



UNC
SCHOOL OF LAW

NORTH CAROLINA LAW REVIEW

Volume 93 | Number 2

Article 3

1-1-2015

FTC v. ACTAVIS: The Patent-Antitrust Intersection Revisited

Glynn S. Lunney Jr.
glunney@law.tamu.edu

Follow this and additional works at: <https://scholarship.law.unc.edu/nclr>



Part of the [Law Commons](#)

Recommended Citation

Glynn S. Lunney Jr., *FTC v. ACTAVIS: The Patent-Antitrust Intersection Revisited*, 93 N.C. L. REV. 375 (2015).
Available at: <https://scholarship.law.unc.edu/nclr/vol93/iss2/3>

This Article is brought to you for free and open access by Carolina Law Scholarship Repository. It has been accepted for inclusion in North Carolina Law Review by an authorized editor of Carolina Law Scholarship Repository. For more information, please contact law_repository@unc.edu.

FTC V. ACTAVIS: THE PATENT-ANTITRUST INTERSECTION REVISITED*

GLYNN S. LUNNEY, JR.**

In FTC v. Actavis, the Supreme Court determined that courts should apply a rule of reason analysis to determine whether using a reverse payment settlement to resolve pharmaceutical patent litigation violates the antitrust laws. Essentially unique to pharmaceutical-patent litigation, a reverse payment settlement involves a payment from the patent-holder to generic challengers in return for the generics dropping their challenge to the patent(s) at issue and agreeing to remain out of the market. Such a settlement agreement enables the patent-holder to maintain exclusivity in the relevant market and to keep prices of the associated pharmaceutical higher than they would otherwise be and, perhaps, higher than they should be.

This Article uses game theory to explore how the legal rules regarding antitrust liability shape the terms upon which parties will settle pharmaceutical patent litigation. The Article demonstrates that, in the absence of any constraints on settlement terms, the parties will settle such litigation in a manner contrary to the purposes of both patent and antitrust laws. Prices for patented pharmaceuticals will remain both high and higher than necessary to foster desirable innovation. Creating a risk of antitrust liability, by applying a rule of reason analysis to these settlements, will constrain the terms upon which the parties may permissibly settle and should do so in a manner likely to promote the purposes of both patent and antitrust laws. Prices for particular patented pharmaceuticals may remain high, but only when and to the extent necessary to promote desirable innovation.

Unfortunately, the Court's approach may not go far enough. Under the Court's rule of reason approach, parties appear to remain free to settle

* © 2014 Glynn S. Lunney, Jr.

** Joseph Merrick Jones Chair, Tulane University School of Law. I would like to thank Jonathan Barnett, Scott Hemphill, Mark Lemley, and the participants at the 2013 Intellectual Property Scholars Conference for constructive feedback on the article.

pharmaceutical patent litigation using a licensed-entry format. Such a settlement format effectively duplicates the substance, but not the form, of the reverse payment format and may lead to prices for patented pharmaceuticals higher than necessary to ensure desirable innovation.

To address this risk, the Court may need to go a step further and effectively require parties to settle pharmaceutical patent litigation using a time of entry format. Under this format, no side payments are made. Instead, the parties agree to a date, between the end of the litigation and the end of the patent's life, at which generic entry may begin. Because the agreed date of entry should reflect the parties' judgment as to the likelihood that the patent-holder will otherwise prevail in the litigation, such a settlement approach should tend to ensure that generic entry is delayed, and prices for the associated pharmaceutical remain high, only to the extent necessary to foster desirable innovation.

INTRODUCTION	377
I. SETTING THE STAGE: THE RISE OF REVERSE PAYMENT	
SETTLEMENTS	384
A. <i>Pharmaceutical Patents and Hatch-Waxman</i>	384
B. <i>Hatch-Waxman Derailed</i>	393
II. THE COURT ACTS	399
III. EVALUATING THE COURT'S DECISION FROM A GAME	
THEORETIC APPROACH: TO SETTLE OR NOT TO SETTLE.....	402
A. <i>Weak Patents, Strong Patents: Why?</i>	402
B. <i>The Basic Framework for Settlement Decisions</i>	405
C. <i>Settlement Decisions in the Face of Legal Rules</i>	410
1. <i>Settlement Rule Regime #1: No-Settlements</i>	411
2. <i>Settlement Rule Regime #2: Reverse Payments</i>	
Allowed.....	415
3. <i>Settlement Rule Regime #3: No Reverse Payments;</i>	
<i>Vary Timing of Patent Invalidation and Generic</i>	
<i>Entry</i>	421
D. <i>Complications: Treating the Symptoms, Not the Disease</i> ..	426
IV. LOOKING FOR A LONG TERM CURE: OF DISEASES AND	
SYMPTOMS.....	435
A. <i>Dealing with Licensed Generic Entry Settlements</i>	437
B. <i>Extending Actavis: Allow Only Variable Time</i>	
<i>Settlements</i>	448
CONCLUSION	453
APPENDIX I: A SIMPLE GENERAL EQUILIBRIUM MODEL OF	
INNOVATION	456

INTRODUCTION

Antitrust and patent law both seek to advance public welfare, but there has long been an undeniable tension between them. Antitrust law seeks to promote public welfare by prohibiting improperly obtained monopoly power and thereby ensuring competitive markets and pricing. Patent law seeks to promote the public welfare by providing incentives for the creation and disclosure of those inventions that satisfy its standards for patentability. Patent law provides these incentives by granting an inventor the right to exclude others from making, using, or selling her patented invention.¹ This set of exclusive rights enables an inventor, at least in some instances, to exclude would-be competitors from a market and to charge a price somewhat above competitive levels for her patented invention. This supracompetitive pricing can provide the incentive necessary for an inventor to recoup her costs. By doing so, it can ensure that the patented invention at issue is devised and disclosed. At the same time, however, this supracompetitive pricing stands in sharp contrast to the competitive pricing that antitrust law seeks to ensure in markets generally.²

In its most recent iteration,³ the Supreme Court revisited the patent-antitrust intersection in *FTC v. Actavis*.⁴ In *Actavis*, the Court confronted the question of whether an agreement by the parties to resolve pharmaceutical-patent litigation through the use of a reverse payment settlement unreasonably restrained trade in violation of section 1 of the Sherman Act and section 5 of the Federal Trade

1. See 35 U.S.C. § 271(a) (2012) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention within the United States . . . during the term of the patent therefor, infringes the patent.”).

2. In his dissent in *FTC v. Actavis, Inc.*, Chief Justice Roberts summarized this tension: “The point of antitrust law is to encourage competitive markets to promote consumer welfare. The point of patent law is to grant limited monopolies as a way of encouraging innovation.” *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013) (Roberts, C.J., dissenting).

3. For cases illustrating the longstanding tension between patent and antitrust law, see, for example, *United States v. Singer Mfg. Co.*, 374 U.S. 174, 189–97 (1963) (holding that a patent cross-licensing agreement to limit competitive entry constituted an antitrust violation); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 376–80 (1952) (holding that using patent licenses to fix prices in a market constituted an antitrust violation); *United States v. Line Material Co.*, 333 U.S. 287, 315 (1948) (reversing the dismissal of an antitrust claim based on the cross-licensing of patents to fix prices in a market); *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 168–83 (1931) (holding that pooling patents in order to fix prices in a market violates the antitrust laws).

4. 133 S. Ct. 2223 (2013).

Commission Act. Essentially unique to litigation between pharmaceutical patent-holders and their would-be generic competitors,⁵ a reverse payment settlement involves a payment from the pharmaceutical patent-holder to the generic drug company. In return for this payment, the generic agrees to drop its challenge to the patent at issue and to remain out of the patent-protected market for some period of time, perhaps until the patent at issue expires.

The stakes for the parties, and for consumers, in this type of pharmaceutical-patent litigation are large. In *Actavis* itself, three generics had challenged the patent protecting the market for Androgrel.⁶ Had the generics succeeded in their patent challenge and entered the market, the generic versions of the pharmaceutical would have cost consumers only a small fraction of the price for the patented, brand-name version.⁷ The availability of lower-priced generics would have cut the brand-name pharmaceuticals' sales by 90% and would have reduced its profits by \$125 million annually.⁸ Rather than face that possibility, the patent-holder in the case, Solvay Pharmaceuticals, agreed in 2006 to pay the generic challengers a share of its expected monopoly profits, and in return the generic challengers agreed to drop their challenges to Solvay's patents and to remain out of the market until 2015.⁹

5. 1 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST* 15-15 to 15-45 & n.161 (2d ed. 2010) (“[W]here only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.”). *But see Actavis*, 133 S. Ct. at 2242–43 (Roberts, C.J., dissenting) (noting that the majority’s claim that reverse payment settlements are unique to pharmaceutical-patent litigation “is not supported empirically by anything the majority cites” and is impossible to prove given that most settlements of patent litigation are confidential). We have data on reverse payment settlements in the pharmaceutical-patent-litigation context but not in other patent contexts because Congress, as part of the Medicare Prescription Drug, Improvement, and Modernization Act, required parties to file such settlements with the FTC. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63. As a result, we know that reverse payment settlements occur in the context of pharmaceutical-patent litigation but cannot definitively determine whether they occur elsewhere.

6. *Actavis*, 133 S. Ct. at 2229.

7. FTC Petition for Writ of Certiorari at 6, *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787 (2012) (No. 12-416); *see also* FTC, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* 8 (2010) [hereinafter *FTC, PAY-FOR-DELAY*], 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> (estimating that the average price for a patented pharmaceutical will fall by 77% within a year of generic entry).

8. FTC Petition for Writ of Certiorari, *supra* note 7, at 6.

9. *Id.* at 6–7. The patent at issue did not expire in 2015. *See Actavis*, 133 S. Ct. at 2229 (noting that the August 31, 2015 agreed entry date was sixty-five months before the patent at issue expired). Rather, 2015 was the date by which Solvay anticipated shifting its

Nor was the settlement at issue in *Actavis* unique. In a 2010 study, the Federal Trade Commission estimated that reverse payment, or “pay-for-delay,” settlements were protecting at least \$20 billion in sales of brand-name pharmaceuticals from generic competition.¹⁰ By keeping generics out, these agreements kept prices for the brand-name pharmaceutical artificially high and thereby cost American consumers \$3.5 billion annually.¹¹ As these agreements became popular as a means for resolving pharmaceutical-patent litigation, wholesalers, retailers, health insurers, and consumers, along with the FTC, began to challenge them as antitrust violations under section 1 of the Sherman Act as well as section 5 of the Federal Trade Commission Act.¹² They argued that but for the reverse payment settlement, the patent litigation would have continued;¹³ had the litigation continued, strong patents might have prevailed, but weak patents would have been struck down.¹⁴ Striking a patent down would allow generics to enter the market and would quickly lead to sharply lower prices for the pharmaceutical at issue.¹⁵ In their view, parties to pharmaceutical-patent litigation were using reverse payment settlements to insulate weak patents from challenge in order to maintain supracompetitive pricing without justification and split the resulting rents.

The parties to these agreements, on the other hand, insisted that a reverse payment settlement did not unreasonably restrain trade; indeed, they contended that such a settlement did not restrain trade at all.¹⁶ While the settlement may have kept a generic out of a market,

customers to a new product with no generic equivalent. FTC, PAY-FOR-DELAY, *supra* note 7, at 6.

10. FTC, PAY-FOR-DELAY, *supra* note 7, at 2.

11. *Id.*

12. *See, e.g., Actavis*, 133 S. Ct. at 2227 (challenging reverse payment settlement as a violation of section 5 of the Federal Trade Commission Act); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 202–08 (3d Cir. 2012) (alleging a reverse payment settlement violated section 1 of the Sherman Act in wholesaler and retailer class actions); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327 (Fed. Cir. 2008) (alleging that reverse payment settlements violated section 1 of the Sherman Act in a suit brought by advocacy groups as well as direct and indirect purchasers).

13. *See Actavis*, 133 S. Ct. at 2229–30 (“The [circuit] court recognized that, if the parties to this sort of case do not settle, a court might declare a patent invalid.”).

14. *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012) (“According to the FTC, the reverse payment settlements unlawfully protected or preserved a monopoly that likely was invalid and that should not be shielded from antitrust attack.”), *rev’d sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

15. *See, e.g., id.* at 1305 (noting the generic company’s forecast that “its generic version of AndroGel would sell for about 25 percent of the price of branded AndroGel”).

16. *Id.* at 1301 (describing drug companies’ argument that holding the reverse payment settlement at issue to be a restraint on trade “would weaken incentives for

this restraint of trade flowed not from the parties' agreement but from the patent itself.¹⁷ A litigant's agreement to settle and stay out of the patent-protected market simply acknowledged the already existing exclusionary force and anticompetitive potential of a presumptively valid patent. Moreover, given the risk, uncertainty, and expense associated with pharmaceutical-patent litigation, the parties should have leeway to settle these cases without incurring antitrust liability. While paying a generic defendant to drop its challenge might seem to suggest that a pharmaceutical patent-holder lacks confidence in its patent, a pharmaceutical patent can be exceedingly valuable. As a result, a patent-holder, even one confident that it will win the litigation, will often be willing to pay in order to insure against even a small risk of invalidity. A large reverse payment should not therefore be taken as proof that the settlement unreasonably restrains trade. Unless the court essentially re-litigates the patent infringement claim within the context of the antitrust suit, there is no way to separate legitimate settlement agreements from those that might be improperly insulating weak patents from attack.¹⁸

As these cases made their way through the court system, the circuit courts reached diametrically opposed conclusions as to whether reverse payment settlements violated the antitrust laws.¹⁹

investing in drug development, which would reduce the number of life-saving or life-enhancing innovations that benefit consumers”).

17. See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065–66 (11th Cir. 2005) (“By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present.”); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003) (“If [the patent holder] had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit.”).

18. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 204 (2d Cir. 2006) (pointing out that the legality of patent settlements turns on “assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement” when attempting to determine the “reasonableness of agreements under the antitrust laws” (internal quotation marks omitted)).

19. Academic commentary is similarly split. For articles condemning reverse payment settlements, see generally David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000) (discussing why patent settlements generally raise competitive concerns, especially in the pharmaceutical context); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012) (noting problems with reverse payment settlements and advocating for a proof “to determine when a reverse payment settlement is necessarily anticompetitive”); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) (discussing antitrust concerns inherent in patent settlements and arguing that “exclusion payments that exceed litigation costs should be presumptively illegal”); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003) (discussing the “benefits and costs of patent settlements” and arguing that “antitrust limits on such settlements are unquestionably needed to prevent abuse of

The Third Circuit, with some support from the D.C. and Sixth Circuits, held that such a settlement agreement presumptively restrained trade and thus violated section 1 of the Sherman Antitrust Act.²⁰ The Second, Eleventh, and Federal Circuits, on the other hand, disagreed. They evaluated the legality of these agreements using a “scope of the patent” approach. As the Eleventh Circuit explained, under this approach, a reverse payment settlement agreement was generally “immune from antitrust attack so long as its anticompetitive effects [fell] within the scope of the exclusionary potential of the patent.”²¹ Under this approach, a reverse payment settlement would violate section 1 of the Sherman Act only if: (i) the agreement extended beyond the patent’s exclusionary scope, either to reach noninfringing products or to extend the exclusion beyond the patent’s term; (ii) the patent at issue had been acquired by fraud on the Patent

the settlement process”). For articles rejecting or warning of the dangers of antitrust scrutiny for reverse settlement payments, see generally Roger Blair & Thomas Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002) (concluding that applying a per se presumption of illegality to patent settlements is inappropriate in part because the settlements are usually “between parties that are not necessarily horizontal competitors”); Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57 (2010) (arguing that reverse payment settlements are not inherently bad, “that the effects of reverse payments are not obvious, can be procompetitive, and that a presumption of anticompetitive effect is thus unwarranted”); Bret M. Dickey & Daniel L. Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. COMPETITION L. & ECON. 615 (2012) (arguing that “a per se rule against ‘reverse payment’ patent settlements could chill the incentives for generic investment” and therefore “deprive consumers of benefits from lower cost generic drugs”); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777 (2003) (arguing that settlements may stimulate development incentive, protect patent holders’ intellectual property rights, and therefore “[i]n many circumstances, a strict per se illegal treatment of such payments would . . . reduc[e] total consumer welfare in the long run”).

20. The Third Circuit enunciated the standard as follows:

Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012). The D.C. and Sixth Circuits have also held that a similar settlement arrangement violated section 1. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 810–11 (D.C. Cir. 2001).

21. *Watson Pharm., Inc.*, 677 F.3d at 1312; see *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1332–37 (Fed. Cir. 2008); *In re Tamoxifen*, 466 F.3d at 212–13; *Schering-Plough Corp.*, 402 F.3d at 1065–66; *Valley Drug Co.*, 344 F.3d at 1311–12.

and Trademark Office (“PTO”); or (iii) the patent infringement claims were “objectively baseless” and hence a “sham.”²²

The Court granted certiorari in *Actavis* to resolve this split and in its opinion, rejected both approaches.²³ Using a reverse payment settlement to resolve pharmaceutical patent litigation was neither presumptively lawful nor presumptively unlawful, the Court held.²⁴ Rather, a court must apply a rule-of-reason analysis²⁵ to determine whether any given reverse payment settlement violates the antitrust laws.²⁶ While the Court left “to the lower courts the structuring of the . . . rule-of-reason” in these cases, the Court identified the size of the reverse payment as a central consideration.²⁷ On its own, a very large reverse payment, one that is substantially more than simply avoided litigation costs, can show the actual adverse effect on competition necessary to establish a rule-of-reason violation.²⁸ Unless the pharmaceutical patent-holder can show that the excessive payment actually represented something legitimate, such as a payment for other services that the generic agreed to provide, a court may justifiably infer that a reverse payment settlement represented an unlawful agreement to purchase market exclusivity.²⁹ While the Court did not finally resolve whether the reverse payment settlement at issue in *Actavis* itself did or did not violate the rule of reason, the Court’s focus on the size of the reverse payment as a key factor in the rule-of-reason analysis will likely make it more difficult for parties in

22. *Watson Pharm., Inc.*, 677 F.3d at 1312; *In re Ciprofloxacin*, 544 F.3d at 1332–37; *In re Tamoxifen*, 466 F.3d at 212–13.

23. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234–38 (2013).

24. *Id.*

25. As a general matter, the rule of reason examines the pro-competitive and anti-competitive consequences of an agreement to determine whether, on balance, the agreement unreasonably restrains trade. In the Second Circuit, for example, the rule-of-reason analysis is a three-step process:

First, the plaintiff bears the initial burden of showing that the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.

Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997) (citations and internal quotation marks omitted).

26. *Actavis*, 133 S. Ct. at 2234–38.

27. *Id.* at 2238.

28. *Id.* at 2234–37.

29. *Id.* at 2237.

the future to settle pharmaceutical patent litigation using a reverse payment structure.

This Article carefully examines the law and economics of reverse payment settlements and evaluates whether the Court's ruling advances or disserves the not-entirely-consistent purposes of the antitrust and patent laws. Part I sets forth the relevant background that led to the rise of reverse payment settlements to resolve pharmaceutical-patent litigation and contrasts the differing positions the circuit courts initially reached on their legality. Part II then turns to, and examines, the Court's decision in *Actavis*, summarizing the issues it resolved and the issues it left open. Part III evaluates the settlement of pharmaceutical patent litigation from a game-theoretic perspective. As we shall see, game theory largely vindicates the Court's decision. By looking at why and how parties will settle under various possible rule regimes, game theory demonstrates that the Court's approach should promote the purposes of both the patent and antitrust laws.

Yet, the Court's decision may not go far enough. As we shall see, the Court's decision is unlikely to resolve completely the use of settlement agreements to insulate weak pharmaceutical patents from attack. Reverse payment settlements may be a symptom, but they are not the disease itself. If weak pharmaceutical patents can be insulated from attack, they generate substantial rents. Those rents give the parties a very strong incentive to settle in a manner that preserves a weak patent and allows them to split the associated rents between themselves. If they can find a way to accomplish that without running afoul of the antitrust law, we should fully expect them to do so. As a result, even if the Court's ruling effectively prohibits the use of reverse payments, this will not be the end of the issue. The parties will likely find some alternative arrangement that achieves the same anticompetitive result. For example, the patent-holder could license generic entry, use vertical price fixing to maintain prices in the associated market, and use the royalty structure to divide the rents between the parties. Part IV examines what might be done to cure this disease, rather than merely treat its symptoms. To do so, we must define a rule regarding reverse payments specifically, and permissible settlement terms more generally, that leads the parties in pharmaceutical-patent litigation to settle in a manner that advances the goals of both patent and antitrust laws.

I. SETTING THE STAGE: THE RISE OF REVERSE PAYMENT SETTLEMENTS

A. *Pharmaceutical Patents and Hatch-Waxman*

To set the stage, we begin with the background legal rules that govern pharmaceutical patent litigation. In most industries, patent litigation begins when one company begins selling a product or using a process that another believes infringes on one or more of its patents.³⁰ While pharmaceutical-patent litigation could arise in this fashion, it does not typically.³¹

In the pharmaceutical industry, a company may not simply start selling a prescription drug. It must first obtain approval from the Food and Drug Administration (“FDA”).³² To obtain such approval for a new drug, the company must submit a New Drug Application (“NDA”) that provides “substantial evidence” establishing the medication’s safety and efficacy.³³ Since the efficacy requirement was added in 1962, the FDA has consistently required double-blind,³⁴ placebo-controlled clinical trials to establish efficacy.³⁵ “Isolated case reports, random experience, and reports lacking the details which

30. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006).

31. In his opinion in *In re Tamoxifen Citrate Antitrust Litigation*, Judge Sack made much of this difference. 446 F.3d at 207; see also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (explaining that Hatch-Waxman essentially redistributes the relative risk assessments of the cost of entry and damages); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2000) (noting that the Hatch-Waxman Act “has the unintended consequence of altering the litigation risks of patent lawsuits”). He argued that it “essentially redistributes the relative risk assessment” found in patent litigation and may well give the generic “the whip hand.” *In re Tamoxifen*, 446 F.3d at 207, 210. Yet, it is the patent-holder’s choice whether or not to sue in response to a paragraph IV certification. If the patent-holder believed that it would be better off doing so, it could simply ignore the paragraph IV certification and wait for actual generic entry to sue.

32. 21 U.S.C. § 355(a) (2012) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”).

33. The Kefauver Harris Amendment added the efficacy requirement to the Food, Drug, and Cosmetic Act in 1962. Act of Oct. 10, 1962, Pub. L. No. 87-781 §§ 102–103, 76 Stat. 780, 783–83; see also *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 615 (1973) (noting when the 1962 amendments became effective and NAS-NRC undertook to appraise the efficacy of drugs).

34. In a double-blind study, neither the patient receiving the medication nor the doctor prescribing it knows whether any given patient is receiving the study medication or the placebo.

35. 21 U.S.C. § 355(a), (d) (requiring “substantial evidence” of efficacy for drug approval and defining “substantial evidence” to mean “evidence consisting of adequate and well-controlled investigations”); 21 C.F.R. § 314.126 (2013) (defining the requirements for “adequate and well-controlled studies”).

permit scientific evaluation” are insufficient to establish a medication’s efficacy.³⁶ As part of the NDA, the applicant must also identify any patents that would protect the new drug.³⁷ If the FDA approves the new drug as safe and effective, the FDA publishes those patents in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” usually referred to as the “Orange Book.”³⁸ The clinical trials necessary to obtain FDA approval for a new drug are expensive, and there is always a risk that the FDA will reject the evidence presented as insufficient to establish the medication’s safety and efficacy. The requirement of FDA approval thus makes the process of bringing a new drug to market long, arduous, and risky.³⁹

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act, to set up a process that allowed for and encouraged early generic entry.⁴⁰ The Hatch-Waxman Act made two changes to existing law to facilitate early generic entry. First, to reduce the time and expense associated with introducing a generic version of an existing pharmaceutical, the Hatch-Waxman Act created an “Abbreviated New Drug Application” (“ANDA”).⁴¹ With an ANDA, a generic

36. 21 C.F.R. § 314.126(e).

37. 21 U.S.C. § 355(b)(1) (“The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”).

38. *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

39. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1300 (11th Cir. 2012) (“Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than \$1.3 billion.”), *rev’d sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The Eleventh Circuit offered these numbers to suggest why we need patent protection for pharmaceuticals. *See id.* at 1300 (“No rational actor would take that kind of a risk over that period of time without the prospect of a big reward.”). Yet, the Eleventh Circuit is mistaken as to the causal direction. We do not need a patent system because pharmaceutical companies spend large sums of money on developing and obtaining approval for new drugs; rather, pharmaceutical companies spend large sums of money on developing and obtaining approval for new drugs because we have a patent system.

40. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; *see also In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (2012) (“In 1984, attempting to jumpstart generic competition with name brand pharmaceuticals, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.”(citing Pub. L. No. 98-417, 98 Stat. 1585 (1984))).

41. Drug Price Competition and Patent Term Restoration Act § 101, 98 Stat. at 1585-89.

drug company need only show that it contains the same active ingredient(s) and is bioequivalent to a previously approved drug.⁴² Having done so, it may then rely on the FDA's determination of safety and efficacy with respect to that previously approved drug to establish the safety and efficacy of the generic.⁴³ Because it can rely on the prior FDA approval, the generic manufacturer can avoid the considerable expense and uncertainty associated with filing its own NDA.

As part of an ANDA, the generic manufacturer must also certify that the proposed generic does not infringe any patent listed with the FDA, and published in the Orange Book, for the drug at issue.⁴⁴ Under the Hatch-Waxman Act, an ANDA applicant may satisfy this requirement by certifying: (i) that no patent information has been filed; (ii) that the patents identified have expired; (iii) that the ANDA applicant will wait until the identified patents expire, setting forth the relevant expiration date(s); or (iv) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic version of the drug at issue.⁴⁵ The final option is known as a "paragraph IV" certification. Filing such a certification constitutes an act of patent infringement, and the generic drug company must give notice to the patent-holder of any such paragraph IV certification.⁴⁶ When the pharmaceutical patent-holder receives notice of a paragraph IV certification, it has forty-five days in which to file a patent infringement suit.⁴⁷ If it does so, the filing of the lawsuit triggers an automatic stay that prevents the FDA from approving the ANDA for the generic drug until the earlier of: (1) thirty months; or (2) the date on which the district court finds that the patent is either invalid or not infringed.⁴⁸

Second, in addition to establishing ANDAs and defining a specific patent-litigation framework for them, Congress also provided a special incentive for generics to challenge pharmaceutical patents.

42. 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

43. *Id.*; see 21 U.S.C. § 355(j)(4); see also *Caraco Pharm. Labs.*, 132 S. Ct. at 1676 (“[The Hatch-Waxman] amendments allow a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand’s NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.”).

44. 21 U.S.C. § 355(b)(2)(A), (j)(2)(A)(vii).

45. 21 U.S.C. § 355(j)(2)(A)(vii).

46. 35 U.S.C. § 271(e)(2)(A) (2012).

47. 35 U.S.C. § 271(e)(5).

48. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Specifically, the Hatch-Waxman Act gives the first company that files a generic ANDA with a paragraph IV certification a 180-day period from the time at which the generic enters the market during which the FDA will not approve subsequent ANDA applications.⁴⁹ When first enacted, the FDA interpreted the Hatch-Waxman Act so as to limit the award of the 180-day generic exclusivity to those generics that successfully defended their paragraph IV certifications against a lawsuit for patent infringement.⁵⁰ However, in 1998, the D.C. Circuit rejected this interpretation.⁵¹ In response, the FDA abolished the successful defense rule and currently awards the exclusivity period to the first ANDA applicant who asserts a paragraph IV certification.⁵² If more than one generic drug company files an ANDA with a paragraph IV certification on the same day, the FDA considers them all “first filers” who share the exclusivity period.⁵³ Nevertheless, the 180-day exclusivity period is available only to the first filer. If the first filer loses its 180-day exclusivity period, for example, by withdrawing its ANDA,⁵⁴ the right to claim the 180-day exclusivity period will not pass to subsequent filers.⁵⁵

Congress provided this 180-day generic exclusivity period as a special incentive to encourage challenges to pharmaceutical patents.⁵⁶ In part, Congress provided the incentive to overcome a collective action or externality problem that plagues patent litigation generally. As generally recognized, most of the benefit from successfully defending against a claim of patent infringement, whether by proving the patent invalid or by showing non-infringement, does not flow to

49. 21 U.S.C. § 355(j)(5)(B)(iv).

50. 21 C.F.R. § 314.107(c)(1) (1995).

51. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998); *Granotec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410, at *7 (4th Cir. April 3, 1998).

52. *See Effective Date of Approval of an Abbreviated New Drug Application*, 63 Fed. Reg. 59,710, 59,710 (Nov. 5, 1998) (codified at 21 C.F.R. § 314.107 (1999)).

53. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb); FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY 4 (2003).

54. In 2003, Congress defined certain “forfeiture event(s)” that would cause the first applicant to forfeit its 180-day exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)–(ii).

55. 21 U.S.C. § 355(j)(5)(D)(iii).

56. *See, e.g., Alfred B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 403–04, 423 (1999) (“The entire purpose of the 180-day exclusivity provision, at the time it was drafted, was to insure that one generic competitor would not get a free ride on the litigation effort of another generic competitor until the party who had borne the cost and risk of litigation had a fair opportunity to recover its litigation costs.”).

the victorious patent defendant.⁵⁷ While prevailing means that a defendant can keep selling the product at issue, it also clears the way for other would-be competitors to sell the same product. Under principles of collateral estoppel, a finding of invalidity or non-infringement against one defendant is binding on the patent-holder in all subsequent litigation.⁵⁸ Thus, to enter the market, other would-be competitors may simply follow the path the first defendant blazed. By opening the door for other would-be competitors, one defendant's win quickly leads to a competitive market generally—a market where we expect prices to fall to marginal cost. As a result, most of the benefits from successfully defeating a claim of patent infringement flow not to any one patent defendant, or even to all potential defendants, but to consumers generally, in the form of lower prices.⁵⁹

Despite the public interest in having the validity of patents litigated,⁶⁰ we should not expect the typical patent defendant to litigate simply because consumers or society generally would be better off if a given patent were invalidated. A typical defendant will instead pursue its own self-interest. Given that it receives only a small part of the total benefit from invalidating a patent, in the absence of some special incentive to litigate, many patent defendants will settle, rather than litigate, even in cases they are likely to win.⁶¹ The 180-day ban on the approval of other ANDAs can provide the necessary incentive to encourage a generic to litigate.

We should be careful, however, before relying too heavily on this collective action justification for the 180-day generic exclusivity

57. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012) (noting that when a generic defendant prevails in patent litigation, “consumers, rather than generic producers, are typically the biggest beneficiaries”).

58. See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (recognizing non-mutual collateral estoppel in patent litigation and holding that a patentee is estopped from asserting a patent against a defendant after a court has found the patent invalid in litigation involving another defendant); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 333–34.

59. See, e.g., *In re K-Dur*, 686 F.3d at 208 (“The FTC estimates that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder’s unit sales and sells for fifteen percent of the price of the name brand product. This price differential means that consumers, rather than generic producers, are typically the biggest beneficiaries of generic entry.” (citation omitted)).

60. See *U.S. v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973); see also *id.* at 58 (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”).

61. See FTC, *PAY-FOR-DELAY*, *supra* note 7, at 3 (noting that even with a high chance of winning, there are a variety of factors that lead many generic pharmaceutical manufacturers to settle, rather than litigate patent claims).

period. Although generally asserted, this collective action problem is often not present, or at least is less pronounced, in pharmaceutical-patent litigation compared to patent litigation generally. For pharmaceutical patents to enter the market, a would-be competitor must both clear the patent and obtain FDA approval. Even though a first generic challenger has won its litigation and begun marketing its generic version of the pharmaceutical, subsequent generics still must obtain FDA approval to begin marketing. If the initial litigation invalidated all claims of the listed patents, subsequent ANDA filers may rely on the initial generic's success to obtain FDA approval. Yet, the initial litigation often does not invalidate every claim of the listed patents.⁶² Only some of the claims may be asserted, or the initial generic challenger may prove non-infringement, rather than invalidity. When that happens, the pharmaceutical patent-holder may still have a valid basis to list the patents in the Orange Book. As long as some patents remain listed in the Orange Book for the new drug at issue, the FDA will not approve other ANDAs until the filers have prevailed in their own litigation.⁶³ While the doctrine of collateral estoppel will be available, a follow-on generic competitor will nonetheless need to assert the doctrine, show that it applies, and prevail before it will obtain FDA approval. As a result, even in the absence of the 180-day generic exclusivity, the delays in obtaining FDA approval may offer the initial generic challenger some time in which to recoup its investment in litigating the patent issues.

Although the collective action problem is therefore somewhat less serious for pharmaceutical patents, Congress provided a special incentive to challenge pharmaceutical patents, but not patents generally. That Congress provided such a special incentive to encourage challenges to pharmaceutical patents, and not patents generally, suggests that pharmaceutical patents, particularly weak pharmaceutical patents, impose uniquely high costs on society.

Pharmaceutical patents impose uniquely high costs for several reasons. While every patent provides exclusivity, in order to enable some degree of supracompetitive pricing, exclusivity is likely to lead to disproportionately high prices with pharmaceutical patents. In part,

62. See, e.g., *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 121 (D.D.C. 2007) ("Patent holders seeking FDA approval must register their patent with the FDA. 21 U.S.C. § 355(b)(1). In the present case, Pfizer maintains its patent via 11 independent claims. FDA Decision at 9. In the patent infringement litigation currently before the Federal Circuit, Pfizer challenged Apotex's certification as to claims 1-3 of its patent. *Id.* Accordingly, the Federal Circuit's ruling encompasses an invalidation of only the first three claims of Pfizer's patent—it is silent as to the remaining claims.").

63. See, e.g., *id.* at 121-22.

this is due to the nature of the markets for pharmaceuticals. Pharmaceuticals can have radically low cross-elasticities of demand.⁶⁴ When there is only one pharmaceutical that can treat or cure a serious or fatal disease or condition, patients are willing to pay almost anything for access to that medication. Moreover, in demanding and offering to pay for access to that medication, a patient can draw not only on her own earning potential but also, given the ubiquity of health insurance, the earning potential of every other individual in her health insurance pool. This means that pharmaceuticals can have prices radically higher than equally valuable inventions in other sectors of the economy.⁶⁵ At the same time, the phrase “deadweight loss,” which economists use to describe the decreased satisfaction consumers experience when they cannot afford a supracompetitive price, takes on a far more literal connotation in the markets for pharmaceuticals.

In addition to these differences in the nature of the markets for pharmaceuticals, there is also a substantial difference in the effectiveness of patent protection. Specifically, patents in pharmaceutical markets are likely to prove far more effective at excluding would-be competitors than patents in other markets. Because the FDA regulates entry into pharmaceutical markets, there are only two ways to enter such markets legally. First, the would-be competitor can use the ANDA approach and offer a generic version of the pharmaceutical at issue.⁶⁶ But to do so, the would-be competitor must prove that its formulation has the same active ingredient(s) and is bioequivalent, leaving little room to vary the generic version sufficiently to avoid a claim of patent infringement.⁶⁷

64. See, e.g., Matthew Herper, *The World's Most Expensive Drugs*, FORBES (Feb. 22, 2010), <http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases.html> (“The nine drugs on our list all cost more than \$200,000 a year for the average patient who takes them. Most of them treat rare genetic diseases that afflict fewer than 10,000 patients. For these diseases, there are few if any other treatments. So biotech companies can charge pretty much whatever they want.”).

65. As discussed, the FTC found an average decline of 77% in pharmaceutical prices following the loss or expiration of patent protection and consequential generic entry. See FTC, *PAY-FOR-DELAY*, *supra* note 7, at 8. I am not aware of any other markets where the loss or end of patent protection leads to a remotely comparable price decrease.

66. See *supra* notes 40–42 and accompanying text.

67. If the patent is to the medication’s active ingredients (known as a “compound” patent), then a generic could not contain the same active ingredients without falling within the patent’s scope. See *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 398 (2d Cir. 2005) (“Zeneca’s tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug.”). If the patent instead is directed only to the specific formulation, coating, or delivery method for the compound, then a

Second, a would-be competitor can undertake its own research in an attempt to identify a non-infringing pharmaceutical to treat the same disease or condition.⁶⁸ However, using this approach would require the would-be competitor to file its own NDA. By attempting to compete by offering its own new drug, rather than a generic version of a previously approved drug, the company may not rely on the ANDA alternative and, as a result, would have to pay for its own set of clinical trials to prove the new drug's safety and efficacy. Although such alternatives sometimes develop, the introduction of a second new drug into a market often entails significant delay⁶⁹ and, in addition, does not usually lead prices to fall as far as they would with generic entry. The developer of the new pharmaceutical has to ensure that prices remain sufficiently high to cover the considerable risk and expense associated with obtaining FDA approval for its own new drug.

In contrast, to enter markets in other fields where patents are available, neither exact copying nor expensive clinical trials are necessary. Rather, would-be competitors have far more leeway to invent around and offer non-infringing, yet still competing, products.⁷⁰ As a result, patents tend to prove more effective at excluding would-be competitors from pharmaceutical markets. We can get some sense for this difference by looking at renewal data. While all patents today may last twenty years from their application date, to obtain the full term the patent-holder must pay a renewal fee at three and a half, seven and a half, and eleven and a half years to keep the patent in force.⁷¹ Where patent-holders allow most non-pharmaceutical patents to lapse after the second renewal payment,⁷² pharmaceutical patent-

generic may plausibly argue non-infringement even though it is bioequivalent and contains the same active ingredients.

68. 21 U.S.C. § 355(b) (2012).

69. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1300 (11th Cir. 2012) (noting that developing a new drug takes ten to fifteen years), *rev'd sub nom. FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

70. Edwin Mansfield, Mark Schwartz & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 *ECON. J.* 909, 913 (1981) ("Contrary to popular opinion, patent protection does not make entry impossible, or even unlikely. Within 4 years of their introduction, 60% of the patented successful innovations in our sample were imitated."); *see also id.* at 913 & 914 n.1 ("In the bulk of the cases, the new product could have been imitated in 2 years or less even if the imitator carried out the project at the most leisurely pace. In practically all cases it could be imitated in 3 years or less.").

71. 35 U.S.C. § 41(b) (2012).

72. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 *Nw. U. L. REV.* 1495, 1504 (2001) (presenting in Table 3 data showing that patentees pay the maintenance fees due twelve years after the patent issues for less than 40% of the patents issued).

holders routinely renew their patents for the full twenty-year term.⁷³ Alternatively, we can look directly at the rents patents generate and their resulting value. In their book, *Patent Failure*, Jim Bessen and Mike Meurer used econometric techniques and estimated that “the aggregate value of United States patents granted to private United States parties in 1991 was about \$4.4 billion in 1992 dollars.”⁷⁴ In contrast, I have estimated that losing patent protection for the antidepressant Prozac, for only thirty-four months out of the patent’s seventeen-year life, cost Eli Lilly \$3.27 billion.⁷⁵ Despite the differences in estimation techniques, the disproportionate value of pharmaceutical patents is readily apparent.

Patents on pharmaceuticals, while they can encourage the development of new, potentially life-saving medications, thus entail some unique costs. Given their unique costs, some countries, such as India, simply refused, for many years, to provide patent protection for pharmaceuticals.⁷⁶ While the Agreement on Trade Related Aspect of Intellectual Property (“TRIPS”) forbade countries from taking that approach,⁷⁷ today, in every developed Western country other than the United States, governments balance the unique costs and benefits of providing patent protection for pharmaceuticals by imposing price controls on pharmaceuticals.⁷⁸ So far, the pharmaceutical industry in the United States has persuaded the government not to follow that course.⁷⁹ Instead, the government has attempted to deal with the

73. See Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1536–37 (2005) (showing that pharmaceutical and drug patents are more likely to be maintained for the full patent term than patents in other technology fields).

74. JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 112 (2008).

75. Glynn S. Lunney, Jr., *On the Continuing Misuse of Event Studies: The Example of Bessen and Meurer*, 16 J. INTELL. PROP. L. 35, 46 (2008).

76. See, e.g., Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 491–92 (2005) (noting that India’s patent law excluded patent protection for pharmaceuticals from 1972 to 2005).

77. Marrakesh Agreement Establishing the World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property, art. 27(1), Apr. 15, 1994, 1867 U.N.T.S. 154 (“[P]atents shall be available and patent rights enjoyable without discrimination as to the . . . field of technology . . .”).

78. See, e.g., Jonathan Ingram, *Eliminating Innovation: How Price Controls Limit Access*, 32 J. LEGAL MED. 115, 115–18 (2011) (discussing various price control schemes in other countries).

79. See, e.g., Matthew Arnold, *Obamacare Reconsidered: A Pretty Good Deal for the Drug Industry*, MED. MARKETING & MEDIA (Mar. 26, 2012), <http://www.mmm-online.com/obamacare-reconsidered-a-pretty-good-deal-for-the-drug-industry/article/233750/> (“But in the end, the industry was able to use its leverage to fend

uniquely high costs that pharmaceutical patents, particularly weak pharmaceutical patents, can impose by encouraging early generic entry.⁸⁰ To that end, the Hatch-Waxman Act provides a less expensive, special application process for FDA approval of generics and provides an incentive, in the form of the 180-day generic exclusivity, for generics to challenge weak pharmaceutical patents.⁸¹

B. *Hatch-Waxman Derailed*

Yet, the Hatch-Waxman approach has not worked out precisely as Congress hoped. While some early generic entry has occurred, the parties to pharmaceutical-patent litigation quickly discovered that they could both be made better off by agreeing to a reverse payment settlement rather than litigating. Almost as quickly, they began facing lawsuits asserting that such settlements violated section 1 of the Sherman Antitrust Act.

In the first pair of antitrust cases involving reverse payments, the Sixth and D.C. Circuits concluded that a reverse payment agreement violated the antitrust laws.⁸² Both cases concerned an agreement between a pharmaceutical patent-holder and a generic with respect to Cardizem CD, a heart medication.⁸³ In September 1995, the generic, Andrx Pharmaceuticals, filed an ANDA, and in December they made the paragraph IV certification.⁸⁴ Within forty-five days, the patent-holder sued, triggering the thirty-month automatic stay on FDA approvals of any ANDAs directed towards Cardizem CD.⁸⁵ While the stay was pending, in mid-1997, the FDA issued a tentative approval of Andrx's ANDA—an approval that would become final when the automatic stay ended.⁸⁶ In response, the pharmaceutical patent-holder agreed to pay the generic \$40 million per year, beginning on the date on which the FDA gave the generic final approval and ending on the date that the generic either entered the market or was found liable for

off provisions that would have allowed direct price controls and restricted drug marketing.”).

80. See H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647 (noting Act sought “to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs”).

81. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 § 101, 98 Stat. 1585, 1589.

82. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 819 (D.C. Cir. 2001) (reversing district court's dismissal for failure to state a claim and remanding for trial).

83. *In re Cardizem CD*, 332 F.3d at 901-04; *Andrx Pharm., Inc.*, 256 F.3d at 804.

84. *Andrx Pharm., Inc.*, 256 F.3d at 803.

85. *Id.*

86. *Id.* at 803-804.

patent infringement in the pending litigation.⁸⁷ Somewhat curiously, the agreement did not settle the litigation between the parties but left it pending. This curiosity had a purpose, however. By leaving the litigation pending, the parties allowed Andrx to hold onto the 180-day generic exclusivity period and created a bottleneck that prevented the FDA from approving any other generic.⁸⁸ When final approval of Andrx's ANDA came on July 3, 1998, the pharmaceutical patent-holder began making payments to Andrx under the parties' agreement, and Andrx, in return, withheld its generic from the market.⁸⁹ It was not until nearly a year later, in June 1999, that the parties settled their litigation, Andrx began marketing its generic, and the 180-day bar on generic approvals began to run.⁹⁰ As a result of the parties' agreement, other generics could not obtain FDA approval to enter the market until December 1999.⁹¹

Although the two cases arose in somewhat different procedural contexts,⁹² both courts concluded that the agreement constituted a horizontal agreement to eliminate competition and allocate market share⁹³—in the words of the Sixth Circuit, “a classic example of a *per se* illegal restraint of trade.”⁹⁴ Although both courts expressed particular concern that the agreement created a bottleneck that prohibited FDA approval of other generics, their reasoning suggested that, even in the absence of the bottleneck, the reverse payment itself constituted a means of illegally buying market share.⁹⁵ Both courts specifically rejected the argument that the existence of a patent insulated the parties' agreement from antitrust challenge.⁹⁶ As the Sixth Circuit explained:

87. *Id.* at 803.

88. *Id.* at 804.

89. *Id.*

90. *Id.*

91. *Id.*

92. In *Andrx Pharmaceutical*, Andrx had sued other generics to clarify its right to the 180-day generic exclusivity. One of the generics, Biovail, counterclaimed, asserting violations of section 1 and 2 of the Sherman Antitrust Act. *Id.* at 804. The district court dismissed the counterclaim, concluding that Biovail could not establish causal antitrust injury. *Id.* Thus, the appeal focused on whether Biovail had adequately pleaded causal antitrust injury. *Id.* In contrast, in *In re Cardizem CD*, various purchasers of Cardizem CD had brought class-action litigation challenging the agreements as an antitrust violation. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 896 (6th Cir. 2003). The appeal arose after the district court granted summary judgment in the plaintiffs' favor, concluding that the undisputed facts established a *per se* violation of section 1. *Id.*

93. *In re Cardizem CD*, 332 F.3d at 908; *Andrx Pharm., Inc.*, 256 F.3d at 811.

94. *In re Cardizem CD*, 332 F.3d at 908.

95. *See id.*; *Andrx Pharm., Inc.*, 256 F.3d at 811.

96. *In re Cardizem CD*, 332 F.3d at 908; *Andrx Pharm., Inc.*, 256 F.3d at 811.

It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market.⁹⁷

In short, using a reverse payment to insulate the patent from challenge and to preserve the patent-generated rents violated the antitrust laws.

Yet, in the next round, the victor's laurel passed, as it were, from antitrust to patent law. In the five years following the Sixth Circuit's decision in *In re Cardizem CD*,⁹⁸ three circuit courts, the Eleventh, the Second, and the Federal, considered antitrust challenges to reverse payment settlements, and each rejected the antitrust claims as a matter of law.⁹⁹ In these courts' view, a reverse payment settlement was effectively immune from antitrust scrutiny as long as the scope of the market exclusion in the settlement did not exceed the potential scope of the patent(s) at issue.¹⁰⁰ If the settlement agreement barred the generic from entering the market for longer than the patent's term, or if the agreement barred the generic from introducing non-infringing products, then it was subject to antitrust scrutiny but, as a general rule, not otherwise. If the settlement's exclusionary scope did not exceed the patent's potential scope, then antitrust liability could be found in only two instances: (1) where the patent was acquired by fraud on the PTO; and (2) where the claims of patent infringement were "objectively baseless," and the litigation a sham.¹⁰¹

97. *In re Cardizem CD*, 332 F.3d at 908.

98. 332 F.3d 896 (6th Cir. 2003).

99. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1324, 1332–37 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065–66 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1308–10 (11th Cir. 2003).

100. *See Schering-Plough Corp.*, 402 F.3d at 1076 ("What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's prosecution. Here, we find that the agreements fell well within the protections of the [] patent, and were therefore not illegal.").

101. *In re Tamoxifen*, 466 F.3d at 213; *see Watson Pharm., Inc.*, 677 F.3d at 1312 ("Our . . . decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.").

For these courts, if the litigation was not a sham, and the patent was not obtained by fraud, there was nothing illegitimate about paying to preserve a patent.¹⁰² As the *Tamoxifen* court explained:

[S]o 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.¹⁰³

True, a willingness to pay to preserve a patent could be taken to “betray[] a fatal disbelief in the validity of the patent or the likelihood of infringement,”¹⁰⁴ but patent litigation is inherently long, complex, and uncertain. Even a patent-holder relatively confident as to its chances may want “to insure against the possibility that its confidence is misplaced, or . . . that a reviewing court might (in its view) render an erroneous decision.”¹⁰⁵

While acknowledging the “troubling dynamic” of reverse payment settlements,¹⁰⁶ these courts emphasized the general judicial policy favoring settlement.¹⁰⁷ A commitment to encouraging settlement might leave room for settlements that “protect patent monopolies that are, perhaps, undeserved.”¹⁰⁸ Yet, the market, and not courts, could deal with that potential problem directly. By paying off one generic challenger, a patent-holder signals a lack of confidence in its patent that will only encourage other challengers.¹⁰⁹

102. See, e.g., *Valley Drug Co.*, 344 F.3d at 1309 (“To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent’s potential exclusionary effects irrelevant to the antitrust analysis.”).

103. *In re Tamoxifen*, 466 F.3d at 208–09.

104. *Id.* at 210.

105. *Id.*

106. *Id.* at 211. (“We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.”).

107. *Id.* at 211–12 (“[S]ettlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents.”).

108. *Id.*

109. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2235 (2013) (“But, one might ask, as a practical matter would the parties be able to enter into such an anticompetitive agreement? Would not a high reverse payment signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges, perhaps too many for the patentee to ‘buy off?’ ”). Congress had also amended the Hatch-Waxman Act in 2003 to provide for forfeiture of a first filer’s claim to the 180-day exclusivity period to eliminate the bottleneck that the exclusivity period otherwise might present. *Id.* at 2234–35.

While a patent-holder might be able to pay off a second or third such challenger, “[t]he point will come when there are simply no monopoly profits with which to pay the new generic challengers.”¹¹⁰ Allowing parties to use reverse payment settlements will therefore not delay the reckoning for weak patents for long, or so these courts believed.¹¹¹

In the end, as long as the settlement did not exceed the patent’s potential scope of exclusion, “[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law.”¹¹² Given a choice, then, between vindicating the purposes of the antitrust laws and those of the patent laws, these courts chose to vindicate the purposes of patent law.

While there was considerable tension between the conclusions of the Sixth and D.C. Circuits, and those of the Second, Eleventh, and Federal Circuits, the Third Circuit’s decision in *In re K-Dur Antitrust Litigation*¹¹³ in 2012 made the circuit split undeniable. In its decision, the *K-Dur* court expressly rejected the “scope of the patent” test that the Second, Eleventh, and Federal Circuits had embraced.¹¹⁴ In its stead, the *K-Dur* court required “a quick look rule of reason analysis.”¹¹⁵ Under the “quick look” approach, in the context of

110. *In re Tamoxifen*, 466 F.3d at 212.

111. As one district court explained:

If courts do not discount the exclusionary power of the patent by the probability of the patent’s being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.

In re Ciproflaxin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 534–35 (E.D.N.Y. 2005) (citations omitted) (internal quotation marks omitted), *aff’d*, 544 F.3d 1323 (2d Cir. 2008); see also Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004) (“In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing.”).

112. *In re Tamoxifen*, 466 F.3d at 212–13.

113. 686 F.3d 197 (3d Cir. 2012).

114. *Id.* at 214.

115. *Id.* at 218.

pharmaceutical-patent litigation,¹¹⁶ a reverse payment would constitute “*prima facie* evidence of an unreasonable restraint of trade.”¹¹⁷ A pharmaceutical patent-holder could rebut this *prima facie* case “by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”¹¹⁸

In reaching this conclusion, the Third Circuit emphasized that while patents are presumed valid, the presumption of validity is merely a procedural device, not a substantive right.¹¹⁹ It shifts the burden to the defendant to prove a patent’s invalidity, but it does not foreclose an invalidity result. Indeed, such results are common.¹²⁰ In the court’s view, we should not foreclose finding an antitrust violation on the grounds that a valid patent already bars competition in the market because the validity and scope of the patent is precisely what was at issue in the underlying litigation before the settlement.¹²¹ As for the possibility that a sufficient number of additional challengers will come forward to ensure that weak patents are eventually struck down, the court expressed its doubts.¹²² As the court noted, by this point, we had already seen cases where a pharmaceutical patent-holder had used its patent-generated rents “to pay off a whole series of challengers.”¹²³ As for the final argument in favor of the “scope of the patent” test, the court acknowledged “the judicial preference for settlement.”¹²⁴ Yet, “while generally laudable,” that preference is grounded in neither statutes nor the Constitution and must give way in the face of “countervailing public policy objectives or, in this case, Congress’s determination . . . that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.”¹²⁵ In any event, the court continued,

116. *Id.* at 216 (“We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry.”).

117. *Id.* at 218.

118. *Id.*

119. *Id.* at 214.

120. *Id.* at 215 (citing an FTC study in which generic challengers prevailed 73% of the time in Hatch-Waxman litigation and Professor Kimberly Moore’s study in which defendants prevailed 42% of the time in patent cases that reached trial).

121. *Id.* at 201–02.

122. *Id.* at 212.

123. *Id.* (citing *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010), where the pharmaceutical patent-holder had successfully bought off four generic challengers).

124. *Id.* at 213.

125. *Id.* at 217.

parties remain free to settle; they just may not use a reverse payment as part of that settlement without risking antitrust liability.¹²⁶

With the stage thus set and a clear conflict between the circuits presented, the issue was ripe for Supreme Court review. All that remained was to await a suitable case. The wait was not long. In April 2012, the Eleventh Circuit issued its decision in *FTC v. Watson Pharmaceuticals*.¹²⁷ In its complaint, the FTC alleged that several reverse payment settlements involving the patented pharmaceutical, Androgel, amounted to “unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act.”¹²⁸ Applying its “scope of the patent” test, the Eleventh Circuit dismissed the FTC’s complaint for failure to state a claim.¹²⁹ In response, the FTC petitioned for certiorari, and the Court granted it.¹³⁰

II. THE COURT ACTS

By a five-to-three vote,¹³¹ the Court reversed the Eleventh Circuit and held that the FTC had adequately set forth a claim that the settlement agreements at issue unreasonably restrained trade and thus violated section 5 of the Federal Trade Commission Act (“FTCA”).¹³² In doing so, it rejected the presumptive legality of such settlements under the scope of the patent test.¹³³ At the same time, it also rejected the presumptive illegality of such settlements, under either the Third Circuit’s approach or the FTC’s position that courts reviewing such agreements should apply a “quick look” analysis.¹³⁴ Rather than adopting either of these approaches, the Court held that reverse payment settlements should be evaluated under the rule of reason.¹³⁵

126. *Id.* at 217–18 (noting that the parties may settle “based on a negotiated entry date for marketing of the generic drug”).

127. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev’d sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

128. *Id.* at 1305.

129. *Id.* at 1309, 1312.

130. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013).

131. Justice Alito did not take part in the Court’s consideration or decision of the case. *Id.* at 2238.

132. *Actavis*, 133 S. Ct. at 2238; *see also* 15 U.S.C. § 45 (2012) (explaining unlawfulness of unfair methods of competition and prevention by the FTC).

133. *Actavis*, 133 S. Ct. at 2230 (holding that the fact that the anticompetitive effects of the settlements fall within the patent’s potential exclusionary scope does not “immunize the agreement from antitrust attack”).

134. *Id.* at 2237.

135. *Id.* at 2237–38.

While the Court left the precise structure of the rule of reason inquiry to the trial court on remand,¹³⁶ the Court did not leave the matter entirely up in the air, as it were. In its analysis, the Court emphasized that the size of the reverse payment itself can provide evidence of both market power and a weak patent. Unless the payment “amount[s] to no more than a rough approximation of the litigation expenses saved”¹³⁷ or “compensation for other services that the generic has promised to perform,”¹³⁸ a large reverse payment may “provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of [the] monopoly profits that would otherwise be lost in the competitive market.”¹³⁹ A large reverse payment establishes that the patent-holder has “the power to charge prices higher than the competitive level.”¹⁴⁰ And “[a]n unexplained large reverse payment would normally suggest that the patentee has serious doubts about the patent’s survival.”¹⁴¹ As a result, a large reverse payment on its own can go far towards establishing a violation of the rule of reason, without the need to litigate, though an antitrust lawsuit, the likelihood that the patent-holder would have succeeded or failed on its patent infringement claim.¹⁴²

As for the suggestion that a reverse payment settlement would attract additional generic challengers and thereby ensure the quick demise of weak patents in any event, the Court articulated two reasons for doubt.¹⁴³ First, only the first filer can claim the 180-day generic exclusivity under Hatch-Waxman.¹⁴⁴ Without the advantage of the 180-day generic exclusivity, a generic has relatively little to gain from successfully challenging a patented pharmaceutical.¹⁴⁵ A successful challenge means that it may enter the market, but it also clears the way for other generics to do so as well. In the face of general generic entry, the incentive for any one generic to challenge a patented pharmaceutical may prove insufficient to provoke serious

136. *Id.* at 2238.

137. *Id.* at 2236.

138. *Id.*

139. *Id.* at 2235.

140. *Id.* at 2236.

141. *Id.*

142. *Id.* at 2236–37 (“In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”).

143. *Id.* at 2235 (“Two special features of Hatch-Waxman mean that the answer to this question is ‘not necessarily so.’”).

144. *Id.*

145. *Id.*; *see supra* text accompanying notes 56–60.

challenges, even with respect to weak patents.¹⁴⁶ Second, in addition to not gaining the 180-day generic exclusivity, a second generic challenger also faces a thirty-month automatic stay on FDA approval.¹⁴⁷ Particularly as the clock winds down on any given patent, a thirty-month automatic delay in entering the market may reduce the potential rents available to a successful generic challenger to a point where the challenger no longer justifies the costs of the necessary litigation.¹⁴⁸

While the Court recognized “a general legal policy favoring the settlement of disputes,”¹⁴⁹ the Court suggested that alternative settlement formats remained available that did not run afoul of the antitrust laws.¹⁵⁰ Specifically, the Court explained that the parties to pharmaceutical patent litigation “may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”¹⁵¹

As for the patent-holder’s desire to buy peace and thereby insure that it will not lose its patent as a result of a judicial mistake or its own misjudgment, the Court held that antitrust law simply trumps patent law on this issue. As the Court explained:

Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.¹⁵²

Chief Justice Roberts, along with Justices Scalia and Thomas, dissented from the Court’s decision.¹⁵³ While they disagreed with the majority on virtually every point, in the end they agreed with the majority that ultimately it came down to a choice as to which law, antitrust or patent, would prevail. Yet, where the majority sided with

146. *Actavis*, 133 S. Ct. at 2235.

147. *Id.*

148. *Id.* at 2243–44, 2246 (Roberts, C.J., dissenting) (detailing the high legal costs associated with litigating patent cases and referencing the majority’s assertion that requiring generics “to wait 30 months before receiving FDA approval to market their drug” will “chill subsequent generics from challenging the patent”).

149. *Id.* at 2234 (majority opinion).

150. *Id.* at 2234–35.

151. *Id.* at 2237.

152. *Id.*

153. *Id.* at 2238 (Roberts, C.J., dissenting).

antitrust law, the dissent sided with patent law.¹⁵⁴ “A patent,” Chief Justice Roberts insisted, “carves out an exception to the applicability of antitrust laws.”¹⁵⁵ As a result, in the dissenters’ view, in the absence of sham litigation or fraud, “[t]he correct approach should therefore be to ask whether the settlement [gave the patent-holder] monopoly power beyond what the patent already gave it.”¹⁵⁶

While the majority did not hold that reverse payment settlements were per se, or otherwise presumptively, illegal under the antitrust laws, the Court’s holding that an unduly large reverse payment can establish a rule of reason violation will likely chill the future use of the reverse payment format.¹⁵⁷ We turn now to a normative evaluation of the Court’s decision. As part of this evaluation, we look to answer several questions, but one in particular: Can we fulfill the purposes of both patent and antitrust laws on this issue, or in the end, must we choose one over the other?

III. EVALUATING THE COURT’S DECISION FROM A GAME THEORETIC APPROACH: TO SETTLE OR NOT TO SETTLE

To evaluate the normative merits of the Court’s decision, we turn to game theory. Rather than rely on intuition and guesswork as to how and why parties will settle, I use game theory to set up a more rigorous structure to test how potential pharmaceutical-patent litigants will react to various rule regimes governing settlement. In subsection B, I will lay out the basic framework. Before we get there, however, in subsection A, we begin with an underlying and fundamental question: Why are some patents weak while others are strong?

A. *Weak Patents, Strong Patents: Why?*

Some patents are weak; some patents are strong. Descriptively, the meaning of weak or strong is simple. It connotes the likelihood that any given patent will prevail in litigation. To prevail in litigation, a patent-holder must overcome whatever invalidity challenges a defendant asserts and demonstrate infringement. Thus, a patent is

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.* at 2246 (“According to the majority, this provision [enjoining the FDA ‘from approving a generic’s application to market a drug for 30 months if the brand name sues the generic for patent infringement within 45 days of that application being filed’] will chill subsequent generics from challenging the patent (because they will have to wait 30 months before receiving FDA approval to market their drug).”).

strong if it: (i) is very likely to overcome whatever invalidity challenges a defendant may assert; and (ii) has sufficient breadth so that its claims, either literally or by the doctrine of equivalents, are very likely to encompass any competing product and thus support a finding of infringement. A patent is weak, on the other hand, if: (i) it is likely to be found or held invalid; or (ii) even if valid, its claims are so narrow that they are not likely to encompass many potentially competing products and, hence, would not be infringed in any event.

That some patents are weak, while others are strong, is not an accident, nor does it reflect a mistake by the PTO. Rather, variable patent strength is an integral part of the structure of the patent system and essential to its goal of ensuring that inventive resources are allocated to their highest valued use. When we look at the broad range of inventions that the patent system can bring forth, we find that some inventions would require the devotion of considerable time, skill, research, and creativity, given the current state of technology, to develop. They represent technical problems that are difficult to solve. They are, in the ordinary sense of the word, hard. In contrast, other inventions are easy.¹⁵⁸ They require very little in the way of time, skill, research, or creativity to develop. Accordingly, some inventions require extensive patent protection for the inventor to recover her cost; others require very little or none at all.

The various requirements of patent law, which together define whether a patent is likely to fail or prevail in litigation, and in that sense, whether a patent is weak or strong, allow us to tailor the level of protection provided to each invention to precisely the level needed to bring it forth. For hard inventions that need something closer to full patent protection to be brought forth, we tailor the doctrine so that the patents on such an invention are likely to prevail in litigation. For easy inventions, which are largely able to recoup their costs through the ordinary workings of the market, patent law may need to provide only a slight additional boost to bring such inventions forth. For such easy inventions, we tailor patent doctrine so that the patents on such an invention have a chance, but only a small chance, of prevailing in litigation. Having weak and strong patents thus allows us to tailor the effective level of patent protection to the difficulty on the invention at issue. With one patent system, we can simultaneously provide strong patents to those inventions that are hard, while providing weak patents to those inventions that are easy. This

158. See Glynn S. Lunney, Jr., *Patents, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 39–56, 68–70 (2004).

provides a mechanism to match the level of patent protection provided to the level necessary and sufficient to bring any given invention forth.

This helps the patent system ensure the efficient allocation of inventive resources. Otherwise, patent law's one-size-fits-all system of protection would vastly overprotect some inventions while underprotecting others. In terms of ensuring an efficient allocation of resources, either overprotecting or underprotecting an invention is equally undesirable.¹⁵⁹ If a desirable invention is underprotected, then the financial returns the patent system provides will prove insufficient to attract the resources necessary to ensure that the invention is devised and disclosed. Those resources will flow to something else, to some other productive activity in the economy that, while it may generate value, will generate less value than the inventive activity at issue. The same misallocation arises if the patent system overprotects a given type of inventive activity. In this case, the patent system would ensure a financial return far more than that necessary to ensure that the inventions at issue are devised and disclosed. By offering such high returns, the patent system would attract too many resources into the overprotected inventive activity. It would attract resources into the overprotected inventive activity and drain them from other uses elsewhere in the economy, even when the other uses would have generated more value. In this case, the overprotected inventive activity becomes the less valuable something else to which resources flow.¹⁶⁰

Both overprotection and underprotection can thus lead to an inefficient allocation of available resources and can thereby disserve patent law's central purpose as a property regime. As we turn our attention to an evaluation of reverse payment settlements, we should keep in mind that the goal of the patent system is not to maximize the financial reward associated with any given invention. Rather, it is to provide an appropriate reward: one that leads individuals to devote their resources to the invention at issue if that represents the highest valued use of those resources, but not otherwise. The various doctrines of patent law that Congress has enacted and that the courts

159. This is a point that I have established and explored in depth with respect to copyright law. See Glynn S. Lunney, Jr., *Copyright's Price Discrimination Panacea*, 21 HARV. J.L. & TECH. 387, 431 (2008); Glynn S. Lunney, Jr., *Reexamining Copyright's Incentives-Access Paradigm*, 49 VAND. L. REV. 483, 641 (1996). It applies equally as well to patent law.

160. For a simple general equilibrium model illustrating this principle, please see Appendix I.

have interpreted help us define various patents as either weak, strong, or somewhere in between in order to ensure such an efficiently appropriate reward—a reward that tends to ensure that our available inventive resources are devoted to their highest valued use.

With this background understanding of the patent system in mind, we turn now to the basic framework for settlement decisions from a game-theory perspective.

B. *The Basic Framework for Settlement Decisions*

When we turn to the choice parties face between litigating and settling, self-interest will lead parties to settle, rather than litigate, when settlement terms can be found that make both parties better off compared to the outcome they each expect from litigating.¹⁶¹ To determine if a proposed settlement would make a party better off, a party must first determine what it stands to gain or lose from litigating. In the pharmaceutical context, patent-infringement lawsuits are usually brought before the generic drug actually enters the market.¹⁶² For that reason, only injunctive relief, not damages, is typically at issue.¹⁶³ The key issue is whether a defendant will or will not be allowed to enter the associated market. By winning the litigation, a plaintiff can preserve exclusivity in the market. A defendant, on the other hand, can ensure its entry by winning. For the plaintiff, then, the expected outcome from litigating is a function of three factors: (i) the plaintiff's expected chance of success in the lawsuit, multiplied by (ii) the present value of the expected rents from preserving the market in its patent-protected state, less (iii) the expected costs, fees, and lost productivity that will result from litigating. Likewise, the expected outcome for the defendant from

161. For the development of game theory models of settlement, see John P. Gould, *The Economics of Legal Conflicts*, 2 J. LEGAL STUD. 279, 279–93 (1973); Keith N. Hylton & Sungjoon Cho, *The Economics of Injunctive and Reverse Settlements*, 12 AM. L. & ECON. REV. 181, 181–95 (2010) (extending model to examine settlement where the relief sought is primarily injunctive rather than damages); William M. Landes, *An Economic Analysis of the Courts*, 14 J.L. & ECON. 61, 61–71 (1971); George L. Priest, *The Common Law Process and the Selection of Efficient Rules*, 6 J. LEGAL STUD. 65, 65–75 (1977) (expanding model to allow the parties to hold differing estimates of the plaintiff's likelihood of success); George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1, 12–17 (1984); Paul H. Rubin, *Why is the Common Law Efficient?*, 6 J. LEGAL STUD. 51, 61–63 (1977).

162. See, e.g., FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 7 (2002).

163. Under section 271(e)(4)(C) of the Patent Act, damages are available in Hatch-Waxman cases “only if there has been commercial manufacture, use, offer to sell, or sale within the United States . . . of an approved drug.” 35 U.S.C. § 271(e)(4)(C) (2012).

litigating is also a function of three factors: (i) the defendant's expected chance of success in the litigation, multiplied by (ii) the expected rents that the defendant will earn if it successfully defeats the patent and enters the market, less (iii) the expected costs, fees, and lost productivity that will result from litigating.

Given these considerations, we can define the value to the plaintiff from litigating in a pharmaceutical patent case as:

$$V_p = RX_p - C, \quad (1)$$

where V_p represents the value to the plaintiff from litigating, R represents the likelihood that the plaintiff will prevail, X_p represents the expected present value of the income associated with maintaining exclusivity in the patented product, and C represents the costs of the litigation.

Similarly, we can define the value to the defendant from litigating in a pharmaceutical patent case as:

$$V_d = (1 - R)X_d - C, \quad (2)$$

where V_d represents the value to the defendant from litigating, and X_d represents the expected present value of the income associated with defeating the claims of patent infringement and entering the market.

While these equations look symmetric and suggest that the stakes for the two parties are similar, they are not. In the usual case, the expected profit to the plaintiff from winning the case, X_p , will usually far exceed, often by an order of magnitude, the expected profit to the defendant from winning the case, X_d .¹⁶⁴ The reason for this is simple. If the plaintiff wins, then it gets to keep the relevant pharmaceutical market to itself and earn the associated monopoly profits. If the defendant wins, it may get a 180-day period where the FDA will not approve other generics, extended perhaps by other FDA delays, but relatively quickly, a prevailing defendant will face widespread generic entry and a consequently competitive market. Once the market becomes competitive, prices will fall to near marginal cost, and a defendant can expect to earn no more than a normal rate of return on its investment. As a result, a defendant will usually have far less to gain than a plaintiff has to lose in this type of pharmaceutical patent litigation.

To get a sense for the asymmetry in the stakes, consider the example of the anti-depressant Prozac. Eli Lilly obtained FDA

164. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209 (2d Cir. 2006).

approval to market Prozac in 1986, and with Eli Lilly's efforts, it quickly became an extremely popular and profitable pharmaceutical.¹⁶⁵ In December 1995, Barr Laboratories filed an ANDA seeking FDA approval to market a generic version pursuant to a paragraph IV certification.¹⁶⁶ After losing at the district court, Barr Laboratories managed to persuade the Federal Circuit that one of Eli Lilly's patents violated the rule against double-patenting style non-obviousness.¹⁶⁷ As a result, rather than expire as scheduled in December 2003, the Federal Circuit ruled that Eli Lilly's patent protection on Prozac would expire thirty-four months early in February 2001.¹⁶⁸ From 1998 through 2001, while protected by patents, Eli Lilly earned revenue from sales of Prozac in the United States of just over \$2 billion annually.¹⁶⁹ When its last patents expired, its revenue from U.S. sales of Prozac fell by almost 80% to just over \$400 million annually.¹⁷⁰ If we take this average loss in revenue, convert sales revenue to income using Eli Lilly's reported gross margin of 77.7%, and apply a discount rate of 10%, then losing the litigation and thirty-four months of patent protection cost Eli Lilly \$3.29 billion.

In contrast, despite its victory, Barr Laboratories gained much less than Eli Lilly lost. According to its SEC filings, Barr Laboratories received revenues of \$367.5 million in its first year selling fluoxetine,

165. *Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 976 (Fed. Cir. 2000).

166. *Id.*

167. *Id.* at 988.

168. *Id.*; see also MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 188 (2005). After the August 9, 2000 decision, Eli Lilly received a six-month extension on the first patent at issue, extending its effective patent protection on Prozac into August 2001. *Id.* We will use the thirty-four months, rather than the twenty-eight months, in this analysis to reflect Eli Lilly's expectations at the time it could have settled the litigation. Using the August 2001 expiration instead would change some of the numbers presented, but it would not change the normative implications of the analysis.

169. See *Eli Lilly & Co.*, Annual Report (Form 10-K), Ex. 13, at 2 (Mar. 28, 2002) ("Fluoxetine product sales in the U.S. decreased 26 percent, to \$1.66 billion, primarily due to generic competition for Prozac beginning in early August 2001."); *Eli Lilly & Co.*, Annual Report (Form 10-K), Ex. 13, at 2 (Mar. 28, 2001) ("Combined sales of Prozac, an antidepressant, and Sarafem in the U.S. increased 7 percent, to \$2.23 billion."); *Eli Lilly & Co.*, Annual Report (Form 10-K), Ex. 13, at 2 (Mar. 30, 2000) ("Prozac sales in the U.S. decreased 8 percent, to \$2.09 billion."); *Eli Lilly & Co.*, Annual Report (Form 10-K), at 14 (Mar. 26, 1999) ("Prozac sales in the U.S. increased 13 percent, to \$2.27 billion."). The data presented here is from my discussion of the Prozac case in an earlier article. See Lunney, *supra* note 75, at 45-46.

170. See *Eli Lilly & Co.*, Annual Report (Form 10-K), Ex. 13, at 2 (Mar. 20, 2003).

the generic version of Prozac.¹⁷¹ However, in its second year, with the end of the 180-day generic exclusivity, Barr Laboratories' sales of fluoxetine dropped to \$7.245 million.¹⁷² By winning the litigation, Barr Laboratories was able to sell its generic formulation for thirty-four additional months and also received the 180-day generic exclusivity revenues.¹⁷³ If we convert revenue to income using an estimated gross margin for Barr of 80%, and the same 10% discount rate,¹⁷⁴ then by winning, Barr Laboratories earned \$294.2 million. While this is a substantial stake by any measure, it represents less than 10% of the amount at stake for Eli Lilly.

Using these numbers to illustrate, we can use equations (1) and (2) to calculate the value to each party from litigating as a function of the expected chance that Eli Lilly will win the lawsuit. For example, if both parties estimate that Eli Lilly has a fifty-fifty chance of winning, then the value to Eli Lilly of litigating is \$1.635 billion. This equals its chance of winning (50%) multiplied by the expected present value of its income from keeping generics out of the Prozac market for thirty-four months (\$3.29 billion), less the expected litigation costs, which I

171. See Barr Pharmaceuticals Inc., Annual Report (Form 10-K), at 2 (Aug. 26, 2002) ("In August 2001, we launched our Fluoxetine 20 mg capsule, the generic equivalent of Eli Lilly's Prozac. For the fiscal year ended June 30, 2002 ('fiscal 2002'), sales of Fluoxetine were \$367.5 million, or 31% of total product sales. On January 29, 2002, our 180-day generic exclusivity period on Fluoxetine ended and, as expected, the FDA approved several other generic versions produced by other companies. As a result, the selling price declined dramatically and we lost market share to competing products. Both factors caused our sales and profits from Fluoxetine to be substantially lower than those earned during the exclusivity period. Faced with other generic competitors for Fluoxetine, we expect Fluoxetine to account for approximately 1% of product sales in fiscal 2003.").

172. Barr Pharmaceuticals Inc., Annual Report (Form 10-K), at 32 (Aug. 26, 2003) ("Fluoxetine accounted for \$7,245 of product sales in fiscal 2003, down from \$367,539 in fiscal 2002 . . .").

173. As discussed, given the court's decision in *Mova Pharmaceuticals* and the FDA's subsequent elimination of the "successful defense" requirement, Barr Laboratories might have been able to keep the 180-day exclusivity period by settling. See *supra* notes 51-52 and accompanying text. Under the current rules regarding the award of the 180-day generic exclusivity, rather than have or not have the exclusivity period, as would be the case if winning or losing the litigation are the only possible outcomes, the trade-off for Barr Laboratories in a litigate-or-settle framework is between the chance of winning and thereby possibly receiving the generic exclusivity income immediately, but also possibly losing the case and hence losing the 180-day exclusivity, or settling and waiting to receive the generic exclusivity income. Under the current rules, by settling, Barr could eliminate the risk of losing the case and thereby losing the 180-day exclusivity as well.

174. These numbers are intended to be for purposes of illustration only. If we used a different discount rate, the numbers would change, but the underlying principles and conclusions would not.

will assume are \$10 million.¹⁷⁵ In contrast, the value to Barr Laboratories of litigating is only \$137.1 million. This equals its chance of winning (also 50%) multiplied by the expected present value of its income from winning (\$294.2 million), less its expected litigation costs, which I will assume are also \$10 million. Using this same mathematical set-up, we can further calculate the value of litigating to each party as a function of the chance that Eli Lilly will win the lawsuit. Table 1 presents the results.

Table 1

The Value of Litigating the Prozac Patents as a Function of the Expected Chance that Eli Lilly Will Win

<u>R</u>	<u>Value (Lilly)</u>	<u>Value (Barr)</u>
100%	\$3,280,000,000	(\$10,000,000)
90%	\$2,951,000,000	\$19,420,000
80%	\$2,622,000,000	\$48,840,000
70%	\$2,293,000,000	\$78,260,000
60%	\$1,964,000,000	\$107,680,000
50%	\$1,635,000,000	\$137,100,000
40%	\$1,306,000,000	\$166,520,000
30%	\$977,000,000	\$195,940,000
20%	\$648,000,000	\$225,360,000
10%	\$319,000,000	\$254,780,000
0%	(\$10,000,000)	\$284,200,000

As Table 1 reflects, the value of litigating to Eli Lilly falls steadily as its chance of success falls. The value of litigating to Barr, on the other hand, runs in the exact opposition direction. But even as the value of litigating to Barr rises, it remains consistently below that of Eli Lilly until Barr is virtually certain to win. This large difference in litigation values is due to the parties' asymmetric stakes. Even when both parties estimate that Eli Lilly has no better than a 10% chance of winning the lawsuit, the value to Eli Lilly from litigating to

175. These numbers are meant to be for purposes of illustration only. Again, if we change the costs of litigation, the numbers would change, but the underlying principles and conclusions would not. I would note, however, that Barr Laboratories' 2001 Annual Report estimated its investment in each patent challenge at \$8 to \$10 million. Barr Pharmaceuticals Inc., Annual Report (Form 10-K), at 7 (Aug. 24, 2001) ("Patent challenges are complex, costly and can take three to six years to complete. They generally require an investment of \$8 to \$10 million per challenge.")

keep its monopoly remains higher than the value to Barr of litigating to enter the market simply because 10% of over \$3 billion is more than 90% of under \$300 million.

The parties will settle, rather than see the litigation through, when they can identify settlement terms that will make both parties better off vis-à-vis litigating.¹⁷⁶ Settlement terms can govern the timing of the generic company's entry, whether immediate, at the end of the patent's term, or somewhere in between. Settlement terms can also include payments from one party to the other. Whatever rule our legal system adopts regarding the legality of reverse payments may restrict the range of settlement options available and may therefore limit the parties' ability to identify settlement terms that will make both better off vis-à-vis the option of litigating. The question is: Can we devise a rule regarding reverse payments specifically, or permissible settlement terms more generally, that lead parties in pharmaceutical patent litigation to settle in a manner that advances the goals of both the patent and antitrust laws?

C. *Settlement Decisions in the Face of Legal Rules*

To examine this question in detail, we will look at how parties to pharmaceutical patent litigation will react in the face of three possible rule regimes. When we consider the rule regimes potentially available, we find, at one extreme, a rule regime that simply prohibits the settlement of pharmaceutical-patent litigation. Under this rule regime, once a party initiates pharmaceutical-patent litigation, the party must see the litigation through. To provide one baseline, this will be our first rule regime. At the other extreme, we find a laissez-faire rule regime that allows the parties to settle on whatever terms they like. To provide a second baseline, this will be our second rule regime. In the context of reverse payments, we will use as a stand-in for this second rule a simplified version of the Second Circuit's rule in *In re Tamoxifen Citrate*.¹⁷⁷ Under this regime, reverse payments are generally permitted, so long as the exclusionary scope of the agreement does not extend beyond the patent's exclusionary scope and term. Finally, as our third rule regime, we will explore the

176. This follows from the general assumption in economics that parties act in their own self-interest.

177. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (“[A]bsent an extension of the monopoly beyond the patent’s scope . . . the question is whether the underlying infringement lawsuit was ‘objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits’. . . . Payments, even ‘excessive’ payments, to settle were therefore not necessarily unlawful.”).

variable time of entry settlement approach the Court suggested in *Actavis*. Under this regime, reverse payments are prohibited, but the parties can vary the time at which the generic may enter the market from immediate entry until the end of the patent's term. Using these various rule regimes, we can examine how the rule regime changes which cases settle and also examine how the resulting settlements impact the competing goals of the patent and antitrust regimes.¹⁷⁸ Ideally, what we are looking for is a rule regime that will lead parties to settle or litigate in a manner that ensures that prices in the associated market remain high enough, but only just high enough, to ensure desirable innovation.

1. Settlement Rule Regime #1: No-Settlements

We start at one extreme and ask what would happen if the law prohibited settlement of pharmaceutical-patent litigation altogether. Knowing this to be the rule, parties will take somewhat greater care before they begin down a path that may lead to patent litigation. A generic drug company will file a paragraph IV certification for an ANDA only if it is prepared for the lawsuit that may follow. Similarly, a pharmaceutical patent-holder will file suit in response to a paragraph IV certification only if it is prepared to follow through on the litigation. Given this legal regime, both parties will take actions that will lead to litigation only if the expected value from litigating the case to completion is positive. Thus, for the pharmaceutical patent-holder, $V_p > 0$, and for the generic, $V_d > 0$. This means that each must expect to recover from the litigation more than it costs, such that:

$$RX_p > C \quad (3)$$

and

$$(1-R)X_d > C. \quad (4)^{179}$$

178. In our initial exploration of these rule regimes, we shall focus on the parties' decision within the context of a single instance of litigation. We shall explore the possibility of successive rounds of litigation in Part IV. See *infra* text accompanying notes 251-55.

179. In other words, both parties will litigate only if it is rational to do so. The patentee will look at its chance of success, R , and the monopoly profits it expects to continue to earn if it wins, X_p , and compare those to the cost of litigation, C . If its expected gain from litigating, which equals its chance of winning multiplied by the monopoly profits it would earn from keeping generic competition out of the market, are sufficient to cover the litigation costs, then it will litigate. If it is certain to lose, perhaps because it knows its patent is invalid, or if it is not earning monopoly profits in any event, perhaps because of other competing pharmaceuticals already in the market, then its expected gain from litigating may not cover its costs. In that case, the patentee would simply allow generic entry without initiating a lawsuit.

So long as equations (3) and (4) are satisfied, both parties will litigate. If equation (3) or (4) is not satisfied, such that the expected value from litigating is negative for one party or the other, that party will avoid taking the steps that may lead to litigation. If the generic estimates its expected return insufficient to cover the expected costs of litigation, then it will not file a paragraph IV certification with its ANDA. If the pharmaceutical patent-holder estimates its return as insufficient to cover its expected costs, then it will not file a lawsuit in response to a paragraph IV certification.

Thus, a "no-settlement" rule will lead to fewer patent cases being filed. However, it may not weed out many cases, as it weeds out only those cases where one party or the other is virtually certain to win. While the costs of pharmaceutical-patent litigation are high, the stakes from winning or losing are usually much higher. Using the figures for the Prozac case, for example, litigation may cost \$10 million for each party, but Barr's gain from prevailing in the litigation was nearly \$300 million, and Eli Lilly's loss was over \$3 billion.¹⁸⁰ Given what they have to gain or lose, Barr Laboratories needs an expected chance of success in the lawsuit of only 3.4% to justify filing a paragraph IV certification. Anything more than a 3.4% chance of earning the \$294.2 million prize from successful litigation will cover the \$10 million that Barr Laboratories expects to spend on the litigation.¹⁸¹ On the other hand, if Barr files a paragraph IV certification, then to preserve its monopoly, Eli Lilly will file suit so long as it believes that it has more than a 0.3% chance of winning the lawsuit. While Eli Lilly might not find the proverbial one-in-a-million long-shot worth litigating, as long as it has even a slight chance of winning the litigation, the billions at stake from preserving exclusivity in the Prozac market will readily cover the estimated \$10 million in litigation costs. Indeed, even if Eli Lilly faced radically higher litigation costs, say \$100 million, rather than \$10 million, Eli Lilly would still file suit in response to a paragraph IV certification so long as it estimated that it had more than a 3% chance of winning the lawsuit.

As a result, while it might weed out a few lawsuits involving very strong or very weak patent infringement claims, a no-settlement rule would likely reduce the number of pharmaceutical-patent cases filed only slightly. Given the substantial rents pharmaceutical patents and the 180-day generic exclusivity offer, it would still make rational

180. See *supra* notes 169–72.

181. See *supra* notes 173–75.

economic sense to file the vast majority of these cases even if both parties knew that they would have to litigate them to final judgment. The key difference then, with a no-settlement rule, would be that more cases would be litigated to final judgment, rather than settle as they do under the current rules.¹⁸²

Such a rule regime would tend to ensure results consistent with both patent and antitrust laws. As discussed, the patent regime seeks to ensure exclusivity in a market so that the resulting financial returns are sufficient to ensure that a given invention is devised and disclosed. The antitrust regime seeks to ensure that consumers have to pay the artificially high prices associated with a patent only to the extent necessary to ensure that the invention at issue is devised and disclosed. As long as the patent rules are well designed, such that a patent-holder's chance of succeeding on a patent-infringement claim reflects the financial return necessary to achieve an efficient allocation of inventive resources, then forcing parties to litigate all pharmaceutical-patent disputes to final judgment would tend to promote allocative efficiency. Litigation to final judgment would tend to ensure that patent-holders, on average, received precisely that inducement sufficient, but no more so, to bring forth desirable innovation.

Under a no-settlement rule, strong patent claims, by definition, would prevail, at least on average. For strong patents, prices would tend to remain high but that would reflect the patent system's judgment that for these inventions, high prices are appropriate. Weak patent claims, on the other hand, would on average fail. Prices would fall but, if the patent system is well-designed, not in ways that would discourage desirable innovations. Of course, as in any human system, mistakes would be made. Infringement claims that should succeed would sometimes fail; claims that should fail would sometimes succeed. Yet, so long as no one mistakenly bankrupted the associated

182. In a 2002 study, the FTC identified 104 first-filer ANDAs with paragraph IV certifications that brand-name pharmaceutical companies received between January 1, 1992, and January 1, 2001. FEDERAL TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 15* (2002). In response to these certifications, the brand-name pharmaceutical company sued the ANDA filers for patent infringement in seventy-five instances. *Id.* Of the seventy-five lawsuits, fifty-three had been resolved by the time of the study. In two of these fifty-three, the patent had expired before the lawsuit was resolved, and the cases were consequently dismissed. *Id.* In another, the NDA was withdrawn before the litigation was resolved, and again the case was dismissed. *Id.* Of the remaining fifty, twenty had been settled, while thirty were resolved by judicial decision. *Id.* Of the thirty judicial decisions, the generic applicant won in twenty-two. *Id.* Thus, rather than the observed 40% settlement rate (twenty out of fifty cases) in this sample, a no-settlement rule would have had a 0% settlement rate.

plaintiff, the mistakes should average out. If they do not, then that suggests a problem with the patent rules that should be addressed directly, rather than through the rules regarding settlement.¹⁸³

While a no-settlement rule thus promotes the policies of both patent and antitrust law, such a rule faces familiar objections. These include: (i) it would force parties to litigate when they would rather not, a troubling result particularly where a party's change of heart is due to information newly acquired during the litigation; (ii) it would be expensive and would require parties to spend resources on litigation, rather than on more productive uses elsewhere; and (iii) it would tie down scarce judicial resources to patent litigation that again might be better used elsewhere.¹⁸⁴ So far, courts have shown little inclination to adopt a no-settlement rule.¹⁸⁵ Even the *Actavis* Court recognized the value of settlements to resolve complex, uncertain, and expensive litigation.¹⁸⁶ Nevertheless, the no-settlement rule has several advantages. While it forces parties to litigate, so long as the rule was clear at the outset, the litigation does not provide many grounds for complaint. Similarly, while the rule forces parties and courts to expend time and resources on patent litigation, the costs of such litigation are a very small fraction of the value of getting these cases resolved correctly. Most importantly, it allows the patent system to do its job. It allows the patent system to provide weak patent protection for easy inventions, and strong patent protection for hard inventions. It thus allows the patent system to promote an efficient allocation of available resources. It also ensures that prices in patent-protected markets are no higher than necessary to bring forth desirable innovation. A no-settlement rule thus promotes the purposes of both the patent and antitrust laws.

183. Moreover, settlement will reflect the parties' expectations as to how the lawsuit will come out. Even if the legal rules are poorly tailored to the purposes of patent law, the parties' settlement will reflect that same poor tailoring.

184. See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005).

185. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202 (2d Cir. 2006) (“Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement.” (quoting *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856–57 (2d Cir. 1998))); *Schering-Plough Corp.*, 402 F.3d at 1075 (“There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.”).

186. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234 (2013) (“The Eleventh Circuit's conclusion finds some degree of support in a general legal policy favoring the settlement of disputes.”).

2. Settlement Rule Regime #2: Reverse Payments Allowed

In contrast, as we shall see, the second rule regime promotes neither purpose. Following the “scope of the patent” approach, the second settlement rule regime generally immunizes reverse payment settlements from antitrust attack. The settlement of a pharmaceutical patent lawsuit would open the door to antitrust liability in only three circumstances: (i) the settlement extends the exclusionary right beyond the scope or duration of the patent(s) at issue; (ii) the patent at issue was acquired through fraud on the PTO; or (iii) the claims of patent infringement were “objectively baseless.”¹⁸⁷ Under this rule regime, a settlement would not subject the parties to antitrust liability even if the amount of the reverse payment exceeded the generic company’s expected profit from winning the lawsuit. Again, as for the other settlement rule regimes, we will assume that the parties will settle if they can find settlements terms, permissible under this rule regime, that makes each party better off settling than it would be litigating.

When we open up the settlement options under this rule regime, we find two differences from the first regime. While I will discuss these differences in more detail, these two differences are: First, generics will pursue invalidity or non-infringement claims, even those they are very likely to lose, in an effort to extort reverse payment settlements from the pharmaceutical patent-holder. Second, so long as the two sides share a similar sense for the pharmaceutical patent-holder’s chance of success in the litigation, every case will settle. In every case, the generic will agree to remain out of the market until the patent expires; only the amount of the payment will vary.

With respect to the first difference, generic companies will file paragraph IV certifications even where they are nearly certain to lose in order to extract a reverse payment settlement from the pharmaceutical patent-holder. As we have seen, where the generic is nearly certain to lose, pursuing litigation to secure generic entry can be a money-losing proposition for the generic firm. In the Prozac example, Barr Laboratories would expect to lose money if it estimated its chance of winning the lawsuit at less than 3.4%. Under the first rule regime, for such cases, the generic will avoid filing a paragraph IV certification. In contrast, if reverse payments are lawful,

187. See, e.g., *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312, *rev’d sub nom.* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333–36 (Fed. Cir. 2013), *cert. denied*, 557 U.S. 920 (2009); *In re Tamoxifen*, 466 F.3d at 212–13.

a generic company may bring a lawsuit in such a case in order to extract a payment from the pharmaceutical patent-holder.

For any given chance of success, the pharmaceutical patent-holder will always have more at stake than the generic.¹⁸⁸ As a result, even a slight chance that the generic may succeed on its claims can confront the pharmaceutical patent-holder with a substantial risk—one that the pharmaceutical patent-holder would be willing to pay to resolve in its favor. Using the numbers from the Prozac example, and assuming that both parties believe that Eli Lilly's claims of patent infringement are very strong, such that Eli Lilly has a 98% chance of success, Barr Laboratories would expect to lose \$4.12 million if it were to litigate the case.¹⁸⁹ It has only a 2% chance of securing early entry into the market and would have to spend \$10 million on litigation to secure that chance. Under a regime prohibiting settlement, Barr would not file a paragraph IV certification in such a case. Yet, if reverse payments are lawful, it might pursue such a paragraph IV certification. While it expects to lose money if it has to litigate to final judgment, Barr Laboratories knows that the expected loss to Eli Lilly from litigation would be even larger. Eli Lilly would face its own \$10 million in litigation costs, and while the risk of losing is very small, even a 2% chance of losing over \$3 billion is a very large number. As a result, there is a possibility that Eli Lilly would pay Barr to settle the litigation and avoid any risk of losing its exclusivity.

While we cannot be sure what terms the parties would finally agree to in such a case, we can define the range of settlements that both parties would prefer to the alternative of litigating such a case to final judgment. If both parties estimated Barr's chance of success at 2%, Barr Laboratories would be willing to settle by agreeing to remain out of the market until the patent(s) at issue expired and would be willing to pay Eli Lilly up to \$4.12 million (its expected loss) to do so. Eli Lilly, on the other hand, would be willing to settle if Barr agreed to remain out of the market until the patent(s) at issue expired and would be willing to pay Barr \$75.8 million to do so. As a matter of economic theory, we cannot confidently predict who would pay whom or how much.¹⁹⁰ It is possible that Barr would pay Eli Lilly a

188. The patentee is fighting for monopoly profits for the patent's remaining duration, while the generic is, at best, fighting for duopoly profits for a 180-day period, followed by competitive returns.

189. I am using in this calculation the higher stake for Barr of \$287.4 million. If we use the lower stake of \$81.4 million, then Barr would expect to lose \$8.4 million by litigating rather than settling and delaying its 180-day generic exclusivity by thirty-four months.

190. Of course, we could throw around terms such as bargaining power and reputation, but those are just different ways of saying we do not know.

sum of up to \$4.12 million to settle the case; it is just as possible that Eli Lilly would pay Barr a sum of up to \$75.8 million to settle the case. While we do not know who will pay whom, or how much, we do know that the parties will settle and that Barr will agree to remain out of the market until the patents at issue expire. Nevertheless, the possibility that a generic could extract a payment from the pharmaceutical patent-holder in such a case, where the generic is so certain to lose that it expects to lose money on the litigation, provides the generic with an incentive to file a paragraph IV certification against even very strong patents. While more paragraph IV certifications will be filed, they will not be filed to prevail in litigation. Rather, generics under this rule regime will file a paragraph IV certification against very strong patents to extort a payment from the pharmaceutical patent-holder. The incentive to file such extortionate claims is not present under the no-settlement rule.

With respect to the second difference, we should expect every pharmaceutical patent case to settle when reverse payments are presumptively lawful. This stands in contrast to the first rule regime, where only a very few cases settle, and the vast majority are litigated to final judgment. When reverse payments are presumptively lawful, the parties can always find some reverse payment, P , that the pharmaceutical patent-holder can offer the generic company to remain out of the market that will make both parties better off settling, rather than litigating.¹⁹¹

As a general rule, a generic company will accept the offer of a payment, P , and agree to remain out of the market until the patent expires if the expected value from settling, S_d , equals or exceeds its expected value from litigating, V_d , or:

$$S_d = P \geq V_d = (1-R)X_d - C. \quad (5)$$

Similarly, the pharmaceutical patent-holder will be willing to offer a payment, P , in return for the generic company's agreement to remain out of the market until the patent expires, if the expected value from settling exceeds its expected value from litigating. The expected value from settling on these terms is the expected profit from exclusivity, less the agreed payment, or:

$$S_p = X_p - P. \quad (6)$$

191. At this point, we are assuming that there is only one generic form. We will examine the case where there may be multiple potential generic entrants in a later section. See *infra* text accompanying notes 247-49.

So long as the payment, P , is such that $S_p > V_p$, the pharmaceutical patent-holder would be better off settling than it would be litigating. Substituting in for S_p and V_p , and simplifying the equation, we can define the payment that a pharmaceutical patent-holder would be willing to offer a generic to maintain exclusivity as:

$$P \leq (1-R)X_p + C. \quad (7)$$

A reverse payment, P , exists that will make both parties better off settling, rather than litigating, if both equation (5) and equation (7) are satisfied, such that:

$$(1-R)X_p + C \geq P \geq (1-R)X_d - C. \quad (8)$$

So long as $X_p > X_d$, there will be some reverse payment, P , that will satisfy equation (8). Given that the pharmaceutical patent-holder will always have more at stake than the generic, we should expect $X_p > X_d$, and as a result, there will always be some reverse payment that will satisfy equation (8). As a result, no matter what value the parties place on the pharmaceutical patent-holder's chance of success, so long as they agree on that value, there will be some reverse payment that will make both parties better off settling and having the generic remain out of the market, rather than litigating.

Moreover, both parties would be better off with a reverse payment settlement that bars generic entry for the full patent term even in those cases where the patent-holder is so certain to lose that the patent-holder would not even bother to file suit at all under the first rule regime. Once we open the door to reverse payment settlements, the pharmaceutical patent-holder will always sue, and we should expect the parties to settle in a manner that prohibits generic entry in return for a reverse payment to the generic company. So long as the rents available with patent protection exceed those available without, the parties will always be better off maximizing their joint profit by maintaining the patent and then splitting the profits in an appropriate manner than they would be allowing generic entry at any point before the patent expires.

In the Prozac example, even if both parties knew that the patent would be invalidated, they could both be made better off by leaving the patent in place and splitting the \$3.29 billion in associated rents, than they would be under any possible settlement that allowed generic entry. Now, it may be in such a case that the "sham" litigation exception would effectively bring such an agreement within the ambit of the antitrust laws. But the "sham" exception would do so only in those extremely rare instances where it is perfectly clear to everyone

that the patent infringement claims were objectively baseless.¹⁹² If the claims of patent infringement were merely extremely weak, rather than completely without merit, the sham litigation exception would not apply. As a result, under the second settlement rule regime, we should expect parties to settle and maintain patents that would otherwise have been struck down.

Compared to a no-settlement rule, a regime allowing reverse payment settlements advances neither the goals of the antitrust laws nor the goals of the patent laws. That it fails to advance the goals of the antitrust laws is relatively clear. With such settlements, parties can insulate even extremely weak pharmaceutical patents from challenge. Consumers continue to pay high prices for certain pharmaceuticals where, but for the settlement, the patent would have been struck down and generic entry would have led to sharply lower prices.

What has so far gone unrecognized is that this *laissez-faire* approach to pharmaceutical-patent settlements also disserves the goals of the patent system. As discussed, the goal of the patent system is not to provide the maximum possible reward for every invention.¹⁹³ Rather, it is to ensure an appropriate reward—one that tends to ensure that available resources are devoted to their highest valued use. A strong patent reflects the patent system's judgment that the invention at issue needs a correspondingly high reward to ensure that inventive resources are allocated efficiently. A weak patent reflects the patent system's judgment that the invention at issue needs a correspondingly low reward to ensure that inventive resources are allocated efficiently.¹⁹⁴

Allowing reverse payment settlements would allow parties to distort the functioning of the patent system and frustrate its purpose. The patent system intentionally provides a low reward to weak pharmaceutical patents. Yet, if we allow reverse payment settlements, the parties could settle, insulate the weak patent from attack, and could thereby enable minor and trivially easy advances in pharmaceuticals to receive disproportionately high rewards. Such a result would lead to inefficiency.¹⁹⁵ For weak pharmaceutical patents,

192. See *Watson Pharm., Inc.*, 677 F.3d at 1312 n.10 (“Although the FTC’s complaint alleges that Solvay was ‘not likely to prevail’ . . . it does not contend . . . that there was no objective basis to believe the patent was valid and infringed. Accordingly, we do not rule out the possibility that sufficient allegations of any of those facts would state a valid antitrust claim.”).

193. See *supra* Part III.A.

194. See Lunney, *supra* note 158, at 39–56, 68–70.

195. The payment made to the generic drug company will tend to reduce, but not eliminate, the excessive returns that the reverse payment settlement option makes

such a settlement would allow the parties to substitute their own selfish desires for a high reward for the patent system's judgment that only a low reward was appropriate. By ensuring such a high reward, inventive resources devoted to easy pharmaceutical research would earn a disproportionately high price, and that high price, in turn, would attract additional inventive resources into easy pharmaceutical research even when those resources could have been used more valuably elsewhere.

This is not merely a theoretical concern. Pharmaceutical companies divert millions of dollars that could have been spent developing new, potentially life-saving medications into developing, patenting, and marketing slight modifications to existing pharmaceutical formulations.¹⁹⁶ They spend these resources to ensure that, when their patents on the original formulations expire, they can switch physicians to the new and newly patented formulation and limit the impact of generic competition.¹⁹⁷ Rather than create new value, they spend time and resources in order to capture value that already exists. While reverse payment settlements are not the sole cause of this so-called "evergreening" phenomenon,¹⁹⁸ by maximizing the rents that weak patents can capture, allowing reverse payment settlements would only encourage this type of wasteful rent-seeking.

In short, allowing reverse payment settlements certainly satisfies the interests of the litigants. Through their use, the litigants can settle every pharmaceutical patent case, ensure that every pharmaceutical patent remains in force, and share the resulting rents between themselves. Yet, allowing such settlements disserves the purposes of both the patent and antitrust laws.

available to pharmaceutical research. The payment will also tend to encourage investment in filing ANDAs with paragraph IV certifications, rather than research into desirable innovation.

196. For discussions of this phenomenon, see Haiden A. Huskamp et al., *Generic Entry, Reformulations and Promotion of SSRIs*, 26 PHARMACOECONOMICS 603, 604 (2008); Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public's Health: Is There a Role for Eminent Domain?*, 295 JAMA 434, 435 (2006).

197. In *Actavis* itself, the generics agreed to remain out of the market until August 31, 2015. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013). This was sixty-five months before the patent at issue expired. *Id.* But it was the year Solvay "anticipated shifting its customers to a new product with no generic equivalent." FTC Petition for Writ of Certiorari, *supra* note 7, at 6.

198. Evergreening is the practice of obtaining new patents on minor variations of, or improvements to, an existing pharmaceutical, principally to extend a manufacturer's claims of patent protection indefinitely. THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, at 99 (Allan M. Fox & Alan R. Bennett eds., 1987).

3. Settlement Rule Regime #3: No Reverse Payments; Vary Timing of Patent Invalidation and Generic Entry

So far, we have explored two settlement rule regimes. The first achieves the dual goals of the patent and antitrust laws but at the expense of forcing parties to litigate to final judgment pharmaceutical-patent litigation. The second regime readily allows the parties to settle as they see fit, but at the expense of sacrificing the goals of both the patent and antitrust laws. In *Actavis*, the Court suggested another possibility that may address all of these concerns. Specifically, the Court explained that parties to Hatch-Waxman pharmaceutical-patent litigation can settle “by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”¹⁹⁹ In this section, we explore the Court’s suggestion and examine a settlement rule regime that allows the parties to agree as to the time at which the patent will become invalid and generic entry will occur,²⁰⁰ but prohibits side payments in either direction. To be perfectly clear, we are not talking about licensed generic entry under this rule regime. Rather, under this rule regime, the settlement specifies a time at which the patent(s) at issue become invalid or otherwise unenforceable and unlicensed generic entry begins. That time must fall between the end of the litigation and the patent’s expiration. When the agreed time arrives, the settling generic manufacturer enters with its own generic and receives its 180-day generic exclusivity. Immediately afterwards, general generic entry then follows.

Under this regime, the key negotiating point for the parties is the time at which the patent will become invalid and generic entry will begin. It can be immediately; it can wait until the patent’s term expires; or it can fall anywhere in between. Depending on the time for entry to which the parties agree, such a settlement will allocate a

199. *Actavis*, 133 S. Ct. at 2237.

200. In its decision, the Court does not state directly that the parties will agree in the settlement that the patent will become invalid or otherwise unenforceable against all generics. *Id.* The Court instead writes that the parties “may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.” *Id.* In this analysis, I am assuming that generic entry occurs generally at the agreed time. If, instead, the settlement agreement allows only one generic entry, then the economics are different from those presented under the analysis of settlement rule regime #4. They will look more like the economics that I will analyze in connection with licensed generic entry in the next section. See *infra* text accompanying notes 238–56.

corresponding fraction, $\phi(t)$, of the net present value of the expected exclusion rents to the pharmaceutical patent-holder. The generic, on the other hand, will receive the same rents that it would capture from winning the litigation but discounted by a factor, $\delta(t)$, to reflect that entry will be delayed until the agreed time. Again, the parties will settle if they can find a time for generic entry to begin, which makes both parties better off settling, rather than litigating.

The pharmaceutical patent-holder will be better off settling rather than litigating so long as the time selected for generic entry leaves it a sufficient fraction of the available exclusion rents, such that:

$$\phi(t) * X_p \geq R X_p - C. \quad (9)$$

The trade off under this settlement approach is that the patent-holder is entitled to prevent generic entry and earn its resulting monopoly profits, but only for some part of the patent's remaining life, rather than face the all-or-nothing uncertainty of litigation. When we simplify equation (9), we find that the pharmaceutical patent-holder will agree to settle so long as:

$$\phi(t) \geq R - C/(X_p). \quad (10)$$

Thus, the minimum time for entry that the pharmaceutical patent-holder would accept reflects fairly directly the parties' shared estimate of the patent-holder's chance of success, less that fraction of the exclusivity rents that the patent-holder expects to spend on the litigation.

The generic company, on the other hand, would be better off settling rather than litigating so long as the net present value of its expected profits from entry at the agreed time leaves it a discounted fraction of the available generic entry rents, such that:

$$\delta(t) * X_d \geq (1-R) X_d - C. \quad (11)$$

While we could similarly solve equation (11) to define the range of settlements acceptable to the generic in terms of the discount factor, $\phi(t)$, we cannot compare the results directly because the patent-holder's fraction, $\phi(t)$, and the generic's discount factor, $\delta(t)$, are different, non-linear functions of the agreed time for entry.

If we examine the issue empirically instead, we find that the suggested settlement format will generally leave a range of possible times for entry that both parties would prefer to litigating. We can illustrate using the numbers from the Prozac example. If we assume that both parties estimate Eli Lilly's chance of success as fifty-fifty, Eli

Lilly would be better off settling and allowing generic entry to begin so long as the net present value of its expected rents under the settlement exceed its expected value from litigating, or \$1.635 billion. Similarly, Barr Laboratories would be better off settling and being allowed entry so long as the net present value of its expected rents under the settlement exceeds its expected value from litigating, or \$137.1 million. Compared to litigating, Eli Lilly would be better off settling so long as it obtains at least sixteen months of market exclusivity.²⁰¹ With sixteen months of market exclusivity and a discount rate of 10%, the net present value of the expected rents from the settlement for Eli Lilly would be \$1.654 billion. So long as Barr agreed to wait at least sixteen months before entering, Eli Lilly would be better off settling rather than litigating.

As it turns out, Barr would be better off settling and being allowed to enter at any time of entry that would allow it to keep its 180-day generic exclusivity.²⁰² Even if Barr agreed to wait for twenty-eight months before entering, it would still receive a discounted present value from the expected rents of \$226.4 million. This is far more than Barr expects to receive should it litigate. The reason for this disparity is simple: While settling forces Barr to wait for its money, settling makes the money guaranteed, by eliminating the risk that Barr might lose the litigation and thereby lose the 180-day generic exclusivity rents altogether. Indeed, Barr would be better off settling even if it had to wait thirty months to enter. While waiting thirty months to enter would cost Barr two months of its 180-day generic exclusivity, the guaranteed rents from just four months of generic exclusivity, thirty months in the future, would still be worth

201. Note that in this example, sixteen months are less than half of the thirty-four months at issue. The fraction \bullet is not the fraction of the time left on the patent, however. Rather, it is the fraction of the net present value of the expected rents. Given a positive discount rate, money earned sooner is worth more than money earned later. As a result, even though sixteen months represents only 47% of the time remaining on the patents, it represents 50.6% of the discounted present value of the expected rents.

202. Under the current forfeiture rules, Barr could keep the 180-day exclusivity if it settled and entered the market one day before Eli Lilly's last patent expired. See 21 U.S.C. § 355(j)(5)(D)(i)(VI) (2012). Moreover, the 180-day exclusivity period itself ends when the last patent would otherwise expire. See *Mylan Labs. Inc. v. Leavitt*, 484 F. Supp. 2d 109, 122–23 (D.D.C. 2007); David E. Korn, Erika Lietzan & Shaw W. Scott, *A New History and Discussion of 180-Day Exclusivity*, 64 *FOOD & DRUG L.J.* 335, 363–65 (2009). Therefore, as a practical matter, to keep the full 180 days, Barr would have to enter six months before the term of the patent at issue would otherwise expire.

\$148.2 million.²⁰³ Such a settlement would still leave Barr better off than its expected return from litigating.

This leaves us with a range of terms that both parties would prefer to litigating. In a fifty-fifty case, Eli Lilly would be willing to settle so long as the parties agreed to delay entry at least sixteen months. Barr would be willing to settle so long as the parties agreed that entry was delayed not more than thirty months. Thus, both parties would be better off settling, rather than litigating, by agreeing to allow a delay of more than sixteen months but less than thirty months. Where within this range the parties will actually settle, we cannot predict.

We can extend this analysis more generally, and can calculate the range of entry dates that the parties would prefer compared to litigating, for different chances of success, R . To illustrate, Table 2 presents, for the thirty-four months remaining on the patents at issue, the shortest delay for generic entry that Eli Lilly would be willing to accept and the longest delay that Barr would be willing to accept for: (i) a strong patent, $R=80\%$; (ii) a medium patent, $R=50\%$; and (iii) a weak patent, $R=20\%$.

Table 2

Acceptable Range of Entry Times as a Function of Eli Lilly's Chance of Success

<u>R</u>	<u>Earliest Acceptable Entry</u>	<u>Latest Acceptable Entry</u>
80%	27 mos.	32 mos.
50%	16 mos.	30 mos.
20%	7 mos.	27 mos.

While not perfect, a variable time approach to settlement offers two advantages compared to our first two rule regimes. First, it leaves parties a viable avenue for settling most pharmaceutical patent cases and thus avoids the disadvantage of a no-settlement regime. Second, it also tends to promote the purposes of both the patent and antitrust laws and thus avoids the disadvantages of the scope of the patent settlement regime.

203. I calculated this number by calculating the per-month profit for the six-month exclusivity period, based upon Barr's reported earnings. Using a 10% annual discount rate, I then determined the present value of four months worth of such profits, beginning thirty months in the future.

This structure serves the purposes of the patent and antitrust laws because, as Table 2 reflects, the parties will settle by agreeing to a term of entry that reflects the pharmaceutical patent-holder's chance of success, R . For stronger patents, with a better chance of success in litigation, the parties will agree to delay entry somewhat longer. For weaker patents, with a lower chance of success, the parties will move the entry date forward. But, in both cases, such an approach is fully appropriate. To the extent that the chance of success, R , reflects the patent system's judgment regarding the level of protection and consequently the reward that a given patented invention deserves, tying the timing of entry to the chance of success directly preserves the patent system's judgment. Similarly, from the antitrust perspective, generic entry and lower prices will come sooner for consumers when the litigation involves a weak patent and will come later when the litigation involves a strong patent. While there is a difference between such an approach and litigating every patent to final judgment,²⁰⁴ such an approach should tend to protect consumers from unjustifiably high prices for patented pharmaceuticals. Under this approach, for weaker patents, consumers will pay the high patent-protected prices but for a shorter period. For stronger patents, consumers will pay the higher prices for a longer period, perhaps even the full patent term. But, in each case, the duration of the high prices would reflect the strength of the patent and hence the judgment of the patent system as to the justifiable period for prices to remain high.

The variable-time-of-entry settlement format is not perfect, however. To achieve the purposes of the patent and antitrust laws as effectively as the no-settlement rule, the parties would have to agree to a time for entry such that:

$$\phi(t) = R. \quad (12)$$

While it is possible that the parties will agree to such a time for entry, it is not inevitable. If the generic challenger is an effective and

204. The difference is that with the settlement approach all of the patents will prohibit entry for some time period. It will be shorter for weaker patents, but there will still be some delay. In contrast, if each patent were litigated to final judgment, many of the weaker patents would be struck down entirely, allowing immediate (or at least post-judgment) entry. Yet, under the litigation approach, some weak patents would survive. It might only be one in ten, but that one would remain valid for its full term. From a consumer welfare perspective, neither approach offers a clear advantage. Whether consumers would be better off by having nine weak patents struck down immediately, while one lingers for its full term, or having all ten weak patents enforced but only for a short time period is impossible to predict. But there is no reason to think that one approach is clearly better than the other.

skillful negotiator, it may be able to push the pharmaceutical patent-holder to accept a settlement with a time for entry close to the earliest time for entry that the patent-holder would accept rather than litigate. In that case, the time for entry might well approximate the optimality condition set forth in equation (12). On the other hand, if the generic challenger is not an effective and skillful negotiator, the pharmaceutical patent-holder may be able to push the generic to accept a settlement with a time for entry close to the latest time for entry that the generic would prefer to litigating. In that case, the Hatch-Waxman Act, as presently structured, will not prove very effective at policing weak patents.

Thus, the extent to which a variable-time-of-entry settlement will advance the goals of the patent and antitrust laws will depend entirely on the relative skill of the generic challenger in negotiating an early time of entry. While there is a possibility that the generic may settle readily, for whatever it can get, in the absence of a reverse payment, its only financial benefit from settling comes from entering as soon as possible. Therefore, it has every reason to push for the earliest possible generic entry. While we cannot be certain where the parties will settle within the range of times for generic entry that make both parties better off settling, at least under this settlement format, the generic's private interests tend to align with the interests of consumers and the public interest more generally.

D. Complications: Treating the Symptoms, Not the Disease

This analysis suggests that, given the options available to it, the Supreme Court got the issue exactly right. By creating a substantial risk of antitrust liability for reverse payment settlements, it made such settlements less likely and thereby advanced the goals of both the patent and antitrust laws. It served the goals of the patent system by preventing private parties from circumventing the rules of the patent system in order to capture inappropriately high returns on easy inventions. It served the goals of the antitrust laws by preventing private parties from entering into agreements that would force consumers to pay unjustifiably high prices for patented pharmaceuticals. At the same time, the Court left the parties a perfectly viable avenue for settling pharmaceutical patent disputes informally and so upheld the longstanding judicial support for settlements—for whatever that is worth.

Before we applaud too loudly and move on, however, there is one small problem with the Court's resolution. It treats a symptom but does not cure the underlying disease. The disease here is that

even relatively weak pharmaceutical patents can generate disproportionately large rents. Finding a way to insulate such weak patents from attack ensures that those rents will continue to flow, leaving the parties free to split them as they see fit. In the Prozac example, if Eli Lilly and Barr Laboratories could have found settlement terms that did not run afoul of the antitrust laws, while leaving Eli Lilly's patents intact, they could have split \$3.29 billion. Even a small share of that is more than the \$300 million that Barr expected to earn from entering the market, even with 180-day generic exclusivity. \$3 billion will also pay for a lot of creative thinking on how to capture the rents available from preserving weak pharmaceutical patents without running afoul of the Court's holding in *Actavis*. Certainly, we should not expect pharmaceutical patent-holders and generics simply to walk away from that money and let it return to consumers through lower prices just because the Court said to do so.

In its opinion, the Court left two possible avenues open for settlements that may preserve weak pharmaceutical patents and their associated rents, yet not run afoul of the antitrust laws. First, as part of the rule-of-reason analysis it adopted, the Court left room for the pharmaceutical patent-holder to prove that a reverse payment had "offsetting or redeeming virtues."²⁰⁵ As the Court explained, such a payment "may amount to no more than a rough approximation of the litigation expenses saved through the settlement."²⁰⁶ Or it "may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item."²⁰⁷ While policing the line between

205. *Actavis*, 133 S. Ct. at 2236. It is also not clear if the Court intended to leave open other procompetitive possibilities. The dissent, for example, suggested that the pharmaceutical patent-holder "will want to use the validity of his patent as a defense" in a rule-of-reason antitrust lawsuit. *Id.* at 2244 (Roberts, C.J., dissenting). Can a defendant argue that it settled to preserve a patent that was necessary to bring forth a life-saving pharmaceutical as a procompetitive benefit of the settlement? The Court seems to suggest that a defendant cannot, but it is not altogether clear. *Id.* at 2237 ("To say this is not to require the courts to insist . . . that the Commission need litigate the patent's validity, [or] empirically demonstrate the virtues or vices of the patent system."). In its decision adopting a quick-look approach, the Third Circuit suggested that a reverse payment settlement might entail a procompetitive benefit when it "enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). We should be careful before adopting such a position, however. Else, we will end up with thinly capitalized generics specifically established to pursue just one case so that the avoid-bankruptcy argument would always be available.

206. *Actavis*, 133 S. Ct. at 2237.

207. *Id.*

compensation for litigation expenses saved and a sharing of patent rents to preserve a weak patent seems reasonably straightforward, policing the line between compensation for other services and the sharing of patent rents is likely to prove far more difficult.

On remand in *Actavis*, these difficulties will likely take center stage. In the agreements before the Court in *Actavis*, each of the generics had agreed to promote the patented pharmaceutical to doctors.²⁰⁸ In its complaint, the FTC alleged that these other services had little value and that the “true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015.”²⁰⁹ Because the case came to the Court on a motion to dismiss, the Court could resolve this dispute readily. Following the rules that govern motions to dismiss, the Court simply accepted as true the pleadings of the complaint. The specific procedural context of *Actavis* thus made resolving the dispute trivially easy. On remand, however, determining the real reason for a particular payment may prove a far more difficult issue to resolve. Moreover, as we move forward, we should expect that issue to become even more difficult as parties adapt to the *Actavis* rules and become more creative in crafting “compensation for other services” covers.²¹⁰

The second avenue the Court left open is more fundamentally troubling, however. Rather than pay a generic to remain out of the market, the pharmaceutical patent-holder could settle these patent disputes by agreeing to license the generic defendant’s entry into the market, while using licensing terms that serve to maintain the patent-holder’s profit-maximizing price.²¹¹ While a traditional percentage-of-revenue royalty license would leave the generic with an incentive to cheat and sell the generic drug at a lower price in order to maximize its own profits, the patent-holder can discourage such cheating by: (i) setting an appropriate per-dose license fee, so that the license fee plus

208. *Id.* at 2229 (“Actavis also agreed to promote AndroGel to urologists.”).

209. *Id.*

210. FTC Petition for Writ of Certiorari, *supra* note 7, at 6. The FTC alleged that the settlements in *Actavis* itself entailed the use of such cover stories. *Id.* Because of the uncertain legality of reverse payment settlements in 2006 (when the parties settled in the case), the settlement agreement between Solvay and Actavis required Actavis to market AndroGel to urologists. *Id.* Similarly, the settlement agreements with Paddock and Par required Paddock to serve as a back-up supplier of AndroGel and Par to market AndroGel to primary-care physicians. *Id.* By agreeing to these roles, Solvay and the generics can contend on remand that the payments were not merely for delayed entry, but they were for these other services.

211. See, e.g., Glynn S. Lunney, Jr., Comment, Atari v. Nintendo: Does a Closed System Violate the Antitrust Laws?, 5 BERKELEY TECH. L.J. 29, 40 (1990).

the marginal cost of the drug equals the drug's profit-maximizing price; (ii) restricting the quantity of the generic drug that the licensee may sell; or (iii) setting a minimum resale price for the generic drug in the license.²¹² Using any of these three approaches would enable the patent-holder to discourage cheating by the licensee and preserve the patent's associated monopoly profits. Just as in the reverse payment settlement, the resulting rents could then be split between the pharmaceutical patent-holder and its generic licensee in whatever manner ensured that both would be better off with the license agreement than they would be litigating.²¹³ Entry would occur—indeed, the patent-holder could readily license more than one generic to enter using this approach—but competition would not.

The *Actavis* Court seemed to leave this path open. It expressly conceded that it had previously upheld a patent license agreement in which the patent-holder specified a minimum resale price in *United States v. General Electric Co.*²¹⁴ The *Actavis* Court further acknowledged that in *United States v. Line Material Co.*,²¹⁵ it had “presume[d] that the single-patentee practice approved in *General Electric* was a ‘reasonable restraint’ that ‘accords with the patent monopoly granted by the patent law.’”²¹⁶ The Court did cite several cases in which it had found antitrust violations when multiple patent-holders attempted to set prices through cross-licenses.²¹⁷ Yet, in the context of Hatch-Waxman pharmaceutical-patent cases, there is typically only one patent-holder. And the Court seemed to leave

212. The patent-holder could achieve the same result with a license that contained limits on the quantities that the generic could manufacture and sell, or by setting the retail price that the generic must charge as a term of the license.

213. Carl Shapiro has identified a number of other structures that parties might use to accomplish an anticompetitive settlement of patent litigation. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 394 (2003) (suggesting anticompetitive structures, including a merger where the purchase price reflects the desired rent division, a reverse payment settlement, a joint venture, and a per unit royalty).

214. *Actavis*, 133 S. Ct. at 2232 (“We concede that in *United States v. General Electric Co.*, 272 U.S. 476, 489, 47 S.Ct. 192, 71 L.Ed. 362 (1926), the Court permitted a single patentee to grant to a single licensee a license containing a minimum resale price requirement.”).

215. 333 U.S. 287 (1948).

216. *Actavis*, 133 S. Ct. at 2232 (quoting *Line Material Co.*, 333 U.S. at 312).

217. *Id.* (citing *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952); *Line Material Co.*, 333 U.S. at 310–11; and *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931)).

intact the right of a single patent-holder to license its patent(s) on such terms as it sees fit.²¹⁸

Resolving pharmaceutical-patent litigation through such a license agreement was not common so long as reverse payment settlements were legal. Compared to the licensing alternative, a reverse payment settlement offered several advantages. First, allowing entry, even licensed entry, may change the market in ways that are largely unforeseeable and difficult to predict. Because of those complexities, getting the right license terms so that both parties prefer the settlement to litigation may prove difficult. A one-time reverse payment is simpler and cleaner from both parties' perspectives and therefore likely to prove easier to negotiate. Second, at least historically, reverse payment settlements could create a bottleneck when used in combination with the 180-day generic exclusivity period, while allowing entry under a per-dose license may not.²¹⁹ Third, reverse payment settlements are better at preserving evergreening options.²²⁰ So long as there has been no entry, the pharmaceutical

218. Indeed, the Court upheld such a vertical price fixing agreement in *General Electric Co.*, even though at that time, vertical price fixing was otherwise a *per se* antitrust violation. See *Dr. Miles Med. Co. v. John D. Park & Sons*, 220 U.S. 373, 409 (1911). In 2007, the Court reversed this *per se* rule and held that vertical price fixing would be evaluated under the rule of reason. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 877 (2007).

219. It may be possible even under today's forfeiture rules for the first generic applicant to make a licensed entry, yet neither forfeit nor begin the start of the 180-day generic-exclusivity period. In dicta, Judge Sack suggested that licensed entry did not begin the generic-exclusivity period. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 196 (2d Cir. 2006) ("The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered and exhausted its 180-day exclusivity period by selling its own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen."). If Judge Sack's dictum is accurate, then a licensed-entry settlement effectively creates a bottleneck prohibiting the FDA from approving other generics until the patents at issue expire. While other generics might file paragraph IV certifications, the pharmaceutical patent-holder can simply refuse to file suit in response, leaving subsequent generics with no effective means to litigate the patent issues. See *Torpharm, Inc. v. Pfizer, Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at *8-12 (D. Del. 2004). However, the FDA has rejected Judge Sack's dicta and ruled that a generic's entry, whether with a licensed generic version manufactured by the patent-holder or with its own generic version, begins the 180-day exclusivity period. See *Mylan Pharm., Inc. v. Thompson*, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001) (upholding ruling of the FDA that the 180-day exclusivity period begins when the generic begins marketing its own generic version or the pharmaceutical patent-holder's generic version of the medication at issue).

220. For example, in the *Actavis* litigation itself, the generics agreed to remain out of the market until August 31, 2015. *Actavis*, 133 S. Ct. at 2229. This was sixty-five months before the patent at issue expired. *Id.* But it was the year Solvay "anticipated shifting its

patent-holder has more leeway to product hop, to shift consumers to a new, and newly patented, formulation of the pharmaceutical at issue, and to use other ways to extend its exclusivity in a pharmaceutical market.

While these concerns may help explain the preference for reverse payment settlements over the last decade, now that reverse payment settlements raise a substantial risk of antitrust liability, the question becomes whether the licensing approach will prove a viable, if imperfect, substitute. We have already seen at least one settlement agreement that approximates the licensing approach. In 1987, Barr Laboratories filed an ANDA seeking to market a generic version of tamoxifen and included a paragraph IV certification.²²¹ In response, the pharmaceutical patent-holder, Zeneca, sued for patent infringement. After the district court held Zeneca's patent invalid, and while the case was on appeal to the Federal Circuit, the parties settled.²²² In return for a \$21 million payment and a non-exclusive license to sell Zeneca-manufactured tamoxifen under Barr's label, Barr agreed to change its ANDA certification from paragraph IV to paragraph III and to wait until Zeneca's patent expired in 2002 before it would begin marketing its own generic version of tamoxifen.²²³

Because of the \$21 million reverse payment, this agreement would presumably violate the antitrust laws under the *Actavis* decision.²²⁴ Yet, the other aspects of the parties' settlement agreement set forth a possible framework for a pure licensing settlement going forward. To satisfy the standard in *Actavis*, the parties would have to reduce the reverse payment, perhaps until it reflected no more than

customers to a new product with no generic equivalent." FTC Petition for Writ of Certiorari, *supra* note 7, at 6.

221. *In re Tamoxifen*, 466 F.3d at 193.

222. As part of the settlement, the parties jointly petitioned the Federal Circuit to dismiss the appeal as moot and to vacate the district court's judgment. *Id.* at 194. Following its procedure at the time, the Federal Circuit granted the motion and vacated the district court judgment. See *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, No. 92-1403, 1993 WL 118931, at *1 (Fed. Cir. March 19, 1993). The Court subsequently held that such a *vacatur* was improper and invalid in nearly all circumstances. See *U.S. Bancorp Mortg. Co. v. Banner Mall P'ship*, 513 U.S. 18, 27-29 (1994).

223. *In re Tamoxifen*, 466 F.3d at 193-94.

224. According to the *Actavis* Court, in a rule-of-reason inquiry, we would initially focus on the size of the \$21 million payment, its relation to the patentee's anticipated future litigation costs, its independence from other services from the defendant that might justify the payment, and the lack of any other precompetitive justification. *Actavis*, 133 S. Ct. at 2237. If litigation costs for this type of claim are approximately \$8 to \$10 million, see *Barr Pharmaceuticals Inc., Annual Report (Form 10-K)*, at 7 (Aug. 24, 2001), then a \$21 million payment might seem unreasonably large.

the litigation costs that settling would save.²²⁵ Given that Hatch-Waxman pharmaceutical-patent litigation is expensive, this might not require much reduction, but it would likely require some.²²⁶ To compensate Barr for the reduced reverse payment, the parties could agree to a lower licensing fee on Barr's sales of the Zeneca-manufactured generic.²²⁷ At the same time, if the licensing fee was set to maintain the retail price at a profit-maximizing level, rather than as a rent division mechanism, the license could instead simply switch and stipulate a minimum resale price directly.²²⁸ Such an approach would sharply limit the generic's ability to cheat on the parties' deal by offering the generic version at a lower price in order to maximize its own profits.²²⁹

While it is possible to extend the *Actavis* rationale to find that such licensed generic entry arrangements violate section 1, the lack of a large reverse payment to trigger the inference of actual competitive harm presents a potential stumbling block.²³⁰ In *Actavis*, the Court

225. Again, this would depend on the size of the payment relative to the saved litigation costs for the patentee, as well as the other legitimate bases for such a payment that the Court identified. *Actavis*, 133 S. Ct. at 2237.

226. *Id.* at 2234.

227. *In re Tamoxifen*, 466 F.3d at 215 ("The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment.").

228. It is not clear whether the license agreement between the parties used a per-dose license fee or a stipulated minimum retail price as a mechanism to keep prices at the appropriate level. But whatever mechanism the parties adopted, it seemed to work. In a subsequent antitrust lawsuit, "[t]he plaintiffs allege[d] that the Barr-distributed Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version." *Id.* at 216; *see also id.* at 194 n.9 ("After the Settlement Agreement, . . . Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex® brand-name version. Barr soon captured about 80 percent of the tamoxifen market.").

229. In the *Tamoxifen* case itself, the price for the licensed generic version remained just 5% below the branded version throughout the license term. *Id.* at 216. In contrast, unlicensed generics, on average, sell for only 15% of the price of the branded pharmaceutical. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012) ("The FTC estimates that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder's unit sales and sells for fifteen percent of the price of the name brand product.").

230. It may prove a stumbling block, particularly for those judges who mistake licensed entry for competition because they apparently do not have a rudimentary understanding of economic principles. *See In re Tamoxifen*, 466 F.3d at 215 (Sack, J.) ("By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been."). In antitrust and economics, two parties do not compete if one sets the prices for both. With the tamoxifen settlement, consumers may have had a choice between the brand and the licensed generic, but as Zeneca set the price for both, the two did not compete. Rather, Zeneca was pursuing a multi-brand strategy, offering

suggested “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness.”²³¹ For the Prozac example, we can use equations (5) and (7) to calculate: (i) the minimum payment Barr will accept to enter into a reverse payment settlement; (ii) the maximum payment Eli Lilly will offer to enter into such a settlement; and (iii) the mean reverse payment. Table 3 presents the results.

Table 3

Reverse Payment Values as a Function of Eli Lilly’s Chance of Winning

<u>R</u>	<u>Barr’s Minimum</u>	<u>Eli Lilly’s Maximum</u>	<u>Mean</u>
100%	(\$10,000,000)	\$10,000,000	\$0
90%	\$19,420,000	\$339,000,000	\$179,210,000
80%	\$48,840,000	\$668,000,000	\$358,420,000
70%	\$78,260,000	\$997,000,000	\$537,630,000
60%	\$107,680,000	\$1,326,000,000	\$716,840,000
50%	\$137,100,000	\$1,655,000,000	\$896,050,000
40%	\$166,520,000	\$1,984,000,000	\$1,075,260,000
30%	\$195,940,000	\$2,313,000,000	\$1,254,470,000
20%	\$225,360,000	\$2,642,000,000	\$1,433,680,000
10%	\$254,780,000	\$2,971,000,000	\$1,612,890,000
0%	\$284,200,000	\$3,300,000,000	\$1,792,100,000

As Table 3 reflects, the mean payment value increases steadily as Eli Lilly’s chance of success falls from 100% to zero. But the inference is not as strong as the *Actavis* Court may hope. The mean payment value is simply the halfway point between the minimum reverse payment Barr would accept and the maximum Eli Lilly would be willing to pay. While a reverse payment anywhere between those two values would make both parties better off settling rather than litigating, neither economic theory nor any other theory provides much guidance as to where within that range we should expect the reverse payment to fall. A generic manufacturer with a very effective and skillful negotiator may be able to extract near the maximum reverse payment from a risk averse pharmaceutical patent-holder, particularly one that ties its officers’ compensation to its stock

different brands at different prices, in order to price discriminate and to maximize its rents from the associated market.

231. *Actavis*, 133 S. Ct. at 2236–37.

performance.²³² In such a case, using the Prozac numbers, the generic might plausibly extract a \$300 million reverse payment, even if the pharmaceutical patent-holder had a 90% chance of success. On the other hand, if the generic manufacturer is the more risk averse or a relatively poor negotiator, the generic might only extract a reverse payment near the minimum. In such a case, again using the Prozac numbers, the generic might extract only a \$255 million reverse payment, even when the pharmaceutical patent-holder has only a 10% chance of success. Depending on the relative bargaining ability of the parties, and holding the market size at issue constant, we might well, but for *Actavis*, have seen instances where larger payments were made in cases involving strong patents and smaller payments were made in cases involving weak patents. Nevertheless, if we assume that, on average, the relative bargaining ability of various generic manufacturers and the relative risk aversion of pharmaceutical patent-holders remain roughly the same across parties, the size of the reverse payment provides at least some evidence as to the parties' judgment concerning the relative strength of the patent at issue.

In contrast, in a license agreement, the minimum retail price is not likely to prove a reliable indicator of the strength of the patents at issue. Whether the patent at issue is strong or weak, in either case, the patent-holder will impose, and the generic will agree to, a minimum retail price that maximizes the rents generated by the pharmaceutical patent. That is the price that maximizes the size of the pie the parties will share. Whether the patent at issue is strong or weak, both parties will want to maximize the associated rents.

Although agreeing to a specific minimum retail price is not evidence of a patent's weakness, the parties' settlement agreement will reflect their judgment regarding the patent's strength. However, that judgment will be reflected, not in the minimum retail price, but in the division of the rents as between the parties. In the same way that we should expect the size of the reverse payment to correlate with a patent's weakness, so too should the division of rents. As the patent becomes weaker and the generic's chance of winning the litigation

232. As I have explained elsewhere, a pharmaceutical patent-holder's stock can fall disproportionately in response to a loss in significant patent litigation. See Lunney, *supra* note 75, at 46-48 (showing that Eli Lilly's stock experienced a -29.20% abnormal return on the day of the Federal Circuit's Prozac decision and a one-day loss in market capitalization of \$35.754 billion); see also Laura E. Pannatoni, *The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126, 127 (2011) (using an event study of litigation outcomes in paragraph IV certification cases and finding a median loss in market capitalization of \$387.78 million when the patent-holder lost the case at the district court).

increases, the generic should be able to negotiate a larger share of the rents a licensed-entry agreement will protect and generate. As with reverse payments, the correlation is not perfect. Given the large gains in trade available in these settlements, there is a wide range of agreed rent divisions that would make both parties better off compared to litigating. Just as with reverse payments, a shrewd generic may be able to extract a larger share of the rents from a pharmaceutical patent-holder with a strong patent than a naïve generic can extract even facing a weak patent. Nevertheless, we should expect, on average, that a generic's ability to extract a larger share of the rents available should provide the same sort of "workable surrogate for a patent's weakness" that a reverse payment provides.²³³

Whether a court will extend the *Actavis* Court's reasoning to find a rule of reason violation based upon a settlement agreement that allows licensed generic entry is unclear. Unlike reverse payments, licenses that allow a defendant to practice the patented invention in return for sharing the financial returns in some fashion or another are exceedingly common as a means for resolving all sorts of patent litigation.²³⁴ The allocation of the returns may also depend on the labor and capital contributions of both parties in ways that are complicated and vary across industries. Where a substantial reverse payment may make the weakness of the associated patent facially evident, it may be far more difficult to sort the sheep from the goats by attempting to parse the rent allocation within a license agreement that permits licensed generic entry.

Thus, the Court's decision in *Actavis*, although a very encouraging step in the right direction, leaves more work to be done. In the next part, I take up what steps we need to take next.

IV. LOOKING FOR A LONG TERM CURE: OF DISEASES AND SYMPTOMS

If we are to cure the disease and not merely treat one symptom, we must first identify the underlying factor or factors that led parties to use reverse payments to settle pharmaceutical-patent litigation. While there are several reasons, they all eventually tie back to one

233. *Actavis*, 133 S. Ct. at 2236–37.

234. Megan M. La Belle, *Against Settlement of (Some) Patent Cases*, 67 VAND. L. REV. 375, 395 (2014) (citing Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. L. REV. 237, 272 (2006)) (stating that "the vast majority of patent cases [about 65–68%] settle" and that "patent litigation is largely a settlement mechanism").

central consideration: The party making the decision whether to settle or litigate does not capture the full benefit of a successful challenge to a pharmaceutical patent. Rather than flow to any one generic manufacturer, or even to all of them together,²³⁵ most of the benefits from a successful challenge to a pharmaceutical patent flow to consumers through lower prices.²³⁶ While there is a certain overlap in the generic's and consumers' interests, we should not expect a generic manufacturer to protect consumers' interests at the expense of its own. Rather, we should fully expect the generic to settle when settling is in its own best interest, even if the settlement imposes substantial and unjustified costs on consumers.

Identifying the underlying causal factors suggests a number of possible approaches to solving the underlying problem that led to reverse payment settlements. We might try to give consumers a more direct voice in the litigation, for example, by requiring judicial approval of any settlement as we do in class action litigation or by giving the FTC the power to intervene in pharmaceutical-patent litigation. Alternatively, we might continue to rely on the current approach of relying on a generic company to vindicate the public interest. If we do, the question becomes whether there are any further steps we should take to align the private interest of the generic more fully with the public interest. In part, this depends upon how parties respond to the *Actavis* decision.

As we move forward, we should watch for two types of settlements that, if present, will indicate continued problems with the Hatch-Waxman approach, even after *Actavis*. First, we may find that parties settle on terms that allow licensed generic entry with an agreed resale price for the generic version of the pharmaceutical. If

235. In a recent paper, Gideon Parchomovsky and Alex Stein propose a solution to this long-recognized problem in intellectual property litigation. See Gideon Parchomovsky & Alex Stein, *Intellectual Property Defenses*, 113 COLUM. L. REV. 1483, 1483 (2013). Specifically, they propose a voluntary-joinder mechanism for defendants that would require other similarly situated defendants to contribute to the cost of one defendant's successful defense. While such a mechanism may help a little, it will not help much. Even if all the generics have to contribute, they still have far less to gain as a group than a pharmaceutical patent-holder has to lose, and they capture only a fraction of the rents redistributed by a successful defense.

236. *Actavis*, 133 S. Ct. at 2234 (presenting a hypothetical in which a patentee generates \$500 million in revenue and noting that “[c]ontinued litigation, if it results in patent invalidation or a finding of non-infringement, could cost the patentee \$500 million in lost revenues, a sum that then would flow in large part to consumers in the form of lower prices”); see also *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012) (noting that the FTC estimates that a generic typically “sells for fifteen percent of the price of the name brand product”; as a result, “consumers, rather than generic producers, are typically the biggest beneficiaries of generic entry”).

this type of settlement becomes common, that would suggest that parties are simply substituting licensed generic entry settlements for reverse payment settlements as the preferred mechanism for preserving weak pharmaceutical patents. Second, we may find that parties settle using the variable-time-of-entry format but with entry consistently delayed until the last six months of the patent's life. If this type of settlement becomes common, that would suggest that generic challengers are not proving very effective at negotiating for an early time of entry against weak patents.

In the next two subsections, I take up how we might address these two indications that Hatch-Waxman is still not working as intended.

A. *Dealing with Licensed Generic Entry Settlements*

If licensed generic entry settlements become common post-*Actavis*, suggesting that licensed entry settlements have become the preferred method for insulating weak pharmaceutical patents from challenge, there are two approaches we might use within the existing Hatch-Waxman structure to address this issue. First, we could modify the Hatch-Waxman rules to tie the 180-day exclusivity to a "successful" assertion of a paragraph IV certification.²³⁷ As an initial step, we could add effective forfeiture provisions, so that the first filer loses the 180-day period if it does not obtain immediate entry. As a next step, we could encourage additional generic challengers by giving the second filer with a paragraph IV certification an opportunity to claim the 180-day generic exclusivity if the first filer loses it. Second, and alternatively, we could extend the reasoning of *Actavis* to bar the use of such a settlement structure under the antitrust laws.

Modifying Hatch-Waxman to tie generic exclusivity to a "successful" assertion of a paragraph IV certification seeks to bring

237. As previously discussed, the FDA once tied the grant of the 180-day generic exclusivity to a "successful defense" in patent litigation. *See supra* notes 50–52. Scott Hemphill and Mark Lemley have proposed re-adopting this approach but would expand "successful defense" to include two additional situations: (i) where the pharmaceutical patent-holder does not sue; and (ii) where the parties settle on terms that allow immediate generic entry. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 949 (2011); *see also* S. 504, 113th Cong., § 2 (2013) (proposing a similar approach). Presumably, they would limit the second option to cases where the generic enters with its own generic version of the medication, so that the 180-day exclusivity period begins to run, rather than entering with a generic version provided by the pharmaceutical patent-holder, which might not start the exclusivity period.

the interests of the generic litigant and consumers more fully into alignment by reducing the fraction of the redistributed rents the generic captures when it settles in a manner likely to be contrary to the interests of consumers. Congress made some attempt at using this method when it adopted rules providing that a generic would forfeit the 180-day exclusivity as part of the Medicare Modernization Act of 2003.²³⁸ As it turned out, however, those provisions lacked much in the way of teeth.²³⁹ We could also combine the discouragement to the first filer to settle litigation from forfeiting exclusivity, with encouragement to a second ANDA filer, by allowing the 180-day generic exclusivity to pass to the second filer if the first filer fails to vindicate the purposes of the exclusivity period (the “floating exclusivity” approach).²⁴⁰ Scott Hemphill and Mark Lemley have proposed such an approach,²⁴¹ and Congress has considered it.²⁴² While these sorts of modifications have a certain common-sense appeal,²⁴³ they are not likely to prove effective and may have unintended, adverse consequences.

The idea behind these modifications is to change the relative costs and benefits of settlement versus litigation enough so that, in at least some cases, the parties can no longer find settlement terms that preserve a weak patent while making both sides better off compared to litigating. For the generic challenger, adopting stronger forfeiture rules would increase the amount a generic would demand in the licensed generic entry settlement as its share of the patent-generated rents. Under the existing rules, settling may delay the onset of the 180-day generic-exclusivity period, but settling does not cause the generic challenger to lose the exclusivity period altogether. In contrast, under stronger forfeiture rules, or a “successful defense”

238. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1102, 117 Stat. 2066, 2457–60.

239. See, e.g., Hemphill & Lemley, *supra* note 237, at 971, 989.

240. *Id.* at 983–84.

241. *Id.*

242. S. 504, 113th Cong., § 2 (2013).

243. As Scott Hemphill and Mark Lemley have argued:

The point of giving generic firms 180-day exclusivity is to encourage them to challenge weak patents and enter the market earlier, lowering prices and benefiting consumers. But 180-day exclusivity has been hijacked. Today, it is a tool that encourages weak challenges to patents in the hopes of prompting settlement, and leads generic firms to settle even strong challenges for delayed entry in exchange for keeping their exclusivity. Consumers are arguably worse off than they would be with no 180-day exclusivity at all. The system can be dramatically improved by a simple rule: Want to get paid a bounty? Earn it.

Hemphill & Lemley, *supra* note 237, at 989.

rule, or some variation thereof,²⁴⁴ a generic that agreed to settle and wait, for example, until the last six months before the expiration of the patent(s) at issue to enter would lose the exclusivity period altogether. For a generic, the rents earned during the 180-day exclusivity period far exceed the rents earned once generic entry occurs generally. Recall in the Prozac example that Barr earned over \$360 million in its first year selling a generic version of fluoxetine with generic exclusivity and only a little over \$7 million each year thereafter. If Barr can settle, agree to enter when the patents have nearly expired, and still retain its 180-day generic exclusivity, then Barr will settle for far less than it would if Barr forfeited the 180-day generic exclusivity period by settling. As a result, this sort of rule change would substantially increase the amount, whether as a direct reverse payment or as a share of the patent-generated rents, Barr would demand before it would settle.

At the same time, changing the rules to allow for floating exclusivity would also reduce the amount a pharmaceutical patent-holder would be willing to pay to settle any given case. If we allow the 180-day generic exclusivity period to pass to a second ANDA filer if the first filer loses it, any payment or share of the patent-protected rents that a pharmaceutical patent-holder offered the first filer in return for dropping a challenge to its patent, the patent-holder would expect to have to pay to the second filer, the third filer, and each successive generic challenger as well. So, presumably, a patent-holder would be willing to pay somewhat less to settle with any given generic challenger.

With the generic challenger demanding more and the pharmaceutical patent-holder willing to pay less, changing the rules and tying the exclusivity period to some measure of “success” in defending the paragraph IV certification may, at the margins, make it more difficult for the parties to find settlement terms that preserve a weak patent while still making both parties better off settling rather than litigating. As a result, it may effectively prevent the parties from settling on anticompetitive terms.

However, as it turns out, the desirability of tying generic exclusivity to a successful assertion of a paragraph IV certification is more complicated than it may initially appear. First, it may not move the margins much and thus may render unattractive only a small sliver of anticompetitive settlements. Second, it may move the margins too much and lead to successive litigation that inappropriately invalidates

244. See *supra* notes 238–43 and accompanying text.

even quite strong patents. Third, it effectively precludes the parties from settling using the variable-time-of-entry structure that the *Actavis* Court suggested.

As to the first two concerns, whether tying exclusivity to a successful defense of the paragraph IV certification would move the margins none, some, or too much depends on two factors: (i) whether barriers to entry, the time patent litigation requires, or other considerations effectively limit the number of successive generic challengers a patent-holder will face; and (ii) the extent to which, if at all, a final judgment in the patent-holder's favor against one generic challenger increases the likelihood that the patent-holder will prevail against subsequent generic challengers. With respect to the first factor, while, in theory, the number of potential generic challengers is unlimited, practical concerns may limit the number of successive generic challengers a pharmaceutical patent-holder can expect to face. In particular, the tacit knowledge and other information costs associated with becoming an effective pharmaceutical patent litigator, as well as imperfections in the financial markets that limit financing for such litigation, may help limit the number of generic challengers. In addition, the time required to complete patent litigation may also limit the number of successive challenges that can be heard within any given patent's life. With respect to the second, as a formal matter, under existing law, non-mutual collateral estoppel bars a losing patent-holder from re-litigating an earlier finding of invalidity or non-infringement against a subsequent generic challenger.²⁴⁵ It does not, however, bar one generic challenger from re-litigating those issues based upon another generic defendant's loss. Yet, while not creating a formal estoppel, the decision of one court to reject invalidity defenses and find infringement may strongly influence another court's subsequent decision on those same issues. With all appeals being heard by panels of the Federal Circuit and many aspects of patent law becoming legal, rather than factual issues, inconsistent validity and infringement results are unlikely. Even if not formally binding on a later court, one court's rejection of the invalidity and non-infringement contentions of a generic challenger may well substantially reduce, if not eliminate, other generic challengers' chances of success on those issues.

In any event, whether the number of generic challengers is limited or unlimited, whether one victory for a patent-holder forecloses defeat or leaves the patent just as vulnerable as it was

245. See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

before the victory, we can illustrate how tying exclusivity to a successful assertion of a paragraph IV certification will change the settlement margins not much or too much by examining two possible scenarios. In the first scenario, there are a limited number, n , of generic challengers to a pharmaceutical patent-holder; and a final judgment of validity and infringement against any one of the generic challengers effectively binds the rest. In the second, there are unlimited generic challengers, and a final judgment of validity and infringement against any one of them does not change the pharmaceutical patent-holder's chance of success in subsequent litigation.

If the assumptions in the first scenario match the real world, then tying the exclusivity period to success will not change the margins much, as long as the number of generic challengers, n , remains small. To see this, we can extend our game theory model to account for n challengers. To ensure more than one generic challenger, we will assume that we modify Hatch-Waxman so that a generic forfeits the 180-day exclusivity period when it settles and that the right to the exclusivity period then passes to the next generic filer in line.²⁴⁶ Given the Court's decision in *Actavis*, the parties will not use the reverse payment settlement structure but will instead adopt a licensed entry settlement.²⁴⁷ Once a generic challenger proves its seriousness in the initial stages of the litigation, the pharmaceutical patent-holder will offer each generic challenger licensed entry, set a profit-maximizing minimum retail price, and divide the resulting rents, such that each challenger receives rents with a discounted present value, P .²⁴⁸ The pharmaceutical patent-holder can either: (i) settle and offer a share of

246. If a generic forfeits the 180-day exclusivity period by settling, but the right to the exclusivity period does not pass to the second filer, then the pharmaceutical patent-holder can offer lower payments to the subsequent filers. In such a scenario, the number of challengers would have to be much higher before the pharmaceutical patent-holder will run out of the rents necessary to pay off each challenger.

247. This will depend on how the district and appellate courts apply *Actavis*. Over time, the *Actavis* decision may prove only a minor irritant to the use of reverse payment settlements, but I am assuming that the decision will lead parties for alternative settlement arrangements that minimize the risk of antitrust exposure. But the framework I use would apply equally as well to reverse payment settlements.

248. Note that the use of P here is intentional. I am pointing out that a licensed entry agreement can amount to nothing more than a reverse payment settlement, except that, rather than a one-time reverse payment of P to stay out, a licensing settlement of this sort, allows entry, and then provides the generic with an identical effective payment, P , amounting to the discounted present value of the rents allocated to the generic by the settlement agreement. The anticompetitive consequences result from the minimum resale price.

its rents with a value, P , to each generic; or (ii) it can litigate once.²⁴⁹ The patent-holder will settle so long as:

$$X_p - nP \geq RX_p - C. \quad (12)$$

As we saw in our analysis of reverse payment settlements, each generic will settle so long as:

$$P \geq (1-R)X_d \leq C. \quad (7)$$

Settlement will make all parties better off compared to litigating so long as equations (12) and (7) are both satisfied. In turn, both equations can be satisfied so long as there are relatively few generic challengers, such that:

$$n \leq ((1-R)X_p + C) / ((1-R)X_d - C). \quad (13)$$

As defined in equation (13), n represents the number of generic challengers to whom a pharmaceutical patent-holder can offer a given share of its monopoly rents, such that both the patent-holder and each of the generic challengers are better off settling rather than litigating. When we apply equation (13) to the numbers I generated for Barr Laboratories and Eli Lilly for the Prozac example, n remains roughly constant for a wide range of expected chances of success. As the parties' shared estimate of Eli Lilly's chance of success rises from zero to 70%, n rises from 11.61 to 12.74.²⁵⁰ In other words, even if Eli Lilly had virtually no chance of success in the litigation, so long as there were fewer than eleven generic challengers to buy off, Eli Lilly would be able to do so. Because the rents available with patent protection so far exceed those available with generic entry, even if each generic thinks it can be the first to win and claim the 180-day generic exclusivity, Eli Lilly could offer each of the eleven a share of its patent rents that would exceed their expected return from litigating.

If the patent-holder expects there to be more than n serious generic challengers, then the parties will be unable to find acceptable settlement terms. Using the Eli Lilly numbers, if there are, for example, more than fifteen serious challengers, then whether Eli Lilly's patent is weak or strong, in either case, Eli Lilly will choose to litigate because there are too many challengers to compensate. Thus,

249. It only has to litigate once given our assumption that the outcome in the first final judgment effectively binds the parties in subsequent litigation.

250. It may seem strange that the number changes so little, but this results from the fact that as Eli Lilly's chance of success falls, it has to pay each generic somewhat more to settle but so does the maximum total amount Eli Lilly is willing to pay to preserve its patent.

this approach separates weak from strong patents, not of its own virtue, but through litigation. When there are more than fifteen serious challengers, Eli Lilly's patent, whether weak or strong, will be litigated. When litigated, we expect, on average, the strong patent to prevail, while the weak patent fails. The floating exclusivity approach thus duplicates the result of a no-settlement rule in this first scenario. Realizing that there will be too many challengers to pay each of them off, the patent-holder will litigate rather than settle. At that point, the floating exclusivity approach shares the strengths of the no-settlement rule. Cases are litigated, rather than settled, with the result that some patents prevail, while others fail. But in each case, so long as the patent rules are working appropriately, success and failure should, on average, reflect the patent system's judgment regarding the effective protection sufficient and necessary to encourage desirable innovation. The probable advantage of this approach, compared to a more straightforward no-settlement rule, is that it achieves a no-settlement result without appearing to prohibit settlement. Frankly, however, if floating exclusivity achieves our goals by amounting to a no-settlement rule, I would prefer an explicit no-settlement rule. A no-settlement rule is both more straightforward and honest, leaving less room for parties to complain of unfair surprise. And it does not require more than eleven serious generic challengers (using the numbers from the Prozac example) to work; it requires only one.

If we adopt the floating exclusivity approach, it is simply unclear whether there would be more than the n generic challengers necessary to replicate the no-settlement rule result. As discussed, under its current rules, the FDA awards exclusivity to the first ANDA application that includes a paragraph IV certification. If on the day that the first such ANDA is filed more than one applicant files such an ANDA, then they are all considered "first applicants," and they share the exclusivity period.²⁵¹ Some drugs have been subject to as many as sixteen first applicants; and in 2005, the average number of first applicants was eleven.²⁵² But the mere filing of a paragraph IV certification does not establish that an applicant would actually have followed through with litigation. If we look at successive litigation

251. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2012). When there is more than one first applicant, the 180-day exclusivity runs from the date "of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant." *Id.* § 355(j)(5)(B)(iv)(I).

252. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2246 (2013) (Roberts, C.J., dissenting) (quoting Brief for the Generic Pharm. Assoc. as Amicus Curiae at 23–24, *Actavis, Inc.*, 133 S. Ct. 2223 (No. 12-416)).

challenges more directly, since the D.C. Circuit forced the FDA to eliminate the “successful defense” requirement for exclusivity,²⁵³ successive challenges to a patent or set of patents directed at a single pharmaceutical market have become less common. Even when the “successful defense” rule was in place, and successive generic challenges occurred, they typically involved far fewer than eleven successive challenges. In the case of tamoxifen, for example, after a settlement with the initial challenger, only three more generic challengers jumped into the fray by filing paragraph IV certifications.²⁵⁴ In the case of ciprofloxacin, after a settlement with the first generic challenger, only four more generic challengers jumped into the fray by filing paragraph IV certifications.²⁵⁵

Thus, in the first scenario, tying the generic exclusivity award to successful entry might not move the margins very much. So long as the number of generic manufacturers willing to finance and pursue pharmaceutical-patent litigation remains small, and so long as one final judgment effectively binds all subsequent challengers, anticompetitive settlements will still occur. Even for very weak patents, the parties will still be able to find a division of rents that would make each of them better off by allowing the patent to remain standing than they would be litigating.²⁵⁶ Moreover, we should not fool ourselves as to how a floating exclusivity approach works in this first scenario. When the number of serious generic challengers exceeds n and the approach works, it works by merely achieving indirectly with many challengers what a no-settlement rule achieves directly with only one generic challenger.

In contrast, in the second scenario, a floating exclusivity approach will move the margins too much. In the second scenario, where there are an unlimited number of generic challengers, and a

253. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998); *Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410, at *7 (4th Cir. April 3, 1998).

254. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 194-95 (2d Cir. 2006) (“In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court’s judgment, three other generic manufacturers filed ANDAs with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen . . .”).

255. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329 (Fed. Cir. 2008).

256. Moreover, if there are more than eleven challengers against the weak patent, there might very well be enough challengers to foreclose such a settlement structure, even for a strong patent. Thus, this modification to Hatch-Waxman might de facto impose a no-settlement rule. While I am comfortable with such a rule regime, I believe that if such a regime is to be imposed, it should be imposed directly and expressly so that parties understand the consequences of filing a paragraph IV certification.

final judgment of validity and infringement against any one of them does not change the pharmaceutical patent-holder's chance of success against the rest, nearly every valuable pharmaceutical patent, no matter how strong, would be struck down. So long as the chance of success was sufficient, given the expected rents available from winning to cover the generic challenger's expected litigation expenses, it would be rational for a generic challenger to pursue litigation. Under this scenario, if that generic challenger lost, this would not alter the chances that a second challenger could win. So if it was economically rational for the first generic challenger to pursue litigation and the second paragraph IV filer could step into the shoes of the first and claim the 180-day generic exclusivity period, it would be equally rational for a second and a third and a fourth to pursue the same claim. Moreover, given an unlimited number of challengers, the pharmaceutical patent-holder would not be able to divide the available rents in a manner that would make each of the challengers better off settling rather than litigating. If there were only five or six generic challengers, as in the first scenario, dividing the rents and settling would be possible. But, in this scenario, there might be 100 challengers, and while the rents available from a pharmaceutical patent can be large, there would simply not be enough to persuade each of the hundred to drop their claims.

As a result, in this second scenario, so long as the expected chance of success for the generic, given the expected rents, covered the expected litigation expenses,²⁵⁷ tying the 180-day exclusivity to success would lead to, in theory, an infinite and, in practice, perhaps a very large, number of generic challenges. Facing a large number of challenges, sooner or later, even very strong pharmaceutical patents would be struck down. While a very strong patent might not be struck down in the first case, or the second, or the third, if we set up the Hatch-Waxman rules to ensure repeated challenges, sooner or later, it would be.

While, in my opinion, the second scenario is not very likely, it serves an important cautionary role. Not all patents that lead to high prices are bad for society. Although I have referred to the profits collected from pharmaceutical patents as "rents," some of them are better characterized as "quasi-rents." They may look like rents, in the sense that they derive from prices in excess of marginal costs—prices

257. In the Prozac litigation, where a successful generic challenger expected to capture \$287.4 million by winning the litigation, the challenger would pursue the litigation, even at an expected cost of \$10 million, so long as it estimated its chance of success as greater than 3.5%.

that are, in that sense, supracompetitive. For some pharmaceutical inventions, they are nonetheless justified because they cover the research and development costs necessary to bring forth the pharmaceutical invention at issue—costs that would not be reflected or recovered under marginal cost pricing. As we devise our Hatch-Waxman mechanism, we need to ensure that while it encourages desirable challenges against weak patents, it does not also encourage undesirable challenges against strong patents. Tying the award of generic exclusivity to a successful defense or to immediate entry, and allowing the award to transfer to a second filer in the event of forfeiture, has the potential to do so.²⁵⁸

The third problem that arises from tying generic exclusivity to a successful paragraph IV assertion is that it would effectively preclude the parties from settling using the variable time-of-entry strategy that the *Actavis* Court suggested. As we have discussed, parties to pharmaceutical patent litigation, rather than allowing immediate entry or waiting for a patent to expire, can agree to some intermediate time at which the patent becomes invalid and generic entry begins. Under the existing Hatch-Waxman rules, a generic challenger would retain its 180-day exclusivity under this framework. It would just be a question of whether it received the generic exclusivity sooner or later. As I have shown, under the existing Hatch-Waxman exclusivity rules, the parties can always find some intermediate time for generic entry to begin, such that the resulting allocation of rents makes both parties better off settling, rather than litigating.²⁵⁹

However, if we tie the 180-day exclusivity to success in the litigation or to immediate entry, so that a generic challenger that settles for delayed entry loses its right to the generic exclusivity period, this approach to settlement will no longer prove viable. By taking away the 180-day exclusivity, the parties would no longer be able to find a time for entry that will make both of them better off compared to litigating. The 180-day generic exclusivity period is simply too valuable to the generic challenger.

To illustrate, in the Prozac example, Eli Lilly and Barr might both agree that Eli Lilly had a strong patent claim, with an 80%

258. Under the current regime, this does not seem to be a problem. Generics tend to challenge weaker patents under the current regime where only the first filer can claim the 180-day generic exclusivity period. See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL L. STUD. 613, 613 (2011).

259. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013); *supra* text accompanying notes 201–02.

chance of success, or they might both agree that Eli Lilly had weak patent claims, with only a 20% chance of success. In either case, so long as Barr gets to keep its 180-day exclusivity as the first paragraph IV filer, they could find a time for generic entry that would divide the available rents so as to make both of them better off settling rather than litigating.²⁶⁰

In contrast, if Barr loses its 180-day generic exclusivity as a result of entering into such a delayed entry settlement, the parties would no longer be able to find a time for entry that works. As previously discussed, most of Barr's rents came from the 180-day exclusivity period. Take that away, and even immediate entry will not generate much in the way of rents for Barr. Even if Eli Lilly agreed to invalidate its patents and allow Barr and the other generics immediate entry, that would not be sufficient to compensate Barr for the loss of the generic exclusivity period. Without the 180-day exclusivity period, the discounted present value of immediate generic entry to Barr would only be \$14.2 million for the thirty-four months at issue. The only cases where Barr might be willing to accept a variable time of entry settlement offer and lose its generic exclusivity period, would be those where Barr believed Eli Lilly was nearly certain to win. Only in those cases would Barr's expected return on litigating and keeping the generic exclusivity be less than \$14.2 million. However, once Eli Lilly's chance of success fell below near certain victory, Barr would be better off litigating. Because of the value of the 180-day generic exclusivity to Barr, even a relatively small chance of winning and earning the generic exclusivity would make litigating a better option than settling, if settling meant losing the generic exclusivity period. Yet, in those cases where Barr would be willing to settle for quick generic entry, even if it meant a loss of the generic exclusivity period, Eli Lilly would not be willing to offer it. If Eli Lilly was reasonably certain to win, Eli Lilly would be far better off litigating than it would be settling on terms that allowed Barr quick generic entry.

For these reasons, tying 180-day generic exclusivity to a generic's success in asserting a paragraph IV certification is probably unwise. While such an approach might prevent some anticompetitive settlements, it would not likely prove very effective at reducing the number of such settlements. At least in theory, there is also some possibility that it may lead to an excessive number of generic challenges and threaten the patent system's goal of encouraging

260. See *supra* text accompanying notes 165–72 and 201–05.

desirable innovation by substantially weakening patents generally. More likely and more importantly, tying exclusivity to success would limit the ability of the parties to settle pharmaceutical patent litigation by setting an intermediate time for generic entry to begin. As this variable-time-of-entry settlement structure offers one of the most promising mechanisms for leaving the parties free to pursue their own self-interest, yet still achieve the goals of both the patent and antitrust laws, we should avoid changing the generic exclusivity rules in a manner that would effectively foreclose such settlements.

These problems would seem to suggest that extending *Actavis* to impose antitrust liability for licensed generic entry settlements represents the preferred alternative. As discussed, the basic structure of the argument for imposing rule-of-reason liability on licensed generic entry settlements follows the structure of the argument the *Actavis* Court used to impose rule-of-reason liability on reverse payment settlements. A licensed entry settlement that allocates a large share of the resulting rents to the generic challenger signals both market power and patent weakness in the same way that a large reverse payment does.²⁶¹ Moreover, just as in the reverse payment context, the inference that a licensed entry settlement unreasonably restrains trade becomes compelling given the parties' decision to forego a variable-time-of-entry settlement structure that would lack the potential for anticompetitive consequences. If we extend *Actavis*, then that still leaves us with the problem of ineffective generic challengers willing to settle for the latest acceptable entry date. Given that most of the value to the generic from entry comes from the 180-day generic exclusivity period, we may see many generics settle so long as they can receive their 180-day exclusivity at the very end of the patent's life.

B. Extending Actavis: Allow Only Variable Time Settlements

While the *Actavis* Court offered variable time of entry settlements simply as an alternative means to settle pharmaceutical-patent litigation,²⁶² I would go further and suggest that the Court should require such an approach to settlements of pharmaceutical-patent litigation. Such an approach channels the self-interest of the generic manufacturer so that it tends to act in the best interest of consumers. By prohibiting side payments, whether direct or through a licensed division of rents, the generic's sole source of rents derives

261. See *supra* text accompanying notes 213–35.

262. *Actavis*, 133 S. Ct. at 2237.

from entering as early as possible. As a result, we do not need to assign a third party, whether a judge, the FTC, or some other actor, to safeguard consumers from unnecessary monopoly power. The generic's own interests will lead it to act in a manner that vindicates the purposes of the antitrust laws by seeking the earliest possible entry.

The problem with this approach, under the current Hatch-Waxman structure, is that it places the generic in the position between choosing: (i) to settle and receive the 180-day generic exclusivity with certainty, albeit delayed until the agreed time for entry; and (ii) to litigate and potentially lose the 180-day exclusivity altogether.²⁶³ As discussed, given this incentive structure, the generic is better off settling and receiving the generic exclusivity period with certainty, even if entry is delayed until near the end of the patent term and even if the patent at issue is very weak. As a result, under the current Hatch-Waxman structure, we might not see much difference in the timing of generic entry between weak patents and strong patents. Whether weak or strong, the parties may simply settle on terms that allow the generic entry during the last six months of the patent's life.

Somewhat surprisingly, we can improve the fit between the time for generic entry the parties will agree to through settlement and the optimal time for generic entry, defined in (12), through a simple change to the Hatch-Waxman rules. Rather than take away the generic exclusivity period if the generic loses the patent litigation, we can guarantee the 180-day generic exclusivity period for the first paragraph IV filer whether the generic wins or loses any resulting patent litigation.²⁶⁴ While such an amendment is counterintuitive, within the context of a variable-time-of-entry settlement, such an approach more fully aligns the generic's interests with those of the public.

If the 180-day period is guaranteed, even if the generic loses the litigation, then the generic's stake in litigation becomes the value associated with entering earlier if it wins the litigation or entering later if it loses. Under this rule regime and a variable-time-of-entry

263. See *supra* note 201 and accompanying text.

264. We can guarantee the 180-day period either for the last six months of the lives of the patent at issues and cut into the value of the patents to that extent, or we can guarantee the 180-day period at the expiration of the patents and impose on consumers higher prices for patented pharmaceuticals for an additional six months. In calculating the values for the Prozac example, I assume that we give the guaranteed exclusivity period at the end of the patent's life if the generic challenger loses the litigation.

settlement format, the generic company will be better off settling rather than litigating so long as the time selected for generic entry leaves it a sufficient fraction of the available generic entry rents such that:

$$(1-\phi(t))X_d \geq (1-R)X_d - C, \quad (14)$$

where X_d is now the difference between the present value of the rents expected from immediate entry and those expected from entering at the expiration of the patent, with the generic retaining the 180-day generic exclusivity in either case.

The parties will settle if they can find a time for entry that makes both of them better off compared to litigating. Settlement will make both better off so long as the parties can identify a time for generic entry such that equations (9) and (14) are both satisfied. Simplifying and solving for $\phi(t)$, we find that both equations will be satisfied so long as:

$$R + (C/X_d) \geq \phi(t) \geq R - (C/X_d). \quad (15)$$

Because all of the variables in equation (15) are positive, the parties will always be able to find some fraction, $\phi(t)$, that satisfies equation (15). While the exact value of $\phi(t)$ will depend on the plaintiff's chance of success, the parties' relevant stakes, and the parties' respective costs of litigation, there will always be some $\phi(t)$ that will make both parties better off settling and allowing generic entry to begin at an appropriate time than they would be litigating. Moreover, the parties will always settle on a $\phi(t)$ that is equal to the plaintiff's ultimate chance of success, R , plus-or-minus a fudge factor. As equation (15) reflects, this fudge factor will equal, on the plus side, the defendant's costs of litigation as a fraction of the defendant's gains from winning, and on the minus side, the plaintiff's costs of litigation as a fraction of its gains from winning.

By guaranteeing the 180-day exclusivity period, we shape the incentives facing the parties so that the parties will agree to a time for generic entry that closely approximates the optimality condition, $\phi(t)=R$. Using the numbers from the Prozac case as an example, Table 4 presents, for the thirty-four months remaining on the patents at issue, the shortest delay for generic entry that Eli Lilly would be willing to accept and the longest delay that Barr would be willing to accept for: (i) a strong patent, $R=80\%$; (ii) a medium patent, $R=50\%$; and (iii) a weak patent, $R=20\%$.

Table 4

Acceptable Range of Entry Times as a Function of Eli Lilly's Chance of Success

<u>R</u>	<u>Earliest Acceptable Entry</u>	<u>Latest Acceptable Entry</u>
80%	27 mos.	30 mos.
50%	16 mos.	20 mos.
20%	7 mos.	10 mos.

While the earliest acceptable entry times remain the same as they were under existing law, guaranteeing the 180-day exclusivity period creates a set of incentives for the generic that move the latest acceptable entry date forward compared to those we saw in Table 2. For a strong patent, the latest acceptable entry date for which the generic will agree to settle with a guaranteed exclusivity period is thirty months, rather than thirty-two months under existing law. For a medium patent, the latest acceptable entry date with guaranteed exclusivity is twenty months, rather than thirty months under existing law. For a weak patent, the latest acceptable entry date with guaranteed exclusivity is ten months, rather than twenty-seven months under existing law.

Rather than leave the wide range of acceptable times that we saw under existing law,²⁶⁵ guaranteeing the exclusivity period narrows the range of acceptable entry times and ties them more closely to the strength of the patent. A generic challenger will still pursue its own interests, rather than those of consumers generally, and if inept, may still settle for the latest acceptable entry time but with guaranteed exclusivity that will be sooner than it is under current law.

By creating a set of incentives that will lead the parties to settle on a time for entry that directly reflects the patent-holder's chance of success, guaranteeing the exclusivity period and using the variable-time-of-entry format for settlement best advances the somewhat conflicting goals of the patent and antitrust laws. Without the need for outside intervention, or judicial second-guessing of a patent's strength in subsequent antitrust litigation, such a framework leads parties to settle on terms that directly reflect the strength of the patent(s) at issue. Parties will settle on earlier entry for weak patents and on later entry for strong patents. Moreover, by guaranteeing the exclusivity period to the first filer regardless of the outcome of any subsequent litigation, we move forward the latest entry date that will

265. See *supra* text accompanying notes 201–03

prove acceptable in settlement to the generic challenger. Through such a guarantee, we shape the incentives facing the generic challenger so that the time of entry becomes tied more closely to the strength of the patent and create a wide variance in the latest acceptable entry date for weak and strong patents.

Nevertheless, restricting the parties' settlement options to a variable-time-of-entry format and guaranteeing the generic-entry period may create two problems. First, such a framework will make pharmaceutical-patent litigation more difficult to settle. In order to settle, the parties must have similar expectations regarding the litigation's likely outcome. But they may not. For a variety of reasons, each side may substantially overestimate its own chance of success. In such a case, finding a time for entry that both will prefer to litigation will prove difficult. In contrast, settling on terms that license the generic's entry, specify a minimum retail price, and then divide the resulting rents, offers very large potential gains in trade for the parties to divide. Because the gains in trade are so large, particularly for weaker patents, the parties can more readily find an allocation of rents that make both sides better off settling rather than litigating, even if each side overestimates its chance of success in the litigation. Yet, if requiring parties to be realistic in their expectations regarding the litigation's likely outcome is the price for ensuring settlements that promote the goals of both patent and antitrust law, it seems like a reasonably small price to pay.

Second, if the value to a generic challenger from entering sooner rather than later becomes small relative to the costs of litigation, then the fudge factor becomes large and the range of entry dates that will prove acceptable to the generic challenger becomes wider. As a general matter, the value of early entry will depend on two factors. The first factor is the magnitude of the rents available from generic entry. These rents will usually depend upon the size of the market for the pharmaceutical at issue. For a drug, such as Prozac, with billions in annual sales, the rents from generic entry, including the 180-day generic exclusivity period, will usually be much larger than they would be for a pharmaceutical with less market demand. This aspect of the fudge factor is not problematic, however, as it serves as a good proxy for the public interest associated with challenging the patents at issue. The social cost of a weak patent increases as the size of the market it protects and the rents it generates increase.

However, the value of early entry also depends upon a second factor—the discount rate. In an era of very low interest rates, where the discount rate may be close to zero, the difference in value

between entering sooner and entering later will be correspondingly small. At the extreme, if the discount rate were zero, a generic challenger would have no incentive to pursue litigation if its exclusivity period were guaranteed. With a zero discount rate, the generic would receive the same value for the 180-day exclusivity period whether it entered immediately or waited until the patents at issue expired. This would remain true whether the patents at issue were weak or strong and whether they generated substantial rents or none at all. As a result, if a generic challenger filed a paragraph IV certification and was sued in response, in a world with a very low discount rate where its generic exclusivity period was guaranteed, it would simply accept a default judgment.

While this is a potential concern for the proposed settlement format, and while interest, and hence discount, rates are currently very low, that represents something of a historical anomaly. If interest rates return to their historical norms,²⁶⁶ then the proposed approach should bring the private interests of the parties to pharmaceutical-patent litigation in line with the underlying public interests at stake and lead the parties to settle on a time for generic entry close to the optimal. Nevertheless, we should remain aware that very low discount rates may frustrate the proposed approach's ability to fulfill the purposes of both patent and antitrust law as we go forward.

CONCLUSION

The strength and weakness of judicial decisionmaking is that it primarily serves simply to resolve the dispute before the court. The *Actavis* decision did a good job of resolving the dispute before it, but it did not and, by the nature of judicial decisionmaking, could not solve the broader problems associated with the very large and unjustified rents that weak pharmaceutical patents can generate. As we move forward, we are likely to observe two types of settlements that reflect the limitations of *Actavis*, even if we optimistically assume that *Actavis* will prove effective at discouraging anticompetitive reverse payment settlements directly.

266. For example, George Akerlof, Kenneth Arrow, Ronald Coase, Milton Friedman, James Buchanan, and other prominent economists used a discount rate of 7% in their amicus brief in *Eldred* to evaluate the present value added by twenty additional years of copyright protection seventy-five years into the future. See Brief for George A. Akerlof et al. as Amici Curiae Supporting Petitioners at 6–7, *Eldred v. Ashcroft*, 537 U.S. 186 (2003) (No. 01-618); see also *Eldred v. Ashcroft*, 537 U.S. 186, 254–57, 268 (2003) (Breyer, J., dissenting) (using a 7% discount rate to evaluate the value of an additional twenty years of copyright protection, seventy-five years in the future).

First, we may see settlements that license generic entry during the patent term, set a minimum resale price in order to maximize profits, and then divide those rents by setting appropriate royalties and other payments. While different in form, such a settlement structure essentially duplicates the anticompetitive effects of a reverse payment settlement, except the reverse payment comes in the form of a division of expected rent. After *Actavis*, we may see such a licensed entry model become the preferred method for insulating weak patents from generic challenges.

Second, to the extent that parties embrace the variable-time-of-entry settlement structure that the Court suggested, we may see the parties consistently agree to delay generic entry to the last six months of the life of the patent at issue. If we see such a pattern, this would suggest that generics are not seriously challenging weak patents but simply settling for the guarantee of 180-day generic exclusivity the settlement ensures, rather than risk losing the generic exclusivity altogether in litigation.

If we see the first problem arise in the settlements that follow *Actavis*, we can address it by extending the reasoning of *Actavis* to find that licensed generic entry settlements violate the antitrust laws under the rule of reason. By requiring sufficiently careful (and expensive) antitrust scrutiny of such licensed generic entry settlements, we can effectively encourage parties to use the variable-time-of-entry settlement format. If we see the second problem arise, where the generic routinely settles for the latest possible entry, we can address it by guaranteeing the generic exclusivity period to the first paragraph IV filer, even if the first filer subsequently loses any resulting patent litigation.

By using the variable-time-of-entry format and guaranteeing the exclusivity period, the only settlement to which both sides would agree will be one where the time for generic entry directly reflects the pharmaceutical patent-holder's chance of success in the litigation. As long as the patent laws are functioning properly, so that the patent-holder's chance of success accurately reflects the strength of the patent necessary and is sufficient to encourage the patent-holder to devise and disclose its invention, this approach should lead to settlements that provide a period of exclusivity and thus an incentive that is also both necessary and sufficient for desirable innovation, as the patent and antitrust laws require.

Requiring parties to settle only within a variable-time-of-entry framework is not a perfect solution. Restricting settlement options tends to cut against the "general legal policy favoring the settlement

of disputes,” a result that even the *Actavis* Court acknowledged.²⁶⁷ Some might go further and argue that by prohibiting the parties from settling on their preferred terms, we are effectively forcing them to litigate.²⁶⁸ But that would be wrong. We are not forcing the parties to litigate; we are simply prohibiting them from settling on terms that violate the law. At the same time, by requiring a variable-time-of-entry approach, we are both reconciling the seeming conflict between the patent and antitrust laws and ensuring that the parties will settle in a manner that promotes the goals of both.

267. *Actavis*, 133 S. Ct. at 2234.

268. *Cf. Nestle Co. v. Chester's Mkt, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985) (“[T]he district court imposed the heavy burden on trademark defendants of having to continue to litigate when they would prefer to settle, a ruling without precedent.”), *overruled on other grounds by U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27–29 (1994).

APPENDIX I: A SIMPLE GENERAL EQUILIBRIUM MODEL OF
INNOVATION

We can illustrate the misallocation that both under- and over-protection can generate using a simple general equilibrium model. Imagine an economy with two types of products toward which inventive resources can be devoted. One type is easy and requires one unit of innovative resources to create. The other type is hard and requires two units of innovative resources to create. However, the hard innovations generate social value for four periods, while the easy innovations generate value for only two periods. For both types, we have a series of five possible innovations towards which resources can be devoted, each generating a uniform social value each period. The most valuable innovation generates five in each period; the second most valuable generates four in each period; the third generates three in each period; and so on. Given that easy innovations generate value for two periods, the most valuable easy innovation generates ten value; five value in each of two periods. In contrast, given that the hard innovations generate value for four periods, the most valuable hard innovation generates twenty value, five each for four periods.

If we assume that we have six units of innovative resources available, then the optimal allocation is achieved when two units are devoted to easy innovations, one each to the top two easy innovations, and four units are devoted to hard innovations, two each to the top two hard innovations. This allocation generates value from the available resources of fifty-four, eighteen from the two easy innovations and thirty-six from the two hard innovations. There is no other allocation of the available innovative resources that will generate more value given the available innovations in which resources can be invested.

To illustrate how markets can work to achieve such an optimal allocation, assume that in the absence of patent protection, innovators capture 100% of the value of their innovation in the first period simply from lead-time advantage and the ordinary working of the marketplace operating against a backdrop of enforceable property and contract rules. With patent protection, an innovator captures 100% of the value of their innovation in the second period as well. Given these assumptions, the market will ensure the optimal allocation of the available innovative resources if our legal rules deny patent protection to the easy innovations and grant patent protection to the hard innovations. Such an approach will yield an effective price for each innovative resource of four and will lead individuals to

devote the available innovative resources to the top two easy innovations and the top two hard innovations—the optimal allocation.

However, if we extend patent protection to the easy innovations as well, then the innovative resources will be inefficiently allocated. Instead of investing the available resources in the top two innovations of each type, the resulting market will lead individuals to devote the available resources to the top four easy innovations and to only the single top hard innovation. By investing the last two innovative resources in the third and fourth easy innovations, an innovator could recover a total of ten for the two units,²⁶⁹ rather than a total of eight for investing the same two resources in the second hard innovation. By extending patent protection to the easy innovations, we “overprotect” them in the sense that the resulting market leads to an inefficient allocation of the available resources. The second hard innovation generates more social value, at sixteen,²⁷⁰ but if we extend patent protection to the easy innovations as well, there will be less private value for the innovator. By overprotecting the easy innovations, resources are misallocated, with resources flowing to the less valuable, easy innovations, rather than the more valuable, hard innovation. In our model, this leads to a reduction in social welfare from fifty-four to forty-eight, reflecting a reduction of more than 10%.

269. The third and fourth easy innovations generate social value of three and two in each of two periods, respectively. With patent protection for easy innovations, the innovator captures the social value each innovation captures for both periods. By investing in the third and fourth easy innovations, an individual would earn a total return of ten for the two resources. In contrast, the second hard innovation generates a social value of four for each of four periods, for a total social value of sixteen. Yet, even with patent protection, an innovator would only capture the social value the innovation creates for two of those four periods, or eight. Since eight is less than ten, an individual could recover more for the last two units of innovative resources available by devoting them to the third and fourth easy innovations, rather than to the second hard innovation.

270. Four units of value in each of the four periods.

