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Information Costs and Reverse Payment Settlements: Bridging the Gap Between the Courts and the Antitrust Agencies

Brenna E. Jenny

INFORMATION COSTS AND REVERSE PAYMENT SETTLEMENTS: BRIDGING THE GAP BETWEEN THE COURTS AND THE ANTITRUST AGENCIES

Brenna E. Jenny†

Abstract

Reverse payment settlements have attracted increased scrutiny due to the controversial presence of a payment from a brand-name drug company to a generic company that is ostensibly preparing to infringe on the branded company's patent. The antitrust agencies and the courts settled into an intergovernmental stalemate regarding the appropriate framework of analysis to apply when reviewing antitrust challenges to these settlements. The FTC and DOJ have viewed the deals skeptically as a vehicle for competitors to split monopoly profits, but the lower courts have generally been deferential to what they identified as an exercise of a patent holder's lawful right to exclude. Much has been written about which side is correct, yet there has been relatively little exploration of the source of the persistent disagreement.

Building off of Henry Smith's property rights theory and the cognitive miser literature from Peter Lee, this Article explains that the long-standing disagreement stems from the judiciary's application of information-cost-saving rules. Courts adopted a formalistic approach that would almost invariably uphold a reverse payment settlement because they tend to apply bright-line rules when dealing with property rights, and they are prone to adjudicate complex patent and patent-related cases in ways that economize on the costs of information processing. Although the Supreme Court resolved the disagreement by adopting a more information-demanding rule of reason approach in FTC v. Actavis, *the cognitive miser phenomenon will continue to affect how courts adjudicate antitrust challenges to reverse-payment settlements.*

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† Associate, Sidley Austin LLP; J.D., Harvard Law School; MPH, Harvard School of Public Health; A.B., Dartmouth College. The author would like to thank Professors Ben Roin and Henry Smith for comments on earlier drafts and Professor Adam Mossoff and Robert Leider for their thoughtful input. The views expressed in this article are exclusively those of the author and do not necessarily reflect those of Sidley Austin LLP and its partners.

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INTRODUCTION

In recent years, there has been a sharp public policy debate over the access to and the cost of prescription drugs. Maximizing the use of generic drugs—which not only cost substantially less than their brand-name counterparts but also deflate the price of the branded versions as well[1]—promises to be a critical component in the fight for an affordable price tag on healthcare. When generic producers seek to enter the market before the expiration of the branded company's patent, the patent holder has the opportunity to enforce its patent rights by filing suit for infringement. The disagreement frequently ends in settlement, and a recent trend is for the settlement to contain an agreed-upon future entry date for the generic drug and a "reverse payment," so named because it is a payment by the alleged victim, the patent holder, to the alleged patent violator.[2] The Federal Trade Commission (FTC) labels such settlements "pay for delay" because it contends that these agreements represent strategic, collusive behavior between firms and reduce competition by generic manufacturers.[3] Others have defended reverse payment settlements as holding the potential for net procompetitive effects.[4] Determining the appropriate level of antitrust scrutiny implicates a complex intersection between patent and antitrust law. The topic has taken on even more significance since the Supreme Court's recent holding in *FTC v. Actavis*, which requires courts to "strike [a] balance" between "patent and antitrust policies" by applying a rule of reason analysis to

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1. *See, e.g.*, FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9 (2002), *available at* http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

2. Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 60 (2010).

3. *See* FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 3 (2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf. *See also* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75, 91-92 ("As long as monopoly profits are greater than joint duopoly profits, the monopolist and the entrant will have an incentive to negotiate in a way that leads to the monopoly level of output and the monopoly price.").

4. *See, e.g.*, Butler & Jarosch, *supra* note 2, at 94-100 (arguing that reverse payment settlements can be either procompetitive or anticompetitive, depending on the context, and outlining six circumstances where reverse payment settlements may have procompetitive effects); Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 647-56 (2007) (describing harms to competition and general welfare that would result from categorically prohibiting reverse payment settlements).

antitrust challenges to reverse payment settlements.[5]

The Supreme Court's decision in *Actavis* follows years of legal challenges by both third-party payers and the FTC. The FTC's suspicions regarding the anticompetitive effects of reverse payment settlements propelled it into a union with the Antitrust Division of the Department of Justice (DOJ), with both agencies ultimately advocating for the application of a "presumptively illegal" framework of analysis. Although the Third Circuit recently did adopt such a test, over the past decade the vast majority of courts—citing the unique legal status of patents as lawful rights to exclude—have upheld reverse payment settlements under a deferential bright-line rule. A gulf existed for years between the approaches of the FTC and DOJ (antitrust agencies) and the courts. As a result, the Supreme Court in *Actavis* resolved not just an inter-circuit split, but an intergovernmental stalemate as well.

Although the Supreme Court settled the dispute as a legal matter, it is still important to understand as a conceptual matter the underlying causes of the starkly different legal rules urged by the antitrust agencies on the one hand and actually adopted by the courts on the other, because the source of the disagreement will continue to impact how courts adjudicate challenges to reverse payment settlements. Courts were subconsciously swayed toward adopting a deferential, bright-line rule for two reasons, both related to economizing information costs. First, such a rule is consistent with the judiciary's broader inclination to apply bright-line rules to disputes over property rights, such as patents. Second, the judiciary's decision to stick with their deferential bright-line rule in place of the agencies' proposals is a reflection of the cognitive miser theory, which predicts the subconscious tendency of humans to apply bright-line rules as a way of efficiently processing dense, complex information. Professor Peter Lee has traced the influence of the cognitive miser phenomenon in the Federal Circuit's general approach to adjudicating patent disputes.[6] Building on his work, this Article illustrates that the cognitive miser phenomenon is not an isolated feature of patent infringement suits, but rather has played a substantial role in antitrust litigation involving patents. Just as the cognitive miser theory explains the Federal Circuit's penchant for formalism, so too does it contribute to the overwhelmingly rejection

5. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013).

6. *See generally* Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2 (2010).

by the lower courts of the antitrust agencies' proposed frameworks in favor of a bright-line rule tending to uphold reverse payment settlements.[7]

Part I introduces the cognitive miser phenomenon as an explanatory tool in the judiciary's approach to patent law. This section also discusses the judiciary's more general propensity to apply bright-line rules when dealing with property rights. The mental shortcuts associated with the cognitive miser phenomenon enable judges to economize on their own information costs when they adjudicate patent disputes; relatedly, when courts apply bright-line rules to property rights, they provide clear signposts as to the contours of these rights, which allows third parties to economize on information costs. Both tendencies have played a substantial role in the courts' overwhelming insistence on applying a permissive bright-line rule, despite increasingly vocal insistence from the antitrust agencies that such an approach harms consumers.

Part II provides an overview of the regulatory structure within which reverse payment settlements are formed. Familiarity with this regime is critical to understanding both the incentives underlying the formation of reverse payment settlements, as well as the judiciary's justification for its approach.

Part III discusses the judiciary's rejection of the FTC and DOJ's initial proposals. During these early years, both antitrust agencies settled on different versions of a rule of reason balancing test. Neither approach gained adherents among the federal courts. The cognitive miser phenomenon predicts the courts' rejection of these nuanced, intensive analyses in favor of a bright-line rule. While the cognitive miser theory was a contributing factor during this phase, the rule of reason proposals faced an additional hurdle, in the form of the background tendency of courts to apply bright-line rules to disputes over property rights.

Part IV analyzes the final evolution of the FTC and DOJ's arguments and their continued lack of success in the courts. This latest impasse was even more singularly driven by the cognitive miser phenomenon. Since 2009, both the FTC and DOJ have coalesced around a legal framework that would deem reverse payment settlements presumptively illegal. Despite the antitrust agencies'

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7. Lee explicitly distances himself from the idea that courts are intentionally sidestepping engagement with thorny patent law issues. *Id.* at 28-29. Likewise, the judicial enthusiasm for a deferential bright-line rule should be viewed as an unconscious manifestation of judges acting as cognitive misers.

unified support around a fairly bright-line alternative, courts, at least until *Actavis*, continued to provide reverse payment settlements with room to grow. The cognitive miser phenomenon predicts the courts' chosen path. The rule that the courts selected not only entails less technological engagement than the antitrust agencies' suggestions, but it preserves opportunities for private resolution of patent disputes, thereby preventing an influx of additional patent suits into federal court.

Part V discusses the road forward in the wake of *Actavis*. The Court acted in accord with its recent trend in the patent law context of replacing appellate court formalism with more flexible, but cognitively burdensome, multifactor tests. Understanding how courts are particularly prone to applying information-cost-saving rules in patent-related cases will be useful because it offers clues as to how courts will apply rule of reason to these antitrust challenges.

I. COURTS AND INFORMATION-COST-SAVING RULES

Many scholars have criticized the Federal Circuit for being too formalistic in its adjudication and succumbing to an overreliance on bright-line rules.[8] Recently the Supreme Court has echoed this criticism as well, striking down formalistic Federal Circuit rules in favor of more holistic standards.[9] The significant cognitive burdens associated with the technological intricacies of patent litigation led Professor Peter Lee to hypothesize that the Federal Circuit's turn to a rule-bound, formalist approach to adjudication is an expression of the cognitive miser theory.[10]

This social psychology theory focuses on the natural tendency of humans to utilize mental shortcuts, such as presumptions and bright-line rules, in areas of informational complexity in order to maximize

8. *See, e.g.*, Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1225 (2008); Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMP. & HIGH TECH. L.J. 1 (2003); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003).

9. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010) ("Section 101 is a 'dynamic provision designed to encompass new and unforeseen inventions.' A categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.'" (citations omitted)); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) ("Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.").

10. Lee, *supra* note 6, at 26-27.

their inevitably bounded ability to comprehend new information.[11] As Lee explains, "In 'systematic' processing, individuals exert considerable cognitive effort to understand information inputs. In 'heuristic' processing, on the other hand, individuals rely on more easily accessible factors such as the identity of the information source or other 'cues' to reach conclusions."[12] Particularly in areas of uncertainty, such as where concepts are new and difficult to understand, we are all more likely to use heuristic processing to facilitate decision-making.[13] Federal Circuit formalism—such as the "TSM" test, which asks judges to look to a finite number of categories for a fairly explicit indication of obviousness[14]—correlates with "inquiry-truncating" rules that reduce technological engagement.[15] Applying bright-line rules rather than standards limits the degree to which judges must grapple with, and comprehend, the ever-more-complex details of disputed technologies[16] and nullifies some of the heavy information costs of wading through a patent dispute.[17]

The cognitive miser theory has explanatory power beyond pure patent infringement suits or the Federal Circuit's docket. Patent law, as the rare intersection between law and science, presents unique challenges for judges who do not have scientific training.[18] Indeed, judges have publicly acknowledged the difficulties presented by

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11. Lee, *supra* note 6, at 25-29. *Cf.* Stephen M. Bainbridge & G. Mitu Gulati, *How Do Judges Maximize? (the Same Way Everybody Else Does—Boundedly): Rules of Thumb in Securities Fraud Opinions*, 51 Emory L.J. 83 (2002) (arguing that judicial opinions in securities fraud cases "commonly rely on rules of thumb-decisionmaking heuristics" due to institutional constraints involving "limited cognitive capabilities, resource constraints, and a judicial desire to move cases off the docket in an acceptable fashion").

12. Lee, *supra* note 6, at 21.

13. *Id*. at 22-23.

14. *See* Bilski v. Kappos, 130 S. Ct. 3218 (2010)

15. Lee, *supra* note 6, at 33-41.

16. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1183 (2002) (describing how the Federal Circuit has applied "what are nominally the same legal rules" quite differently based on what industry the patent is situated within, which has caused district courts to similarly "apply[] the Federal Circuit rules in different ways depending on the technology at issue").

17. *See* Lee, *supra* note 6, at 33-41.

18. *See, e.g.*, Ass'n for Molecular Pathology v. Myraid Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (Scalia, J., concurring); Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 115 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912) ("I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils . . . .") (Hand, J.).

"judicial engagement with technology."[19] Drawing on studies showing that technological information places significant cognitive burdens on those without applicable background knowledge, Lee argues that when faced with the intricacies of patent disputes, judges outside of the Federal Circuit (who generally lack scientific training and significant patent litigation experience) are placed in a situation particularly conducive to the adoption of cognitive shortcuts.[20] If our system's experts unwittingly act as cognitive misers, then our system's generalists are even more likely to do so. Although forum selection has created a concentration of patent suits in certain district courts,[21] patents remain a small percentage of any district court's docket and the vast majority of patent cases are managed by district court judges who, on average, preside over one patent case per year.[22] Because appeals from district court decisions "arising under" patent law are the exclusive purview of the Federal Circuit,[23] it is particularly rare for appellate judges to review patent-related claims. Therefore, most of the judges faced with challenges to reverse payment settlements are unaccustomed to patent law and its related legal issues. Over the past decade, the cognitive miser phenomenon has significantly impacted the judiciary's response to arguments from the antitrust agencies regarding when a reverse payment settlement should be struck down as anticompetitive. Selecting bright-line rules to adjudicate cases in this immensely complex intersection of patent and antitrust law is consistent with judges engaging in heuristic processing.

The Federal Circuit's preference for bright-line rules in the context of patent disputes mirrors the judiciary's more general tendency to apply formalistic rules when adjudicating property rights, although the two trends are driven by distinguishable motivations. Bright-line rules in property disputes also serve an information-cost-saving function, but instead of allowing *judges* to cognitively economize, bright-line rules for property disputes primarily allow

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19. *See* Lee, *supra* note 6, at 9-13 (2010) (collecting comments by members of the judiciary).

20. *See id.* at 23-25.

21. Mark A. Lemley, *Where to File Your Patent Case*, 38 AIPLA Q.J. 401, 405-07 tbl.2 (2010).

22. Jay P. Kesan & Gwendolyn G. Ball, *Judicial Experience and the Efficiency and Accuracy of Patent Adjudication: An Empirical Analysis of the Case for a Specialized Patent Trial Court*, 24 HARV. J. L. & TECH. 393, 422-23 (2011).

23. *See, e.g.*, Christopher A. Cotropia, *"Arising Under" Jurisdiction and Uniformity in Patent Law*, MICH. TELECOMM. & TECH. L. REV. 253, 262 (2003).

third parties to economize, by clearly establishing the contours of a property holder's rights. As Professors Thomas Merrill and Henry Smith have explained, property rights are "in rem—they bind 'the rest of the world.'"[24] In rem rights involve an identified owner of an identified resource, and they are generally protected by an exclusion regime in which the owner is given broad discretion to choose how he will use his resource, and others will be excluded from engaging in conflicting uses.[25] The information costs related to the type of right affects how the right is governed: when the population of duty holders is large, simple rules are needed to "reduce[] the processing costs that would be high for such a large and anonymous audience."[26] An exclusion strategy uses "rough signals or informational variables" to "protect an indefinite class of uses with minimal precision."[27] Courts are freed from gathering information and then evaluating the reasonableness of an owner's use of his property; owners are free to use their property without justifying their decisions to third parties.[28] In sum, the nature of property rights is conducive to administration through bright-line rules, because such rules allow the rest of the world to easily identify the contours of the property right at a low cost.[29]

Smith contrasts in rem rights with in personam rights, which are obligations binding only certain identified people, such as those arising out of a contract between a few definite parties.[30] In personam rights are typically delineated through a governance regime, which entails the use of more flexible rules to prescribe norms regarding permitted and restricted uses.[31] Governance strategies will be used when it is cost-effective, from an information-cost perspective, to

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24. Thomas W. Merrill & Henry E. Smith, *The Property/Contract Interface*, 101 COLUM. L. REV. 773, 777 (2001).

25. Henry E. Smith, *Exclusion Versus Governance: Two Strategies for Delineating Property Rights*, 31 J. LEGAL STUD. S453, S454 (2002) [hereinafter *Exclusion Versus Governance*]. *See also* Henry E. Smith, *Exclusion and Property Rules in the Law of Nuisance*, 90 VA. L. REV. 965, 978 (2004) ("On the dutyholder side, the message is a simple one—to 'keep out'—and this simultaneously protects a reservoir of sues for the owner without officials or dutyholders needing to know what those might be.") [hereinafter *Nuisance*].

26. *Exclusion Versus Governance*, *supra* note 25, at S455.

27. *Nuisance*, *supra* note 25, at 978.

28. *Id.* at 983.

29. Merrill & Smith, *supra* note 24, at 790. One of the examples Merrill and Smith cite of a formalistic rule governing in rem rights is "the common law rule that the person in possession of a resource is presumed to have a property right." *Id.* at 803. The presumption of validity in the patent context would serve a similar function.

30. *Exclusion Versus Governance*, *supra* note 25, at S455.

31. *Id.*

place a larger informational burden on a few identified people.[32] Although property rights are generally governed by an exclusion regime, governance rules may be added in certain contexts to provide supplementary fine-tuning.[33] One example is when courts evaluate land use in a nuisance suit.[34] This shift from the exclusion side of the spectrum towards the governance end is more likely to occur as the value of the resource at issue rises, because the advantages of the additional precision provided by governance rules will outweigh their concomitantly weightier information costs.[35]

It is well-established that patents are a type of property right,[36] but the property rights secured by patents are not considered coterminous with their real property counterparts. For example, whether patents are property rights protected by the Takings Clause is an open question,[37] and the majority approach is to view patents as entailing only the narrower right to exclude, versus the more expansive rights of use, possession, and disposition associated with real property.[38] Nonetheless, scholars have noted that the conceptual framework associated with real property has influenced the treatment of patent rights.[39] Even the Supreme Court has evoked the intuition that patents, like other property rights, should be clearly defined, remarking that, "[L]ike any property right, [a patent's] boundaries should be clear. . . . [A] patent holder should know what he owns, and

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32. Merrill & Smith, *supra* note 24, at 789-90.

33. *Exclusion Versus Governance*, *supra* note 25, at S456.

34. *Nuisance*, *supra* note 25, at 985.

35. *Id.* at 989.

36. *See* 35 U.S.C. 261 (2006) ("[P]atents shall have the attributes of personal property."); *see also* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002) (characterizing the patent laws as securing "a property right"); James v. Campbell, 104 U.S. 356, 358 (1881) (describing how a patent "confers upon the patentee an exclusive property in the patented invention").

37. *Compare* Zoltek Corp. v. United States, 442 F.3d 1345, 1352-53 (Fed. Cir. 2006) (holding that patents are not property protected by the Takings Clause), *with* Zoltek Corp. v. United States, 672 F.3d 1309, 1329 (Fed. Cir. 2012) (Dyk, J., dissenting) ("The en banc court's action is also particularly striking insofar as it vacates the earlier *Zoltek* decision that the United States is not liable on a takings theory."). *See generally* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689 (2008) (arguing that the Takings Clause applies to patents).

38. *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 4 (3d ed. 2004); *but see generally* Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321, 374 (2009) (criticizing the "exclusion concept of patents" based on "the more substantive conceptual content of nineteenth-century patent doctrines").

39. *See, e.g.*, Mark A. Lemley, *Romantic Authorship and the Rhetoric of Property*, 75 TEX. L. REV. 873, 895-903 (1997) (book review); Mossoff, *supra* note 38, at 370-75.

the public should know what he does not."[40] The real property-patent relationship is an example of Professor Adam Mossoff's more general observation that the "content of a legal entitlement creates a conceptual framework within which courts craft legal doctrines to secure the various elements of this entitlement."[41] This insight predicts that courts will apply bright-line rules when analyzing reverse payment settlements—regardless of the cognitive challenges of patent litigation—because these disputes involve a type of right that courts view as conducive to solution by bright-line rules.

This Part has described the two conceptual factors that entice courts to use a bright-line rule when confronted with antitrust challenges to reverse payment settlements. As Parts III and IV will describe, these two factors alternately played different roles based on whether the agencies were proposing multifactor balancing tests or competing versions of bright-line rules. Before proceeding to this analysis, it is important to provide an overview of the regulatory framework that has influenced the creation of reverse payment settlements.

II. REGULATORY BACKGROUND

Reverse payment settlements are created in the shadow of a very particular regulatory scheme designed not only to guarantee safe drugs, but also to incentivize their creation in the first place, by ensuring that intellectual property rights do not stifle competition.[42] Indeed many courts and even the DOJ have characterized reverse payment settlements as a direct result of the incentives created by the regulatory regime for drug approvals.[43] Familiarity with this regulatory environment is important for understanding the incentives of branded and generic companies when they challenge a patent or enter into a settlement terminating such a dispute.

Companies that wish to market a new drug must submit a New Drug Application (NDA) to the FDA and receive approval to market the product to the general public.[44] NDAs reflect the results of

40. *Festo*, 535 U.S. at 731. *See also* Mossoff, *supra* note 38, at 694-95 (describing how the *Festo* Court applied concepts and terminology drawn from real property takings doctrine to the patent infringement case before it).

41. Mossoff, *supra* note 38, at 374.

42. *See, e.g.*, Devlin, *supra* note 4, at 638.

43. *See, e.g.*, *In re* Tamoxifen Antitrust Litig., 466 F.3d 187, 206-07; Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074; Brief for the United States as Amicus Curiae at 1, *In re* Tamoxifen Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (No. 06-830).

44. 21 U.S.C. § 355(a) (2010).

clinical studies and must indicate that the drug is safe and effective for use.[45] The NDA process does not confer patent protection, and manufacturers must separately navigate the U.S. Patent and Trademark Office's (USPTO's) application process. Patent information is listed in the FDA's Orange Book, along with other details about a drug such as active ingredients.[46]

The Drug Price Competition and Patent Restoration Act of 1984, known as the Hatch-Waxman Act (Hatch-Waxman), controls the process by which generic drugs enter the market.[47] A generic manufacturer is required to submit an Abbreviated New Drug Application (ANDA), which encompasses a far less rigorous application process as compared to an NDA because while the product must exhibit bioequivalence to its branded counterpart, it need not go through the same regimen of clinical trials.[48] As part of the ANDA, the generic manufacturer must also certify that the patent protection on the generic's brand-name equivalent does not prohibit production of the generic.[49]

Reverse payment settlements are generally preceded by a generic manufacturer's submission of a "paragraph IV certification"[50] claiming either that the branded manufacturer's patent is invalid or the generic product differs from the brand-name equivalent in such a way as to avoid infringing on the patent.[51] After the generic submits a paragraph IV certification, the holder of the patent at issue is notified.[52] If the branded manufacturer files suit within forty-five days of notification, then the FDA must initiate a thirty-month stay on approval of the generic product.[53] This thirty-month stay provides the branded manufacturer with a significant incentive to sue the paragraph IV filer, regardless of the confidence it has in its case.

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45. *Id.* § 355(b)(1).

46. FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (33d ed., 2013).

47. Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of Titles 15, 21, 28, and 35).

48. *See* 21 U.S.C. § 355(j)(2)(A). *See also* FOOD & DRUG ADMIN., CENTER FOR DRUG EVALUATION AND RESEARCH, SUBMISSION OF SUMMARY BIOEQUIVALENCE DATA FOR ANDAS (2011), *available at* http://www.fda.gov/downloads/Drugs/.../Guidances/UCM134846.pdf.

49. 21 U.S.C. § 355(j)(2)(A)(vii) (2010).

50. So named for its location in paragraph IV of Title 21. 21 U.S.C. § 355(j)(2)(A)(vii) (2010).

51. *Id.* § 355(j)(2)(A)(vii)(IV).

52. *Id.* § 355(j)(2)(B).

53. *Id.* § 355(j)(5)(B)(iii). The stay can end before thirty months have passed if a court rules that the patent is either invalid or not infringed. *Id.* § 355(j)(5)(B)(iii)(I).

Generic companies, too, have a significant incentive to file paragraph IV certifications in the first place. In order to expedite the entry of generic products, Hatch-Waxman motivates generic manufacturers to make paragraph IV certifications by giving the first filer a 180-day period of exclusivity.[54] During this time period, other generic products cannot compete on the market because the FDA is prohibited from approving their ANDAs.[55] The 180-day period begins to run when the paragraph IV filer initiates "commercial marketing" of the drug.[56] As some courts and commentators have noted, inviting generic producers to challenge patents has created an environment in which branded companies bear nearly all of the potential downside to litigating, while generic companies enjoy nearly all of the potential upside:

> [U]nder 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. Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period . . . during which it would be the exclusive seller of the generic drug in the market.

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54. *Id.* § 355(j)(5)(B)(iv). *See also* Fed. Trade Comm'n, *supra* note 1, at 7, 57 ("The 180-day exclusivity period thus increases the economic incentives for a generic company to be the first to file an ANDA containing a paragraph IV certification. Through this 180-day provision, the Amendments also provide an incentive for generic companies to litigate patents that may be invalid and to 'design around' patents to find alternative, non-infringing forms of patented drugs."). If multiple companies file on the same initial day, all will enter the market together for 180 days. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 4 (July 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf.

55. 21 U.S.C. § 355(j)(5)(B)(iv) (2010).

56. *Id.* § 355(j)(5)(B)(iv)(I).

> The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question.[57]

As such, branded companies do face significant incentives to settle and avoid final judgment in a lawsuit that challenges their patent.

Hatch-Waxman was initially susceptible to manipulation if a generic manufacturer holding the right to a 180-day exclusivity period delayed the start of its commercial marketing. The FDA was still prohibited from approving ANDAs for analogous generic products until the end of the 180-day period, but by failing to initiate commercial marketing, the first filer prevented the clock from beginning to tick. A "bottleneck" was created: by not acting on its exclusivity period, the first filer could block all other generic producers who filed behind it from entering the market.[58] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) amended Hatch-Waxman to prevent the creation of bottlenecks.[59] The first paragraph IV filer must market the drug within seventy-five days of FDA approval of its application or within thirty months of filing, whichever occurs sooner.[60] Both of these deadlines are termed "forfeiture events," and if the first filer does not market its drug in time, it loses the 180-day exclusivity period.[61] While this modification has the salutary benefit of avoiding the bottleneck issue, the exclusivity period evaporates forever: if the first filer triggers a forfeiture event, none of the subsequent generic filers are eligible for the 180-day exclusivity period.[62] The availability of the exclusivity to only the first *filer*, and

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57. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206-07 (2d Cir. 2006). *See also* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1073-74 (11th Cir. 2005) (calling the Commission's insistence that the parties could have settled, sans reverse payment, on an earlier entry date a "myopic" proposition); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003); William J. Newsom, *Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform*, 1 HASTINGS SCI. AND TECH. L.J. 201, 227-29 (2009).

58. *See* Fed. Trade Comm'n, *supra* note 1, at viii; *Prepared Statement of the Federal Trade Commission: Hearing on Barriers to Generic Entry Before the Special Committee on Aging*, 20-21 (July 20, 2006) (statement of Jon Leibowitz, Fed. Trade Comm'n).

59. Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in scattered sections of 21 U.S.C.).

60. 21 U.S.C. § 355(j)(5)(D)(i)(I) (2010).

61. *Id.* §§ 355(j)(5)(D)(i)-(ii).

62. *Id.* § 355(j)(5)(D)(iii).

not the first generic *entrant*, has implications for the impact of reverse payment settlements on generic entry. If a brand-name manufacturer and a generic entrant form a reverse payment settlement, the timing of the resulting arrangement tends to create a forfeiture event. Although other generic companies can subsequently file paragraph IV certifications and challenge the patent, the incentives for doing so are significantly lower without the later reward of exclusivity.[63]

Because Hatch-Waxman's regulatory structure was intended to incentivize generic entry, the FTC is particularly attuned to allegations that companies are manipulating Hatch-Waxman to minimize or delay entry of generic products. FTC investigations of settlements between brand and generic manufacturers first became public in 1999, and the Agency released its first major study on the issue in 2002.[64] The study examined settlements between pharmaceutical companies since 1992 and concluded that of the twenty final settlements related to ANDA litigation, nine involved payment from the branded manufacturer to the generic.[65] Bothered by this trend, the FTC study requested legislation that would require brand and generic manufacturers to submit copies of their settlement agreements to the FTC.[66] This request was granted in 2003 as part of the Medicare Modernization Act, and the FTC began compiling annual summaries of reverse payment settlements.[67]

Reverse payment settlements have occurred with increasing frequency over the past decade, and FTC Chairman Jon Leibowitz has described them as "almost an epidemic."[68] Between 2004 and 2009, sixty-six settlements between branded and generic pharmaceutical

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63. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 101, 131-32 (2006) (arguing reverse payment settlements remove the "most vigorous competitor" from the field, leaving only less motivated subsequent filers to challenge the patent). The majority and dissent in Actavis sparred over the extent to which these incentives are truly lowered so significantly that a generic without an opportunity to obtain the 180-day exclusivity period would lack sufficient incentive to file a paragraph IV certification and attempt to enter the market prior to the patent's expiration. *Compare id.* at 2246 (Roberts, C.J. dissenting) *with* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2235 (2013).

64. Fed. Trade Comm'n, *supra* note 1, at vii-viii.

65. *Id.* at 31.

66. *Id.* at vi.

67. *See, e.g.*, FED. TRADE COMM'N, BUREAU OF COMPETITION, SUMMARY OF AGREEMENTS FILED IN FY 2 (2005), *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/fy2005drugsettlementsrpt.pdf.

68. Press Release, Fed. Trade Comm'n, FTC Testimony: Stopping "Pay-for-Delay" Drug Settlement Agreements is a Top Competition Priority (July 27, 2010), *available at* http://www.ftc.gov/opa/2010/07/antitrust.shtm (on file with author).

companies involved a payment from the branded company and an agreement by the generic to forego entry until some date in the future.[69] During this time period, the settlements occurred with rapidly increasing frequency—in 2004, there were zero, and by 2009, there were nineteen.[70] Each of the next two years featured roughly thirty reverse payment settlements.[71] The FTC recently calculated that each reverse payment settlement delays entry of generic competitors in the patent holder's relevant market for an average of seventeen months, with a cumulative resulting cost of $35 billion to American consumers over the next ten years.[72]

This Part has explained how the detailed regulatory regime of the Hatch-Waxman Act forms a backdrop for the antitrust-patent disputes before the courts. Regardless of whether Hatch-Waxman created unforeseen incentives for patent litigants to enter into reverse payment settlements, such adversaries turned co-defendants undeniably possess unique incentives to do so. The complexity of the resulting antitrust-patent intersection also provides insight on the attractiveness of cognitive shortcuts in this context.

III. THE EARLY YEARS: STRUGGLING TO FIND A LEGAL FRAMEWORK

Citing the rising incidence of reverse payment settlements, the FTC initially sought to have them banned under a per se illegal rule. The FTC soon abandoned this position when even some of its own members acknowledged that the harsh bluntness of this rule was ill-suited to the complexity of reverse payment settlements. In its place, the FTC advocated a more flexible rule of reason inquiry. The courts rebuffed this approach as well. Rejection of a rule of reason standard is directly consistent with the cognitive miser phenomenon. An

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69. Fed. Trade Comm'n, *supra* note 3, at 1.

70. *Id.*

71. FED. TRADE COMM'N, BUREAU OF COMPETITION, OVERVIEW OF AGREEMENTS FILED IN FY 2 (2011), *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/1110mmaagree-2.pdf.

72. Fed. Trade Comm'n, *supra* note 3, at 2. *But see* BRET DICKEY, JONATHON ORSZAG, & ROBERT WILLIG, A PRELIMINARY ECONOMIC ANALYSIS OF THE BUDGETARY EFFECTS OF PROPOSED RESTRICTIONS ON "REVERSE PAYMENT SETTLEMENTS" (2010), *available at* http://compass-lexecon.s3.amazonaws.com/prod/cms-documents/f72bfed6f1de5f73/Dickey_Orszag_Willig_CBO.pdf (disputing the reliability of the FTC's calculations in its 2010 study); *see also* Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 307-08 (2011) (explaining why prohibiting settlements may not necessarily result in lower drug prices).

additional force was also at work during this time period, namely the fundamental mismatch between the rule of reason and the type of rules traditionally used in the adjudication of property disputes.

A. The Rise and Fall of a Per Se Illegal Rule

The Sixth Circuit was the first appellate court to reach the merits of an antitrust challenge to a reverse payment settlement, and it struck down the settlement as per se illegal.[73] The case, *In re Cardizem*, was a suit brought by third-party drug purchasers, and it challenged an interim settlement that included a reverse payment.[74] Among other terms of the deal, the generic company—who had been the first to file—promised not to relinquish or transfer its 180-day period of exclusivity, ensuring (under the pre-Medicare Modernization Act regime) that a bottleneck would be created.[75] Even though the statutory thirty-month stay ended before the resolution of the litigation and the generic company's product had received FDA approval, the generic did not bring the drug to market.[76] The crux of the plaintiffs' claim was that, but for the payments from the branded to the generic company, the latter would have introduced its product much sooner.[77] The district court held that the agreement was per se illegal as a horizontal market division, and the Sixth Circuit Court of Appeals affirmed.[78]

The FTC was not involved with *In re Cardizem*, but it did endeavor to broaden the adoption of the per se illegal rule. Shortly after the *In re Cardizem* district court decision, the FTC brought a complaint against Schering-Plough Corporation (Schering) and two

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73. Two years before this case, the D.C. Circuit Court of Appeals did review a challenge to the same reverse payment settlement, but only in the context of standing to challenge the settlement. *See* Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 807-10 (D.C. Cir. 2001).

74. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 899-900 (6th Cir. 2003).

75. *See id.* at 902.

76. *Id.* at 903.

77. *Id.* at 904.

78. *Id.* at 905-07. Categories of restraints of trade that always or almost always have anticompetitive effects will be deemed "per se" illegal. Regardless of any competitive justifications, courts will assume they are an unreasonable restraint of trade in violation of the Sherman Act. "As a consequence, the per se rule is appropriate only after courts have had considerable experience with the type of restraint at issue, and only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason." Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 886-87 (2007) (citation omitted).

would-be generic producers of a Schering product called K-Dur.[79] Although the FTC urged an Administrative Law Judge (ALJ) to follow the district court's decision in *In re Cardizem* and label the settlement a per se illegal market division, the ALJ insisted that a per se framework of analysis was inappropriate.[80] Reverse payment settlements were then still a "novelty," and the economic impact was not "immediately obvious," rendering rule of reason the superior approach.[81]

Under the ALJ's rule of reason framework,[82] the FTC was required to first prove that the settlements had an anticompetitive effect.[83] Because the agreements allowed both generic producers to sell their drugs prior to the expiration of Schering's patent, the ALJ determined that the FTC could only meet its burden of proof by showing that, absent the settlement terms, these generics would have entered the market earlier than the terms of the settlement allowed.[84] The FTC admitted that there was no proof an earlier entry date would have occurred, and the ALJ upheld the settlement based on the FTC's failure to prove anticompetitive effects.[85]

The FTC's complaint counsel appealed the ALJ's adverse

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79. Schering-Plough Corp., Upsher-Smith Labs., & Am. Home Prods. Corp., 2002 WL 1488085, at *1 (F.T.C. June 27, 2002).

80. *Id*. at *83.

81. *Id*. at *84-85. The ALJ also found *In re Cardizem* to be not particularly persuasive caselaw because they involved interim agreements, unlike the final settlements in *Schering-Plough* which ended the dispute between parties, allowing them to reap the oft-cited benefits of settlement, such as avoiding the cost and uncertainty of protracted litigation. *See id*. at *84.

82. A rule of reason inquiry is a case-by-case analysis of whether a particular restraint of trade is unreasonable. "Courts today apply a 'burden-shifting' approach in applying full-blown rule-of-reason analysis: (1) the plaintiff bears the initial burden to prove that the agreement had anticompetitive effects; (2) if it does, the burden of going forward shifts to the defendants to establish procompetitive justifications for the agreement; and (3) if the defendants sustain their burden, the burden shifts back to the plaintiff to show that the anticompetitive effects of the agreement outweigh its procompetitive effects or that the procompetitive effects could have been achieved in a less anticompetitive manner." JOHN J. MILES, 1 HEALTH CARE AND ANTITRUST L. § 2A:11 (2013).

83. *Schering-Plough Corp.*, 2002 WL 1488085, at *88.

84. *Id*. at *89-90.

85. *Id*. at *90, 98. Even though the two generic versions at issue had received final FDA approval in November 1998 and June 1999, the ALJ found "no credible evidence" either manufacturer would have sold their products while still engaged in patent litigation: were they to later lose the case, these sales would subject the companies to the potentially "dire consequences" of paying damages based on the sales of their infringing generic. *Id*. at *92. *But see* Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001) ("We also reject [the generic company's] argument that any rational actor like itself would not market its generic drug until the patent infringement suit against it was resolved . . . . A reasonable juror could conclude that . . . but for the agreement, [the generic] would have entered the market.").

decision to the Federal Trade Commission sitting as an appellate body (Commission).[86] Although the FTC's complaint counsel continued to urge adoption of a per se illegal rule, the Commission agreed with the ALJ that rule of reason was the proper approach.[87] The Commission disagreed, however, with the ALJ's particular method of analyzing anticompetitive effects within the rule of reason.[88] The ALJ had implied that, absent a court decision on the merits in the underlying patent litigation, there was no way to discern with sufficient certainty whether the settlement payments prevented an otherwise earlier generic entry from occurring—in other words, whether the settlement had anticompetitive effects.[89] The Commission advanced a litany of reasons for why it was neither necessary nor practical to look at the merits of the underlying patent litigation when weighing the anticompetitive effects of a reverse payment settlement.[90] Primarily, the Commission was concerned that this type of ex post inquiry was "unreliable" and risked a chilling effect on future settlements.[91]

The Commission instead wanted the focus to be on the generic entry date that would have prevailed in "a differently crafted settlement" between the parties, namely one without a reverse payment.[92] When parties select a future generic entry date in isolation, without any money changing hands, the Commission viewed this date as reflecting the parties' estimations of the strength

86. The FTC holds a unique role as both prosecutor and judge. After the FTC brings a complaint to its own ALJ, complaint counsel for the FTC may appeal the initial decision of the ALJ back to the Commission. *See* 24 AM. JUR. *Defending Antitrust Lawsuits* § 16 (1977).

87. Schering-Plough Corp., 136 F.T.C. 956, 971-72 (2003).

88. *Id.* at 964-65, 992.

89. *Id.* The respondent drug companies had also argued that "proof of anticompetitive effects requires proof on the merits of the underlying patent claims." *Id*. at 992.

90. *Id.* at 969, 998. When the Supreme Court in *Actavis* mandated application of the rule of reason, it was notably more sanguine about the role of a mini patent trial, explaining that it would not "require the courts to insist . . . that the [FTC] need[s] to litigate the patent's validity," but leaving open the possibility that some courts may wish to engage in this analysis when applying rule of reason. *See* FTC v. Actavis, 133 S. Ct. 2223, 2237-38 (2013). *But see* Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, *in* 3 ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY 2127, 2131 (2008). Addanki and Daskin argue that evaluation of the anticompetitive effects of a reverse payment settlement "must consider the likely outcomes under litigation," but that such an inquiry into the underlying patent litigation would be significantly less burdensome than a full trial, because a court need only determine whether the entry date was later than the expected time of entry resulting from litigation. *Id*. For example, if a settlement split the remaining patent period in half—allowing generic entry at the midway point of the remaining period of patent protection—then a court need only determine whether the patentholder was less than fifty percent likely to have prevailed at trial.

91. *Schering-Plough Corp.*, 136 F.T.C. at 997-98.

92. *Id.* at 994.

of their own case.[93] In contrast, an agreement on a future entry date combined with a payment from the patent holder to the generic indicates "there must have been some offsetting consideration."[94] Unless there was some additional consideration given to the branded manufacturer, "it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[95] Complaint counsel for the FTC conceded that if it failed to show by a preponderance of the evidence that the reverse payment "exceeded, by a substantial amount," the branded company's reasonable estimation of the value of the consideration received from the generic, then the FTC would have failed to prove anticompetitive effects.[96]

During its appellate review, the Commission has the power to make additional findings of fact,[97] and the Commission found that the amount of money Schering gave to the generic companies was unreasonably high in light of the consideration supposedly received by Schering.[98] This created a prima facie case of anticompetitive effects, shifting the burden to the respondent companies to establish the settlement's offsetting procompetitive effects.[99] The Commission found that the settlements failed a rule of reason inquiry because the companies could do no more than "suggest hypothetical benefits."[100] After the Commission refused to apply a per se illegal rule, the FTC halted its efforts to spread the Sixth Circuit's rule.[101] Courts, too, began adopting a new approach.

Although this bright-line rule is certainly consistent with the type of rule courts typically apply to property rights, its simplicity makes

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93. *Id.* at 987. *But see* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEXAS L. REV. 283, 313-22 (2012) (arguing that even settlements with a predetermined future entry date but no reverse payment are more likely than not anticompetitive).

94. *Schering-Plough Corp.*, 136 F.T.C. at 988.

95. *Id.*

96. *Id.* at 1004.

97. AM. JUR. *supra* note 86. Appellate review of this fact-finding is performed under the traditional deferential standard of review. *See* FTC v. Ind. Federation of Dentists, 476 U.S. 447, 454 (1986) ("[A reviewing] court must accept the Commission's findings of fact if they are supported by 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'").

98. *Schering-Plough Corp*., 136 F.T.C. at 1002-04, 1053.

99. *See id.* at 988, 1002.

100. *Id.* at 999, 1002.

101. *See* Brief of Respondent-Appellant at 37-38, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (abandoning its previous emphasis on the propriety of a per se standard and explaining it would work within a rule of reason framework).

its unpopularity seem inconsistent with the cognitive miser phenomenon. Yet even as the Commission viewed reverse payment settlements with skepticism, it recognized that their potential procompetitive effects rendered them ill-suited for per se illegal treatment.[102] As the Supreme Court has explained, "the *per se* rule is appropriate only after courts have had considerable experience with the type of restraint at issue, and only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason."[103] The antitrust agencies have since acknowledged that the categorical harshness of a per se illegal rule is not appropriate in this context.[104] The cognitive miser phenomenon predicts the adoption of heuristics and mental shortcuts; it does not predict the adoption of modes of analysis recognized as inapplicable. Furthermore, the judicial rejection of the per se illegal rule has been in favor of an almost equally bright-line rule, the choice of which, as will be discussed below, can largely be explained by the cognitive miser phenomenon.

B. Courts Reject Rule of Reason in Favor of (Almost) Per Se Legal

After the per se illegal rule lost steam, the FTC began to work to convince courts to adopt an approach similar to the rule of reason analysis that the Commission had applied in *Schering-Plough*. The FTC's rule of reason framework was premised on a view of patent protection as "probabilistic": a patent-holder's ability to exclude others is not absolute; rather, the ability to exclude is a function of the odds that the patent holder can successfully invoke the patent to exclude competitors.[105] In other words, the expected length of patent protection must be discounted by the possibility that it cannot be successfully wielded by the holder to fend off challengers.[106] The

102. *Schering-Plough Corp.*, 136 F.T.C. at 971-72.

103. Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 887 (2007) (internal citations omitted).

104. *See* J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Remarks at the American Conference Institute's Paragraph IV Disputes Conference (Dec. 7, 2001), *available at* http://www.ftc.gov/speeches/rosch/111207paragraphIV.pdf; Brief for the United States in Response to the Court's Invitation at 19-20, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)).

105. *See* Brief of Respondent-Appellant, *supra* note 101, at 41-42.

106. The view of patent protection as "probabilistic" has sparked contentious debate. Some commentators agree with the FTC. *See, e.g.*, Mark A. Lemley & Carl Shapiro, *supra* note 3, at 75; Keith Leffler & Christofer Leffler, *Probabilistic Nature of Patent Rights: In Response to Kevin McDonald*, 17 ANTITRUST 77 (2003); Carl Shapiro, *Antitrust Limits to Patent*

implication of this conception of patents was the type of "what if" estimation articulated in the Commission's decision: the amount of competition achieved by the settlement—the time until generic entry to market—must be compared with the amount of competition that "would have been expected absent the payments."[107] This latter level of competition would be reflected in the parties' "collectively expected outcome of litigation," namely the entry date that would have been selected in a settlement without a reverse payment (or the "hypothetical no-payment compromise on the entry date").[108] Under this logic, payment from a branded company is to purchase delay and push the entry date back, beyond the date the parties would have selected in a hypothetical settlement without a reverse payment. However, the FTC still bore the burden of proof to show a "direct causal link" between the entry date and the payments; generally, this would be established by showing that the branded company had received inadequate consideration in exchange for its payments.[109]

The FTC's rule of reason approach was still out of sync with the judiciary. Courts continued to select a bright-line rule, but now a rule of near per se *legality* was quickly gaining converts. In 2003—the same year that the Sixth Circuit decided *In re Cardizem*—the Eleventh Circuit was faced with a challenge to a pair of reverse payment settlements between Abbott and two generic companies.[110] Three years earlier the district court had published an opinion mirroring the *In re Cardizem* district court in finding the settlements to be per se illegal market divisions.[111] In *Valley Drug* the Eleventh

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Settlements, 34 RAND J. ECON. 391, 395 (2003) (characterizing patents as a "bundle of uncertain and imperfect rights"). Others have criticized this view as contradicting the treatment courts normally accord patents. *See, e.g.*, Butler & Jarosch, *supra* note 2, at 101 & n.235 ("Rights are traditionally found when enforceable, but [the probabilistic patent view] argues that whatever right a patent grants does not reach full strength until actually enforced."); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1049-52 (2004); Kevin D. McDonald, *Hatch-Waxman Settlements and Antitrust: on "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68. Courts have consistently refused to view patent protection as "probabilistic." *See, e.g.*, FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312-14 (11th Cir. 2012); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008). However the Court in *Actavis* implicitly accepted the theory. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (explaining that a payment "likely seek[ing] to prevent the risk of competition" is itself "the relevant anticompetitive harm").

107. Brief of Respondent-Appellant, *supra* note 101, at 42-43.

108. *Id.* at 44.

109. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068 (11th Cir. 2005). *See also* Schering-Plough Corp., et al., 136 F.T.C. 956, 1003-04 (2003).

110. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296 (11th Cir. 2003).

111. *In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1348 (S.D. Fla.

Circuit rejected the lower court's per se illegal treatment and pioneered a new approach.[112]

Because patents give their owners a lawful right to exclude others, the court explained that competitors' horizontal agreement to divide a market did not necessarily create an antitrust violation.[113] This was particularly true because patent disputes operate in an environment with a pre-existing anticompetitive restraint.[114] The judicial inquiry must instead revolve around the "exclusionary power" of the patent.[115] Even if a patent has been ruled invalid, its exclusionary power must nonetheless be analyzed, because the reasonableness of the agreement should be judged from the ex ante perspective of the parties.[116] The court expressed concern that threatening settling parties with antitrust liability if the branded company subsequently loses the patent suit would discourage settlement, particularly given the significant uncertainty inherent in the complexity of patent litigation.[117] Although the *Valley Drug* court conceded that reverse payments may indicate the patent holder's lack of confidence in the validity of its patent, "the asymmetries of risk and large profits at stake" mitigated the potential strength of such an assumption.[118] Two years after *Valley Drug*, the Eleventh Circuit had an opportunity to revisit the treatment of reverse payment settlements when the *Schering-Plough* respondents appealed the Commission's decision. In *Schering-Plough* the Eleventh Circuit reiterated its initial approach, distilling a three-part test for antitrust liability from *Valley Drug*: courts faced with a contested reverse payment settlement must examine "(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."[119]

The Eleventh Circuit was silent as to what determines the scope

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2000) *rev'd sub nom*., Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).

112. *Valley Drug*, 344 F.3d at 1309.

113. *Id*. at 1305. Nor did the court agree that rule of reason is appropriate. *See id*. at 1311 n.27.

114. *Schering-Plough Corp.*, 402 F.3d at 1066.

115. *Valley Drug*, 344 F.3d at 1306.

116. *Id*. at 1306-07.

117. *Id*. at 1308. *See generally* James Farrand et. al., *"Reform" Arrives in Patent Enforcement: The Big Picture*, 51 IDEA 357 (2011).

118. *Valley Drug*, 344 F.3d at 1309-10. *See also supra* Part II.

119. *Schering-Plough Corp.*, 402 F.3d at 1066 (citing *Valley Drug*, 344 F.3d at 1312). The court found that the agreements did not exceed the scope of this protection, because the Commission had inappropriately discounted the ALJ's findings of fact that the consideration Schering received in exchange for its payments was in fact reasonable. *Id*. at 1070-72.

of a patent's "exclusionary potential." The FTC initially interpreted this test as allowing reverse payment settlements to be virtually per se lawful so long as the parties agreed on a generic entry occurring no later than the date of the patent's expiration.[120] The Second Circuit effectively adopted this interpretation of the Eleventh Circuit's decisions—and then applied such a test—when it faced its first reverse payment settlement case in *In re Tamoxifen*.[121] Citing *Schering-Plough*, the Second Circuit explained that the unique environment of patent protection rendered agreements valid if they did not "exceed the 'scope of the patent's protection.'"[122] The Second Circuit's test is known as the "sham litigation" rule:[123] "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."[124]

Once a court finds that the underlying patent suit is not facially frivolous, the settlement will be upheld so long as it does not "extend the reach" of the patent.[125] For the *In re Tamoxifen* court, this inquiry involved the review of a few easy-to-determine factors. The court noted that the agreement did not forbid the generic company from marketing products unrelated to the one at issue in the patent litigation, there was no bottleneck created,[126] and just eight months after the settlement became effective, the generic would be able to sell a version of the branded drug under license from the patent holder.[127] The Second Circuit agreed with the *Schering-Plough* panel that Hatch-Waxman's structure "encourages" reverse payment settlements

120. Petition for Writ of Certiorari at 15, Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688).

121. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006).

122. *Id.* (quoting Schering-Plough v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005)).

123. *See, e.g.*, Brief for Dep't of Justice as Amicus Curiae at 19, Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688).

124. *In re Tamoxifen*, 466 F.3d at 208-09.

125. *Id.* at 213.

126. The settlement required the first generic filer to amend its ANDA and remove its paragraph IV certification, enabling the FDA to approve subsequently filed ANDAs. *Id.* at 214. However, the *In re Tamoxifen* panel was under the erroneous impression that other generic manufacturers were not only free, in the absence of a bottleneck, to challenge the patent, but would be incentivized to do so based on "potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement suit lawsuit." *Id.* As discussed earlier, the 180-day exclusivity period is available only to the first filer, not the first successful challenger.

127. *Id.* at 213-16.

as a way to "insure against" loss.[128] Furthermore, even if the underlying patent was weak and the holder was likely to lose its suit, the court explained that the statutory presumption of a patent's validity meant that "settlement is merely an extension of the valid patent monopoly."[129]

Like the Eleventh Circuit, the Second Circuit had another opportunity to revisit its posture toward reverse payment settlements. However, unlike the *Schering-Plough* court, this subsequent panel was not so sanguine about the wisdom of its initial decision. The Second Circuit's opinion in *Arkansas Carpenters* was a brief one. The panel explained that *In re Tamoxifen* compelled the conclusion that the agreement at bar did not exceed the scope of the patent and therefore was not an antitrust violation.[130] Although the court delineated multiple reasons why it might be willing to revisit its approach, and the FTC submitted an amicus brief in support of a rehearing,[131] the Second Circuit ultimately refused to reconsider en banc.[132]

In between the Second Circuit's decisions in *In re Tamoxifen* and *Arkansas Carpenters*, the Federal Circuit also adopted the sham litigation rule, in a case known as *In re Cipro*.[133] The *In re Cipro* plaintiffs had advanced the FTC's probabilistic patent protection

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128. *Id.* at 206, 210.

129. *Id.* at 211.

130. Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 106 (2d Cir. 2010) (per curiam), *cert. denied*, 131 S. Ct. 1606 (2011). Although the *In re Tamoxifen* panel erroneously believed that a second-in-time generic filer could still obtain the 180-day exclusivity period, the *Arkansas Carpenter* court did not refer to this potential reward as being available to subsequent filers. Yet the court still acknowledged that under the sham litigation test, the companies had not "manipulate[ed] . . . the exclusivity period." *Id.* at 107. This implies that, at least in the Second Circuit, unlawful manipulation of the exclusivity period will be found only if a bottleneck is formed, but not if the creation of a settlement erases the existence of a 180-day exclusivity period. The court's focus, then, is on whether generic companies are permitted, under the regulatory scheme, to challenge a patent, and not on whether their incentives have been so diminished by the loss of the exclusivity bounty that they realistically may never attempt to challenge. *Cf.* Hemphill, *supra* note 63, at 126-42 (arguing that "[p]roblematic settlements are feasible even where there is no formal bottleneck to FDA approval, because buying off the single firm with bounty eligibility carries a strong prospect of allocative harm.").

131. Brief Amicus Curiae of Fed. Trade Comm'n in Support of Rehearing En Banc, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)).

132. Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir. 2010). Judge Pooler, a member of the *Arkansas Carpenters* panel, wrote an impassioned dissent urging Congress or the Supreme Court to step in. *Id.* (Pooler, J., dissenting)

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

theory, but the district court refused to "discount the exclusionary power of the patent by any probability that the patent would have been invalid."[134] Similarly, the Federal Circuit explained it was following the Second and Eleventh Circuits in concluding that absent "evidence of fraud before the PTO or sham litigation," a court need not consider the likelihood of patent invalidity.[135] A court's analysis properly revolves around "whether the agreements restrict competition beyond the exclusionary zone of the patent," where the outer bounds of a patent's exclusionary zone were implicitly defined as a deal that applied only to the allegedly infringing product, forbid generic entry no later than the expiration date of the patent, and did not create a bottleneck.[136]

The FTC was not a party to the *In re Cipro* litigation, but it submitted an amicus brief to the Federal Circuit. In this brief, the FTC began shifting gears towards a framework of analysis that would make reverse payment settlements presumptively illegal. Portions of the FTC's brief continued to advocate for its "hypothetical no-payment compromise on the entry date" test.[137] Yet while the FTC had previously announced that the challenger bore the burden of proving anticompetitive effects by establishing inadequate consideration,[138] this requirement was omitted from the FTC's *In re Cipro* brief. By arguing that any settlement with a reverse payment and predetermined generic entry date beyond the 'hypothetical no-payment entry date' was anticompetitive, without any particular showing by the challenger, the FTC was implicitly pursuing a rule of presumptive illegality. The FTC's only explicit request, however, was that reverse payment settlements not be given a per se legal safe harbor.[139]

Little has been mentioned thus far of the DOJ, and for good reason. From 2003 to 2009, the DOJ concertedly distanced itself

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134. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005) *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008) *and aff'd in part sub nom*. Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010).

135. *In re Ciprofloxacin*, 544 F.3d at 1336.

136. *See id.* at 1335-36.

137. Brief of Amicus Curiae Fed. Trade Comm'n in Support of Appellants and Urging Reversal at 16-17, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 1:00-MD-01383).

138. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068 (11th Cir. 2005). *See also* Schering-Plough Corp., et al., 136 F.T.C. 956, 1003-04 (2003).

139. Brief of Amicus Curiae Fed. Trade Comm'n in Support of Appellants and Urging Reversal at 4, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 1:00-MD-01383).

from the FTC's fight against reverse payment settlements. The DOJ first weighed in on the issue after the Supreme Court requested its perspective on *In re Cardizem*.[140] The DOJ admitted that per se treatment was inappropriate,[141] but argued that the case could be distinguished from the recently-decided *Valley Drug* and therefore review was unwarranted.[142] In response to a similar request two years later, the DOJ recommended against the Court granting certiorari in *Schering-Plough*.[143] Exemplifying their predilection for avoiding the debate, the DOJ advanced the dubious claim that the Eleventh Circuit panel had not fully addressed the FTC's suggested test for liability, and this potential disconnect made the case a poor choice for review.[144] The DOJ also focused on the absence of any pressing circuit split, repeating arguments from its *In re Cardizem* brief regarding why there was no inherent inconsistency between the Sixth and Eleventh Circuits.[145] The Second Circuit had recently published its *In re Tamoxifen* decision, but the DOJ argued this outcome, too, did not conflict with *Schering-Plough*, despite *In re Tamoxifen*'s explicit adoption of the sham litigation rule and the DOJ's continued insistence that the Eleventh Circuit in *Schering-Plough* had applied a different test.[146] The DOJ similarly encouraged the Court to forego hearing *In re Tamoxifen*.[147]

Although the DOJ's brief to the Supreme Court regarding *In re Tamoxifen* did characterize the sham litigation rule as "insufficiently stringent,"[148] the DOJ was palpably less concerned than the FTC

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140. Brief for the United States as Amicus Curiae at 1, *In re* Cardizem Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) (No. 03-779). The FTC also signed the brief alongside the DOJ, perhaps fearful that the Sixth Circuit's per se framework would be struck down as too extreme, with a resulting invitation to courts to apply significantly more permissive filters.

141. *Id.* at 9, 12.

142. *Id.* at 11-15.

143. Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 1.

144. *See id.* at 15-16. On this point the DOJ appears to be on shaky footing. It is not immediately clear how the Eleventh Circuit panel misunderstood or otherwise failed to engage with the FTC's suggested test for liability: the court noted and rejected the Commission panel's reliance on "the entry dates that 'might have been' agreed upon in the absence of payments as the determinative factor." *Id.* This inquiry is what the FTC, in its brief, had urged the Eleventh Circuit to focus upon. *Compare* Schering-Plough v. FTC, 402 F.3d 1056, 1062 (11th Cir. 2005) *with* Brief of Respondent-Appellant at 44, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688-AA), 2004 WL 3557972.

145. Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 16-18.

146. *Id.* at 18-19.

147. Brief for the United States as Amicus Curiae at 1, *In re* Tamoxifen Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (No. 06-830).

148. *Id.* at 1, 12-13.

about the potential anticompetitive effects of reverse payment settlements. The DOJ departed from the FTC not just in terms of the extent of their skepticism, but doctrinally as well. In contrast to the FTC's subjective rule of reason approach—focused on the parties' expected outcome of the litigation—the touchstone of the DOJ's test during the Bush administration years was an objective analysis of the parties' ex ante chances of winning the underlying patent litigation.[149] Yet despite floating this alternate rule of reason test in its briefs to the Supreme Court, none of the lower courts ever adopted this proposal.

C. Explanations for Judicial Rejection of the Rule of Reason Framework

1. Judicial Rejection Cannot be Explained by Mere Disagreement with the Antitrust Agencies' Particular Rule of Reason Tests

One could posit that courts and the antitrust agencies were unable to see eye-to-eye during the rule of reason phase because courts viewed the agencies' particular proposals as doctrinally flawed. For example, courts may have been skeptical of some of the presumptions undergirding the FTC's rule of reason test. The FTC insisted that the generic entry date in a hypothetical settlement without a reverse payment would be an accurate proxy for the parties' expectations of the outcome of the underlying patent litigation.[150] But the presence during negotiation of varying degrees of risk aversion undercuts the FTC's implicit assumption that there are no benign reasons for selecting an entry date earlier than the one expected as a result of litigation. Particularly where substantial existing business is tied to a patent, the risk of "losing it all" in litigation may cause the patent holder to select an earlier entry date, simply because the additional certainty is worth sacrificing a mere possibility of even later generic competition.[151] In adopting the sham litigation rule,

149. *Id.* at 12; Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 11 & n.1. The DOJ did not fully elucidate the role its "limited examination of the merits of the [patent] claim" would take, other than to encourage courts "at a minimum" to conduct such an inquiry when applying the rule of reason. Brief for the United States as Amicus Curiae, *supra* note 147, at 12-13.

150. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296 (11th Cir. 2003).

151. *See* Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, *in* 3 ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY 2127, 2131 (2008); Schildkraut, *supra* note 106, at 1060-62; *see also* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2244-45 (2013) (Roberts, C.J. dissenting); *but see* Elhauge & Kreuger, *supra* note 93, at 44-45 (disputing the relevance of risk aversion to the determination of which reverse payment settlements are

several courts have cited an analogous intuition described by Judge Posner: "It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of rights. No one can be *certain* that he will prevail in a patent suit."[152]

The issue of risk aversion is even more salient in this context due to the disparate risk-to-reward ratios faced by each party during litigation. In order to incentivize generic entry, Hatch-Waxman significantly skewed these ratios: the branded company cannot obtain infringement damages and thus has little upside to litigating, aside from protecting its existing patent; yet the branded company faces a devastating downside in the form of losing its patent altogether.[153] In contrast, the generic company will lose only litigation costs if it proceeds, while enjoying a shot at a substantial upside—exclusive generic sales.[154] The resulting landscape makes litigation a far more painful option for the branded company, and it may therefore be willing to accept an entry date that is earlier than it otherwise expects to occur as a result of litigation. The Commission made a similar observation during its disposition of the *Schering-Plough* matter.[155] Courts both criticized the FTC's standard for failing to adequately account for disproportionate risk[156] and made the related remark that

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anticompetitive).

152. Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003); *see also In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1338 (Fed. Cir. 2008) (citing *Asahi Glass*, 289 F. Supp. 2d at 992); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006) (citing *Asahi Glass*, 289 F. Supp. 2d at 991.); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1067 (11th Cir. 2005) (citing *Asahi Glass*, 289 F. Supp. 2d at 991.); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 527 (E.D.N.Y. 2005) (citing *Asahi Glass*, 289 F. Supp. 2d at 992.).

153. *See In re Tamoxifen*, 466 F.3d at 206-07.

154. *Id.* Assuming, of course, the generic is the first filer. Otherwise, the generic company's upside is smaller, as simply one of multiple generics in the market.

155. *See* Schering-Plough Corp., et al., 136 F.T.C. 956, 991 (2003) ("The shift in the relative bargaining power of the litigating parties may mean—assuming other factors are held constant—that pioneers will have to accept earlier entry dates in settlement than they would otherwise have had to do. *The baseline for a competitively benign settlement may have shifted*." (emphasis added)); *see also* Brief for the United States as Amicus Curiae at 10-11, *In re* Tamoxifen Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (No. 06-830). If risk aversion has caused the "benign settlement" date to shift to an earlier timeframe, then the reverse payment could also be seen as purchasing time to regain the entry date that would have prevailed if the parties were bargaining in a risk-neutral environment. Thus, the reverse payment would just be purchasing the branded company the time it lost as a result of Hatch-Waxman's intentional risk restructuring.

156. *In re Tamoxifen*, 466 F.3d at 207; *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 n.11, 1338 (Fed. Cir. 2008).

reverse payment settlements are a natural byproduct of Hatch-Waxman.[157]

This intuition that the Hatch-Waxman statutory scheme drives companies to avoid the risks of litigation and settle seems incompatible with the FTC's assumption that risk aversion by the branded company would not artificially advance a settlement's entry date. Yet courts could have overcome any perceived oversight in the FTC's arguments by incorporating consideration of risk aversion into a comprehensive rule of reason inquiry. Instead, courts responded by rejecting the rule of reason altogether.

The DOJ's objective rule of reason test—premised on an assessment of the underlying patent litigation—provided another option to courts dissatisfied with the FTC's proposal. The DOJ floated its version in amicus curiae briefs to the Supreme Court.[158] Although these briefs did not fully elucidate the particular analysis that would drive the DOJ's rule of reason balancing test, courts still could have used the DOJ's suggestions as a foundation for building their own rule of reason test. Despite skirting the potential pitfalls related to risk aversion, the DOJ's approach also never gained momentum with the lower courts. As with the FTC, if courts disliked specific aspects of the DOJ's proposal (namely, assessing the patent's validity),[159] they could have emphasized other factors. Yet still, courts responded by completely rejecting rule of reason.

The judiciary simply distanced itself from the rule of reason when adjudicating these cases.[160] Even after declaring that the dynamics of Hatch-Waxman push companies into settling, the Second

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157. *In re Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074. The DOJ acknowledged the same dynamic at play. *See* Brief for the United States as Amicus Curiae at 10, *In re* Tamoxifen Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (No. 06-830) ("The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.").

158. *See* discussion *supra* pp. 127-28.

159. *See In re Tamoxifen*, 466 F.3d at 203-04 (citing and agreeing with other courts that rejected the suggestion that they assess the merits of a patent's validity).

160. When the Federal Circuit affirmed the district court's application of the sham litigation rule, it approvingly noted that the lower court had properly undertaken "a full rule of reason analysis." *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008). However, the Federal Circuit upheld the settlement under the sham litigation rule. *See id*. at 1336-37. The apparent discrepancy is reconciled by the Federal Circuit's conclusion that where "all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent." *Id.* at 1336.

Circuit seemed primarily concerned with the "inevitable, lengthy, and expensive" trial resulting from application of the rule of reason.[161] The rejection seems to have more to do with the rule of reason approach itself than of any particular facet of the antitrust agencies' proposals.

2. Rule of Reason: Inconsistent with Cognitive Misers and In Rem Rights

The cognitive miser phenomenon predicts the judiciary's rejection of the antitrust agencies' rule of reason balancing tests. The concurrent propensity to apply a bright-line rule when dealing with property rights compounded the effect of the cognitive miser phenomenon, doubly driving the judiciary away from the antitrust agencies' suggestions during their rule of reason phase.

As discussed above, the judiciary's conceptual link between patents and real property has affected the way courts analyze patent-related disputes. The FTC and DOJ's rule of reason tests, then, presented a mode of analysis courts viewed as incongruent with the underlying property right at issue. When courts apply the legal norms associated with in rem rights, they generally apply rules that "turn on one or a small number of publicly observable states of fact,"[162] which is a stark contrast to the antitrust agencies' rule of reason tests. The merits of an underlying patent suit are quite far from publicly observable facts, yet disentangling such a suit was the messy threshold inquiry imposed by the DOJ test. Courts would have to decide, based on their estimated outcome of a suit that was never litigated, whether to uphold a settlement as within a patent holder's property rights. Such speculation does not make it easy for the patent holder or the public to know the contours of the property rights at issue. When presented with disputes over property rights, courts are accustomed to applying a bright-line rule that avoids specifying impermissible uses, and therefore this type of inquiry would have been very unintuitive to courts. The FTC's rule of reason test was similarly amorphous in terms of providing guidance to third parties about the contours of a patent holder's rights. The rallying cry of the sham litigation rule, that a patent holder "is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts," [163] is far more in sync with the

161. *In re Tamoxifen*, 466 F.3d at 212 n.26.

162. Merrill & Smith, *supra* note 24, at 803.

163. *Compare In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 210 (2d Cir. 2006)

typical exclusion rule governing in rem rights than a rule of reason test.

Implementing either the FTC or DOJ's rule of reason test also would have posed a conceptually burdensome task. The judiciary's broad repudiation of rule of reason in this context, then, corresponds with a cognitive miser's general inclination to instead apply a bright-line rule. The DOJ's test required a mini patent infringement trial as a threshold determination, a task which is notoriously resource-intensive.[164] The FTC's test was analogously complex. Courts were instructed to speculate about the parties' "hypothetical no-payment compromise on the entry date," and use this date as a competitive baseline: any subsequent entry would be purchased protection, and not supplied by the patent.[165] This is a comprehensive, holistic inquiry, commanding courts to first imagine a settlement that was never made—one without a reverse payment—and then look to the subjective views of the settling parties in determining the generic entry date they would have selected. The plaintiffs and drug company defendants would conjure up different dates, each side invoking a boundless set of factors to buttress their estimate. Furthermore, it seems likely that the parties would use the merits of the underlying patent suit as ammunition. The companies would seek to show they believed there was at least a moderately high chance the patent would be upheld in court, a perception that would justify selection of a relatively late settlement entry date. In general, holistic standards require more intensive interaction between judges and their subject matter,[166] and this test is no exception. Even though its application would not per se require a plenary assessment of the patent dispute, it threatens significant judicial engagement not only with the patented

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(quoting Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 702 F Supp. 2d 986, 993 (N.D. Ill. 2003)) *with*, *Nuisance*, *supra* note 25, at 978.

164. *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013) (recognizing the Eleventh Circuit's "underlying practical concern" that applying antitrust scrutiny to reverse payment settlements might require a "time consuming, complex, and expensive" litigation regarding the validity of the patent); Rohm & Hass Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997) ("Patent litigation frequently is complex, long, and difficult.").

165. Brief of Respondent-Appellant at 44-46, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688-AA), 2004 WL 3557972; *see also* Brief of Amicus Curiae Fed. Trade Comm'n in Support of Appellants and Urging Reversal at 18-20, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 1:00-MD-01383).

166. *See* Lee, *supra* note 6, at 62; *cf.* Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 39 (1984) ("The traditional Rule of Reason falls prey to all of the limits of antitrust. It assumes that judges can tap a fount of economic knowledge that does not exist, and it disregards the costs of judicial decisionmaking (including the costs of damning efficient conduct by mistake or design).").

innovation and the challenger's allegedly non-infringing alternate, but a host of other factors the parties would call up as ex post support to justify a hypothetical ex ante selection of an entry date.

Thus while the cognitive miser phenomenon predicts courts would reject a rule of reason approach in favor of a bright-line rule, it is only partially responsible for the judiciary's actions during the rule of reason period. The tension between a rule of reason framework and courts' usual treatment of property was the other major factor driving the judiciary's divergence from the antitrust agencies. This competing influence was removed, however, once the antitrust agencies began to offer up alternative bright-line rules. The courts' choice of their particular bright-line rule over these other options—creating the intergovernmental stalemate the Supreme Court resolved in *Actavis*—can be identified as primarily a manifestation of the cognitive miser phenomenon.

IV. THE QUICK-LOOK ERA

Although they initially advocated rule of reason tests, the antitrust agencies have since shifted to "quick look," a framework of antitrust analysis much less hospitable to defendants. Under the quick look doctrine, courts conduct an abbreviated analysis. Where a "great likelihood of anticompetitive effects can easily be ascertained,"[167] plaintiffs need not establish that the defendant's conduct actually has caused or is likely to cause anticompetitive effects.[168] Instead, the burden immediately shifts to the defendant to show procompetitive justifications for his conduct.[169] In other words, the activity is presumptively illegal. After its rule of reason proposal failed to gain any traction in the courts, the FTC began to advocate this type of approach. The FTC's posture evolved in this direction despite courts consistently rejecting its comparatively lenient rule of reason test in favor of the still more indulgent sham litigation rule. The FTC's decision to move farther away from the majority judicial approach was likely due to the FTC's new partnership with the DOJ. Since 2009, the DOJ has assumed an active role in the fight against reverse payment settlements. The result is that the DOJ and FTC are now unified in presenting courts with a presumptively illegal framework. As Part III will discuss, the quick-look tests offered by the antitrust

167. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

168. Geoffrey D. Oliver, *Of Tenors, Real Estate Brokers and Golf Clubs: A Quick Look at Truncated Rule of Reason Analysis*, ANTITRUST, Spring 2010, at 40.

169. *See id.*

agencies supply a fairly formalistic approach to resolving challenges to reverse payment settlements. But the district and appellate courts, with one recent exception, continued to utilize their own formalistic approach, the sham litigation rule. The selection of this particular bright-line rule is a classic manifestation of the cognitive miser phenomenon.

A. Antitrust Agencies Unite to Advocate for "Quick-look" Treatment

1. DOJ Sets Forth a Quick-Look Test

In the summer of 2009 the DOJ abandoned its previous noncommittal attitude, presenting a radically different perspective on reverse payment settlements in response to a request from the Supreme Court for input on *Arkansas Carpenters*.[170] Notably, this is the first post-Bush administration brief submitted by the DOJ on this topic.[171] In contrast to the DOJ's previous muddled writings on the topic, the DOJ put forth a specific, and aggressive, test for when reverse payment settlements should be deemed to violate antitrust laws.[172] Although ostensibly seeking to apply the rule of reason,[173] the DOJ's test avoids a totality of the circumstances inquiry and instead applies a quick-look test by making reverse payment settlements presumptively unlawful.[174]

The DOJ's test was far more inquiry-truncating than a rule of reason approach. Reflecting rationales first articulated by the Commission in its *Schering-Plough* decision, the DOJ explained that because the generic entry date parties would choose in the absence of payment reflects their perception of the likelihood of prevailing at trial, a settlement encompassing a reverse payment is "naturally viewed" as purchasing a longer period of exclusion, absent any other

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170. Brief for the United States in Response to the Court's Invitation at 1, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)).

171. *See* Steven Seidenberg, The Flip Side of 'Reverse Payments,' ABA JOURNAL (Feb. 1, 2010, 3:00 AM), http://www.abajournal.com/magazine/article/the_flip_side_of_reverse_payments/.

172. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24. This test is reminiscent of the framework of analysis applied by the Commission in its *Schering-Plough* decision, except that the antitrust agencies do not bear the burden of proving inadequate consideration. *See* Schering-Plough Corp., et al., 136 F.T.C. 956, 988, 991 (2003).

173. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24.

174. *Id.* at 9-10.

consideration provided by the generic manufacturer.[175] Based on the assumption that a settlement featuring both a reverse payment and a predetermined entry date in the future involved the purchase of additional exclusion time, the DOJ argued reverse payment settlements should be considered presumptively anticompetitive.[176] Plaintiffs need only make a prima facie showing of the existence of a reverse payment settlement—by pointing to a settlement that included both a payment from a branded company to a generic and an agreement to end litigation and set a future generic entry date—before the burden shifts to the defendant companies.[177]

In order for the settlement to survive, defendants must rebut a plaintiff's prima facie case, by showing that the settlement did not result in a level of competition significantly less than they expected to occur if the patent suit was litigated to a final judgment.[178] If the defendants can show that the amount of the reverse payment is roughly in line with the litigation costs avoided by the patent holder, then they have met their burden of proof.[179] In contrast, if the amount of the payment is "greatly in excess" of saved litigation costs, the defendants will need to show that "despite the reverse payment, the agreed upon entry date and other terms of entry reasonably reflected [the brand and generic companies'] contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration."[180] The DOJ admitted some reverse payment settlements may lead to a level of competition greater than what would have occurred as a result of

175. *Compare* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 21-22, *with* Schering-Plough et al., 136 F.T.C. 956, 987-88 (2003). However, the DOJ's test differed from the Commission's proposed test in that instead of estimating generic entry that would have occurred under a settlement without a reverse payment, the DOJ suggested that courts estimate the generic entry that would have occurred if the parties had not settled at all, and instead the patent litigation reached a final judgment. *See* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 28.

176. *See* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 22. *But see* Butler & Jarosch, *supra* note 2, at 88 (arguing that the DOJ's position that reverse payment settlements are presumptively anticompetitive rests on erroneous assumptions).

177. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 23, 27.

178. *Id.* at 28.

179. *Id.* at 28-29.

180. *Id.* at 30-31. *See also* Elhauge & Krueger, *supra* note 93, at 297-312 (setting forth a mathematical proof indicating that "when a reverse payment exceeds the patent holder's anticipated litigation costs, a court can be confident that" the settlement is anticompetitive, absent very narrow grounds for rebuttal).

litigation.[181] Such an outcome would only affect claims for damages, however, and the DOJ did not view it as weighty enough to justify a rule of reason liability standard.[182] The DOJ explicitly disavowed any type of embedded trial regarding the merits of the underlying patent litigation, warning that it would "unduly complicate" an antitrust case.[183]

The DOJ's quick-look test explicitly contradicted two positions the DOJ had made in its earlier, otherwise noncommittal briefs to the Supreme Court. First, the DOJ had previously noted that a rule of law which subjects reverse payment settlements to "near-automatic invalidation" could "potentially frustrate" the ability of patent holders to exclude competition falling within the scope of their patent's protection.[184] This concern fell by the wayside when the DOJ switched to a test with a starting presumption of illegality. Second, the DOJ had argued that the competing values of patent and antitrust law merited a test that would objectively calculate the parties' relative chances of winning the underlying patent litigation, by looking to an ex ante assessment of "evidence extrinsic to the settlement."[185] The DOJ had criticized the FTC's contemporaneous approach of imagining a hypothetical no-payment settlement date, because it gave too much weight to the parties' own views of their relative chances of success.[186] Starting in 2009, however, the DOJ adamantly rejected any such "objective" inquiry into the merits of the underlying patent litigation, instead embracing a subjective quick-look test.[187]

2. FTC Shifts to Quick-Look

The FTC began its final phase of evolution by introducing a quick-look test inspired by the DOJ's earlier objective rule of reason approach. When hearing *In re Androgel*, the Eleventh Circuit was faced with yet another challenge to a reverse payment settlement.[188] The FTC attempted to reinterpret and reframe *Valley Drug* and

181. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24-25.

182. *Id.*

183. *Id.* at 25-27.

184. Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 10-11.

185. *Id.* at 10-12.

186. *See id.* at 11-12.

187. *See* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24-25; *see also id.* at 26 n.9 (acknowledging "some tension" between the DOJ's previous writings and its current views).

188. *See In re* Androgel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga. 2010)

Schering-Plough as capable of coexisting with a presumptively illegal test.[189] In its brief to the district court, the FTC admitted it had previously interpreted Eleventh Circuit case law as requiring the same "end-of-patent-term standard"[190] that the Second and Federal Circuits used.[191] The FTC emphasized, however, the "ambiguity" in the Eleventh Circuit's past decisions, such that the task of examining the "scope of the exclusionary power of the patent" did not foreclose analyzing the strength of the underlying patent as an element of this inquiry.[192] Under this view, a patent that is likely invalid or not infringed simply does not have the same exclusionary power as a "strong patent."[193] Thus, although a court facing an antitrust challenge need not "assess direct evidence of the underlying patent

189. *See* Plaintiff Fed. Trade Comm'n's Consolidated Opposition to Defendants' Motion to Dismiss at 14, *In re* Androgel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga. 2010) (No. 1:09-CV-00955-TWT).

190. Also referred to as the sham litigation standard.

191. *See* Plaintiff Fed. Trade Comm'n's Consolidated Opposition to Defendants' Motion to Dismiss at 14, *In re* Androgel Antitrust Litig., 687 F. Supp. 2d 1371 (N.D. Ga. 2010) (No. 1:09-CV-00955-TWT).

192. *Id.* at 14-15. In its brief to the Eleventh Circuit regarding *Schering-Plough*, the FTC had originally read *Valley Drug* as adopting a rule much like the one it articulated during the *In re Androgel* litigation. *See* Brief of Respondent Fed. Trade Comm'n at 16, Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688). Under this interpretation, the requirement to analyze the "exclusionary potential" of the patent mandated an inquiry into "[h]ow successful the patentee was likely to be in excluding" the generic challenger, in other words, an evaluation of the merits of the underlying patent litigation. *Id.* Following *Schering-Plough*, the FTC viewed the Eleventh Circuit as adopting the sham litigation rule. *See* Petition for Writ of Certiorari at 14-15, Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688). In its *In re Androgel* brief, however, the FTC argued that *Valley Drug* and *Schering-Plough* adopted a framework distinct from sham litigation. Plaintiff Fed. Trade Comm'n's Consolidated Opposition to Defendants' Motion to Dismiss, *supra* note 191, at 14. In support of this contention, the FTC cited *Valley Drug*'s remand to the district court "for consideration of the 'protection afforded by the patents' based on 'the likelihood of [the patentee] obtaining such protections' at the time of the agreement." *Id*. (quoting Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)). The FTC also found support for its new interpretation in the last paragraph of the *Schering-Plough* opinion, which mentioned the "need to evaluate the strength of the patent." *Id.* (quoting *Schering-Plough*, 402 F.3d at 1076). Since 2006, the DOJ had similarly argued that the Eleventh Circuit caselaw allows, or at least does not foreclose, an inquiry into the strength of the patent. *See* Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 22-24. The case for ambiguity is made more plausible by the full history of *Valley Drug*: after the Eleventh Circuit remanded the case to the district court for a consideration of the "exclusionary potential" of the patent, the district court proceeded to analyze the likely outcome of the pending patent litigation. *In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1299 (S.D. Fla. 2005). Such an inquiry, according to the district court, was mandated by *Valley Drug*'s holding; if this was a misconception, the *Schering-Plough* court did nothing to correct it.

193. Plaintiff Fed. Trade Comm'n's Consolidated Opposition to Defendants' Motion to Dismiss, *supra* note 191, at 20.

claims," courts cannot disregard "complaint allegations that the patent was invalid or so narrow that it would not prevent generic entry on its own."[194] Correspondingly, the FTC articulated a new test consistent with its updated interpretation of *Valley Drug* and *Schering-Plough*: if an objective analysis of the underlying patent litigation, made at the time the settlement was formed, indicates it is more likely than not that the generic product would have ultimately entered earlier than the date allowed by the settlement terms—either "through final resolution of the patent litigation or through entry not stopped by a preliminary injunction"—then the payment "must be seen" as purchasing delay, and as such, the settlement is unlawful.[195]

In other words, the FTC attempted to persuade the Eleventh Circuit that under the first prong of the *Valley Drug*/*Schering-Plough* test—which inquires into the exclusionary potential of the patent—the court should analyze a patent's strength in a type of mini-trial, and use this result to discount the official length of a patent's protection. This calculation generates a length of patent protection provided by the patent itself, and the FTC assumes in a but-for world where the parties never settled, generic entry on average would have occurred immediately after the expected length of patent protection. A later generic entry date under a settlement is presumed to have been purchased by the reverse payment, in violation of antitrust law (absent proof by the defendants of offsetting procompetitive effects). This test harkens back to the DOJ's original suggestion that courts analyze the merits of the underlying patent litigation, an inquiry which the FTC had previously disavowed in favor of a subjective inquiry into the parties' expectations regarding generic entry. The difference between the two is that while the DOJ incorporated this inquiry into a rule of reason balancing test,[196] the FTC suggested it as the starting point of a presumptively illegal rule.[197]

The *In re Androgel* district court refused to consider the scope of the patent as diminished by the probability that a patent holder would litigate and lose, describing such a view of a patent's exclusionary

194. *Id.* at 1-2, 25.

195. Brief for Plaintiff-Appellant Fed. Trade Comm'n at 21-32, FTC v. Watson Pharm., Inc., No. 1:09-CV-00955-TWT (11th Cir. Apr. 25, 2012). Alternately, if the Eleventh Circuit Court of Appeals viewed its precedents as establishing an end-of-patent-term (or sham litigation) rule, then the FTC urged the court to adopt the "presumptively illegal" rule articulated by the DOJ in its *Arkansas Carpenters* brief. *Id.* at 43-44.

196. *See* Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 11.

197. Plaintiff Fed. Trade Comm'n's Consolidated Opposition to Defendants' Motion to Dismiss, *supra* note 191, at 3-4.

power as inconsistent with the Eleventh Circuit's reasoning in *Valley Drug*.[198] In an emphatic opinion, the Eleventh Circuit affirmed the district court, rebuffing the FTC's invitation for it to engage in the "turducken task" of "deciding a patent case within an antitrust case about the settlement of the patent case."[199] The court put aside any ambiguity about its precedent and explicitly upheld the reverse payment settlement under the sham litigation rule.[200]

The FTC's *In re Androgel* briefs were written against the backdrop of the Eleventh Circuit's relatively extensive experience with reverse payment settlements. In contrast, the Third Circuit Court of Appeals was contemporaneously facing a case of first impression. The suit arrived to the Third Circuit following the district court's application of the sham litigation rule.[201] Notably, that same week, another district court in the Third Circuit also announced it would adopt the sham litigation rule.[202] Working from a clean slate in the Third Circuit, the FTC chose to advance the DOJ's new quick-look test. [203]

For the first time, the efforts of the antitrust agencies were met with success. The Third Circuit in *In re K-Dur* adopted a presumptively illegal test, although it did not rely on the DOJ's suggestion to tether the analysis to the settling parties' subjective views of the patent litigation's likely resolution.[204] Under the Third Circuit's test, any payment from a branded company to a generic

198. *In re* Androgel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371, 1377 (N.D. Ga. 2010).

199. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012).

200. *Id.* at 1312.

201. *In re* K-Dur Antitrust Litig., CIV.A.01-1652(JAG), 2009 WL 508869 (D.N.J. Feb. 6, 2009) *report and recommendation adopted*, CIV. A. 01-1652 JAG, 2010 WL 1172995 (D.N.J. Mar. 25, 2010).

202. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 528-29 (E.D. Pa. 2010), *abrogated by In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).

203. Brief of the Fed. Trade Comm'n as Amicus Curiae Supporting Appellants and Urging Reversal at 24-26, *In re* K-Dur Antitrust Litig., No. 10-2077 (D.N.J. Mar. 25, 2010); *see also* Rosch, *supra* note 104. While this may seem to be an abrupt change from the "merits of the patent litigation" quick-look test it was pressing upon the Eleventh Circuit in *In re Androgel*, the FTC was making a strategic decision. If the Eleventh Circuit interpreted its earlier ambiguous "exclusionary potential of the patent" language as encompassing an inquiry into the patent's validity, then it could adopt the FTC's offering—and officially turn away from the sham litigation rule—without breaking from precedent. Although the FTC gave the *In re Androgel* court an opportunity to adopt a quick-look test without explicitly reversing course, the FTC still had a backup argument. Should the court interpret its prior case law as adopting a sham litigation rule, the FTC urged it to split with precedent and adopt the quick-look test set forth by the DOJ in *Arkansas Carpenters*. Brief for Plaintiff-Appellant Fed. Trade Comm'n, *supra* note 195, at 43-44.

204. *In re K-Dur*, 686 F.3d at 218.

would be prima facie evidence of an antitrust violation. The settling parties can overcome this presumption by producing evidence either of adequate consideration that the branded company received in exchange for the payment or an increase in competition as a result of the payment.[205] The Third Circuit also confirmed that it would not look to the merits of the underlying patent litigation.[206]

The rigorous scrutiny requested by the antitrust agencies and imposed by the Third Circuit in *In re K-Dur* stands as an anomaly to the deferential treatment accorded to patent holders by the overwhelming majority of lower courts throughout the decade spanning from *Valley Drug* up to *Actavis*. The sham litigation rule's popularity even spread to state courts as well. In October 2011, the California Court of Appeals affirmed an earlier Superior Court decision applying the sham litigation rule to uphold a reverse payment settlement as valid under the state's analogue to the Sherman Act.[207]

By ultimately requiring "the FTC [to] prove its case as in other rule-of-reason cases," the Supreme Court in *Actavis* adopted what could be viewed as a compromise between the bright-line rule popular in the lower courts and the one preferred by the antitrust agencies.[208] Although the Supreme Court ended the intergovernmental stalemate, it is important to understand why the courts selected the approach they did, because the conceptual factors that propelled courts toward the sham litigation rule will impact how they structure their rule of reason analyses.

B. Why did the Courts not see Eye-to-Eye with the Antitrust Agencies?

The utter lack of common ground between the lower courts and the antitrust agencies raises the question of why courts maintained—in the face of increasingly insistent objection from the antitrust agencies—that reverse payment settlements deserve such permissive treatment. While doctrinal disagreement with the two quick-look

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205. *Id.* As an example of the latter method of rebutting the prima facie case, the court cited the scenario where "a modest cash payment . . . enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug." *Id*.

206. *Id.*

207. *In re* Cipro Cases I & II, 134 Cal. Rptr. 3d 165, 169 (Cal. App. 4th. 2011), *review granted*, 269 P.3d 653 (Cal. 2012) ("We hold that a settlement of a lawsuit to enforce a patent does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent, unless the patent was procured by fraud or the suit for its enforcement was objectively baseless.").

208. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

tests could provide at least a partial justification, the cognitive miser phenomenon offers a persuasive explanation for the adoption of the sham litigation rule.

1. Judicial Rejection of the Quick-Look Tests Moves Beyond Doctrinal Disagreement

Under one view, the continued gap between the courts and antitrust agencies during the quick-look phase could simply reflect disagreement with either the general appropriateness of quick-look or the specific iterations proposed by the agencies.

Quick-look is an important tool in the antitrust analysis, but it is not a multipurpose tool, and courts may have disputed the propriety of applying quick look in this context. Quick-look should be used only in limited circumstances, namely "when the great likelihood of anticompetitive effects can easily be ascertained."[209] Where a defendant can articulate "plausibly" procompetitive effects, such that a court cannot "initially dismiss [them] as presumptively wrong," quick-look review is inappropriate.[210] Some commentators have argued that there are credible procompetitive justifications for reverse payment settlements.[211] Even the DOJ has acknowledged the existence of plausible procompetitive effects.[212] Those who criticized the use of quick-look scrutiny were vindicated when the Court in *Actavis* explicitly rejected as inappropriate the FTC's invitation "to proceed via a 'quick look' approach."[213] Yet courts never relied on this explanation in their decisions, and even if it was *sub silentio* driving their rejection of the quick-look approach, this justification would not explain why courts chose the sham litigation rule instead.

Even assuming that the quick-look approach constituted the proper level of scrutiny in this context,[214] one could argue that courts

209. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

210. *Id*. at 775.

211. Butler & Jarosch, *supra* note 2, at 112-13. For these reasons, Butler and Jarosch argue that the DOJ's quick-look framework is inappropriate. *Id*. at 113-14. The authors focus on both direct and indirect procompetitive effects, such as greater long-term investment and innovation. *See also* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 504 (2007); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 760-65 (2004) (describing the "innovation costs" of prohibiting reverse payment settlements); Schildkraut, *supra* note 106, at 1060-67.

212. For an explanation of why the DOJ believes quick-look is appropriate here, see Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24-25.

213. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

214. *See* Brief for Plaintiff-Appellant Fed. Trade Comm'n, *supra* note 195, at 18-19

rejected the quick-look tests advanced by the antitrust agencies because they were uncomfortable with the premise of these particular proposals. Both the FTC's objective quick-look test from *In re Androgel* and the subjective quick-look test suggested by the DOJ in *Arkansas Carpenters* implicate the concept of probabilistic patent protection, which has drawn vocal criticism.

Under the objective quick-look test (as presented by the FTC to the Eleventh Circuit in the *Actavis* litigation), a reverse payment settlement would be struck down if a court determines it is more likely than not that the patent holder would have lost his suit against the generic.[215] Application of this test generates an objective estimate (as viewed from the time of the settlement's formation) of the probability the patent holder would have successfully wielded his patent in court to exclude a generic challenger. If that probability is below 50% then the reverse payment settlement is unlawful.[216] The Eleventh Circuit strongly rejected the contention that a patent holder with a 49% chance of winning its patent dispute—in other words, a patent holder likely to lose—should be deemed to have a patent with an exclusionary potential of zero.[217] A patent, the court insisted, must be given its full "*potential* exclusionary power" when determining the scope of the right to exclude.[218]

The subjective quick-look test relies on a similar presumption of probabilistic protection. Where the settlement's date of generic entry does not occur until the patent's expiration, the defendants have failed to rebut the prima facie case of anticompetitive effects, even if the parties to the settlement establish their genuine belief that the trial court more likely than not would have barred generic entry until the date of patent expiration.[219] The DOJ rationalized this facet of its

(articulating several factors which make reverse payment settlements worthy of the skepticism attached to quick-look analysis); *see generally* Elhauge & Krieger, *supra* note 93.

215. Brief for Plaintiff-Appellant Fed. Trade Comm'n, *supra* note 195, at 22.

216. *In re Androgel* involved an appeal from the district court's grant of defendants' motion to dismiss, based on an FTC complaint alleging the patent holder was "not likely to prevail" in its suit against the generic challengers. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1301 (11th Cir. 2012). Accordingly, the appeal focused on whether 'unlikely to prevail' sufficiently pled an antitrust violation. *Id*. The implication of the FTC's test is that when a patent holder is *likely* to win its underlying suit, the settlement would not constitute an antitrust violation. However, the FTC did not discuss the level of scrutiny to be applied in the latter scenario.

217. *Watson*, 677 F.3d at 1312-13 (11th Cir. 2012).

218. *Id.*

219. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 29.

quick-look test by explaining that given multiple settlement cases involving a generic company with less than a 50% chance of winning, at least one such case litigated to conclusion would "presumably" result in the generic challenger winning and entering.[220] Therefore, a reverse payment settlement with entry timed at the patent's expiration would be "anticompetitive because it eliminates the *possibility* of competition from the generic prior to the expiration of the patent."[221] This argument reflects the assumption, advanced by some economists, that "consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts."[222] The theory takes a macro view, aggregating hypothetical potential reverse payment settlements and emphasizing that even if the patent holder was significantly more likely than not to prevail in each suit, if all were litigated, then on average some generic entry would have occurred prior to settlement. Because consumers have a property right in that "possibility of competition" prior to the expiration of the patent, destruction of the possibility is anticompetitive. These arguments are the flip side of the probabilistic patent protection coin: the probability a patent will fail to enable its holder to exclude a generic challenger is the possibility of competition, and this possibility should inure to consumers' benefit.

With near uniformity, the lower courts criticized probabilistic patent protection as incompatible with the rights accorded to patent holders.[223] As one court noted, adopting the "concept of a public property right in the outcome of private lawsuits" would be tantamount to imposing an unprecedented "duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the

220. *Id*. at 30.

221. *Id*. at 29-30.

222. *See* Shapiro, *supra* note 106, at 396. Carl Shapiro held the position of Chief Economist at the Antitrust Division of DOJ from 2009-2011. *Haas Faculty Serve in Federal Government*, UNIVERSITY OF CALIFORNIA-BERKLEY, http://www.haas.berkeley.edu/faculty/gov.html (last visited Feb. 15, 2013). *See also In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 531 (E.D.N.Y. 2005) (describing the FTC's "reli[ance] on the economic analysis advocated by Professor Carl Shapiro regarding consumers' 'expected' gain from the patent challenge").

223. *See*, *e.g*., FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312-13 (11th Cir. 2012); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008); *In re* K-Dur Antitrust Litig., CIV.A.01-1652(JAG), 2009 WL 508869, at *24–25 (D.N.J. Feb. 6, 2009) *report and recommendation adopted*, CIV. A. 01-1652 JAG, 2010 WL 1172995 (D.N.J. Mar. 25, 2010); *but see In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).

consumer."[224] Commentators have pointed out that allowing a plaintiff to leverage even a low possibility of harm into actual harm is a radical departure from traditional civil burdens of proof, which require the plaintiff to prove that the defendant was more likely than not the source of his harm.[225] Potentially anticompetitive agreements are also generally held to this same standard; even if there is a possibility of diminished competition, the agreement will not be struck down unless that possibility is more likely than not to occur.[226] In contrast, the "probabilistic patent protection" school of thought effectively condemns an agreement if any possibility of diminished competition results. Marc Schildkraut, former Assistant Director of the FTC, has expounded up the unusual nature of this approach:

> Consider, first, a merger subject to Section 7 of the Clayton Act. The parties to the merger freely concede that the merger has no efficiency benefits. The merging parties are not direct competitors. There is, however, a 10 percent chance that the acquirer will enter the acquired party's market in the next few years. Under the [probabilistic patent protection theory], the merger should surely be condemned—there is a 10 percent diminution of uncertain competition. Of course, antitrust tribunals using . . . traditional civil standards would not condemn this merger.[227]

Applying either of the agencies' quick-look tests would entail adopting the probabilistic patent protection theory, including implications that are arguably incongruous with the standard judicial approach to antitrust challenges specifically and causation more generally. Although the majority's opinion in *Actavis* was premised on an acceptance of the probabilistic patent protection theory, the dissent mounted a fervent attack on the coherence of this theory, particularly when taken to its logical extensions.[228] Courts may have had valid doctrinal reasons for selecting alternate frameworks.

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

225. Schildkraut, *supra* note 106, at 1049 (citing RESTATEMENT (SECOND) OF TORTS § 433B cmt. 1 (1965)); *see also* Schering-Plough Corp., Upsher-Smith Labs., & Am. Home Prods. Corp., No. 9297, 2002 WL 1488085, at *1 (F.T.C. June 27, 2002). There are exceptions, of course, including strict liability and comprehensive statutory schemes, such as the National Childhood Vaccine Injury Act of 1986, which dispenses with the causation requirement for individuals who suffer certain delineated side effects following administration of a vaccine. *See* Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073-74 (2011).

226. Schildkraut, *supra* note 106, at 1049.

227. *Id.* at 1050.

228. *Compare* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2238 (2013), *with* Schildkraut, *supra* note 106, at 2240 (Robert, C.J., dissenting).

Beyond doctrinal disagreement, the credibility of the antitrust agencies on the topic of reverse payment settlements may have been burdened by the judiciary's sense of whiplash over the past decade. Both agencies have significantly altered their approaches, generally with little justification. The DOJ began by vaguely intimating that an objective assessment of the merits must be utilized as part of a rule of reason approach.[229] It then switched to a subjective inquiry,[230] rejecting its previous suggestion to litigate the patent infringement question as "neither necessary nor appropriate."[231] Not only did the mode of analysis shift, but the DOJ's entire attitude transformed. Initially the DOJ adopted a solicitous posture, noting that the "public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."[232] The DOJ later insisted the settlements should be viewed as presumptively unlawful.[233] Although the FTC's attitude toward reverse payment settlements has been consistently chilly, it has undergone a similarly lurching evolution in terms of suggested frameworks. After a brief stint of advocating a per se illegal prohibition, the FTC attempted to persuade courts to adopt a subjective assessment of the parties' expectations, as embodied in a "hypothetical no-payment compromise on the entry date."[234] Despite initially rejecting as deeply flawed any attempts to objectively assess the merits of the underlying patent litigation,[235] the FTC would later offer up such a test in the *In re Androgel* litigation, while almost simultaneously signing on to the DOJ's new subjective quick-look test. To the extent these changes signal the speaker's uncertainty as to how reverse payment settlements should be reviewed, courts may have been even more inclined to disregard the antitrust agencies' offerings altogether.

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229. *See* Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 11.

230. The focus is on a "comparison between competition under the settlement and with what [the defendants] expected had the patent infringement suit been litigated to judgment." Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 28.

231. *Id*. at 24.

232. Brief for Dep't of Justice as Amicus Curiae, *supra* note 123, at 10-11.

233. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 10.

234. Brief of Respondent-Appellant at 44, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688-AA), 2004 WL 3557972.

235. Schering-Plough Corp., et al., 136 F.T.C. 956, 998 (2003).

But even if the strong trend of courts rejecting the antitrust agencies' proffered tests could be chalked up to tarnished credibility or doctrinal disagreement, it would leave unresolved the question of why courts coalesced around the sham litigation rule as their particular resolution. This rule is not without its own doctrinal weaknesses; yet the lower courts tended to respond to criticism by raising up as a shield both the law's general preference for settlement and the specific factors incentivizing settlement between companies acting under the shadow of the Hatch-Waxman regulatory scheme.[236] But settlement is no panacea. Some commentators have attacked "the standard presumption that settlement should always be encouraged," pointing out that settlements bear attendant costs because they can "reduce the legal system's ability to distinguish between legitimate and harmful activities."[237] Criticism of the sham litigation rule derives from just such a concern, namely that generously allowing settlement here will fail to deter patent holders from diverting some of their monopoly profits to potential generic competitors who could, and otherwise would, legitimately enter the market without infringing on the patent.[238] Courts were persistently undeterred by the suggestion that this may be one of the areas where settlement imposes significant adverse spillover effects. As the Second Circuit explained, settlement in this context is to be encouraged, "even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents."[239] Furthermore, courts generally sidestepped the issue of whether, despite achieving the traditional benefits of settlement, the parties' agreement nonetheless violated antitrust laws.

The nearly unwavering judicial trajectory in support of the sham litigation rule is also noteworthy given how little the courts engaged with allegations of misplaced reliance on the statutory presumption of validity.[240] This presumption is often cited as the reason d'être for viewing reverse payment settlements as valid and logical extensions of a patent holder's right to exclude.[241] There is a heightened

236. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1337 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 211-12 (2d Cir. 2006).

237. Ezra Friedman & Abraham L. Wickelgren, *No Free Lunch: How Settlement Can Reduce the Legal System's Ability to Induce Efficient Behavior*, 61 S.M.U. L. REV. 1355, 1366, 1373 (2008).

238. *Id.* at 1372 & n.75.

239. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212 (2d Cir. 2006).

240. 35 U.S.C. § 282 (West 2013) ("A patent shall be presumed valid.")

241. *See, e.g.*, *In re Cipro*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 211; Schering-

standard of proof connected to this presumption, and a challenger can only overcome it by presenting clear and convincing evidence, rather than a preponderance of the evidence.[242] Yet as the Federal Circuit has explained, the statutory presumption of validity is but "a procedural device," serving to place the burden of persuasion on the alleged infringer.[243] As such, when patent holders seek a preliminary injunction, for example, they cannot rely upon the presumption as affirmative evidence they will win on the merits.[244] Some commentators have argued that allowing patent holders to obtain antitrust immunity based on the presumption of validity enables the statutory presumption to be transformed from a procedural device into substantive evidence of validity, despite the Federal Circuit's well-established prohibition on such a maneuver.[245] In the course of adopting and applying the sham litigation rule, even the Federal Circuit cited the presumption of validity but did not engage with this line of reasoning.[246] The Third Circuit identified this same criticism as one basis for its rejection of the sham litigation rule.[247]

To the extent the sham litigation rule is premised upon the presumption of validity, its foundations are even shakier where the underlying patent suit involves only claims of non-infringement. Although courts have cited the statutory presumption of validity as a factor compelling their adoption of the sham litigation rule and corresponding rejection of the concept of probabilistic patent protection, there is no statutory presumption of infringement or non-infringement. Consequentially, when a branded company files a suit alleging infringement, it bears the burden of proving that the

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Plough v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).

242. Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2247 (2011).

243. New Eng. Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed. Cir. 1992).

244. *Id.*

245. *See, e.g.*, Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 64 (2009); Joseph Vardner, Note, *The Statutory Presumption of Patent Validity in Antitrust Cases*, 25 HARV. J.L. & TECH. 225, 231-35 (2011). *See also* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 18-19 (citing *In re* Etter, 756 F.2d 852, 856 (Fed. Cir. 1985); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983)). Other commentators have argued that it is particularly misguided to place such great reliance on the presumption of validity because flaws in the patent approval process create significant doubts about the validity of the underlying patent in the first place. *See, e.g.*, Alan Devlin, *Revisiting the Presumption of Patent Validity*, 37 SW. U. L. REV. 323, 333-36 (2008).

246. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1337 (Fed. Cir. 2008).

247. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012).

competitor's product infringes on its patent.[248] The rationale for rejecting probabilistic patent protection does not fully translate to a reverse payment settlement borne out of allegations of infringement, rather than invalidity.

This tension was particularly palpable in *In re K-Dur*.[249] The plaintiffs argued their case merited application of a rule other than sham litigation because infringement, and not validity, was the original point of contention between the branded and generic companies.[250] Surely, they explained, the absence of an infringement presumption implies there is but a probability the generic would be kept off the market, and therefore courts should view patent protection as probabilistic.[251] Despite acknowledging the lack of a statutory presumption of infringement, the *In re K-Dur* district court refused to "discount the exclusionary power of [the] patent based on the possibility that it was not infringed by the [generic products]."[252] The court's rationale for this position amounted to little more than pointing out that, despite the absence of a presumption of *non-infringement*, there is no statutory presumption of *infringement*, and if the court discounted the patent's exclusionary power by the likelihood of non-infringement, it would be tantamount to assuming infringement existed.[253] The FTC had also raised this point in *Schering-Plough* and *In re Cipro*, but both courts of appeals rejected the argument and insisted on applying the sham litigation rule, regardless of the type of underlying claim.[254] This line of thinking has been particularly criticized because excluding non-infringing drugs cannot lie within a patent's exclusionary scope.[255] The Third

248. *See, e.g.*, Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1301 (Fed. Cir. 2011).

249. *In re* K-Dur Antitrust Litig., CIV.A.01-1652(JAG), 2009 WL 508869, at *25 (D.N.J. Feb. 6, 2009) *report and recommendation adopted*, CIV. A. 01-1652 JAG, 2010 WL 1172995 (D.N.J. Mar. 25, 2010), *rev'd* 686 F.3d 197 (3d Cir. 2012).

250. *Id.*

251. *Id.*

252. *Id.*

253. *See id.*

254. The FTC argued in *Schering-Plough* that because *Valley Drug*'s underlying patent litigation dealt with a claim of invalidity and *Schering-Plough*'s dealt with infringement, the Eleventh Circuit should analyze the latter under a framework distinct from *Valley Drug*; the court disagreed. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075-76 (11th Cir. 2005). *In re Cipro* dealt with an underlying patent suit involving both claims of invalidity and non-infringement, but the Federal Circuit panel did not differentiate between the two types of suits, and instead broadly held that unless the litigation was a sham, inquiry into the patent's validity was inappropriate. *See In re* Ciprofloxacin, 544 F.3d at 1328, 1337.

255. *See, e.g.*, Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26

Circuit represented the views of many of the sham litigation rule's detractors when it characterized application of the rule as "particularly misguided" in the infringement context.[256]

Judicial insistence on creating a broad safe harbor within which parties to patent litigation can freely settle on a relatively expansive set of potential terms created a chasm between the perspective of the antitrust agencies and the lower courts (with the exception of the Third Circuit's defection).[257] By coalescing around a presumption of illegality, the antitrust agencies were inclined to err on the side of overdeterrence and capture all anticompetitive settlements, even if legitimate ones were struck down in the process. Indeed the DOJ has admitted that under its rule, some reverse payment settlements that would otherwise create more competition than if the parties had not settled may be terminated.[258] In contrast, the sham litigation rule reflects a preference for underdeterrence. Even if a reverse payment settlement may have delayed generic entry, the lower courts were willing to let it survive, displaying a remarkable hesitancy to revisit the intricacies of a settlement.[259] These fundamentally different preferences for how reverse payment settlements should be treated moves beyond simple dissatisfaction with the particular frameworks

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SANTA CLARA COMPUTER & HIGH TECH. L.J. 141, 162 (2010).

256. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012).

257. Politics may initially appear to be a tempting explanation for the impasse, particularly given the composition of the majority and the dissent in *Actavis*. (Justice Breyer, writing for Justices Kennedy, Ginsburg, Sotomayor, and Kagan, rejected the sham litigation rule, while the more conservative trio of Chief Justice Roberts and Justices Scalia and Thomas would have approved the use of the sham litigation rule. FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013). Justice Alito was recused from the proceedings). *Id.* To be sure, the sham litigation rule's sharpest critics in the lower courts were also concentrated amongst the appointees of Democratic presidents, for example: Judge Pooler (Clinton, Second Circuit), *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212 (2d Cir. 2006) (Pooler, J. dissenting), and Judge Sloviter (Carter, Third Circuit), *In re K-Dur Antitrust Litig*., 686 F.3d. But judges appointed by both Democratic and Republican presidents perpetuated the trend in the lower courts by adopting the sham litigation rule, for example: Judge Anderson (Carter, Eleventh Circuit), Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003) (Judge Anderson authored the *Valley Drug* opinion), Judge Sack (Clinton, Second Circuit), *In re Tamoxifen*, 466 F.3d, Judge Trager (Clinton, E.D.N.Y.), *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), Judge Greenaway (Clinton, D. N.J., Obama, Third Circuit), *In re* K-Dur Antitrust Litig., 338 F. Supp. 2d 517 (D. N.J. Sept. 29, 2004), and Judge Kravitch (Carter, Eleventh Circuit) and Judge Farris (Carter, Ninth Circuit, sitting by designation). FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012).

258. *See* Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 24-25; *see also* Butler & Jarosch, *supra* note 2, at 120-21 (explaining that the DOJ framework will lead to an increase in Type I errors).

259. *See In re Ciprofloxacin*, 544 F.3d at 1337; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212 & n.26 (2d Cir. 2006).

suggested by the antitrust agencies, and hints at some additional motivation for the judiciary's course of action. The especial burdens generated by patent litigation, which would be rendered even greater if a rule of overdeterrence with respect to settling was adopted, was pushing the judiciary towards the adoption of a permissive bright-line rule.

2. Courts as Cognitive Misers

Judicial adoption of the sham litigation rule bears a strong resemblance to judges acting as cognitive misers, particularly given that many of the district and appellate judges faced with reverse payment settlement cases do not have the patent law expertise of the Federal Circuit. When employing the sham litigation rule, courts appeared content to uphold reverse payment settlements so long as they allowed for entry prior to patent expiration and did not evince a palpable manipulation of Hatch-Waxman, for example by creating a bottleneck or obtaining a thirty-month stay via the filing of objectively baseless litigation. Otherwise, courts have explained that if a patent really is weak, generic companies will continue to attack it, and a brand-name manufacturer will not be able to afford ongoing protection through repeated reverse payment settlements.[260] Manipulation of Hatch-Waxman and entry prior to patent expiration served as the cognitive shortcuts by which judges would decide whether to strike down a reverse payment settlement under antitrust law. If a reverse payment settlement fell within a broad safe harbor, the court needed to undergo only minimal engagement with both the patented innovation at issue and the details of the consideration the parties exchanged. When viewed from the perspective of cognitive misers, judicial willingness to cling to the sham litigation rule was a symptom of the search for a bright-line rule-based approach.

Yet the FTC's objective quick-look test and the DOJ's subjective quick-look test are both relatively formalistic, and both are what Professor Louis Kaplow would term "presumptive rules," in that the "rule applies unless there appears to be sufficient reason not to apply it."[261] Therefore at first blush, adopting either of these frameworks

260. *See, e.g.*, FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008) *and aff'd in part sub nom*., Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010); *but see In re* K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012).

261. Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 561 n.6 (1992).

may appear just as consistent with the cognitive miser phenomenon. However upon closer inspection, the cognitive miser phenomenon does in fact predict the judiciary's adverse response to the antitrust agencies' proposals.

First, although the quick-look test the FTC put forward in *In re Androgel* avoided a comprehensive rule of reason analysis, the test required an adjudication of the underlying patent claims as a threshold issue. Engaging in a trial-within-a-trial, even where the embedded trial does not reflect an adversarial proceeding between the parties who actually have adverse interests in its outcome, is not a new proposition; for example courts for years have done so in the context of malpractice claims against attorneys.[262] Yet while resolution of the antitrust challenge would be fairly straightforward once the merits of the claims were analyzed,[263] adjudicating a patent dispute as a threshold inquiry in an antitrust challenge is not particularly conducive to heuristic shortcuts, as discussed previously with respect to the DOJ's initial rule of reason proposal. Such a task would add significant patent-related technological engagement to antitrust suits.

Indeed this aspect of the FTC's objective quick-look test appeared to pose the biggest affront to the Eleventh Circuit in *In re Androgel*. Some may interpret the court's aversion as flowing simply from a general institutional concern over scarce resources. The Supreme Court in *Actavis* openly speculated that "a general legal policy favoring the settlement of disputes" and an "underlying practical concern . . . that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent"—which would necessarily "prove time consuming, complex, and expensive"—were driving the sham litigation rule's popularity.[264] The Court even chided the Eleventh Circuit for adopting a rule based on a single rationale, "the desirability of settlements."[265] Moving settled claims back into the spotlight of litigation undeniably imposes systemic costs on the courts as institutions, the parties as litigants, and

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262. *See, e.g.*, Joseph H. Koffler, *Legal Malpractice Damages in a Trial Within a Trial—A Critical Analysis of Unique Concepts: Areas of Unconscionability*, 73 MARQ. L. REV. 40, 41 (1989).

263. It would be straightforward, at least, if the patent holder was found more likely than not to have lost the underlying suit. In this case, the settlement would be illegal. However, the FTC never elucidated the framework for analyzing whether a settlement was anticompetitive where the patent holder *was* likely to have won. *See In re* Cipro Cases I & II, 134 Cal. Rptr. 3d 165, 169 (Cal. App. 4th. 2011), *review granted*, 269 P.3d 653 (Cal. 2012).

264. FTC v. Actavis, Inc., 134 S. Ct. 2223, 2234 (2013).

265. *Id.* at 2237.

the public as taxpayers. As the Eleventh Circuit pointed out, the FTC's test would erase most of the benefits of settlement, as parties would be forced to litigate the very claims they had sought to avoid litigating.[266] Across a spectrum of legal areas, courts frequently cite a general public interest in settlement as a means of ending complex and expensive litigation.[267] The Eleventh Circuit was likely sensitive to these traditional concerns when considering which test to adopt. Any mode of analysis requiring litigation of claims otherwise disposed of out of court imposes burdens the judiciary will be disinclined to accept, absent offsetting benefits.[268]

This rationale ultimately falls short because the Eleventh Circuit moved beyond praising the traditional benefits of settlement, to also address concerns specific to the task of analyzing patents. In closing, the court first emphasized its strong distaste for "attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment."[269] But the court then went on to explain how this undertaking was all the more inappropriate because it and its appellate colleagues outside the Federal Circuit were "ill-equipped to make a judgment about the merits of a patent infringement claim."[270] Congress intended for "appeals involving patent issues" to be handled by the Federal Circuit alone, and the FTC's approach would be "in tension" with this goal.[271]

To a certain extent, this is a valid point. While any district court can be called upon to analyze the merits of a patent infringement claim—bringing to bear no more expertise than the Eleventh Circuit—its decision is ultimately subject to review by the Federal Circuit. In contrast, under the FTC's test, a decision at least implicating the merits of a patent infringement suit could completely

266. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1314 (11th Cir. 2012).

267. *See, e.g.*, Ehrheart v. Verizon Wireless, 609 F.3d 590, 594-95 (3d Cir. 2010); Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed. Cir. 2001); United States v. Glens Falls Newspapers, Inc., 160 F.3d 853, 856-57 (2d Cir. 1998).

268. *Cf.* William B. Rubenstein, *A Transactional Model of Adjudication*, 89 GEO. L.J. 371, 373 (2001) (arguing that civil litigation has evolved into transactional deals, largely driven by a "judicial branch [which] has a vested interest in transactions that create finality because they are thereby absolved of adjudicatory work").

269. *Watson Pharm.*, 677 F.3d at 1315.

270. *Id.*

271. *Id.* When Congress created the Federal Circuit in 1982, it granted the court exclusive jurisdiction over appeals "from a final decision of a district court . . . relating to patents." 28 U.S.C. § 1295(a)(1) (2011).

circumnavigate Federal Circuit scrutiny.[272]

But the Eleventh Circuit appears to protest too much. The Federal Circuit is not the sole arbiter of all "appeals involving patent issues." Instead, a more limited pool of claims, namely those "arising under" patent law, fall within the exclusive jurisdiction of the Federal Circuit.[273] Not all claims implicating patent questions "arise under" patent law.[274] Patent law and antitrust have coexisted in cases both within the Federal Circuit[275] and outside of it.[276] Indeed, patent law has for years crept into cases outside of the Federal Circuit in a variety of contexts,[277] and continues to do so with little suggestion that ex-Federal Circuit appellate courts should be stripped of their jurisdiction to hear them. The Eleventh Circuit certainly made no attempt to argue it lacked jurisdiction over the case because the claims should be viewed as "arising under" patent law. Instead, the court couched its comment within a discussion of its own lack of expertise. In other words, if the court were to apply the FTC's framework, the claims would still be properly before the court from a jurisdictional perspective, but in terms of institutional experience the task of adjudication would be better channeled through the more technologically-savvy Federal Circuit.[278] In order to avoid a perceived mismatch between subject matter and expertise of the

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272. *See* Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 808-09 (1988) (explaining that a case raising patent law only as a defense does not fall within the exclusive jurisdiction of the Federal Circuit and therefore is appealed to the regional circuit court of appeals).

273. *See* Biotechnology Indus. Org. v. Dist. of Columbia, 496 F.3d 1362, 1367 (Fed. Cir. 2007) ("This court has exclusive jurisdiction to review cases . . . 'arising under' the patent laws.").

274. 8 CHISUM, CHISUM ON PATENTS § 21.02[1].

275. For example under the affirmative defense of "patent misuse," patent holders who "impermissibly broaden[] the physical or temporal scope of the patent grant," generally through a violation of antitrust law, will be unable to enforce their patents against alleged infringers. *See, e.g.*, Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1326-31 (Fed. Cir. 2010).

276. *See, e.g.*, *In re* DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677 (2d Cir. 2009); Covad Communications Co. v. Bell Atl. Corp., 398 F.3d 666 (D.C. Cir. 2005) ("Our review of the patent courts' opinions convinces us that Bell Atlantic's case against Covad was not objectively baseless.").

277. *See, e.g.*, Wisc. Alumni Research Found. v. Xenon Pharm., Inc., 591 F.3d 876 (7th Cir. 2010); Dawn Equip. Co. v. Micro-Trak Sys., Inc., 186 F.3d 98 (7th Cir. 1999).

278. In a similar vein, some have suggested that reverse payment settlements be handled solely through the patent system, rather than using antitrust law and generalist courts. *See* Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 318-33 (2011) (arguing that a superior method of differentiating between pro- and anticompetitive reverse payment settlements would be to send the disputed patent through the Patent and Trademark Office's patent reexamination proceedings).

adjudicator, the court rejected the FTC's test in favor of the sham litigation rule. Just as "Federal Circuit formalism creates hard-edged rules that reduce the weight and scope of technological inquiries,"[279] the sham litigation rule creates a framework that significantly reduces the necessity of inquiring into the patented technology that was the subject of the contested settlement.

If courts are unconsciously receptive in this context to applying a rule in lieu of a holistic standard, and one that avoids mimicking a miniature patent trial, why stick with the sham litigation rule when the DOJ's bright-line presumptively illegal rule also avoids any assessment of the patent dispute? Two forces related to the cognitive miser phenomenon drove the judiciary's preference for the sham litigation rule over a DOJ-type presumptively illegal rule. First, a presumptively illegal rule is still much more information-demanding than the sham litigation rule. Second, such a rule threatens adverse long-term consequences for courts, not merely in terms of fewer settlements in general but a greater influx of patent litigation.

A presumptively illegal rule requires the defendants to bear the burden of proof to show the payment was not for delay. The settling defendants start with an uphill battle because, as described above, this type of approach views the possibility of competition between the companies as a property right held by consumers. In light of the foregoing discussion regarding exclusion rules and in rem rights, it is unsurprising that the DOJ selected a fairly bright-line rule to protect the consumers' property right—hence the presumption that a conflicting 'use' of this property right by the settling companies will not be tolerated. However, a presumptively illegal test flips the perspective of the entitlement holder. Instead of protecting a patent holder's property right, the test is concerned with protecting consumers' property right in the possibility of competition. The DOJ did blunt its exclusion rule by interposing elements of a governance regime and allowing a reverse payment settlement to survive in certain narrow situations. Defendants could rebut a plaintiff's prima facie case of anticompetitive effects (created whenever there is a settlement with a predetermined entry date and compensation flowing from the branded to the generic company), by showing that the settlement did not result in a level of competition significantly less than they expected to occur if the patent suit was litigated to a final

279. Lee, *supra* note 6, at 41.

judgment.[280]

Interjecting a cost-benefit analysis as a backstop serves as a departure from the pure exclusion end of the exclusion-governance spectrum, but the move is entirely consistent with this theory of property rights. As Professor Smith explains, elements of governance are often added to an exclusion regime as "a supplemental fine-tuning" device when "the pressure on and value of resources rise."[281] The FTC has estimated that delayed entry of a generic by even one year has a multi-million dollar impact on third-party payers and consumers.[282] The DOJ evidently views drug policy as sufficiently complex, and the intellectual property at stake sufficiently valuable, to merit application of a test offering more flexibility than a pure exclusion rule could provide. The generic companies in any given settlement may be in vastly different positions in terms of their own financial strength and the merits of their claimed right to market a generic product. If the settling parties can show that the generic manufacturer would actually be unlikely to both win in court and have the capacity to timely become a vigorous competitor, the DOJ has in effect determined that consumers are better off if the settling companies are permitted to act in ways contrary to what it has defined as the consumers' property right.[283]

But the additional nuance from this supplemental governance regime comes, as always, with a price, and when courts evaluate the defendants' rebuttal, they bear far higher information costs than when they apply the sham litigation rule. As discussed above, if the amount of the payment is not roughly in line with the branded company's saved litigation costs, the DOJ would require the defendants to prove that the settlement's entry date truly reflected their evaluations of the likely outcome of the underlying litigation. The DOJ acknowledged "precision is impossible" with respect to this counterfactual inquiry, but maintained that settling parties could successfully defend themselves by "providing a reasonable explanation" of other consideration received in exchange for the reverse payment.[284] When the Third Circuit adopted a presumptively illegal rule in *In re K-Dur*,

280. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 28.

281. *Nuisance*, *supra* note 25, at 989.

282. Fed. Trade Comm'n, *supra* note 3, at 2.

283. *Cf. Nuisance*, *supra* note 25, at 978-79.

284. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 31-32.

it described two ways for defendants to rebut the prima facie case. The first option was the DOJ's inquiry into the value of other consideration the branded company had received in exchange for its payment; the second, "probably rare" option would allow a patent holder to show that the reverse payment settlement "offers a competitive benefit that could not have been achieved in the absence of a reverse payment," such as where "a modest cash payment . . . enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug."[285]

As an initial matter, the premises of the Third Circuit's test confirm that the second option will rarely be a realistic option for most defendants. This rule begins with the presumption that the settlement erased some possibility of competition. Accordingly, the defendants would have to show that this possibility of competition would not actually have come about and thus the settlement, with its pre-expiration entry date, would in fact lead to more competition than if the parties had not entered into the settlement. One way of demonstrating that the possibility of competition was but a mirage would be to establish that the patent holder would have won in court. But because the Third Circuit refused to look at the merits of the underlying patent suit, the defendants would be relegated to showing that, even assuming the patent posed no obstacle, the generic company was not in a position to enter the market. Realistically, only a narrow segment of settling defendants have such a relationship. For all practical purposes, then, they would have had to pursue the first option.

To succeed, the defendants would need to provide a thorough explanation of the technology at issue in order to facilitate a decision by the judge over the reasonableness of the consideration exchanged. Particularly in comparison with the sham litigation rule, this would entail considerable technological engagement. The sham litigation rule, which does not offer a rebuttal phase, avoids this type of inquiry. Far less information is necessary for a judge to determine that the underlying infringement suit was not baseless, the settlement did not restrict sales of drugs not at issue in the patent litigation, and entry occurred prior to the expiration of the patent.

There is a second facet to the explanation of how the cognitive miser phenomenon drove the vast majority of courts to select the sham litigation rule over the presumptively illegal rule. The very

285. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

preference for a bright-line rule with a default that stems the long-term flow of patent litigation is consistent with courts acting as meta-cognitive misers. Adopting a rule that facilitates reverse payment settlements means parties are more likely to settle potential future patent disputes, allowing judges to avoid altogether the technological engagement required by a patent infringement suit.

A presumptively illegal rule threatens to siphon off patent disputes that would have been settled out of court and instead forces the judiciary to review these notoriously complex cases.

Not only does the rule's default bar settlement—in contrast to the sham litigation rule's default, which upholds the settlement—but it is difficult to imagine a defendant overcoming the prima facie case. The cumulative effect is an ex ante decrease in the incentive to attempt to settle at all.[286] Moreover, adopting a presumptively illegal rule could have spillover effects and inhibit a broader scope of patent-related agreements. The test implicitly presumes consumers have a property right in the possibility of competition prior to the expiration of the patent. Once this concept establishes a toehold, ex-pharmaceutical industry patent settlements or even licensing agreements between patent holders and potential competitors could be vulnerable to the chilling threat of an antitrust suit.[287]

Applying the sham litigation rule does simultaneously address some of the more short-term concerns driving settlement in general, namely protecting the limited institutional resources of the courts (and indirectly, the public fiscally). However, as this section will explain, reverse payment settlements are not the type of litigation that tends to be the subject of lighter judicial scrutiny. The generalist judge's often uncomfortable relationship with patent litigation provided the supplemental impetus to overcome the ardent objections from the antitrust agencies that broadly allowing all but the most egregious reverse payment settlements is injurious to the public.

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286. *See* Schildkraut, *supra* note 106, at 1049 (predicting that the "likely" result of courts applying a DOJ-type quick-look test based on probabilistic patent protection would be "far fewer settlements of patent litigations").

287. *See* Kevin D. McDonald, *Hatch-Waxman Settlements and Antitrust: on "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 72-73 ("If we define patents as having diminished 'strength,' why should protection of that alleged 'consumer surplus' be limited to settlements? Consider licenses. As Shapiro perceptively observes, '[v]irtually every patent license can be viewed as a settlement of a patent dispute.' When a patentee grants any license, therefore, should the government be scrutinizing the royalty rate to ensure that consumers face a price low enough to preserve their 'property right' in the possibility that the patent is invalid?"); *see also* FTC v. Actavis, 133 S. Ct. 2223, 2245 (2013) (Roberts, C.J., dissenting).

When appellate courts have adopted the sham litigation rule, they have generally been affirming a district court's decision to apply the same approach.[288] As the adjudicators on the front lines of patent litigation, district courts would have been particularly prone to selecting a framework of analysis not simply out of a general concern that settlement be encouraged, but as long-run cognitive misers seeking to stem the growing tide of patent claims. District courts have been experiencing a marked increase in patent litigation. In 2007, plaintiffs commenced 2,896 patent cases, and by 2011 this figure had increased by nearly 40%.[289] As district judge Patti Saris has noted, "Patent litigation is like the neurosurgery of litigation: it is hard scientifically and it is hard legally."[290] The Federal Circuit reverses district court patent decisions with relative frequency (as compared to the district court reversal rate in other areas of law), and Judge Saris further reflected that the "high reversal rate demoralizes many federal district court judges," rendering district courts nothing but "a weigh station along the way to" having their appeal heard by the Federal Circuit.[291] Given the combination of a technologically challenging area of law and a sense among at least some judges that it is also an area in which they achieve less success, a rule threatening to further inhibit settlement when patent cases are already on the rise would seem a ghastly specter.

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288. *See* FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012) (affirming approach of *In re* Androgel Antitrust Litig., 687 F. Supp. 2d 1371, 1378 (N.D. Ga. 2010)); Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010), as corrected (June 17, 2010), *cert. denied*, 131 S. Ct. 1606, 179 L. Ed. 2d 517 (U.S. 2011) (affirming approach of *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005)); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (same); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (affirming approach of *In re* Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 129 (E.D.N.Y. 2003)). Before the Third Circuit Court of Appeals rejected the sham litigation rule, both district courts faced with the choice chose the sham litigation rule. *See* King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 529 (E.D. Pa. 2010); *In re* K-Dur Antitrust Litig., CIV.A.01-1652(JAG), 2009 WL 508869 (D.N.J. Feb. 6, 2009) report and recommendation adopted, CIV. A. 01-1652 JAG, 2010 WL 1172995 (D.N.J. Mar. 25, 2010).

289. STATISTICS DIV., OFFICE OF JUDGES PROGRAMS, JUDICIAL BUSINESS OF THE UNITED STATES COURTS 130 (2011). Before 2007, the numbers were fairly level, for example in FY 2005 there were 2,720 patent cases filed in district court. STATISTICS DIV., OFFICE OF JUDGES PROGRAMS, JUDICIAL BUSINESS OF THE UNITED STATES COURTS tbl C-2 (2006). In FY 2003 there were 2,700 patent cases filed. STATISTICS DIV., OFFICE OF JUDGES PROGRAMS, JUDICIAL BUSINESS OF THE UNITED STATES COURTS tbl C-2 (2004).

290. The Honorable Kathleen M. O'Malley et. al., *A Panel Discussion: Claim Construction from the Perspective of the District Judge*, 54 CASE W. RES. L. REV. 671, 682 (2004).

291. *Id.*

Although the appellate courts were not as directly affected as the district courts by an increase in patent litigation, they would still reap institutional benefits from a rule that, by making most reverse payment settlement challenges futile, keeps them out of court. Furthermore, the appellate courts were aware of, and seemed to sympathize with, the added patent caseload the district courts would face if forced to apply a rule of presumptive illegality. The Second Circuit expressed concern that a rule "severely restricting patent settlements" would "forc[e] patent litigation to continue."[292] The Eleventh Circuit explained that a rule "foreclose[ing] a patentee's ability to settle its infringement claim" would increase "[p]atent litigation[, which] breeds a litany of direct and indirect costs."[293] Although appellate courts would not need to adjudicate the resulting jump in patent infringement suits both they and the district courts predicted would result from a rule of presumptive illegality, the appellate courts were palpably concerned with the consequences of such a rule.

That judges may act in ways that create institutionally advantageous case management is not a new proposition,[294] and in the recent era of austerity and budget cuts, the issue of how limited judicial resources affects the organization and output of the courts has received increased attention.[295] Professor Bert Huang has documented an analogous phenomenon, triggered by the Board of Immigration Appeals' (BIA) decision in 2002 to initiate a concerted effort to clear out a backlog of deportation cases.[296] Particularly because most of the BIA's subsequent decisions involved upholding deportation orders, the federal courts of appeals faced a deluge of

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292. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006).

293. *Schering-Plough*, 402 F.3d at 1074-75.

294. *See, e.g.*, Jonathan R. Macey, *Judicial Preferences, Public Choice, and the Rules of Procedure*, 23 J. LEGAL STUD. 627, 623-35 (1994) (arguing that judges are prone to using the rules of procedure in ways that will enable them to avoid presiding over cases which they do not wish to decide on the merits).

295. *See, e.g.*, Marin K. Levy, *Judicial Attention As A Scarce Resource: A Preliminary Defense of How Judges Allocate Time Across Cases in the Federal Courts of Appeals*, 81 GEO. WASH. L. REV. 401 (2013) (describing how courts institute case management practices such as staff attorney review and no argument submission so as to use limited judicial resources in a way that maximizes error correction and law development); Andrew B. Coan, *Judicial Capacity and the Substance of Constitutional Law*, 122 YALE L.J. 422 (2012) (arguing that limited judicial capacity has influenced the Supreme Court's decisionmaking in "high volume" and "high stakes" constitutional cases, by "creat[ing] strong pressure on the Court to embrace hard-edged categorical rules, defer to the political process, or both").

296. Bert I. Huang, *Lightened Scrutiny*, 124 HARV. L. REV. 1109, 1122 (2011).

petitions for review.[297] The avalanche happened to be concentrated in the Second and Ninth Circuits and continued unabated for several years, thereby setting the stage for a natural experiment. Huang compared the overall reversal rate of district court opinions in the Second and Ninth Circuits with the reversal rate in the other, relatively unaffected circuits.[298] In the two circuits enduring a surge in BIA appeals, the rate at which district courts were reversed dropped significantly.[299] Huang dubbed this phenomenon "lightened scrutiny": because the influx of BIA appeals severely strained the resources of the Second and Ninth Circuits, these courts effectively chose to triage, shifting resources at the margins away from review of district court decisions and toward review of the BIA cases.[300]

Selection of the sham litigation rule reflects a similar type of institutional decision to employ lightened scrutiny on reverse payment settlements. First, this application of lightened scrutiny implicates concerns over limited capacity. Patent cases are notoriously resource-intensive,[301] so much so that district courts have increasingly adopted local rules applicable only to patent litigation, with the goal of streamlining their resolution.[302] Alongside the 40% increase in patent cases from 2007–11, there was also a 5.8% increase in total cases[303] and the average number of cases per judgeship rose from 380 to 427.[304] To the extent the rise in patent litigation has strained present and threatened future district court resources, it seems natural that it contributed to the subconscious decision to effectively apply lightened scrutiny to reverse payment settlement cases. If the path to settlement is obstructed, courts may reasonably fear that they will not have the resources to deal with the resultant increase in patent litigation. Applying the sham litigation rule mitigates the costliness of technological engagement in the long run, by allowing would-be

297. *Id.* at 1122-23. BIA decisions are appealed directly to the appellate court with jurisdiction over the state in which the immigration judge who initially processed the foreign national is located. *Id.* at 1123, 1125.

298. *Id.* at 1130-34.

299. *Id.*

300. *Id.* at 1137.

301. *See* AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY (2011).

302. JOESPHE E. CWIK, LITIGATION STRATEGIES FOR INTELLECTUAL PROPERTY CASES (2012), *available at* 2012 WL 1670113.

303. STATISTICS DIV., OFFICE OF JUDGES PROGRAMS, JUDICIAL BUSINESS OF THE UNITED STATES COURTS 10 (2011).

304. *Id.* at 16.

patent litigants to pursue a broader range of settlement terms.[305]

Using the sham litigation rule as a mechanism to apply lightened scrutiny may reflect not only a judicial concern with more patent litigation in the long term, but an intuition that more intensive adjudication of reverse payment settlement cases is an inefficient use of resources. As Judge Saris's comments allude to, many district courts may lack confidence they are getting it right when they analyze legal issues involving patents. The sham litigation rule is consistent with triaging to shift resources to areas where they will have a greater marginal benefit—in other words to where courts are more comfortable they can accurately apply their legal acumen.

This motivation also explains why the judiciary's triage of resources away from reverse payment settlements otherwise seems to conflict with how courts otherwise tend to allocate their limited resources. Professor Marin Levy analogously hypothesized that appellate courts seeking to maximize their "output" of "error correction and law development" would "seek out certain cases—those that are complex and those that present novel issues of law" and apply relatively higher levels of judicial resources to these cases, while "certain kinds of cases—repeating appeals, patently frivolous appeals, and those that have received at least one meaningful review before reaching the appellate courts" would receive "less judicial attention."[306] Levy found that appellate court case management techniques were consistent with her predictions.[307] For example, cases involving repeating issues such as sentencing appeals are very frequently decided on the briefs primarily by staff attorneys, while cases that were already reviewed prior to arriving on the district court's docket, such as Social Security and BIA appeals, are also given no-argument status at very high rates.[308] Implementing these types of institutional case management rules allow judges to maximize the "output" achieved with fairly fixed inputs by "spend[ing] less of their own attention"—arguably the most costly and limited judicial resource—"on cases that they thought could be

305. Defenders of reverse payment settlements argue that different positions in terms of risk aversion and information asymmetries can lead to situations where bargaining would be unlikely to lead to a mutually agreeable settlement if reverse payments were off the table. *See* John P. Bigelow, *Pharmaceutical Patents, Settlements, "Reverse Payments," and Exclusion*, CPI ANTITRUST CHRONICLE 4-5 (June 2012).

306. Levy, *supra* note 295, at 435.

307. *Id.*

308. *Id.* at 436-38.

corrected without full judicial treatment."[309]

District courts, as much as the appellate courts Levy analyzed, would be incentivized to maximize the value of their legal output within the constraints of fixed resource inputs. Levy's work, then, predicts that antitrust challenges to reverse payment settlements, as "complex" cases involving "novel issues of law," should receive "full judicial treatment."[310] Yet both district and appellate courts crafted a legal rule that insulates the vast majority of such cases from almost any judicial review. The judiciary seems to have manifested a conviction that pouring resources into these cases would not maximize the value of their legal output.

Shifting resources away from areas in which they feel relatively ill-equipped to adjudicate accurately is also a way of deferring to those with greater expertise: the parties themselves. Such deference to authority is yet another typical expression of the cognitive miser phenomenon.[311] Indeed, the assumption that the parties, rather than the courts, know best was a recurrent element of judicial approval of the sham litigation rule. As the District Court for the Eastern District of New York explained, it is to be "expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments."[312] If a branded manufacturer were able to slip through a settlement that effectively pays a generic to stay off the market, courts frequently explained that the economics of the situation predicts it would not be a long-term problem, particularly given Hatch-Waxman's incentives for generics to file suit.[313] Courts are aware that patents are a particularly effective promoter of innovation in the pharmaceutical industry,[314] and they may have believed that a judge's decision about whether generic entry occurred "too late" under a settlement would simply end up being wrong more often than not, disturbing the balance of incentives to innovate.[315]

309. *Id.* at 431.

310. *Id.*

311. Lee, *supra* note 6, at 24.

312. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005). See also FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012); In re Tamoxifen, 466 F.3d at 211-12. In choosing the alternate course, the Third Circuit Court of Appeals explicitly disagreed that "subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger." *In re* K-Dur Antitrust Litig., 686 F.3d 197, 215 (3d Cir. 2012).

313. *See In re Ciprofloxacin*, 363 F. Supp. 2d at 535.

314. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507-15 (2009).

315. *Cf.* Frank H. Easterbrook, *On Identifying Exclusionary Conduct*, 61 NOTRE DAME L.

The parties themselves know more about the relevant technology and relative strength of the patent, and through private bargaining may reach a more accurate assessment of when, prior to patent expiration, generic entry is warranted.[316]

Some might argue that selection of a default rule that upholds reverse payment settlements simply reflects the oft-noted preference in the antitrust context for Type II errors (wrongly allowing an anticompetitive agreement to stand) over Type I errors (wrongly condemning an agreement as anticompetitive).[317] But this explanation fails to account for the dramatic nature of the split between the courts and the antitrust agencies. Many commentators have noted that the antitrust agencies have also participated in the judiciary's trend toward preferring Type II errors over Type I errors.[318] But the antitrust agencies have become so convinced of the anticompetitive effects of reverse payment settlements that they have

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REV. 972, 977-78 (1986) ("[T]he rules must accommodate the judges' limits, rather than the other way around. In other fields, the inability of judges to decide what is efficient business conduct and what is not is a foundation for powerful rules compelling judges to keep their hands off—in corporate law this is known as the business judgment doctrine. Why should antitrust law demand of judges and juries answers that other branches of the law know courts cannot supply?").

316. *Cf.* Brief of Various Law & Economics Professors as Amici Curiae in Support of Respondents at 24-25, eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (No. 05-130) ("Often price is not the only important term in these deals and courts are woefully inadequate compared to the marketplace for determining and enforcing these other terms . . . [P]rivate ordering among parties can lead to textured contracts having many terms including price but also including a host of seemingly esoteric and unique provisions—such as technical support, field-of-use or territory limitations, grant-backs, cross-licenses, payment schedules, most-favored-nation provisions, etc. . . ."); *Nuisance*, *supra* note 25, at 985 ("Given positive information costs, there is good reason to think that using the exclusion strategy often yields a better result than would combining governance rules and devices to minimize strategic behavior. Under governance rules, a court has to weigh the value of various uses . . . . Where courts have limited abilities to identify and evaluate the competing information about uses presented by parties . . . [they] can engage in strategic behavior that defeats the owner's investment in the asset.").

317. *See* Alan Devlin & Michael Jacobs, *Antitrust Error*, 52 WM. & MARY L. REV. 75, 113-15 (2010); *see also* Fred S. McChesney, *Talking 'Bout My Antitrust Generation: Competition For and in the Field of Competition Law*, 52 EMORY L.J. 1401, 1413 (2003) (describing shift in antitrust law toward a preference for Type II errors, based on a perception that their cumulative effect is less costly to general welfare); Easterbrook, *supra* note 166, at 15-17 (explaining that Type 1 errors are often more harmful than Type II errors because it is generally easier for the market to undercut and correct for monopolies than to correct for judicial errors).

318. *See, e.g.*, William Bradford, *The Creation and Destruction of Price Cartels: An Evolutionary Theory*, 8 HASTINGS BUS. L.J. 285, 291 (2012); Devlin & Jacobs, *supra* note 317, at 79-83; Lawrence M. Frankel, *The Flawed Institutional Design of U.S. Merger Review: Stacking the Deck Against Enforcement*, 2008 UTAH L. REV. 159, 171-72 (2008) (discussing how institutional design of merger review incentives underenforcement by the FTC and DOJ).

selected a rule that openly acknowledges its preference for Type I errors. Courts, nonetheless, have stayed the course. The judiciary's preference for committing a Type II error rather than a Type I error, despite the agencies' implicit insistence that the invariably anticompetitive effect of these settlements overcomes any theoretical basis for preferring Type II errors, is a reflection of the cognitive miser phenomenon. If courts feel particularly pessimistic about their accuracy in identifying the truly anticompetitive deals, the agencies' vocal complaints about the especial harm these settlements pose would fall on deaf ears. Courts would prefer to avoid expending significant resources by entangling themselves in the details of the dispute, and instead commit a Type II error and allow the market participants to straighten out the consequences.

Prior to *Actavis*, courts consistently rejected the notion that the additional precision supplied by the DOJ's rule would be worth the costs of attempting to develop for themselves the necessary information about the settlement. The judiciary's overwhelming preference for the sham litigation rule indicates that they do not believe the benefits created by the extra precision and over-deterrence of the DOJ rule outweigh the costs of the sham litigation rule's under-deterrence, and it is the cognitive miser phenomenon driving this calculus.

V. ENDING THE IMPASSE

With the courts generally refusing to apply the strict review called for by the antitrust agencies, both sides had become entrenched in diametrically opposed positions. Congressional subcommittees entertained proposed legislative solutions to the disagreement, but no bill ever attained significant momentum,[319] despite the FTC's pleas to

319. Failed Senate proposals include Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007); Preserve Access to Affordable Generics Act, S. 3582, 109th Cong. (2006). Comparable bills have been introduced in the House, only to similarly stall in sub-committees. *See* Protecting Consumer Access to Generic Drugs, H.R. 1706 (2009); Preserve Access to Affordable Generics Act, H.R. 1432, 110th Cong. (2007). There have been several attempts to attach anti-reverse payment settlement provisions to other pieces of legislation—for example one such provision was added initially added to the Patient Protection and Affordable Care Act. Jared A. Favole, *Health Bill Drops Ban on Deals Between Brand-Generic-Drug Makers*, WALL ST. J. (Mar. 18, 2010 12:01 AM), http://online.wsj.com/news/articles/SB10001424052748704743404575128554066715036. One senator even sought to add a ban on reverse payment settlements to the bill reauthorizing FDA user fees, but the suggested amendment was voted down by a wide margin. U.S. Senate, U.S. Senate Roll Call Votes 112th Congress—2nd Session, On the Amendment (Bingaman Amdt.

Congress.[320] For nearly a decade the Supreme Court, too, stayed above the fray by repeatedly declining to grant certiorari in a reverse payment settlement case. The Court's decision in *Actavis* ended the impasse, but it did not terminate the impact of the cognitive miser phenomenon on antitrust challenges to reverse payments settlements. This driving force behind the persistence of the intergovernmental stalemate will significantly impact how the lower courts choose to execute the open-ended mandate in *Actavis*.

The Supreme Court rejected both the majority approach among the lower courts and the position of the antitrust agencies. The FTC sought approval of the minority rule from the Third Circuit.[321] The settling drug companies asked the Supreme Court to affirm the Eleventh Circuit and give its blessing to the sham litigation rule. The dissenters would have done so, insisting that "the rights conferred by the patent . . . form[] the zone within which the patent holder may operate without facing antitrust liability."[322] The majority instead held that, as in most antitrust challenges, courts must apply the rule of reason.[323] In effect, the Court settled on a compromise between the two warring factions.

In taking such a middle ground, the Supreme Court acted very much in keeping with its recent patent law decisions. As Professor Lee has observed, while the Federal Circuit has adopted a formalistic approach to patent litigation, the Supreme Court has been trending towards a "holistic" standard-based approach, requiring lower courts to "engage in multifactored examinations of inventions and their technological context."[324] Recently, and repeatedly, the Supreme Court has criticized the Federal Circuit for being too formalistic.[325] In

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No. 2111).

320. *See, e.g.*, Fed. Trade Comm'n, *supra* note 3, at 6; Rosch, *supra* note 104; Jon Leibowitz, Chairman, Fed. Trade Comm'n, Remarks at the Center for American Progress (June 23, 2009).

321. Brief for the Petitioner at 41, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027.

322. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2238 (2013) (Roberts, C.J., dissenting).

323. *Id.*

324. Lee, *supra* note 6, at 46-47.

325. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010) ("Section 101 is a 'dynamic provision designed to encompass new and unforeseen inventions.' A categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.'" (citations omitted)); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) ("Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content

turn, the Court has been accused of adopting broad, unwieldy standards, which it enjoys the luxury of rarely having to apply.[326] By rejecting the proposals of the parties before it as unnecessarily rigid and instead mandating a more amorphous inquiry, the Court mirrored its recent patent infringement decisions.

The Court left open "the structuring" of this rule of reason inquiry but observed that the likelihood of anticompetitive effects will depend on the payment's "size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[327] Despite listing several potential factors to consider, the opinion's concluding paragraph observes that trial courts are free to exercise great discretion in structuring their analyses, so long as they avoid "the use of antitrust theories too abbreviated . . . [or] consideration of every possible fact or theory irrespective of the minimal light it may shed on [the antitrust analysis]."[328] Simply warning lower courts against being too brief or too exhaustive confers upon them considerable unguided discretion. In particular, courts will have to answer four major questions as they decide how to proceed. The first is the extent to which the strength of the patent holder's infringement lawsuit can serve as a counterweight against factors otherwise indicating anticompetitive effects; or, vice versa, the extent to which a purportedly weak claim for infringement will be used as the signal of an anticompetitive settlement. Regardless of the answer to this question, courts must next determine what additional factors they will consider as part of their analyses. Third, one of these factors will undoubtedly be the size of the reverse payment, which the Court emphasized is a useful proxy for the likelihood of anticompetitive effects. But it is less clear how courts should use size to ascertain accurately this likelihood. Most would agree that the unique context of any given settlement demands a more nuanced inquiry beyond looking to the sheer magnitude of the payment. Finally, courts must determine which settlements are not encompassed within the ruling in *Actavis*, in other words which settlements need not undergo a rule of reason analysis. The cognitive

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of issued patents.").

326. *See* Lee, *supra* note 6, at 63 ("[T]he Court is free to announce broad, policy-oriented standards without considering the difficulties of applying them in myriad technological contexts. In an economic sense, the Court's preference for standards imposes an information-cost externality on district judges.").

327. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

328. *Id.* at 2238.

miser phenomenon sheds light on how the lower courts are likely to respond.

As to the first question, courts will generally be loath to rely on any significant inquiry into the merits of the patent infringement suit. The *Actavis* majority confidently predicted that litigating the very patent dispute the parties had attempted to bypass would itself be a largely avoidable task.[329] When the DOJ proposed a quick-look test, it shared the Court's optimism regarding the "unlikely" need to use "mini-trials of patent validity . . . in determining whether competition was unreasonably restrained."[330] The dissent criticized this sentiment as wishful thinking, prophesizing that settling defendants will stay silent on this issue only if they are barred from bringing it up.[331] When adopting a presumptively illegal rule, even the Third Circuit agreed "there is no need to consider the merits of the underlying patent suit."[332] Despite adopting a radically different approach than the majority of the lower courts, the Third Circuit's refusal to incorporate the merits of the underlying patent infringement suit into its inquiry was notably consistent with the sham litigation rule. Litigating the patent dispute as a threshold inquiry to an antitrust suit is simply a task any cognitive miser would prefer to avoid, and in fact is one nearly every court thus far has avoided. As courts move forward, they will likely take the Supreme Court up on its offer and generally find it "normally not necessary to litigate patent validity."[333] Regardless of how accurate this factor is as a proxy for anticompetitive effects, courts are unlikely to accord it a central role in their rule of reason analyses.

In its place, courts will turn to factors they can ascertain more reliably and at lower cost. Lee has argued that the high information costs often attendant to multi-factor balancing tests can be mitigated if the Supreme Court provides lower courts with guideposts more

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329. *Id.* The majority may have recognized that focusing on the strength of the patent holder's infringement lawsuit undercuts a purported rule of reason approach, by de facto imposing a per se bar on reverse payment settlements. This is so because there would be little incentive for parties to ever enter into a reverse payment settlement if they knew they would almost inevitably have to litigate the infringement suit anyway as part of an antitrust challenge. *See* Butler & Jarosch, *supra* note 2, at 115 & n.295.

330. Brief for the United States in Response to the Court's Invitation, *supra* note 170, at 31 n.13.

331. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2244 (2013).

332. *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

333. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2244 (2013).

clearly structuring its expected inquiry.[334] For example, the Court could delineate a relatively constrained set of weighted factors for courts to analyze.[335] Although *Actavis* did not curb lower courts' potential information costs in this manner, courts can engage in some self-help. Providing clear and consistent indications of the factors they will analyze under the rule of reason acts as a roadmap for each court's subsequent decisions. It also serves to signal to the litigating parties the type of factors they should focus upon, which narrows the scope of the arguments presented to the court. There will also be an added institutional benefit of easing some of the uncertainty potential litigants may feel, thereby encouraging pharmaceutical companies to still enter into settlements.

In addition to remaining predictable, the factors will likely be objectively quantifiable indicia relating to the context of the settlement. Well before the *Actavis* decision, Professors Butler and Jarosch argued in favor of a rule of reason approach and offered up a set of six factors targeting "the context and characteristics of the [reverse payment] settlement."[336] Butler and Jarosch acknowledged the significant information costs imposed by a rule of reason test.[337] However, they were confident their proposal could at least streamline the analysis by channeling a court's attention to the most significant indicators of the settlement's potential anticompetitive effects, and all without litigating the patent dispute.[338] The type of factors Butler and Jarosch suggest, such as the difference in time between the settlement's entry date and the patent's expiration date, whether the patent holder has market power, and the financial health of the generic company,[339] are a good institutional fit for district courts because they more closely mirror the type of fact-finding these courts have experience in performing. Courts remain in familiar territory and minimize the cognitive burdens of applying rule of reason.

Size of the payment is also one of the factors Butler and Jarosch argue should be examined.[340] But they eschew strict numerical

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334. Lee, *supra* note 6, at 66-68.

335. *Id.*

336. Butler & Jarosch, *supra* note 2, at 115-19 (explaining that courts should consider "1) Market power; 2) The entrance date allowed by the reverse-payment settlement; 3) The relative size of the reverse payment; 4) The ANDA filer's ability to market the drug without a reverse payment; 5) Sham litigation; and 6) Suspect side deals").

337. *Id.*

338. *Id*. at 115.

339. *See id*. at 115-19.

340. *Id.*

thresholds for when a reverse payment will be deemed anticompetitive and instead assert that courts should evaluate the size of the payment relative to the value of the patent and the litigation costs parties likely would have incurred.[341] As with the other factors suggested by Butler and Jarosch, this type of inquiry requires courts to compare a characteristic of the settlement with objectively quantifiable factors, which courts can ascertain at relatively minimal cost because they are accustomed to engaging in this type of fact-finding. Furthermore, by announcing the metrics against which the size of a reverse payment will be measured, courts allow parties, during the course of settlement negotiations, to calculate when a payment risks becoming so large that courts would view it as raising a red flag. By broadcasting a range of payments that they will generally consider to be low risk, courts allow parties to react accordingly when structuring a settlement. As a result, the antitrust agencies would be less likely to view bringing a challenge to court as an efficient use of agency resources.[342]

Finally, courts will probably tend to narrow the breadth of *Actavis*'s application, cabining its relevance to settlements involving a flow of cash, rather than other forms of compensation, from the brand-name to the generic company. The Court's opinion leaves ambiguity as to the spectrum of settlements now subject to rule of reason antitrust scrutiny. So far, every challenged reverse payment settlement has involved a cash payment from the brand-name company. And while the FTC's brief to the Supreme Court in *Actavis* was most skeptical of the "extraordinary and distinguishing feature of reverse-payment agreements . . . a substantial cash payment from the brand-name manufacturer that holds a patent," in a footnote the FTC pondered "what other consideration would similarly justify a 'quick look' analysis," besides "direct payments of money."[343] The Court expressed concern over "payment in return for staying out of the market" but neither limited the form of the payment to cash nor even

341. *Id*. at 117.

342. *See generally* James Langenfeld & Daniel R. Shulman, *The Future of U.S. Federal Antitrust Enforcement: Learning From Past and Current Influences*, 8 SEDONA CONF. J. 1 (2007) (discussing factors that influence federal antitrust enforcement trends); *Cf.* WILLIAM E. KOVACIC, FED. TRADE COMM'N, THE FEDERAL TRADE COMMISSION AT 100: INTO OUR 2ND CENTURY THE CONTINUING PURSUIT OF BETTER PRACTICES 59 (2009) (describing how the FTC's ability to achieve its mission of protecting consumers depends on efficient allocation of agency resources).

343. Brief for the Petitioner, *supra* note 321, at 30, 36 n.7.

defined the term "reverse payment settlement."[344] Indeed, as the dissent points out, the Court's rationale for applying rule of reason antitrust scrutiny to the settlement before it extends equally to other forms of consideration flowing from a brand-name to a generic company.[345] This is so because whatever the form of compensation the patent holder transfers to a generic company, the patent holder could still be using "its monopoly profits to avoid the risk" of losing its patent through litigation.[346] Third-party payers or the FTC may seek to challenge settlements with non-cash consideration as subject to a rule of reason analysis under *Actavis*. Courts will have a decision to make regarding whether they are free, consistent with *Actavis*, to apply the sham litigation rule to such settlements. The Third Circuit already has district courts in disagreement on this question.[347]

For the same reason the courts favored the sham litigation rule in the first place, they will be disinclined to expand rule of reason scrutiny to settlements only *arguably* falling within the purview of *Actavis*. By narrowing the scope of the holding in *Actavis*, courts can stake out a pool of settlements still viable under the sham litigation rule. In a decision the day before the Supreme Court granted certiorari in *Actavis*, a district court acted analogously to constrain the Third Circuit's ruling in *In re K-Dur*.[348] The district court concluded that the Third Circuit had used the term "reverse payment" to mean "cash payment," not other forms of consideration.[349] Because the settlement at issue involved only non-cash consideration from a brand-name company to a generic, the district court ruled that the plaintiffs had failed to state a claim under the Sherman Act.[350] In effect, the district court created a new bright-line rule to constrain application of the presumptively illegal rule and avoid having to strike down a settlement that terminated a patent infringement suit. Courts confronted with construing *Actavis*'s rule of reason mandate will also

344. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013).

345. *Id*. at 2245 (Roberts, C.J., dissenting).

346. *Id*. at 2232.

347. *Compare In re* Lipitor Antitrust Litig., No. 12-cv-2389 (PGS), 2013 WL 4780496 (D.N.J. Sept. 5, 2013) (denying drug companies' motion to dismiss and rejecting contention that *Actavis* did not apply because the settlement did not involve a monetary payment) *with In re* Lamictal Direct Purchaser Antitrust Litig., No. 12-cv-995 (WHW), 2012 WL 6725580, at *6-7 (D.N.J. Dec. 6, 2012) (holding that *Actavis* applies only to settlements involving monetary payments).

348. *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12-cv-995 (WHW), 2012 WL 6725580, at *6-7 (D.N.J. Dec. 6, 2012).

349. *Id*.

350. *Id*. at 7.

similarly tend to create bright-line rules with the consequence of narrowing the case's applicability and allowing courts to continue to utilize the sham litigation rule.

CONCLUSION

Almost uniformly, the lower courts persisted in granting reverse payment settlements a broad safe harbor from antitrust scrutiny. Like the courts, the antitrust agencies also selected a bright-line rule, but the agencies would have erred on the side of over-deterrence, striking down a reverse payment settlement unless the defendants could overcome a presumption of illegality. Courts often endorse settlement as a desirable alternative to fully litigating a dispute. Yet the reverse payment settlement context has been unusual because the courts have done so in the face of the antitrust agencies' vehement insistence that settlement here will almost always entail costs to consumers—through higher drug prices—that outweigh any savings from curtailed litigation. The consistent ease with which courts have overcome this friction implies propulsion by additional motivation. The tendency of courts to apply bright-line rules as information-cost-saving devices when dealing with both property rights and complex patent and patent-related cases explains their decade-long divergence from the antitrust agencies. Additionally, by giving reverse payment settlements less scrutiny, courts hoped to facilitate patent settlements, thereby allowing them to apply their institutional resources to cases they were more confident they could accurately adjudicate. Although the Supreme Court ultimately ended the intergovernmental stalemate by requiring courts to analyze reverse payment settlements under a rule of reason approach, the cognitive miser phenomenon will remain relevant in this area of law. Under *Actavis*, courts have considerable discretion in presiding over antitrust challenges to reverse payment settlements. By considering how courts are susceptible to acting as cognitive misers, parties can more accurately tailor their arguments to those the court will tend to find persuasive.