challenge and thereafter manipulate the brand-name manufacturer into parting with some of its monopoly profits or allowing it to enter the market sooner than it would under litigation.").

302. *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: AN FTC STAFF STUDY 4 (2010).

303. *See infra* Part IV.H.

304. *See supra* notes 274-276 and accompanying text.

305. *See supra* notes 287-291 and accompanying text.

306. *See* Paul Bailin, *A Reverse Perspective on Reverse Payment Settlements* 17 (May 2010) (unpublished student paper), *available at* http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965635.

307. *See id.*

at stake in the litigation, and the alleged infringing party believes there a 90% chance that it will be found to have infringed at trial, then the rational alleged infringer will typically be willing to pay up to $9 million to settle the litigation. If the alleged infringer believes that there is only a 10% chance it will be found to have infringed at trial, then it will only be willing to pay up to $1 million to settle the litigation. This is not the case in Hatch-Waxman litigation, where the parties' incentives are aligned toward settlement regardless of the merits of the underlying infringement claim:

> [C]onsider a traditional patent infringement settlement, one where the patent holder (PH) has lost, say, $10 million in profits during a year (Y1) in which the infringing manufacturer (IM) was on the market. When negotiating a settlement under which IM will agree to leave the market and pay damages to compensate PH for part of its loss, the interests of the two parties are fully opposed. IM has no future market prospects (at least until PH's patent expires), and so it can "win" only by having to pay less of the $10 million in compensation to PH. Importantly, in this scenario, consumers have already derived some benefit from the year's worth of competition during Y1. The parties are now left to divvy up what was left of the Y1 market after purchasers took the consumer surplus in the form of reduced prices. That is, the potential settlement pie to be divided by the parties, based on their expected outcomes at litigation, is what is left *after* consumers have gained some economic benefit from competition. Consumers are not players in this zero-sum game.[308]

Hatch-Waxman litigation results from a constructive infringement – the mere filing of a Paragraph IV certified ANDA.[309] The patent holder has not experienced any actual losses due to the marketing of an infringing compound; consequently, there is no set sum of damages at stake in the litigation.[310] The size of settlement is instead constrained only by the patent holder's expected profits from selling the drug as a monopolist.[311] Because the brand-name drug maker's profits selling as a monopolist will be greater than the sum of two firms' profits selling in a market with generic competition,[312] each party is made better off by excluding generic entry and splitting the monopoly profits.[313] For this reason, the generic challenger will frequently gain more

308. *Id.* (emphasis in original).

309. *See supra* notes 93-94 and accompanying text.

310. *See* Bailin, *supra* note 306, at 22.

311. *See id.*

312. This is often true even accounting for the generic's 180 duopoly bounty. *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283, 298 (2012).

313. *See* Carrier, *supra* note 287, at 73.

through settlement than by prevailing in the infringement litigation.[314] Consider the following scenario:

> PH has been charging a monopoly price of $100 for a pill which costs $10 to produce, based on a patent set to expire in five years. If IM were to put a generic version on the market, and other generics were to follow, assume the price would drop to $12 per pill. Here, a PFD agreement might entail IM agreeing to stay off the market for three years, in exchange for PH paying it $15 per pill for 70 percent of PH's sales volume (assume that this would be IM's expected market share in a competitive market). PH continues to receive a monopoly price of $85 on those sales during the three year period of market exclusivity, earning a per-pill profit of $75, and PH receives $15 per pill for doing absolutely nothing, versus a $2 profit if it were to actually commercialize its drug.[315]

The presence of such incentives means that the parties will choose to settle *irrespective of the validity of the underlying patent* and their expectations of success at litigation.[316] That the crucial piece of information which should determine the legality of an exclusionary settlement plays little or no role in the parties' decision to reach such a settlement is extremely problematic.

The scope of patent test might make sense if the generic entrant's expected gains from prevailing in the infringement litigation exceeded the patent holder's willingness to pay for exclusion.[317] If this were the case, the parties would be positioned as adversaries, and if a settlement were struck, the terms would take into account each party's perceived likelihood prevailing in infringement litigation.[318] Because the parties' willingness to settle would be determined by their assessments of the validity of the underlying patent, a liability rule that defers to the parties decision to settle would not, on average, tend to produce settlements that restrain competition when the patent would have otherwise been invalidated.[319] Unfortunately these conditions, which would require joint profits to be higher with entry than without, can only exist if the patent holder lacks market power.[320] This is highly unlikely in the case of the patent holder for a blockbuster drug.[321] Further, it would not be rational for a patent holder to make a reverse payment if it did not be-

314. *See* Bailin, *supra* note 306, at 22.
315. *Id.* at 23.
316. *See id.*
317. *See* Elhauge & Krueger, *supra* note 312, at 315.
318. *See* Bailin, *supra* note 306, at 22.
319. *See id.* at 23.
320. *See* Elhauge & Krueger, *supra* note 312, at 310.
321. *See id.*

lieve it had market power that would be threatened by generic entry.[322] If it were the case that entry would increase joint profits, then settlement payment would flow in the usual direction, with the generic entrant making payment to the patent holder to drop its infringement challenge.[323] Thus, the presence of a reverse payment confirms that the general conditions exist such that the joint profits of monopoly are higher than in duopoly, higher in duopoly than in triopoly, and so forth.[324] As a result, the incentives of brand-name and generic manufacturers are strongly aligned to preclude discovery of the underlying fact of patent validity or infringement that should determine the legality of these settlements.

Much of the defense of these settlements rest on the notion that the enhancement to innovation incentives that patent policy seeks to protect is un-

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322. *See id.* at 310-11 ("[T]he patent holder's willingness to make a reverse payment that exceeds its anticipated litigation costs necessarily means that it believes it has market power.").

323. *See id.* at app. A. Elhauge and Krueger discussed reverse payment:

> Proof That Reverse Payments Cannot Be Necessary for Settlement If Joint Profits with Entry Exceed the Patent Holder's Profits Without Entry
>
> ***Weak Patent***
> $T_{max} = \theta_E (1- L) + [\theta_E L(P_N - P_Y) + C_E + R]/E$
> $T_{min} = \theta_P - (C_P + R)/(P_N - P_Y)$
> The parties can settle only if $T_{max} > T_{min}$
> $\theta_E(1- L) + [\theta_E L(P_N - P_Y) + C_E + R]/E > \theta_P - (C_P + R)/(P_N - P_Y)$
>
> Thus, if R increases by org] from 0 or any positive number, the left side (T_{max}) will increase by ə/E and the right side (T_{min}) will increase by ə/($P_N - P_Y$).
>
> Therefore, if $P_N - P_Y < E$ (just $P_N < P_Y + E$ rearranged) then ə/E < -/ ($P_N - P_Y$), meaning that increasing a settlement payment by org] can only make it less likely that $T_{max} > T_{min}$. A corollary is that that if $P_N - P_Y < E$ but the parties nevertheless settled, the parties must have necessarily been able to settle without any reverse payment.
>
> ***Strong Patent***
> $T_{max} = \theta_E + L(1- \theta_E) + (C_E + R)/E$
> $T_{min} = \theta_P + L(1- \theta_P) - (C_P + R)/(P_N - P_Y)$
>
> Increasing R by org] from 0 or any positive number can only reduce $T_{max} - T_{min}$ if $P_N - P_Y < E$ because then T_{max} would increase by only θ/E and T_{min} would increase by the greater ə/($P_N - P_Y$). Therefore, if $P_N - P_Y < E$ but the parties nevertheless settled, the parties must have necessarily been able to settle without any reverse payment.

Id.

324. *See id.* at 298 (citing Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets*, 99 J. POL. ECON. 977, 984 (1991); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75, 84 (1997); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 43 (2005)).

deterred if a patentee is deprived of this method to protect its patent rights.[325] However, there are nonobvious effects that also must be considered in assessing the net effect on innovation incentives.[326] Elhauge and Kreuger demonstrate that the availability of these settlements creates a legal regime that is much more likely to over reward pseudo-innovation, thereby threatening the promotion of genuine innovation.[327]

> [S]ettlements that exclude entry increase patent-holder profits more for weaker patents than for stronger patents. For example, the holder of a weak patent that is only 5% likely to be deemed a valid innovation could use such a settlement to secure exclusion throughout the entire patent term, even though its patent is 95% likely to be deemed a non- innovation, while the holder of an ironclad patent that is 100% likely to be deemed a true innovation could not increase its exclusion period through settlement because it would already expect 100% exclusion from litigation.[328]

The net reward for pseudo-innovation becomes greater relative to the net reward for genuine innovations because genuine innovation is harder, more costly, or less certain than pseudo-innovation. [329] This can cause a reduction in the rate of true innovation.[330] Indeed, many commentators have criticized the prevailing business practices in the pharmaceutical industry on precisely these grounds.[331] This has obvious implications with regard to undermining the innovation promoting goals underlying patent policy. For the present analysis, these observations lend empirical support to the notion that the availability of reverse settlements will tend to incentivize firms to produce a larger number of weaker patents,[332] which, combined with the reduced incentive of generic rivals to police weak patents,[333] will tend to produce Type II errors. As a result, the number of objectively invalid patents remains intact because the number of reverse settlements will be high, and

325. *See id.* at 294.
326. *See id.*
327. *See id.*
328. *Id.*
329. *See id.*
330. *See id.*
331. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (2005) (arguing that pharmaceutical companies overinvest resources in extending patent monopolies of non-innovative compounds and marketing them as therapeutic advances); Donald W. Light & Joel R. Lexchin, *Pharmaceutical Research and Development: What Do We Get for All That Money?* 2012 BRIT. J. MED. 345:e4348 (2012) (noting that revenues within the pharmaceutical industry have outpaced research and development costs by a factor of six).
332. *See* Elhauge & Krueger, *supra* note 3123, at 295.
333. *See* Carrier, *supra* note 2878, at 73.

consumers will suffer the resulting higher costs and lower output.[334] Empirical data appears to confirm the notion that fewer fully litigated infringement cases will result in greater market exclusion than would have resulted had the cases not settled.[335] Therefore, if the brand-name and generic parties are left to act on their mutual incentive to allocate the market regardless of whether it was likely to be deemed lawful under the patent, the unlawful allocation of pharmaceutical markets is likely to be erroneously acquitted in a large number of instances.

E. Probability of Type I Errors

An erroneous decision regarding the antitrust liability of parties using reverse payments will result in Type I errors when it falsely convicts innocent conduct (i.e., convicts a settlement in which a potential generic entrant is excluded no more than the extent to which is lawfully permitted by virtue of a valid patent). In such cases, had the Paragraph IV infringement litigation reached conclusion, a finding of patent validity and infringement would have resulted in an equal or greater exclusionary effect than the terms of the reverse payment agreement, and the costs of litigation would have been incurred without any offsetting gains to consumer access. Alternately, parties could be subjected to treble damages simply for having guessed wrong about what a court later determines about the scope and validity of the patent.[336] But while permitting reverse payments will result in a high frequency of Type II errors,[337] the converse is also true: prohibiting these settlements will result in some instances of Type I errors where patent holders will not be able to exclude rivals even when they should.

The literature advocating lenient antitrust treatment of reverse payments is replete with concerns over the competency of courts to correctly adjudicate patent rights.[338] A fair assessment must acknowledge that the objective exist-

334. *See* Elhauge & Krueger, *supra* note 3123, at 294.

335. For example, the FTC found that between 1992 and 2002, generic entrants prevailed in seventy-three percent of Paragraph IV litigation that was litigated to judgment. *See* FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, EXECUTIVE SUMMARY viii (2002), *available at* http://www.ftc.gov/os/2002/ 07/genericdrugstudy.pdf.

336. *See* Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1308 (11th Cir. 2003) ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.").

337. *See supra* Part IV.D.

338. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antritrust Litig., 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) "([N]o matter how valid a patent is – no matter how often it has been upheld in other litigation . . . or successfully reexamined . . . – it is still a gamble to place a technology case in the hands of a lay judge or jury . . . . Even

ence of patent validity and/or infringement may differ from the decision in the infringement litigation because patent trials are often highly complex and because lay juries may simply get it wrong.[339] In light of the inherent uncertainty in placing patent rights in the hands of a lay judge or jury, patent holders will often estimate their probability of success at litigation far lower than their actual confidence in the validity of the patent.[340] Even supremely confident patent owners believe that their chances of prevailing in the litigation rarely exceed 70%.[341] A minimum 30% risk of anticipated monopoly profits being driven down to competitive levels for the remaining life of the patent will create a considerable bargaining zone for the brand-name and generic manufacturers to settle the litigation with a reverse payment.[342] This uncertainty subjects a firm to a number of costs associated with uncertain business planning, in addition to the obvious need to discount anticipated returns when deciding to invest in research and development.[343]

In this sense there are two potential instances in which a rule condemning reverse payments would result in decisions that erroneously punish a patent holder. First, patent holders could incur antitrust damages for using reverse payment to exercise their lawful right to exclude a generic entrant.[344] However, this type of error would occur under a regime in which such condemnation applied only a presumption of illegality or otherwise allowed for some exceptions in which reverse payments would be lawful. Firms would respond to a rule that held reverse payments to be per se unlawful by instead litigating the infringement cases or striking settlements without reverse payments, meaning possible decision errors would be limited to an erroneous decision in the infringement litigation.[345] Since a deferential regime will not tend to produce false convictions, and a prohibition on reverse payments will

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the confident patent owner knows that the chances of prevailing in [patent] litigation rarely exceed seventy percent . . . . Thus, there are risks involved even in that rare case with great prospects." (citations omitted) (internal quotation marks omitted)); Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 626 (2006) ("[T]he risk of an erroneous decision in a patent case is a simple fact of life.").

339. *See* Bernard & Tom, *supra* note 338, at 626.

340. *See id.*

341. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d at 208 (referencing defendant's memorandum in opposition to motion for partial summary judgment).

342. *See id.*

343. *See id.*

344. *See, e.g.*, Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003); *see also* Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, *in* 21 RESEARCH IN LAW AND ECONOMICS: ANTITRUST LAW AND ECONOMICS 475, 484 tbl.4 (John B. Kirkwood ed., 2004).

345. Shapiro, *supra* note 344, at 395.

cause parties to not enter into reverse payment agreements in the first place, the Type II error risks relevant to a per se rule are confined to the risk of an erroneous outcome in the infringement litigation.

It is important to appropriately characterize this error. Recall that the grant of a patent represents a probabilistic property right,[346] a right to "try to exclude" as opposed to a "right to exclude."[347] It is true that patent litigation is highly uncertain and imperfect.[348] However, the resulting decision in infringement litigation – a legal determination of whether the patent at issue can lawfully exclude the conduct of that particular alleged infringer – is perhaps the only instance where status of a patent right is definitively known.[349] The probabilistic nature of patent rights perhaps receives too little attention by advocates of the scope of patent test. For example, one commentator characterizes the situation as follows:

> Suppose, hypothetically, that a patent owner believes there to be a 60% chance that its patent will be held valid and infringed, and a 40% chance that it will be held invalid or not infringed. Suppose it also perceives that, absent an agreement, the generic will enter prior to the conclusion of the patent litigation. If the settlement prevents such entry, then 40% of the time it will have prevented a price decrease to consumers, *but 60% of the time it will have prevented the theft of intellectual property.*[350]

Bernard proceeds to argue that the social costs occasioned by a regime that permits "theft" of patent rights are sufficiently large to justify reverse payments as a means of prevention.[351] This characterization is problematic in two respects. First, it privileges non-judicial assessments of patent validity, specifically the USPTO's initial grant and the perspectives of the patentee and the generic rival. The USPTO's "rational ignorance"[352] in determining the initial grant of the patent, and the incentive alignment[353] between the patentee and the generic entrant to keep the patent exclusion intact, counsels strongly against relying on such non-judicial determinations in this in-

346. *Id.*
347. *Id.*
348. *Id.*
349. *See supra* notes 74-75 and accompanying text.
350. Bernard & Tom, *supra* note 338, at 622 (emphasis added).
351. *See id.* at 622-23 ("This theft is not merely of private concern. The implicit bargain [of the patent system] is that [for society as a whole] the short-term loss in static allocative efficiency [caused by patents] will be more than offset by the gain in dynamic efficiency resulting from the reward to innovation that patents confer.") (internal quotation marks omitted).
352. *See supra* notes 51-72 and accompanying text.
353. *See supra* Part IV.D.

stance.[354] For all its inefficiencies, an infringement trial at least eliminates the need to assess whether entry is valid or unlawful in probabilistic terms and instead provides a conclusive determination about whether the generic entrant did in fact infringe or, alternately, whether the brand-name had no legal right to exclude because of invalidity or non-infringement.[355] Second, Paragraph IV litigation provides for a declaration of patent infringement *prior* to market entry, including a stay on entry until the resolution of the litigation,[356] which in most instances will safeguards against any "theft" intellectual property. As a result, it is difficult to see how a liability rule which encourages fully litigated infringement claims will tend to produce false convictions because the assertion of those rights in court represents the full exercise of the rights conferred under the patent.

While the concern about jury competence to decide increasingly technical patent cases certainly appears valid, it is difficult to quantify. Assessments of the accuracy of jury verdicts are difficult because it is difficult to benchmark verdicts with any objective measure of accuracy. Some studies have compared the performance of district court findings with specialized patent tribunals, finding no significant rate of reversal by the Federal Circuit Court of Appeals.[357] Other studies have looked at the twenty-eight percent reversal rate of district court findings by the Federal Circuit on claim construction maters.[358] Further, even acknowledging legitimate skepticism about courts' ability to decide patent infringement cases with accuracy and consistency, there is an important qualitative difference between error verdicts and errors that result because the law gives parties an incentive collude to thwart discovery of the underlying merits. A fully litigated, adversarial infringement case, including the availability of appellate review, represents the legal system's most thorough means of resolving the uncertain status of the patent.[359]

Finally, regardless of how justified concerns of inaccurate verdicts may be, the reverse payment problem is not an instance where the law

354. See *supra* note 322 and accompanying text.

355. *See supra* notes 74-75 and accompanying text.

356. Although, this stay is capped at thirty months. *See supra* note 96 and accompanying text.

357. *See, e.g.*, David L. Schwartz, *Courting Specialization: An Empirical Study of Claim Construction Comparing Patent Litigation Before Federal District Courts and the International Trade Commission*, 50 WM. & MARY L. REV. 1699, 1700 (2009) ("This study does not find any evidence that the patent-experienced ALJs of the ITC are more accurate at claim construction than district court judges or that the ALJs learn from the Federal Circuit's review of their decisions.").

358. *See* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 38 (2001) (evaluating results of de novo review of district court claim construction and questioning the notion that judges represent a more competent alternative for patent adjudication than juries).

359. *See supra* notes 74-75 and accompanying text.

should recognize litigation uncertainty as a reason to permit parties to circumvent its fundamental truth finding process. This is because the parties' settlement decisions occasion costly externalities, which are borne by consumers.[360] In a purely private dispute, settlement should be permitted because the rights at stake in litigation do not impact anyone but the parties to the settlement.[361] In patent settlements, the incentives of the parties are aligned against a large, unrepresented constituency – consumers, with any bargaining discrepancies between the settling parties essentially being subsidized out of consumers' pockets.[362] Consumers are left with a level of access lower than what would have prevailed under expected outcomes of litigation,[363] and encouraging litigated patent trials means that the consumer interest underlying patent and antitrust policy enters into the result.[364] Because of these concerns, the risks stemming from erroneous infringement verdicts are both less probable and of a fundamentally less concerning character than the risk of false acquittals resulting from a regime which is highly deferential to pay-for-delay agreements.

F. Cost of a False Conviction: Magnitude of False Convictions

Probabilities of error alone do not tell the whole story. This analysis must also consider the magnitude of loss caused by the commission of each respective error type.[365] Recall that a per se prohibition on settlements utilizing reverse payments would not produce errors in the sense that courts would be deciding and inappropriately imposing antitrust liability in cases before them because parties would not enter such settlements where they were condemned per se.[366] The more important result of a regime that prohibits reverse payments is that the cost of patent uncertainty is borne by the holders of patents.[367] This cost will not just include the actual resources such as legal and judicial time but also the reduced innovative efficiency that may result from over deterring benign exercises of patent exclusion and the changes to

360. *See supra* Part IV.D.

361. *See, e.g.*, Transcript of Oral Argument at *55, FTV v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416) ("[F]or instance, if you had two . . . firms fighting over a million dollars and each firm decided internally, 600,000 is the least I will accept. If they stuck to their guns, the case could not be settled. Now, if the public could be made to kick in an additional 200,000, then each of the firms could get its 600,000 and walk away content. But we don't pursue the policy in favor of settlement to that degree.").

362. *See* Shapiro, *supra* note 344, at 394.

363. *See id.* at 396.

364. *See id.* at 395.

365. *See* Bernard & Tom, *supra* note 338, at 627.

366. *See supra* note 317 and accompanying text.

367. *See* Bernard & Tom, *supra* note 338, at 626-27.

investment decisions resulting from less certain exclusionary rights.[368] "Dynamic innovative efficiency in the context of pharmaceutical patent litigation relates to how effectively the Hatch-Waxman Act provides incentives to pioneer drug manufacturers to develop and market drugs."[369] This risk commands great attention – as Judge Easterbrook noted, "An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses."[370]

A pioneer pharmaceutical manufacturer faces the following incentives to innovate:

> A firm will sink funds into research and development when the present value of the expected future income stream from the developed product meets or exceeds its development and production costs. In calculating the expected future income stream of the product, the company will account for the possibility that a successful and profitable patent will be declared by a court to be invalid. Settlement operates as a form of insurance against the risk of a declaration of invalidity. By providing a range of certain outcomes, settlement increases the ex ante value of a drug to manufacturers who maintain even a nominal level of risk aversion. Thus, settlements form part of the Hatch-Waxman set of incentives to innovate in the pharmaceutical field, and their removal or restriction in this arena could be damaging in the long term.[371]

Pharmaceutical firms rely on the profits earned from "blockbuster drugs" not only to recoup the research and development costs of those particular drugs but also to subsidize losses sunk into research projects that do not yield a marketable drug and the production and marketing of loss-making or less profitable drugs.[372] The importance of patents to pharmaceutical innovation illustrates the potential social harm from unjustified generic entry,[373] and consumers certainly would bear much of the loss caused by a reduction in pharmaceutical innovation.[374] While the magnitude of this type of harm is extremely difficult to quantify, estimates of the value of pharmaceutical innovation generally can shed some light: one study indicates that that new drugs accounted for 40% of the total increase in life expectancy from 1986 to

368. *See id.*

369. Hastings, *supra* note 301, at 34.

370. Frank H. Easterbrook, *Ignorance and Antitrust*, *in* ANTITRUST, INNOVATION, AND COMPETITIVENESS 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992).

371. Hastings, *supra* note 301301, at 48.

372. *Id*. at 46.

373. *Id*. at 57.

374. *Id*. at 34.

2000;[375] another study found that each additional dollar spent on using a newer prescription medicine (instead of an older one) saves roughly $3.95 in other health care costs;[376] and yet another study found that reductions in heart disease mortality in the U.S. between 1970 and 1998 were worth approximately $1.1 trillion per year and that the gains from pharmaceutical innovation in heart disease alone could amount to more than $300 million per year.[377] Proponents of reverse payments are right to point out the consumer welfare stake in preserving adequate incentives for pharmaceutical innovation. The question then becomes, to what extent would innovation actually suffer under a regime that prohibited the use of reverse payments?

There is reason to believe that a number of effects would mitigate any threat to innovation incentives resulting from less deferential assertion of patent rights. First is the tendency of settlements to reduce the reward for true innovation vis-a-vis pseudo-innovation, thereby distorting a firm's investment choice toward pseudo-innovation and leading to a lower rate of true innovation.[378] Indeed, it has become a popular criticism that pharmaceutical firms are overly focused on creating compounds just different enough from a pioneer compound to extend patent protection but that only provide minimal or nonexistent therapeutic improvements.[379] Prohibiting reverse payments may therefore help recalibrate incentives toward producing the type of bona fide innovation that the patent system seeks to promote.

Second, the argument that reverse payments are necessary to preserve or enhance the expected value of patents overlooks that litigation uncertainty is only one relevant source of patent devaluation.[380] The need to make large exclusion payments to a potential generic rival forces a patentee to depart with an often substantial share of the patent's value.[381] Similarly, availability of reverse payments also incentivizes generic firms to seek Paragraph IV entry based on the value of the drug and not the strength of the patent.[382] Even for strong patents, generic challengers can almost always leverage the inherent uncertainty of infringement litigation to "rent-seek" off of valuable patents.[383] The relative certainty of this payoff to the generic means that they

375. Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001* 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003).

376. Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241, 248 (2001).

377. Kevin M. Murphy & Robert H. Topel, *The Economic Value of Medical Research*, *in* MEASURING THE GAINS FROM MEDICAL RESEARCH: AN ECONOMIC APPROACH 41, 41-42 (Kevin M. Murphy & Robert H. Topel eds., 2010).

378. *See* Elhauge & Krueger, *supra* note 312, at 394-95.

379. See *supra* notes 306-312 and accompanying text.

380. *See* Hastings, *supra* note 301, at 54.

381. *See id.*

382. *See id.* at 56.

383. *See id.* at 54.

have little reason to base their challenges on the strength of the patent, so they might as well challenge good patents.[384] As a result, holders of strong patents are "collateral victims of a policing mechanism that is ineffective at tackling bad patents."[385] If reverse payments were not available, generic challengers' gain from filing a Paragraph IV certification would be far less certain, and there they would be more likely to make a Paragraph IV certification only if a patent was actually vulnerable.[386] By removing the incentive for generics to target patents based on their value and not their strength, strong patents would be better protected from both litigation risk and value extraction by rent-seeking generics.[387] Depending on the extent of these effects, a prohibition on reverse payments may better promote the very innovation incentives that proponents of reverse payments worry about. At a minimum, the combination of these effects will tend to mitigate the magnitude of loss occasioned by any reduced innovation resulting from the removal of reverse payments as a means of protecting patents.

G. Costs of False Acquittals

A false acquittal will occur when a brand-name manufacturer and generic challenger use reverse payments to restrict competition in the market for a drug beyond the exclusion that would have resulted from a properly decided infringement case. Part IV(D) has demonstrated why parties face an incentive to settle regardless of the merits of the underlying patent claim, making false acquittals very likely under a regime that permits settlement so long as the settlement excludes competition only within the formal scope of the patent.[388] Therefore, the loss occasioned by the commission of a false acquittal will include the loss of what economists call "static allocative efficiency."[389] The loss of static allocate efficiency can be quantified as the difference in total wealth that will be produced in a market that remains monopolized only because a patent that would have otherwise been invalidated is permitted to restrain entry into the market by reverse payments, and the level of wealth had the generic challenger prevailed in litigation and introduced competition

384. *See id.*
385. *Id.*
386. *See id.*
387. *See id.*
388. *See supra* Part IV.D.
389. *See* Hastings, *supra* note 301, at 49 ("Commentators such as Hemphill, Hovenkamp, and Lemley argue that reverse payments are suspicious on the understandable presumption that if a drug maker is willing to pay another to drop a challenge and stay off the market for a number of years, the likelihood seems greater that the patent in question is weak or ill-gotten. Thus agreements involving such payments effectively safeguard bad patents, and force lengthened monopoly and later duopoly prices that society should not have to pay.").

into the market for the drug.[390] This is precisely the type of efficiency that antitrust law seeks to promote.[391] These costs will arise both when a court erroneously acquits a defendant in an antitrust challenge to a reverse payment, as well as when parties opt to engage in reverse payments that go unchallenged because the applicable antitrust laws make conviction difficult.

The FTC released a study in 2010 (FTC Study) that attempted to quantify the magnitude of the allocative inefficiencies resulting from these settlements.[392] The FTC Study first observed the dramatic differences that competition can make in the market for a drug, noting that generic prices "can be as much as 90 percent less than brand prices."[393] The study analyzed settlements that occurred between January 1, 2004, and September 30, 2009,[394] and found that reverse payments on average prohibit generic entry for nearly seventeen months longer than agreements without payments.[395] The FTC Study concluded that prohibiting reverse payments in settlements would save consumers an average of 3.5 billion dollars per year.[396] This cost appears to far exceed any added decision costs that would result from a greater number of challenges litigated to judgment,[397] the most commonly cited rationale for encouraging settlement.

H. Availability of Alternative Settlement Mitigates the Costs of Per Se Illegality

It is more likely that pharmaceutical firms will be much better positioned to respond to a harsh liability rule in a way that reduces the costs of that rule than that consumers will be able to respond to a deferential rule in a way that reduces the costs of collusive behavior. While pay-for-delay settlements are more desirable to both brand-name and generic manufacturers

390. *See id.* at 49-50.

391. *See supra* Part II.A.

392. FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: AN FTC STAFF STUDY (2010) [hereinafter FTC STUDY].

393. *Id.* at 1 ("For example, brand-name medication that costs $300 per month might be sold as a generic for as little as $30 per month.").

394. *Id.* at 7.

395. *Id.* (calculating average using a weighted average based on sales of the drugs).

396. *Id.* at 1. The study did acknowledge that by that varying assumptions regarding the probability of reverse settlement and the average delay resulting forum the settlement; this number could range from 7.5 billion on the high end to .6 billion on the low end. *Id.* at 8. The FTC Study arrived at 3.5 billion (and 35 billion over the next 10 years) by using what it considered to be the most "reasonable" estimates based on the means of the data. *Id.* At any point in this range, the dollar cost of falsely permitting a settlement to restrain generic competition imposes staggering cost on consumers. *Id.*

397. *See supra* Part IV.C.

than other types of settlement,[398] there remains the question of whether such payments are essential if infringement litigation is to be settled at all.[399] Experience provides reason to believe they are not. From 2000-2004, when the enforcement was aggressive and antitrust precedent most hostile to reverse payments, not one of the settlement agreements reported to the FTC involved reverse payments.[400] However, parties were still able to find terms on which to settle their infringement litigation, and these terms were much less restrictive to competition.[401] It was only in 2005, after the *Schering* and *Tamoxifen* courts blessed these agreements, that the pay-for-delay trend took off. In 2005, three out of eleven settlements included such payments,[402] and in 2006, fourteen of twenty-eight settlements contained these provisions.[403] These numbers suggest that, while pay-for-delay agreements are attractive to the parties, less restrictive alternatives often will prove to be sufficient to avert litigation costs. For example, parties can cross-license various patents without insisting on market division,[404] divide up the remaining patent term and permit for early entry,[405] or license the patent in exchange for royalty payments from the patentee.[406] These types of agreements all have some sort of procompetitive benefit and, more importantly, pit

398. *See supra* Part IV.D.

399. *See* BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005 1 (2006) [hereinafter FTC 2005 FILINGS], *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

400. The requirement that parties file their settlements with the FTC was a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and therefore the only reported year in the 2000-2004 sample was 2004. *See* BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004 1 (2005), *available at* http://www.ftc.gov/os/2005/01/05107medicareactrpt.pdf. Still, the FTC noted in the initial 2004 report that it "is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product. Neither the six settlements entered in 2000 and 2001 nor the fourteen settlements reported under the MMA contained payments in exchange for the generic's agreement not to market its product." *Id.* at 4.

401. *See* FTC 2005 FILINGS, *supra* note 400, at 4.

402. *Id.* at 3.

403. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 4 (2007) [hereinafter FTC 2006 FILINGS], *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf.

404. Hovenkamp, et al., *supra* note 19, at 1723-24.

405. *See id.* at 1736.

406. *Id.*

the parties in an adversarial rather than collusive posture, which ensures that the underlying merits of the infringement litigation factor into the settlement calculus.[407] But because these arrangements are likely to be sufficient to avoid litigation[408] many of the costs and uncertainties associated with infringement litigation can still be avoided, thereby mitigating the concerns about a per se rule against reverse payments.

IV. CONCLUSION

The preceding analysis explores many important determinants of error costs relevant to the desirability of applying harsh or deferential antitrust rules to pay-for-delay settlements. By carefully considering risk of error resulting from a regime that permits or prohibits reverse settlements,[409] as well as the magnitude of the cost resulting from the commission of each respective error type,[410] this analysis suggests that a per se illegality of reverse payments provides the most efficient liability to guide courts and firms in evaluating settlements of Paragraph IV litigation. Pharmaceutical firms are better able to respond to a harsh liability rule in a way that reduces the cost of a rule than consumers are able to respond to a deferential rule in a way that reduces the costs of collusive behavior. The gain to the settling parties at the expense of consumers can represent a huge transfer of wealth to the settling parties, often beyond what is justified by the patent.[411] The risk of these types of errors, along with the massive costs that they impose in terms of lost wealth, justifies a harsh rule. When dealing with an issue where courts have far from perfect information there will remain error costs in the other direction.[412] However, because this risk of error will force parties to litigate their disputes to conclusion, or strike a settlement that pits the parties in an adversarial posture, the law should be more comfortable with these types of errors.[413] While rule of the reason approach has been declared the law, a rule of per se illegality – while imperfect – presents the most efficient rule for resolving the problem of pay-for-delay settlements in Paragraph IV patent disputes.

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407. To illustrate, consider a brand-name manufacturer with ten years remaining on its patent. If it believes it has a seventy percent chance of prevailing at trial, then it is willing to give up three years of the patent term to avoid litigation. Under these less restrictive settlements, consumers will enjoy a level of competition that better approximates what would have resulted had the infringement cases been litigated to judgment.

408. *See* FTC 2005 FILINGS, *supra* note 400.

409. *See supra* Part IV.D, IV.E.

410. *See supra* Part IV.F, IV.G.

411. *See supra* Part IV.F.

412. *See supra* Part IV.E, IV.G.

413. *See supra* Part IV.G.