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PAYING FOR DELAY: PHARMACEUTICAL PATENT SETTLEMENT AS A REGULATORY DESIGN PROBLEM

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Over the past decade, drug makers have settled patent litigation by making large payments to potential rivals who, in turn, abandon suits that (if successful) would increase competition. Because such "pay-for-delay" settlements postpone the possibility of competitive entry, they have attracted the attention of antitrust enforcement authorities, courts, and commentators. Pay-for-delay settlements not only constitute a problem of immense practical importance in antitrust enforcement, but also pose a general dilemma about the proper balance between innovation and consumer access.

This Article examines the pay-for-delay dilemma as a problem in regulatory design. A full analysis of the relevant industry-specific regulatory statute, the Hatch-Waxman Act, yields two conclusions. First, certain features of the Act widen, often by subtle means, the potential for anticompetitive harm from pay-for-delay settlements. Second, the Act reflects a congressional judgment favoring litigated challenges, contrary to arguments employed to justify these settlements. These results support the further conclusion that pay-for-delay settlements are properly condemned as unreasonable restraints of trade. This analysis illustrates two mechanisms by which an industry-specific regulatory regime shapes the scope of antitrust liability: by creating (or

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limiting) opportunities for anticompetitive conduct as a practical economic matter, and by guiding as a legal matter the vigor of antitrust enforcement in addressing that conduct.

> *"[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."*
>
> —Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP[1]

INTRODUCTION

To what extent do legislative enactments shape the scope of antitrust liability? The answer is not purely a matter of antitrust law. Antitrust's basic law, the Sherman Act, takes a famously broad approach in its two major liability-setting provisions. Section 1 purports to condemn "[*e*]*very* contract, combination . . . , or conspiracy, in restraint of trade";[2] section 2 forbids a firm to "monopolize."[3] These provisions do not much constrain antitrust enforcement agencies or courts. Subsequent interpretation has narrowed the scope of section 1 to *unreasonable* restraints[4] and given content to the ill-defined concept of "monopolization." A law referred to as "the Magna Carta of free enterprise"[5] can hardly be expected to determine the results of particular cases. Instead, enacted antitrust law is generally understood to grant agencies and courts a broad license to develop policy in an incremental fashion.[6]

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[1] 540 U.S. 398, 411–12 (2004) (quoting Town of Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)). Justice Scalia wrote the opinion of the Court in *Trinko*; then–Chief Judge Breyer authored *Town of Concord*.

[2] 15 U.S.C. § 1 (2000) (emphasis added).

[3] *Id.* § 2.

[4] The claimed statutory hook for this result is that "restraint of trade" imported the common-law understanding of trade restraint law as it existed in 1890, "along with its dynamic potential." Bus. Elecs. Corp. v. Sharp Elecs. Corp., 485 U.S. 717, 732 (1988).

[5] United States v. Topco Assocs., 405 U.S. 596, 610 (1972); *see also* Appalachian Coals, Inc. v. United States, 288 U.S. 344, 359–60 (1933) ("As a charter of freedom, the Act has a generality and adaptability comparable to that found to be desirable in constitutional provisions.").

[6] *See, e.g.*, Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 688 (1978) (explaining that Sherman Act authorizes "the courts to give shape to the statute's broad mandate by drawing on common-law tradition"). Academics share this understanding. *See, e.g.*, Einer Elhauge, *Preference-Estimating Statutory Default Rules*, 102 COLUM. L. REV. 2027, 2044 (2002) (acknowledging that statutes delegate to courts "ongoing judicial resolution" of antitrust matters); William N. Eskridge, Jr. & John Ferejohn, *Super-Statutes*, 50 DUKE L.J. 1215, 1231–37 (2001) (using Sherman Act as classic example of "broadly enabling" statute); John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2444–45 n.212 (2003) (noting "independent policymaking discretion" provided to agencies and courts under statutes such as Sherman Act); Thomas W. Merrill, *The Common Law Powers of Federal Courts*, 52 U. CHI. L. REV. 1, 44–46 (1985) (commenting that section 1 of Sherman Act represents implied delegated lawmaking). For a critique of this view, see Daniel A. Farber & Brett H. McDonnell, *"Is There a Text in This Class?" The Conflict Between Textualism and Antitrust*, 14 J. CONTEMP. LEGAL ISSUES 619 (2005).

Also relevant here is section 5 of the Federal Trade Commission (FTC) Act, 15 U.S.C. § 45(a)(2) (2000), which grants the FTC power to prevent "unfair methods of competition,"

That license has limits, for two other kinds of regulatory law address firm conduct within the ambit of antitrust. One important and familiar source is intellectual property law, particularly patent law. Accounts of the intersection between antitrust and patent law emphasize the conflict in means between the two.[7] The usual account of antitrust law emphasizes allocative efficiency: avoidance of the distortion that results when consumers' unwillingness to pay high prices diverts them to less desirable substitutes.[8] The instrumental case for patent law, by contrast, depends upon high prices as a means to reward and thereby encourage innovation, a source of "dynamic" efficiency.[9] Because many competitive practices both distort allocation and provide a dynamic benefit, the conflict in means between antitrust and intellectual property can be stark. A substantial literature seeks an optimal reconciliation between these competing values by encouraging innovation without sacrificing too much consumer access.[10]

Intellectual property law, however, is not the only kind of regulatory enactment that affects antitrust decisionmaking. This Article isolates and examines a second overlap between antitrust and regulatory law, the ways in which an *industry-specific regulatory regime* alters the contours of antitrust enforcement. A particular regulatory regime sets the boundaries of feasible anticompetitive conduct. At the same time, it embodies a specific congressional judgment about the proper balance between

understood by the FTC in this context to be "for the most part[] co-extensive with the Sherman Act." *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part VI, n.107 (F.T.C. Dec. 8, 2003).

7 *See, e.g.*, 1 HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 1.3 (2002 & Supp. 2005), and sources cited therein (discussing interaction of intellectual property and antitrust law).

8 *See, e.g.*, RICHARD A. POSNER, ANTITRUST LAW 9–32 (2d ed. 2001) (describing centrality of allocative efficiency to antitrust analysis and considering objections). A policy that promoted prices *below* marginal cost would also harm allocative efficiency.

9 *See, e.g.*, Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1822 (1984) ("[W]hen patent policy is . . . implicated, profit plays a central role, because it serves as a reward—and, in turn, an incentive—for the inventive activity that produces the benefits of the patent system.").

10 *See, e.g.*, John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449 (1997) (emphasizing importance of cumulative innovation for optimal balance between patent and antitrust, and advocating greater protection of follow-on innovators); William F. Baxter, *Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis*, 76 YALE L.J. 267 (1966) (characterizing balance between competition and innovation as problem of optimal subsidy to innovators); Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761 (2002) (proposing industry-specific adjustments to antitrust-patent balance that vary depending upon technology of innovation); Kaplow, *supra* note 9 (analyzing optimal balance by assessing ratio between reward to innovator and deadweight loss resulting from patentee's practice); Stephen M. Maurer & Suzanne Scotchmer, *Profit Neutrality in Licensing: The Boundary Between Antitrust Law and Patent Law*, 8 AM. L. & ECON. REV. (forthcoming 2006) (arguing that certain profit-preserving practices by patentees are permissible under antitrust law).

competition and innovation in an industry. Both effects shape antitrust enforcement in often subtle ways. Identifying the impact of an industry-specific regulatory regime in a particular context requires careful, sustained attention to the principal features of the relevant regulatory scheme. That general project, though difficult, is also necessary to identify the boundaries of permissible competitive conduct in regulated industries as diverse as telecommunications, financial services, and—the primary focus of the present analysis—pharmaceuticals.

"Pay-for-delay" settlements in the U.S. pharmaceutical industry pose a puzzle of great current importance in antitrust enforcement. Such settlements emerge as an alternative to patent litigation between the manufacturer of a patented drug—call it the "innovator"—and its would-be rival, a so-called "generic" drug maker seeking to market a competing version of the same drug prior to the patent's scheduled expiration. If the generic firm wins in litigation, either by establishing that the patent is invalid or not infringed by the generic firm's competing product, the generic firm wins the means to enter the market prior to scheduled expiration. Successful pre-expiration challenges reallocate billions of dollars from producers to consumers.[11]

The antitrust issue arises when the two drug makers settle the patent suit prior to its litigated conclusion. In some settlements, the innovator pays the generic firm a large sum, the generic firm agrees to abstain from entry, and the parties agree to dismiss the patent suit. The effect of such pay-for-delay agreements is to remove the possibility of early competition in the drug, and to deny consumers the allocative benefit of low prices, which would have followed with some probability had the litigation proceeded to conclusion.

The Federal Trade Commission (FTC), the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has insisted that pay-for-delay agreements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade.[12] By contrast, some, though not all, federal appellate courts have permitted the settlements.[13] The difference of opinion is not limited to the courts: The Solicitor General not only declined to support an FTC petition seeking Supreme Court review of one pay-for-delay case, but filed an unusual, contrary brief expressly disagreeing with the FTC approach.[14]

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11 See *infra* Part I.A.2 for further discussion of pre-expiration patent suits.

12 See *infra* Part I.B for further discussion of these antitrust suits.

13 See *infra* notes 83–85 and accompanying text for a discussion of the conflicting case law.

14 *Compare* Petition for Writ of Certiorari, FTC v. Schering-Plough Corp., No. 05-273 (U.S. Aug. 29, 2005), 2005 WL 2105243, *with* Brief of the United States as Amicus Curiae, FTC v. Schering-Plough Corp., No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441. After offering the Solicitor General an opportunity to participate in its petition for certiorari, *see* 15 U.S.C. §

Economists and legal scholars have devoted substantial attention to these cases, in light of their economic importance and deepening doctrinal confusion about their resolution.[15] Commentators have framed the cases as

56(a)(3)(A), (C) (2000), the FTC had proceeded alone under its independent litigation authority; the Court then invited the Solicitor General to express the views of the United States.

[15] For technical economic analyses considering liability, compare Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, *in* 4 INNOVATION POLICY AND THE ECONOMY 145, 159–73 (Adam B. Jaffe et al. eds., 2004) (advocating liability for certain settlements and noting where law affords players opportunities to manipulate system), Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 RES. L. & ECON. 475 (2004) (similar), and Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (2003) [hereinafter Shapiro 2003a] (similar), with Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660–62 (2004) (arguing that under certain conditions, settlements are efficient and should be permitted). *See also* Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* 3–4 (FTC, Working Paper No. 281, 2006) (arguing that settlement undermines subsequent entrants' incentive to challenge patent, thereby harming consumers).

Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) [hereinafter Hovenkamp et al. 2003], provides a road map for courts considering the antitrust treatment of a broad range of intellectual property settlements and is inclined toward imposing liability for pay-for-delay settlements. Additional articles favoring liability include Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 18–19, 22–31 (2004) [hereinafter Hovenkamp, *Sensible Rules*] (advocating rebuttable presumption of liability); Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 712 (2004) [hereinafter Hovenkamp et al. 2004] (arguing that presumption of liability is less costly than case-specific analysis); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 54 (2004) (arguing in favor of per se rule of liability); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1767, 1787 (2003) (arguing in favor of rule of presumptive liability). *See also* Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, ANTITRUST, Summer 2002, at 53, 53 [hereinafter Brodley & O'Rourke 2002] (advocating statutory changes to facilitate detection of anticompetitive agreements); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, ANTITRUST, Summer 2003, at 70, 71–72 [hereinafter Shapiro 2003b] (arguing in favor of liability when settlements deprive consumers of litigation's expected benefits).

For analyses generally opposing liability, see, for example, Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 710–11 (2004) [hereinafter Crane 2004] (arguing that presumption of liability leads to costly error); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Applications*, 54 FLA. L. REV. 747, 753 (2002) [hereinafter Crane 2002] (similar); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68, 69 (arguing that presumption of liability circumvents question of patent validity); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1034–35 (2004) (arguing that imposing presumption of liability indulges in undesirable probabilistic analysis). One analysis, 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, 778–79 (2003), opposes liability in the narrow context of "partial" or "interim" agreements that do not resolve the litigation but merely block entry pending its resolution. Thomas Cotter's approach offers qualified support for some pay-for-delay settlements. Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse*

part of the wider debate about the intersection of patent and antitrust, and frequently seek to resolve these cases at that level of generality. For example, one prominent economic analysis, in advocating liability for pay-for-delay settlements, relies upon the proposition that, as a general matter of patent and antitrust, consumers have an entitlement "to the level of competition that would have prevailed, on average, had the two parties litigated."[16] Opponents of liability frequently pitch their arguments in similarly broad terms.[17] Focusing upon the importance of patent law for resolving this antitrust problem is both enlightening and readily comprehensible: Pharmaceutical innovators rely to an unusual degree upon patents to protect their profits, and drug profits are a major part of what patents protect.[18]

However, this perspective is incomplete. Existing analyses, though attentive to the antitrust-patent intersection, have overlooked the importance of the antitrust–*regulated industry* intersection. A major objective of this Article is to fill that gap by examining in detail the industry-specific regulatory scheme that governs competition in the pharmaceutical industry, the Drug Price Competition and Patent Term Restoration Act of 1984,[19] commonly known as the Hatch-Waxman Act, and related regulations of the Food and Drug Administration (FDA).

The regulatory design perspective advanced here has two payoffs. First, the analysis provides a sound basis for resolving the antitrust treatment of pay-for-delay settlements in the pharmaceutical industry. Second, in the course of resolving this particular antitrust question, the analysis offers a road map for resolving antitrust problems in other regulated industries, by giving shape and structure to the judicial command quoted at the outset of this Article: "[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[20]

Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship, 71 ANTITRUST L.J. 1069, 1090–93 (2004); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1816 (2003) [hereinafter Cotter 2003].

16 Shapiro 2003a, *supra* note 15, at 396; *see also* Shapiro 2003b, *supra* note 15, at 70.

17 *See, e.g.*, Schildkraut, *supra* note 15, at 1046–49 (offering general settlement-oriented defense of pay-for-delay agreements).

18 See *infra* Part I.A.1 for a discussion of the close connection between patents and pharmaceuticals.

19 Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme in Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtits. A–B, 117 Stat. 2066, 2448–64 (codified at 21 U.S.C. § 355 (Supp. III 2003)), an Act better known for providing a new prescription drug benefit.

20 Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411–12

In particular, antitrust analysis should recognize and reflect a regulated industry setting in two important respects. First, the industry-specific regulatory regime serves as an economic input in antitrust analysis by setting the boundaries of feasible anticompetitive conduct by regulated parties. Second, the regime is a legal input, for the regime embodies a specific congressional judgment about the balance between competition and innovation. That judgment is *in pari materia* with the open-ended analysis of antitrust law and constrains its operation. Careful engagement with regulatory facts and economic theory within an industry is necessary to identify these two inputs as part of an adequate antitrust analysis.

The Hatch-Waxman regime affects, through both economic and legal mechanisms, the contours of antitrust law as applied to pharmaceutical competition. First, as an economic matter, the Act alters the prospect for anticompetitive conduct by regulated parties. An important feature of the regime is a large incentive to litigate the validity and scope of an innovator's patents, a "bounty" worth hundreds of millions of dollars for a major drug. The bounty has an unusual form: In the case of a determination of invalidity or noninfringement, the generic firm enjoys a 180-day exclusive right to market a generic version of the drug in competition with the innovator, effectively a duopoly during that period, before other generic firms are permitted to enter the market.[21]

But *only the first generic firm* to challenge an innovator's patents has any prospect of earning the bounty.[22] Because no other firm has a similar opportunity, buying off the first challenger is an effective means to head off the most potent threat to entry. Previous accounts have neglected this effect, ascribing the feasibility of agreement instead to a different feature—an "approval bottleneck" that denies later generic firms the opportunity to receive FDA approval—that is present in some, but not all, pay-for-delay agreements. Courts have misperceived the availability of the bounty, resulting upon occasion in serious error.[23] In addition, the bounty can provide a means, generally overlooked, for the innovator to compensate a generic firm. A settlement that guarantees the bounty to a generic firm can provide a disguised payment for delay, making possible an allocative harm

(2004) (quoting Town of Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)).

21 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

22 21 U.S.C. § 355(j)(5)(D)(iii) (Supp. III 2003); 21 C.F.R. § 314.107(c)(1)–(2) (2006). See *infra* Part II.A.2 for further discussion.

23 For a vivid example, see *In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244 (2d Cir. Aug. 10, 2006), in which the court relied, as a reason to deny antitrust liability, upon the mistaken notion that the innovator's settlement agreement with the first filer would "open[] the [relevant] patent to immediate challenge" by other firms, "spurred" in part by the supposed availability of the 180-day exclusivity period. *Id.* at *22. See *infra* Part II.A.2 for further discussion of this case.

even where little or no cash changes hands.

Second, as a legal matter, the Act reflects a congressional judgment, unexplored in the literature, about the balance between competition and innovation. This judgment is important, given one set of arguments made against liability for pay-for-delay settlements—that they should be allowed because patent policy reflects an inclination toward settlement and a preference for innovation even at the expense of immediate consumer access. But whatever the general norms of patent policy, an industry-specific scheme alters that norm within its domain. The Hatch-Waxman Act imposes upon certain pharmaceutical innovators an effective tax on innovation. The incidence of taxation, however, is highly uneven. For some innovators, a different set of industry-specific features comes to the fore—a series of distinctive protections for innovators that serve to delay entry by a generic firm. These features effectively subsidize certain pharmaceutical innovations. Congress's use of decentralized litigation to implement the resulting tax-and-subsidy scheme is an instrument present in pharmaceutical regulation, but missing from the patent system generally. This industry-specific feature undermines and displaces the general norms thought to favor settlement.

This Article concludes that a settlement should be accorded a presumption of illegality as an unreasonable restraint of trade if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm. This view differs sharply from the result reached by most courts that these settlements should be permitted.[24] This view also differs from the pro-liability position of the FTC and some commentators by applying the presumption not only to settlements with an "approval bottleneck" or with large cash payments, but also to settlements without a bottleneck and with little or no cash payment.

The Article proceeds in three Parts. Part I describes the pay-for-delay settlement problem and disagreement about its resolution among enforcement agencies, courts, and commentators. Part II explains the means by which the industry-specific regulation of pharmaceuticals alters the scope of anticompetitive activity by regulated parties. Part III assesses the congressional judgment about competition and innovation offered by the Hatch-Waxman Act, and shows how this judgment undermines certain arguments against antitrust liability. The Conclusion discusses the utility gained by understanding other antitrust problems through the lens of regulatory design.

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[24] *See, e.g.*, *Tamoxifen*, 2006 WL 2401244, at *1; Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005).

I
THE PAY-FOR-DELAY DILEMMA

A. Pharmaceutical Innovation and Competition

1. Innovation and Patent Policy

There is generally thought to be a close fit between pharmaceuticals and patent policy. Drug makers rely heavily upon patent protection: New drugs are developed in anticipation of the profits that patents secure. Almost uniquely, in this industry a patent is considered necessary to recoup an initial investment.[25] A new drug is essentially an information good—once its formula is understood, it is relatively straightforward and cheap for others to manufacture it without incurring similar research and development costs.[26] Drug companies, compared to innovators in other industries, cannot as easily rely upon a head start, complementary assets, and scale of production as means to preserve profits.[27] Nor can a drug maker easily keep the chemical formula secret. For blockbuster drugs as with blockbuster films, the ability to legally exclude rivals from offering a copy preserves the return from a massive initial investment. Economic theory predicts that the expectation of profits from new discoveries will

[25] For example, large-scale surveys of research and development employees have indicated that patents are unimportant for appropriating returns from research and development in most industries, with pharmaceuticals providing an important exception. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY (SPECIAL ISSUE) 783, 795–96, 819 (discussing survey commenced in 1981 that shows that pharmaceutical and other chemical manufacturers valued patents particularly highly as means of appropriation); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 23–25 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) (reporting, among results of 1994 survey, that pharmaceutical industry is rare sector in which patents are used to appropriate rents); *id.* at tbl.1 (reporting that patents are considered effective basis for protection in fifty percent of surveyed product innovations in drug industry; most other industries had lower rates).

The present analysis has two significant limitations. First, not only patents, but also government and university research efforts, are important to the development of pharmaceuticals. Second, although this Article focuses upon the appropriation basis for and profit-protecting effect of patents, other motivations and effects may be important as well. *See, e.g.*, Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002) (analyzing patents' role in credibly conveying to outside observers information held by patentees); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005) (emphasizing distinctive role of aggregations of patents in patent system's functions).

[26] This is not always so. For example, so-called "biologics" derived from living sources are relatively difficult to make and replicate, providing their manufacturers with an additional source of protection. *See, e.g.*, Val Brickates Kennedy, *Amgen CEO Assesses Generic Threat*, MARKETWATCH, Mar. 1, 2006, http://www.marketwatch.com (search for "Amgen CEO") (reporting Amgen CEO's comment that generic biologics are relatively difficult to manufacture).

[27] Such factors are not unimportant to drug companies, but they are neither necessary nor sufficient for commercial success.

induce investment in research, development, and testing.[28] The available empirical evidence suggests that higher drug profits are indeed correlated with greater research and development efforts.[29]

Pharmaceuticals are thought to possess an unusually simple technology of innovation. In other industries, the technology of innovation is cumulative and incremental, with the set of potential innovators widely dispersed. When an innovation developed elsewhere is itself the raw material for further invention, strong, multiple rights of exclusion can lead to underuse.[30] Cumulative innovation is an important complication for intellectual property policy,[31] but it is less important for pharmaceuticals.[32] Partly as a result, pharmaceuticals have been associated with the case for strong patents.[33]

2. Competitive Entry Prior to Patent Expiration

The reality of pharmaceutical innovation and competition is more complicated than this initial account suggests, for the law provides not only a right of exclusion, but also an elaborate regulatory scheme to test the validity and scope of a pharmaceutical patent. As explained in some detail

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[28] F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 927, 929 (2004) (explicating prediction of economic theory that prospective profits induce expenditures for research, development, and testing).

[29] Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005) (reporting positive correlation between profit and research spending).

[30] For careful discussions of this problem, see Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 667–79 (1998); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 122–26 (Adam Jaffe et al. eds., 2001).

[31] For discussions of these complications, see generally LAWRENCE LESSIG, THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD 205–15 (2001), which discusses the difficulties in achieving innovation through patent policy when innovation is cumulative, and SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 127–96 (2004), which discusses the roles of cumulative innovation and licensing in innovation policy.

[32] Cumulative innovation is not entirely unimportant. In the overlapping field of biotechnology, patented research tools are an "upstream" input into the development of new therapies, raising a potential "downstream" underuse problem, which is discussed in Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998). For an empirical analysis suggesting that patented research tools have not hampered innovation in practice, see John P. Walsh et al., *Working Through the Patent Problem*, 299 SCI. 1021 (2003). *See generally* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001) (arguing that biopharmaceutical patents on upstream invention pose potential threat to competition and cumulative innovation, and that both patent law and antitrust enforcement must check this threat).

[33] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1615–17 (2003) (matching pharmaceutical industry with normative case for patents that are "broad, stand alone, and confer almost total control over subsequent uses of the product").

below, if an innovator's patent is found invalid or not infringed, a generic rival may enter the market prior to the scheduled expiration of the patent. Early generic entry is an important source of allocative benefit to consumers.

Under the Federal Food, Drug, and Cosmetic Act, an innovator must demonstrate that a drug is safe and effective before the FDA will approve it for marketing.[34] Making that demonstration as part of a so-called New Drug Application (NDA)[35] is a lengthy, expensive process, consuming years and many millions of dollars to conduct the necessary clinical trials.[36]

Once an NDA has been approved, a generic firm can market a competing version of the drug without repeating that process provided it adheres to the strictures of the Hatch-Waxman Act. The basic regime, established by the Act in 1984, has remained unchanged in its main features, even after substantial statutory revisions in 2003. The generic firm files an application called an Abbreviated NDA (ANDA) demonstrating, among other things, the bioequivalence of its product and the brand-name product.[37] Establishing bioequivalence is not trivial but is much less expensive than NDA clinical trials, requiring an outlay on the order of $1 million.[38]

An ANDA may seek pre- or post-expiration marketing of a generic drug. ANDAs for post-expiration marketing seek to secure entry once the relevant patents have expired. An ANDA directed to *pre-expiration* marketing of a generic drug, by contrast, contains a "Paragraph IV" certification asserting that the innovator's patents are either invalid or not

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34 21 U.S.C. § 355(d) (2000).

35 For the statutorily required application process, see 21 U.S.C. § 355(b) (2000 & Supp. III 2003); JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 306–07 (2005).

36 See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003), which reports the results of a confidential survey of drug companies with respect to a random sample of approved compounds. The mean out-of-pocket cost for clinical tests of the sampled compounds is $130 million (all figures in 2000 dollars). *Id.* at 162 tbl.1 (summing items in "mean cost" column). Not all investigational compounds reach the end of all three phases of human testing and animal tests; if an estimate of the cost of failure is attributed to the successes, the cost per approved new drug rises to $282 million. *Id.* at 165. Applying an eleven percent annual discount rate to the later outlays, the capitalized cost is $467 million. *Id.* In the authors' estimation, the costs of clinical tests constitute more than half the total cost of drug development. *See id.* at 166 (separately estimating out-of-pocket and capitalized preclinical costs to be $121 million and $355 million respectively).

37 21 U.S.C. § 355(j)(2)(A), (8)(B) (2000) (listing requirements and defining bioequivalence). The requirements include, aside from bioequivalence, demonstrations that the generic drug contains the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling. § 355(j)(2)(A).

38 *See* Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61,640, 61,645 (Oct. 29, 2003) (reporting estimates of ANDA preparation and filing costs between $300,000 and $1 million).

infringed by the generic product.[39] A generic firm might argue that the patent is invalid because it was procured inequitably,[40] or inherently anticipated by the prior art,[41] or because the drug's initial testing violates the public use bar.[42] Alternatively, the firm might contend that it has devised a noninfringing bioequivalent form of the drug—for example, a different crystalline structure of the same active ingredient,[43] or a different way to accomplish some desirable time-release feature of the innovator's drug.[44]

Submitting an ANDA containing such a certification—call it an ANDA-IV—is an act of infringement[45] that often prompts the innovator to file a patent suit. If the court determines that the relevant patents are invalid or not infringed, the generic manufacturer, if it was the first firm to file an ANDA-IV (an important qualification discussed in Part II), enjoys a 180-day exclusive right to market a generic version of the drug in competition with the innovator, effectively creating a duopoly for that period.[46]

Several other features of the regulatory regime delay the moment at which a generic firm can begin enjoying the 180-day period. For example,

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39 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). There are three alternative certifications, called "Paragraphs" (although they are actually subclauses) I, II, and III. § 355(j)(2)(A)(vii)(I)–(III). The first two permit immediate approval on the grounds, respectively, that the required information has not been filed by the innovator or that the relevant patents have expired. § 355(j)(2)(A)(vii)(I), (II). A Paragraph III certification concedes that one or more patents have not expired, and that approval is not sought until expiration. § 355(j)(2)(A)(vii)(III).

40 *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005) (noting first ANDA filer's inequitable conduct argument).

41 *See, e.g.*, SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1334 (Fed. Cir. 2005) (invalidating patent on grounds of inherent anticipation by prior patent).

42 *See, e.g.*, SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1308 (Fed. Cir. 2004) (invalidating patent for violating public use bar of 35 U.S.C. § 102(b) during clinical trials), *vacated on reh'g en banc*, 403 F.3d 1328 (Fed. Cir. 2005), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

43 *See, e.g.*, SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1023 (N.D. Ill. 2003) (describing defendant's noninfringement claim), *aff'd*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated on reh'g en banc*, 403 F.3d 1328 (Fed. Cir. 2005), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

44 *See, e.g.*, Complaint Counsel's Trial Brief at 17–18, *In re* Schering-Plough Corp., No. 9297 (F.T.C. Jan. 23, 2002), 2002 WL 1488085 [hereinafter Schering Trial Brief], *available at* http://www.ftc.gov/os/adjpro/d9297/020123cctb.pdf (describing generic firm's contention that its product had composition and viscosity different from that specified in innovator's patent).

45 35 U.S.C. § 271(e)(2)(A) (2000).

46 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003). The 2003 amendments altered the operation of the exclusivity period in important respects. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457–58 (2003). One major effect was to remove a statutory bottleneck that resulted when a first-filing generic firm neither marketed its product nor secured a judicial determination of invalidity or noninfringement; in that event, the FDA was powerless to approve the ANDA-IVs of subsequent filers. For further discussion, see *infra* Part II.A.3.

if the innovator's drug contains a novel active ingredient,[47] the FDA must not accept an ANDA-IV in the first four years after NDA approval.[48] Moreover, once the ANDA-IV is filed, and provided that the innovator files a patent suit in response, a statutory stay operates to block FDA approval for the first several years of the suit's pendency.[49] That "thirty-month" stay, as it is often but inaccurately called, can last for more than three years.[50]

Pre-expiration challenges are a frequently deployed mechanism for the early introduction of generic competition. Since 1984, generic firms have filed pre-expiration challenges involving more than 200 drugs, apparently at an increasing rate.[51] Of the ten best-selling drugs of 2000, nine attracted challenges.[52] With respect to the most important new drugs, pre-expiration litigation is the norm, not the exception.[53]

These challenges often secure early entry by generic rivals. The FTC

47 More precisely, a drug containing no "active moiety" already approved in another NDA. 21 C.F.R. § 314.108(a) (2006).

48 *See* 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs with Paragraph I, II, or III certifications. *Id.*

49 § 355(j)(5)(B)(iii) (2000 & Supp. III 2003). The stay goes into effect provided that the innovator files suit within forty-five days of receiving notice of the certification. *Id.*

50 The default maximum duration of the stay is thirty months, measured from the innovator's receipt of notice, provided that notice is received by the innovator no earlier than the point five years after the innovator's marketing approval. § 355(j)(5)(B)(iii). If the generic firm files an ANDA-IV during the first year of its eligibility to do so—that is, between four years and five years after NDA approval—then the stay is lengthened so that it ends five years plus thirty months after the marketing approval date. § 355(j)(5)(F)(ii). The maximum increase is less than a year, because the innovator's receipt of notice is necessarily later than the four-year point. The district court can also lengthen or shorten the stay in response to uncooperative behavior by either party. § 355(j)(5)(B)(iii).

51 *See* FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 10 (2002) [hereinafter FTC STUDY] (reporting challenges involving 130 drugs between 1984 and 2000, including challenges involving 104 drugs between 1992 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act" Before the S. Comm. on the Judiciary*, 108th Cong. 117 (2003) (statement of Timothy Muris, Chairman, FTC) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

52 *See* Robert Pear, *Spending on Prescription Drugs Increases by Almost 19 Percent*, N.Y. TIMES, May 8, 2001, at A1 (listing, as top ten sellers, Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zoloft); CTR. FOR DRUG EVALUATION & RESEARCH, FDA, PARAGRAPH IV PATENT CERTIFICATIONS AS OF SEPTEMBER 14, 2006, http://www.fda.gov/cder/OGD/ppiv.htm (including all but Glucophage in list of drugs that have attracted Paragraph IV challenges). Although Glucophage appears to have attracted no challenge, an extended-release variant, Glucophage XR, has attracted a challenge. *Id.*

53 *But cf.* Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, REGULATION, Summer 2004, at 54, 57 ("[W]hatever the dramatic tales in individual cases, litigation is the exception and not the norm. In the vast majority of cases—approximately 95 percent of the time—generics are content to wait until patent expiration to begin commercial sales (although recent trends point toward more patent challenges)."). The source and nature of the ninety-five percent figure is left unstated but is probably a reference to the FTC's determination that ninety-four percent of the more than 8000 ANDAs filed between 1984 and 2000 lacked a Paragraph IV certification. FTC STUDY, *supra* note 51, at 10.

studied challenges initiated between 1992 and 2000 involving 104 drugs.[54] Of the fifty-nine drugs whose challenges were neither pending nor settled at the end of the study period, the innovator declined to sue with respect to twenty-nine,[55] effectively permitting rapid generic entry. The generic firm won in another twenty-two cases.[56] ANDA challenges have led to pre-expiration competition for many major drugs.[57]

B. The Competitive Harm of Paying for Delay

Innovators faced with generic competition have shown considerable ingenuity in maximizing the returns from a successful drug. Some strategies, such as an improved variant of an existing drug or a discount to price-sensitive customers, arguably provide immediate benefit to consumers. That is not true, however, of a pay-for-delay settlement of a pre-expiration patent challenge. The basic settlement structure is simple, though individual settlements offer many variations on the theme. The generic firm abstains from entry, the innovator agrees to pay the generic firm a large sum, typically in the tens or hundreds of millions of dollars,[58]

54 FTC STUDY, *supra* note 51, at 10.

55 *Id.* at 15 fig.2-1.

56 *Id.* The innovator won in the remaining eight cases. *Id.* These figures ignore two cases in which the patent expired before the litigation was resolved, and one in which an NDA was withdrawn before the litigation was resolved. *Id.*

57 Of the ten best sellers from 2000, at least four—Paxil, Prilosec, Prozac, and Zocor—have seen pre-expiration competition. *See, e.g.*, Jenna Greene, *Big Pharma's Big Leap*, IP L. & BUS., Jan. 1, 2006, at 40, 42 (noting August 2001 launch of generic Prozac and September 2003 launch of generic Paxil, each with 180-day exclusivity); *KUDCO's Omeprazole Generic Launched in the US*, MDIS PUBLICATIONS, Dec. 11, 2002, *available at* 2002 WLNR 220240 (reporting launch of generic Prilosec by subsequent filer following first-filer agreement to relinquish exclusivity); *FDA, Court Clear Way for Teva's, Ranbaxy's Generic Zocor*, GENERIC LINE, June 23, 2006 (on file with the *New York University Law Review*) (noting approval of generic Zocor, with exclusivity for different dosages granted to different firms). Other major drugs that have seen early competition include Allegra, Glucophage XR, Macrobid, Neurontin, OxyContin, and Wellbutrin SR. Press Release, Barr Pharmaceuticals, Inc., Barr Says Court Denies Preliminary Injunction to Halt Generic Allegra Sales (Jan. 27, 2006), http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=809655 (noting generic Allegra launch with exclusivity in September 2005); *Alpharma, Ivax Share Generic Metformin ER Exclusivity*, GENERIC LINE, Dec. 3, 2003 (on file with the *New York University Law Review*) (describing pre-expiration competition from generic Glucophage XR); Mylan Pharm., Inc. v. FDA, No. Civ. A. 104CV242, 2005 WL 2411674, at *2 (N.D. W. Va. Sept. 29, 2005) (noting launch of generic Macrobid with exclusivity); Leila Abboud, *Diminutive Alpharma Takes a Risky Slap at Drug Titan Pfizer*, WALL ST. J., Oct. 11, 2004, at C1 (describing pre-expiration competition from generic Neurontin); *Generic OxyContin Gives Purdue Pain*, MED AD NEWS, Aug. 1, 2005, at 8, 8, *available at* 2005 WLNR 13598257 (reporting launch of generic OxyContin with exclusivity); *Generic Wellbutrin SR Shipped After Andrx 180-Day Deal*, GENERIC LINE, Apr. 7, 2004 (on file with the *New York University Law Review*) (reporting pre-expiration launch of generic version of 150-milligram Wellbutrin SR after first filer agreed to relinquish exclusivity eligibility).

58 *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005) (reporting payment of $398 million over six years), *notice of appeal filed*, Nos.

and the parties agree to dismiss the patent suit. The agreement may also provide for limited pre-expiration entry.

Consider, for example, a pre-expiration challenge involving the anti-ulcer medication Zantac, which settled on the eve of trial.[59] Under the terms of the settlement, the generic firm conceded the validity of the patents at issue and agreed not to market a competing drug.[60] In exchange, Glaxo, Zantac's manufacturer, paid the generic firm in cash[61]—the size of the payments, though not disclosed,[62] probably exceeded $100 million[63]—and other consideration.[64] The settlement was quite valuable for Glaxo as well. At the time of the settlement, Zantac was the world's best-selling prescription medicine, with annual U.S. sales of about $2 billion,[65] and

05-2851, -2852 (2d Cir. June 7, 2005); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068 (11th Cir. 2005) (reporting payment of $60 million).

59 Eric Reguly, *Shares in Glaxo Rise as Lawsuit Is Settled—Glaxo Wellcome*, TIMES (London), Oct. 24, 1995, at 25.

60 Press Release, Glaxo Wellcome PLC, Glaxo Wellcome PLC Re Genpharm Litigation (Oct. 23, 1995) [hereinafter Zantac 1995 Press Release] (on file with the *New York University Law Review*) (announcing settlement).

61 *Id.*

62 *Id.* (noting merely that total was "not considered as material" to Glaxo Wellcome's overall results).

63 Zantac was one of the drugs included in the FTC's study of pay-for-delay settlements. *See* FTC STUDY, *supra* note 51, app. C at A-16. The Zantac settlement was reached within the study period, and therefore should appear as part of a table listing settlements that entailed a cash payment in exchange for a delayed entry date. *See id.* at 32 tbl.3-3.

The table describes the major details of each such settlement but disguises the identity of the drug products involved. However, for some settlements discussed in the FTC study, the identity of the drug products can be inferred by matching the FTC-provided details to publicly available information. One of the settlements, involving "Drug Product I," featured a payment of $132.5 million, made in part to settle additional patent litigation; a delay of one year, nine months between agreement and expiration; and innovator sales exceeding $1 billion. *Id.*

Several factors support the conclusion that Drug Product I is Zantac. First, Drug Product I is the only drug listed on the FTC's table whose sales (like Zantac's) exceeded $1 billion in the year of agreement. *Id.* Second, Product I's delay of one year, nine months matches the delay between the Zantac agreement and the expiration of the first patent in issue. *See* Zantac 1995 Press Release, *supra* note 60 (noting agreement in late October 1995); Press Release, Glaxo Wellcome PLC Re Zantac Patent Litigation (Apr. 7, 1997) (on file with the *New York University Law Review*) (noting July 1997 expiration of basic patent). Third, Product I's settlement of additional patent litigation, an unusual feature of the agreement, fits the Glaxo-Genpharm pact, which also settled parallel Zantac litigation outside the United States. Zantac 1995 Press Release, *supra* note 60. Fourth, Drug Product I fits none of the cases, described in notes 67–68 *infra* and accompanying text, that have received antitrust attention from the FTC or private parties.

64 Genpharm and related companies also received licenses and supply agreements to sell a generic version of Zantac in several other countries. Zantac 1995 Press Release, *supra* note 60. In addition, Genpharm retained entitlement to the exclusivity period, for which it appears to have received consideration when it later waived exclusivity in favor of a subsequent filer. *See* Granutec Inc. v. Shalala, 46 U.S.P.Q.2d 1398, 1403, 1405 (4th Cir. 1998) (characterizing Genpharm's waiver of exclusivity as "quite lucrative"). See *infra* Part II.B.1 for a discussion of retained exclusivity.

65 *Annual Report: Top 100 Drugs: Histamine H(2) Receptor Antagonists*, MED AD NEWS, May 1, 1996, at 1, 36, *available at* 1996 WLNR 4446118 (reporting that in 1995, Zantac was

removing the risk of early generic entry appears to have conferred upon Glaxo a multibillion-dollar benefit.[66]

Pay-for-delay agreements in the pharmaceutical industry have been an important focus of FTC enforcement efforts and private litigation. The FTC has challenged settlements involving four drugs.[67] Private antitrust suits have challenged settlements involving at least nine drugs, including the four challenged by the FTC.[68] Not every settlement has attracted an antitrust challenge. Of the settlements identified in the FTC study, about half of them may have escaped antitrust challenge, including Zantac.[69]

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world's best-selling prescription medicine, with U.S. sales of $2.15 billion).

66 *See* Reguly, *supra* note 59 (noting almost £2 billion increase in Glaxo market valuation immediately following settlement); *see also Soothing Glaxo's Ulcers*, FIN. TIMES (London), Oct. 24, 1995, at 20 ("With so much at stake, the fact that Glaxo is having to pay Genpharm to turn it from a competitor into a distributor [in certain non-U.S. markets] is money well spent."); Zantac 1995 Press Release, *supra* note 60 (quoting Glaxo CEO's statement that "[t]his settlement is a business decision which eliminates the risk of the Genpharm challenge").

67 Challenges involving three of the drugs—Hytrin, Cardizem CD, and BuSpar—resulted in consent decrees. *See In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (Hytrin consent decree); *In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3946, 2000 WL 681849 (F.T.C. May 22, 2000) (same); *In re* Hoechst Marion Roussel, Inc., No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (Cardizem CD consent decree); *In re* Bristol-Myers Squibb Co., No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing BuSpar consent decree). With respect to the fourth drug, K-Dur, the innovator and first-filing generic firm chose to litigate rather than settle with the FTC. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058–59, 1061–62 (11th Cir. 2005).

68 For the four drugs where private litigation has run in parallel with FTC challenges, see *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 899–900 (6th Cir. 2003); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1295–96 (11th Cir. 2003) (Hytrin); *In re* Buspirone Patent Litig., 185 F. Supp. 2d 363, 365–66 (S.D.N.Y. 2002); *In re* K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 521–22 (D.N.J. 2004).

The five additional drugs are Nolvadex, Cipro, Naprelan, Procardia XL, and—most recently—Plavix. *See In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244, at *1, *3 (2d Cir. Aug. 10, 2006) (Nolvadex); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 516–17 (E.D.N.Y. 2005) (Cipro); Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1231 (11th Cir. 2005) (Naprelan); Biovail Corp. v. Mylan Labs., Inc., No. 1:01CV66, 2002 U.S. Dist. LEXIS 6726, at *8–9 (N.D. W. Va. 2002) (Procardia XL); Amended Complaint and Demand for Jury Trial at 1–2, Kroger Co. v. Sanofi-Aventis, No. 1:06-cv-00163-HJW (S.D. Ohio July 31, 2006), 2006 WL 2503664 (Plavix).

69 The FTC study raises antitrust concerns about final settlements involving fourteen drug products. FTC STUDY, *supra* note 51, at 26 (noting that fourteen settlements corresponding to fourteen drug products had potential to delay FDA approval of subsequent applicants). Six final settlements from this period prompted antitrust challenges: BuSpar, Nolvadex, K-Dur, Cipro, Procardia XL, and Naprelan.

Five of the six drugs can be matched to the disguised information in the FTC report, by means of a matching process analogous to that described in note 63 *supra*. The first four are likely Drug Products J, K, L, and M, respectively, listed in the FTC study, *supra* note 51, at 32 tbl.3-3, and Procardia XL is likely the second of two supply agreements discussed *id.* at 30. The remaining drug, Naprelan, is difficult to identify based upon publicly available information.

That leaves eight final settlements among those identified by the FTC which appear to have attracted no antitrust challenge. One of these is likely the Zantac settlement, *see supra* text accompanying notes 59–66; the other seven are unknown.

For a while the threat of antitrust condemnation stemmed the tide of new pay-for-delay settlements, or at least those with a large cash component.[70] More recently, however, innovators and generic firms have reversed course, reaching a spate of new agreements in 2005 and 2006.[71] One prominent settlement involving Plavix, a blockbuster blood thinner, did not achieve its full effect, due in part to a unique regulatory setting that effectively required the parties to secure pre-approval of the agreement.[72]

In addition to these final settlements, the FTC reports interim settlements (interim in the sense discussed in note 15 *supra*) involving three drugs. *See* FTC STUDY, *supra* note 51, at 34 & n.11 (reporting four settlements, two of which address capsule and tablet forms of the same drug). Hytrin and Cardizem CD account for two of these, *see Valley Drug Co.*, 344 F.3d at 1300–01; *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902–03, and the third settlement is unknown.

70 The blockbuster Prozac provides an illuminating example. The CEO of first-filing generic firm Barr "stated publicly that he was open to a $200 million settlement—plus a guarantee that Barr would be able to sell Prozac before [innovator] Lilly's patent expired." Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, at 118. Lilly's CEO rejected that overture; as he put it, "we felt that settling violated antitrust laws, and it isn't morally right." *Id.*

For a more systematic assessment, the FTC data is a useful source. The FTC's study period covers ANDA-IVs for which innovator notification occurred between 1992 and 2000, and covers the subsequent progress of those applications only through mid-2002. Since the December 2003 amendments to the statutory scheme—that is, following a gap in the data of more than a year—drug companies have been required to file settlements with the FTC. Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003). A brief report issued by the FTC states that no settlement entered into in the first nine months of 2004 included a cash payment in exchange for delay. *See* BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004, at 4–5 (2005), *available at* http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf [hereinafter FTC STUDY UPDATE]. Moreover, the FTC was aware at that point of no settlement after 1999, when the FTC commenced investigation of these settlements, that included a cash payment in exchange for a generic firm's agreement not to market a product. *Id*. at 4.

71 *See* BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005, at 3–4 (2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf (reporting that, among agreements received during period of October 2004 through September 2005, three agreements covering five products included both compensation to generic firm and restriction upon generic marketing); Jon Leibowitz, Comm'r, FTC, Remarks at Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust: Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! 5–6 & n.12 (Apr. 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf (reporting that between October 2005 and April 2006, "more than two thirds of approximately ten agreements" included payment); Leila Abboud, *Branded Drugs Settling More Generic Suits*, WALL ST. J., Jan. 17, 2006, at B1 (reporting settlements of patent litigation reached in 2005 for major drugs, including Provigil, Niaspan, Effexor, and Ditropan XL).

72 To take full effect, the settlement agreement required approval by the FTC and state attorneys-general, under the terms of an earlier consent decree meant to address prior alleged anticompetitive activity by a settling innovator firm. *See In re* Bristol-Myers Squibb Co., No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing consent decree); John Carreyrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense of $4 Billion Drug*, WALL ST. J., Sept. 2, 2006, at A1. The states denied approval, whereupon the settling generic firm launched its product, despite the absence of a district court adjudication of the infringement

Federal antitrust enforcers have commenced a close examination of this and other recent settlements.[73]

The FTC's concern is straightforward. Privately optimal agreements that impose large negative effects upon nonparties frequently raise antitrust concerns.[74] In an agreement between competitors, consumers are the relevant nonparties. Despite consumers' aggregate economic interest—for the short-run consumer gain from lower prices exceeds producers' reduced profits—collective action problems present an obstacle to paying off producers who (unless legally constrained) will act at the consumers' expense.[75] A rival's effort to remove a patent-based barrier to entry, like a price cut, provides an indirect allocative benefit in the course of a private pursuit of profit. An agreement that reduces this benefit[76] constitutes a "treat[y] with [a] competito[r]"[77] that is the classic object of section 1 of the Sherman Act. Indeed, the arrangement here bears a strong resemblance to the facts of *Palmer v. BRG of Georgia, Inc.*,[78] in which the Supreme Court considered an agreement reached between competing bar review course providers, pursuant to which one provider withdrew from the market in exchange for payments.[79] There, the Court had little trouble identifying the agreement as an illegal restraint of trade.[80]

A substantial economic literature reaches a similar conclusion. Economic modeling has shown formally that settlements that include a cash payment from the patentee to the infringer provide consumers with less welfare, on average, than seeing the litigation to completion.[81] The conclusion that this loss gives rise to an antitrust violation depends upon

suit. Carreyrou & Lublin, *supra*. For further discussion of the agreement and early launch, see *infra* notes 118 and 210.

73 *See, e.g.*, Carreyrou & Lublin, *supra* note 72; Kristina Henderson, *Cephalon: FTC Seeks Info on Provigil Settlement*, DOW JONES CORP. FILINGS ALERT, July 13, 2006 (on file with the *New York University Law Review*) (reporting FTC request for additional information in connection with settlement involving drug Provigil).

74 For a powerful, general economic account of contracting at the expense of nonparties, see generally Ilya Segal, *Contracting with Externalities*, 114 Q.J. ECON. 337 (1999).

75 If transaction costs were low enough, consumers could band together and make a large fixed payment in exchange for marginal-cost pricing, either by contracting with or owning the producer. *See generally* HENRY HANSMANN, THE OWNERSHIP OF ENTERPRISE 149–223 (1996) (discussing examples of consumer-owned enterprises).

76 An important complication for calculations of consumer welfare in the pharmaceutical context is that often, purchases are made not directly by the consumers, but by insurance companies or government on the consumers' behalf.

77 United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 116 (1975).

78 498 U.S. 46 (1990) (per curiam).

79 *Id.* at 46–47.

80 *Id.* at 49–50; *see also* United States v. Topco Assocs., 405 U.S. 596, 608 (1972) (holding that competitor agreements allocating territories to minimize competition are illegal).

81 *E.g.*, Bulow, *supra* note 15, at 165–68; Shapiro 2003a, *supra* note 15, at 407–08. For a critique, see McDonald, *supra* note 15, at 69; for a rebuttal, see Shapiro 2003b, *supra* note 15, at 73–75.

acceptance of the view, on which these models are premised, that consumers are entitled as a matter of antitrust law to the average benefits of litigation.[82]

C. Justifying Payment for Delay

Paying for delay works an allocative harm. Yet courts have adopted a relatively sympathetic, albeit highly uneven, stance toward pay-for-delay settlements. Two circuits have rejected antitrust condemnation of pay-for-delay settlements, at least absent direct evidence of invalidity or noninfringement.[83] Another circuit has fashioned a rule of per se illegality.[84] Other circuits may weigh in soon.[85]

Four overlapping justifications have supported the courts' willingness to overlook the allocative harm.

1. The Judicial Reflex Favoring Settlement

First, these agreements settle litigation, and settlements are in certain respects desirable, because they conserve litigation expense and benefit parties who are in the best position to arrange their own affairs. Judicial opinions permitting pay-for-delay settlements frequently rely upon the

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[82] *See* Shapiro 2003a, *supra* note 15, at 396.

[83] *See In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244, at *1 (2d Cir. Aug. 10, 2006) (declining to impose antitrust liability where generic firm accepted cash payment from innovator and agreed to delay entry); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (same); *see also* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304, 1312–13 (11th Cir. 2003) (rejecting per se condemnation of interim settlement involving drug Hytrin as "premature," and remanding for further proceedings).

The state of the law in the Eleventh Circuit is not entirely clear. One panel considering a settlement denied dismissal with a brief analysis relatively sympathetic to antitrust liability. Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1235–36 (11th Cir. 2005) (concluding that facts pled were sufficient to state Sherman Act claim). In addition, on remand from the court of appeals decision in *Valley Drug*, a district court found antitrust liability on the particular facts of that case. *In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1286 (S.D. Fla. 2005) (condemning Hytrin settlement as per se violation of Sherman Act).

[84] *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (condemning, as per se violation of Sherman Act, agreement to refrain from introducing generic drug). See also Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809–12 (D.C. Cir. 2001), which considered the same settlement later condemned by the Sixth Circuit in *Cardizem*, and in dicta reached a similar conclusion.

[85] The Ninth Circuit may soon weigh in on the same settlement (involving the drug Hytrin) considered in the Eleventh Circuit's *Valley Drug* opinion. One case that had been part of the multidistrict litigation considered in *Valley Drug* was released to its original court, the Central District of California. After a trial, the jury returned a verdict for defendants. *See* Jury Verdict, Kaiser Found. v. Abbott Labs., No. 2:02cv2443 (C.D. Cal. Apr. 4, 2006). Both parties have appealed to the Ninth Circuit (docketed as Nos. 06-55687 and 06-55748).

The Third Circuit may eventually consider the same settlement (involving the drug K-Dur) considered in the Eleventh Circuit's *Schering* opinion. *See In re* K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 530–33 (D.N.J. 2004) (concluding that plaintiffs' allegations stated claim of anticompetitive conduct using similar analysis as FTC in *Schering*).

view that the benefits of settlement weigh against antitrust liability,[86] echoing the Supreme Court's view, expressed more than a century ago, that settling patent litigation is "a legitimate and desirable result in itself."[87] Or, as one appellate court has put the general proposition, "sound judicial policy . . . requires that settlements be encouraged, not discouraged."[88]

Partly this result simply reflects a judicial reflex in favor of settlement. This reflex may be unusually acute due to the highly technical nature of pharmaceutical patent cases, which many federal judges prefer to avoid. Settlement also saves litigation costs, which can be quite substantial—millions of dollars per side for a major pharmaceutical patent case.[89] Saved litigation expense arguably offsets the allocative loss.

2. The Effect on the Parties' Incentives

Second, the litigation settled is patent litigation, and patent policy provides reason to favor innovation over competition, and to permit practices that might ordinarily be condemned as antitrust violations. Permitting a wide range of settlements benefits both patentees and infringers—benefits that underpin what we might call the innovator's and infringer's arguments for patent exceptionalism. These arguments are introduced here and discussed further in Part III.

The innovator's argument is that a lenient policy toward settlement increases patentee profits, which preserves and improves the incentive to innovate. The cases[90] and commentary[91] note this advantage of permitting

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86 *See, e.g.*, *Schering*, 402 F.3d at 1076 (emphasizing "costs of lawsuits to the parties," "public problems associated with overcrowded court dockets," and "correlative public and private benefits of settlements"); *Valley Drug Co.*, 344 F.3d at 1308 n.20 ("The cost and complexity of most patent litigation is a familiar problem to the court system. The cost savings of settlement . . . are equally widely-recognized" (internal citations omitted).); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) (expressing concern that restrictive settlement rule would chill desirable settlements); *see also In re* Schering-Plough Corp., No. 9297, 2002 WL 1488085, ¶ 384 (F.T.C. June 27, 2002) (relying upon Professor Robert Mnookin's testimony that settlement is beneficial by economizing on litigation expense, including distraction and time spent on litigation).

87 Bement v. Nat'l Harrow Co., 186 U.S. 70, 93 (1902) (discussing license agreement that settled "a large amount of litigation regarding the validity of many patents").

88 Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1221 (4th Cir. 1976); *see also* Speed Shore Corp. v. Denda, 605 F.2d 469, 473 (9th Cir. 1979) (noting "deeply-instilled policy of settlement," which must be balanced against unreasonable restraint claim); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) ("Settlement is of particular value in patent litigation . . . .").

89 AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 2005, at 22 (2005) (reporting median expense of $4.5 million for patent litigation with more than $25 million at risk). The innovator is likely to spend more, as it has more at stake in the case.

90 *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244, at *13 (2d Cir. Aug. 10, 2006) (arguing that restrictive settlement rule "would heighten the uncertainty surrounding patents and might delay innovation"); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (arguing that restrictive settlement rule would

settlement. This view has a statutory hook—the Patent Act, which provides a potential legal basis for an authoritative, highly innovation-protective stance regarding the proper tradeoff between innovation and consumer access, to which antitrust law should conform.

The infringer's interests normally assume a secondary role in discussions of the interaction between patent policy and antitrust law. But as Judge Richard Posner noted in a case concerning the antitrust treatment of certain pharmaceutical agreements, restrictions on an infringer's opportunity to settle affect its incentives: "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement . . . ."[92] That case was not about a pay-for-delay settlement, but the quoted dictum, and its conclusion that *limiting* such settlements "might well be thought anticompetitive,"[93] has proved influential among some courts that have considered pay-for-delay settlements.[94]

3. The Generality of Pay-for-Delay Settlement

Third, the underlying economic structure of a pay-for-delay settlement generalizes beyond the particular cases under consideration. The pharmaceutical industry settlements that have received so much attention are merely the most visible and dramatic examples of this economic structure. Suppose, for example, that a patentee sues an alleged infringer who has entered the market, and the alleged infringer later agrees to exit the market, in exchange for which the patentee waives a claim to accrued damages. This agreement matches the basic pay-for-delay structure: a conferral of value that heads off litigation that, if the alleged infringer won, would increase consumer access. Although there is no cash payment, the alleged infringer's prior entry makes forgiveness of accrued damages a

undermine innovator's incentives for research, thereby harming consumers); *Valley Drug Co.*, 344 F.3d at 1308–09 (expressing concern that restrictive rule would "undermine . . . patent incentives," "impair . . . incentives for disclosure and innovation," and "decreas[e] the value of patent protection").

91 For commentary making this point, see, for example, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 525 (2002); Cotter 2003, *supra* note 15, at 1809; Crane 2004, *supra* note 15, at 705; Crane 2002, *supra* note 15, at 749; Langenfeld & Li, *supra* note 15, at 778, 797–805.

92 Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

93 *Id.*

94 *See Tamoxifen*, 2006 WL 2401244, at *15 (repeating with approval quoted statement from *Asahi*); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (same); *see also In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 527 (E.D.N.Y. 2005) (describing *Asahi* approach); David Balto, *Bringing Clarity to the Patent Settlement Debate: Judge Posner's* Asahi *Decision*, 23 BIOTECHNOLOGY L. REP. 168, 170 (2004) (approving *Asahi* approach).

source of compensation by the incumbent.[95] Nor is the waiver a necessary component of the deal; the essential problem is unchanged if the alleged infringer exits and pays the patentee a sum less than the value of the patentee's infringement claim.[96] In this case, too, the settlement likely brings less expected consumer benefit than taking litigation to conclusion.

It is far from clear that, *as a general matter*, consumers are entitled to the expected outcome of the avoided litigation. Courts and commentators have revealed difficulties in claiming such a general right on behalf of consumers, if that right undermines the availability of settlement in other industries.[97] A satisfactory account of the circumstances under which a private party may be pressed into service as an "unwilling private attorney[] general"[98] has proved elusive. Imposing liability for pharmaceutical pay-for-delay settlements introduces the specter of antitrust liability in a wide range of cases in which settlement imposes negative externalities upon consumers.

4. Payments as a "Natural By-Product" of Regulation

A final reason given to resist antitrust liability for pay-for-delay settlements relies upon the role of pharmaceutical regulation in altering the incentives of the parties, compared to the usual incentives of patentees and infringers. In particular, courts have seized upon the fact that a generic firm has a strong incentive to challenge an innovator but faces little risk. The generic firm's infringement is by certification rather than entry—indeed, entry is barred by the automatic stay—so the generic firm is not

95 Prior entry and accrued damages distinguish waiver-for-exit settlements from the term-division settlements discussed in Part II.B.1.

96 For example, take a setting for which a damage-plus-waiver agreement is the settlement outcome, and increase the amount of damages accrued, so that the alleged infringer must now make a payment to satisfy the patentee.

97 *See, e.g.*, *Tamoxifen*, 2006 WL 2401244, at *16 n.20 ("'[*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements'" (quoting *Asahi*, 289 F. Supp. 2d at 994 (emphasis and alteration in original)).); *Cipro*, 363 F. Supp. 2d at 529 (expressing concern that restrictive settlement rule "could not logically be limited to drug patents, and would work a revolution in patent law"); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (noting that even in "traditional" settlements, "implicit consideration" flows from patentee to infringer, implying that restrictive rule for pharmaceutical settlements would apply to other industries as well); Schildkraut, *supra* note 15, at 1047–49 (arguing that restrictive rule with respect to pharmaceutical patent settlements jeopardizes settlements of patent litigation in other industries as well).

98 Nestle Co. v. Chester's Mkt., Inc., 756 F.2d 280, 284 (2d Cir. 1985) (discussing, in trademark context, problem of enlisting private parties as attorneys general); *see also Cipro*, 363 F. Supp. 2d at 531 ("This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation . . . .").

subject to large damages if it loses the suit.[99] Whereas a settlement of litigation in which entry had already occurred might include a payment from the infringer to the patentee, a settlement in the present context, if settlement is to occur at all, must necessarily include a payment from the patentee to the infringer. From this, some courts, echoed by the Solicitor General, have concluded that "[r]everse payments are a natural by-product of the Hatch-Waxman process."[100]

These courts are right to recognize the importance of the regulatory regime, but judicial treatments reflect deep confusion about the implications of that regime. True, paying for delay is "natural," in the sense that the result is not unexpected given the incentives of the parties; the parties, if not legally constrained, will prefer pay-for-delay settlement to litigation. But that fact in no way *justifies* payments for delay.[101] No doubt many government actions—activities that effectively narrow the set of suppliers from whom the government can purchase, for example[102]—make price-fixing easier. But such an action provides no necessary protective coloration to oligopolists who subsequently choose to collude. To understand the effects of the regulatory regime requires a deeper examination of the incentives it creates.

II
REGULATORY DESIGN AND ALLOCATIVE HARM

As noted in the previous Part, the pharmaceutical industry is most commonly associated with the simplest model of the patent system. But in fact, in defining the incentives of pharmaceutical innovators, the regulatory scheme reflects a number of idiosyncratic choices. The differences start with the most basic, the term length of protection. Pharmaceutical innovations enjoy longer-lasting protection than innovations in other industries, which partly offsets the time consumed by clinical trials.[103] The

99 That is not to say that the generic firm has *nothing* at risk, for if it loses the suit, its investment in proving bioequivalence and in litigation will have been wasted.

100 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005) (alteration in original) (quoting *Cipro*, 261 F. Supp. 2d at 250–51) (internal quotation marks omitted); *see also Tamoxifen*, 2006 WL 2401244, at *15 (quoting language approvingly). The Solicitor General quoted this language approvingly in a brief to the Supreme Court. Brief of the United States as Amicus Curiae, FTC v. Schering-Plough Corp., *supra* note 14, at 7.

101 *See, e.g.*, Hovenkamp et al. 2003, *supra* note 15, at 1758 (noting that it does not follow from rationality of exclusion payments that payments cannot be anticompetitive).

102 Calvin Biesecker, *Federal Contract Bundling, Driven by DoD, Reaches 10-Year High, Report Says*, DEF. DAILY, Oct. 11, 2002 (reporting Defense Department's increasing inclination to consolidate contracts in larger bundles, which only large companies are equipped to fulfill, with possible consequence of higher prices due to less competition among bidders).

103 In particular, a one-year extension for every two years spent in clinical trials, plus the time spent in post-trial FDA approval, subject to the limitations that the extension may not exceed five years or leave a remainder exceeding fourteen years. *See* 35 U.S.C. § 156(c), (g)(1)(B), (g)(6)

effective term is extended by another six months if the drug maker performs tests to evaluate the drug's pediatric health benefits.[104] And certain drugs treating "rare diseases or conditions" are outside even this highly modified scheme; they receive sui generis seven-year exclusivity.[105]

The Hatch-Waxman bounty—the 180-day duopoly granted to a generic firm that wins a pre-expiration challenge—is another major difference. This Part explains how that feature of the regulatory arrangement widens the prospect for allocative distortion, relative to the usual patent regime. It does so, first, by ensuring that a pay-for-delay settlement is (if legal) an attractive and feasible proposition for the innovator and generic firm. Second, the ability of an innovator to *guarantee* a bounty to a generic firm, an opportunity unavailable under litigation, is a significant noncash means to pay for delay.

Recall the form that this bounty takes: The first generic firm to file an ANDA-IV enjoys the exclusive right to market a generic version of the drug for 180 days. The legal form of the exclusivity is a delay in FDA approval of any other firm's ANDA-IV.[106] Winning a patent suit is one route to exclusivity. For example, if an innovator's generic rival secures a judgment that the relevant patents are invalid or not infringed, the FDA may approve the generic firm's ANDA, freeing the firm to market its competing generic version, protected initially by the exclusivity period.

Winning a suit is not the only route to exclusivity. Exclusivity merely requires FDA approval of the first filer, which can be secured without litigation if the innovator declines to sue the first filer, as may occur if the innovator's patent is very likely invalid or not infringed.[107] For a time, the FDA resisted this straightforward understanding of the statutory text, insisting instead upon a "successful defense" before granting exclusivity[108]

(2000).

104 21 U.S.C. § 355a (2000 & Supp. III 2003).

105 Orphan Drug Act, 21 U.S.C. §§ 360aa–dd (2000); *see* Geeta Anand, *Lucrative Niches: How Drugs for Rare Diseases Became Lifeline for Companies*, WALL ST. J., Nov. 15, 2005, at A1 (discussing drug companies' use of Orphan Drug Act exclusivity).

106 21 U.S.C. § 355(j)(5)(B)(iv).

107 With respect to those challenges discussed in the FTC study, *supra* note 51, in which the innovator declined to sue the first filer within the required forty-five days, *see supra* note 55, the study does not reveal how many of the twenty occurred after the demise of the successful defense requirement or enjoyed exclusivity.

Declining to sue might reflect the view that a good-faith basis is absent, or the view that the benefits do not justify the expense. FDA approval normally requires a year or more, even without a suit, and so litigation of an easy case might not outlast the FDA process. Moreover, initiating a suit resolves uncertainty about the validity and scope of the patents, and there may be strategic benefits to retaining uncertainty, both in moderating the pricing of the first generic entrant and in deterring additional, subsequent entrants.

108 *See* 21 C.F.R. § 314.107(c)(1) (1995) (amended in 1998 to remove "successful defense" requirement).

but abandoned the interpretation after its judicial rejection.[109]

The reward provided by the bounty is valuable, worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug.[110] The bounty thus provides a substantial inducement to challenge drug patents. A bounty-hunting generic firm will go on the attack if the drug is very valuable or the innovator's patents very weak (likely invalid or not infringed), or both. With respect to very valuable drugs, the challenge is justified even if the ex ante likelihood of success is low. The more valuable the drug, the lower the threshold probability of success necessary to justify a challenge. A generic firm can justify a challenge with just a one-in-five chance of success, provided that the innovator's sales range in the hundreds of millions of dollars; the level of sales for a best-selling drug likely justifies a challenge with a prospect of success of just one percent.[111] It is therefore no surprise that so many of the best-selling drugs have attracted challenges.

A. The Feasibility of Payment for Delay

1. General Conditions

A pay-for-delay agreement must satisfy two conditions to make

[109] This interpretation was rejected by several federal courts, then repudiated by the FDA. *See* Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (holding that plain language of § 355 "does not include a 'successful defense' requirement"); CTR. FOR DRUG EVALUATION & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 4 (1998), *available at* http://www.fda.gov/cder/guidance/2576fnl.pdf (stating that "FDA will not enforce the 'successful defense' provisions" and "intends to formally remove" them from Code of Federal Regulations). The demise of the interpretation was strongly foreshadowed in an early district court opinion authored by Judge Harold Greene, of AT&T consent decree fame, which made clear the inadequacy of the FDA's initial argument as a textual matter. *See* Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989) (finding no textual basis for requiring successful suit to trigger exclusivity), *appeal dismissed*, 43 F.3d 712 (D.C. Cir. 1989).

[110] For example, Apotex reportedly earned between $150 million and $200 million from the exclusivity period on Paxil, a blockbuster antidepressant. Comment of Apotex Corp. in Support of Citizen Petition of Mylan Pharmaceuticals, Inc. at 4, No. 2004P-0075/CP1 (F.D.A. Mar. 24, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf [hereinafter Comment of Apotex Corp.]. That large reward, moreover, came despite competition from an additional generic firm licensed by GlaxoSmithKline, Paxil's manufacturer. *Id.* See the Conclusion for further discussion.

[111] For a back-of-the-envelope calculation, suppose that a generic firm can expect fifty percent market penetration during a half of a year of protected duopoly, with a profit margin of two-thirds, and no profits otherwise. If entry has a probability p of success, the innovator's annual sales are S, and the generic firm's entry expense is $10 million, then its expected profits are $pS/6 – $10 million. The generic firm breaks even provided that $pS > $60 million. Thus a drug with $300 million in sales supports a challenge that is twenty percent likely to succeed. A drug with $6 billion in sales supports a challenge that is one percent likely to succeed.

practical sense for the parties. The first condition is a *gain from trade*: The patentee loses more under early entry than the alleged infringer gains. This condition is likely to be satisfied where the new entrant serves exactly the same market as the incumbent, for total duopoly profits are normally less than monopoly profits.[112] In some settings, however, entry rather than deferral may lead to higher total producer profits, as when the entrant has superior access to a market, a unique means to price discriminate, or lower costs.[113]

Competition between innovators and generic drug makers satisfies the gain-from-trade condition.[114] Consider, for example, a generic firm's challenge with respect to Plavix. Without entry, Plavix's manufacturer might expect to earn, say, $10 billion in profits from U.S. sales during the drug's remaining patent life.[115] If it loses a patent challenge, then it and the successful generic firm would share duopoly profits for 180 days, with small profits thereafter once additional firms entered the market. In that event, $1 billion might be a plausible estimate of each firm's profits.[116]

If the parties reach a settlement ending the dispute and no other generic firm initiates a challenge, the joint gain from an entry-preventing agreement is $8 billion—the innovator's $10 billion no-entry profit, less the $2 billion jointly earned under entry. If the two share the joint gain equally and invalidation is certain, the innovator would pay the rival $5 billion to induce the rival to abandon its suit.[117] Purchasers would lose the

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112 In the limiting case, duopolists jointly achieve the same profit-maximizing price and quantity of a monopolist.

113 Where entry increases total profits, the entrant can pay the incumbent for permission to enter (if it lacks an entitlement to do so) or, if licensing is unavailable, simply enter and then pay damages, provided they are not too high.

114 *See, e.g.*, Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements*, *in* ECONOMIC APPROACHES TO INTELLECTUAL PROPERTY POLICY, LITIGATION, AND MANAGEMENT 251, 255–60 (Gregory K. Leonard & Lauren J. Stiroh eds., 2005) (contrasting cases in which entrant's gains are less or more than patentee's losses).

115 Assuming, for example, five years of remaining patent protection, $2 billion in U.S. profits per year, and a discount rate offset by profit growth.

116 Typically, the innovator retains price-insensitive customers and may even raise prices somewhat, while the generic firm sells at a roughly thirty percent discount. *See, e.g.*, MORGAN STANLEY EQUITY RESEARCH, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS 4 (2004) [hereinafter QUANTIFYING THE IMPACT]; *see also* Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 335–36 (1992) (noting initial price rise by innovator upon introduction of generic competition). A rough measure employed by industry analysts is to assume that volume drops by one-half during the interim period. *See* QUANTIFYING THE IMPACT, *supra*, at 8.

117 After paying the settlement fee, the innovator would retain $5 billion in profits, a $4 billion improvement upon entry. The rival would enjoy a $5 billion profit, once again a $4 billion ($5 billion–$1 billion) improvement upon entry.

An equal-sharing approach is customary for these analyses. For a theoretical justification of this approach, see Ariel Rubinstein, *Perfect Equilibrium in a Bargaining Model*, 50

$8 billion that is transferred to producers instead, plus billions more in deadweight loss from the resulting allocative distortion. If invalidation is uncertain, the stakes are lowered accordingly; a twenty-five percent chance of invalidation makes the expected gain from trade $2 billion, implying an equal-sharing payment of $1.25 billion.

Not only does an agreement benefit the generic firm compared to its expected return from litigation (otherwise the generic firm would not agree), but in fact the generic firm does even better than it would have, had it won the suit. Nor is a cash payment the only way for an innovator to confer value upon a generic firm. Indeed, the actual Plavix settlement lacked a large cash payment.[118] Part II.B.1 explains how an innovator can confer value upon the generic firm without cash. But for now, it is enough to note that some conferral is necessary in order for the parties to take joint advantage of the gain from trade.

The second general condition is that the settlement must offer an *effective means to delay entry*. If there are many potential challengers, and paying one merely attracts others, a payoff does little good. Even a cursory review of the mechanisms for generic competition, however, suggests that this condition will be satisfied in the pharmaceutical context. A firm must file an ANDA-IV to be eligible for a settlement. The ANDA-IV contains a demonstration by the generic firm that its proposed product is bioequivalent to the innovator's drug, and that the firm is capable of

ECONOMETRICA 97 (1982). It can be doubted, however, whether the generic firm's $1 billion gain under competition ought to be considered as part of the alternative to settlement (the "threat point") within an alternating-offers game such as Rubinstein's. *See generally* John Sutton, *Non-Cooperative Bargaining Theory: An Introduction*, 53 REV. ECON. STUD. 709, 712–17 (1986) (evaluating how "outside option" available to one party affects Rubinstein's model). If the $1 billion is treated instead as an outside option, the relevant gain is $9 billion, and the payment $4.5 billion.

[118] Two versions of the agreement were proposed to regulators, both reprinted in Bristol-Myers Squibb Co., Quarterly Report (Form 10-Q), Exhibits 99.1, 99.2 (Aug. 8, 2006). Both versions include a payment described as compensation for the generic firm's inventory. *Id.* Exhibit 99.1, ¶¶ 13, 18(i); Exhibit 99.2, ¶¶ 10, 14(i). The initial version also included a breakup fee, payable to the generic firm if the agreement failed to receive regulatory approval, which increased with the length of delay in receiving a response from regulators. *Id.* Exhibit 99.1, ¶ 18. The revised agreement omits mention of a breakup fee, but the generic firm has alleged that the fee remained an unwritten term of the deal that its bargaining partner failed to report to regulators. Carreyrou & Lublin, *supra* note 72. That discrepancy, together with a second unwritten term (a commitment not to launch an authorized generic), is reportedly the basis for a criminal referral to the Justice Department. *Id*.

Paying a generic firm to delay its launch, purportedly in order to seek regulatory approval, raises serious antitrust concerns, particularly if the likelihood of approval is low. Even without the breakup fee, there are other ways the innovator might compensate the generic firm for its agreement to accept delay—for example, by agreeing to reduce the generic firm's exposure to damages should it launch its product prior to a district court adjudication. Such a term was included in the Plavix settlement. *See id.* (reporting that agreement provides for reduced damages); Bristol-Myers Squibb Co., *supra*, Exhibit 99.1, ¶ 18(iii); Exhibit 99.2, ¶ 14(ii).

making the proposed product.[119] The challenge process requires a detailed description of the basis for belief of invalidity or noninfringement for each relevant patent of the innovator.[120] To be a credible threat to the innovator, a generic firm must undertake these expenses (one generic firm cannot free-ride on another's showing of bioequivalence) and be prepared to see the suit to conclusion.[121] The number of firms capable of such action is limited.

Moreover, the generic firms are not identically situated. The firms have differing views about their prospect of success in a particular challenge, different information about the infirmities of an innovator's patents, differing abilities to make a bioequivalent version of the drug, and different speeds in developing a noninfringing alternative, as well as different estimates of the drug's future profitability. As a result, firms will have different incentives to bring a challenge. As evidence for this, it was not until 2003 (nineteen years after the establishment of the regulatory regime) that the FDA issued guidelines to deal with multiple filings on the same day.[122]

2. The First Filer's Unique Eligibility for the Statutory Bounty

Once the first generic firm files an ANDA-IV, a sharp difference in incentives emerges between that ANDA-IV filer and all other generic firms, because *only the first filer is eligible for the exclusivity period*. Even if the first filer loses, withdraws, or settles, a subsequent filer does not become eligible for the bounty. (Whether a subsequent filer becomes eligible for FDA approval, a distinct issue, is discussed in the next section.) FDA regulations issued in 1994 make clear that only the first-filed ANDA

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119 *See* 21 C.F.R. § 314.94(a)(9) (2006) (requiring ANDA filers to provide materially identical information to that required for NDAs); § 314.50(d)(1) (describing NDA requirements).

120 *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Supp. III 2003). Prior to the 2003 amendments, the requirement was codified at 21 U.S.C. § 355(j)(2)(B)(ii) (2000).

121 It might appear that a large number of well-funded entities could credibly threaten to initiate challenges in order to extract payoffs, but multiple factors limit this possibility in practice. First, their very number would make it pointless to pay off just one of them. Second, the credibility of such a threat is undermined by the technical requirements involved in actually filing an ANDA-IV, though this difficulty might be contracted around. Third, without the filing of a challenge, it is more difficult to establish that the resulting agreement is in settlement of litigation.

122 CTR. FOR DRUG EVALUATION & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 3, 4 (2003), *available at* http://www.fda.gov/cder/guidance/5710fnl.pdf. By July 2003, the issue had arisen twice, once in 1999 and again in 2002. *See* Citizen Petition of Zenith Goldline Pharmaceuticals, Inc. (F.D.A. Aug. 8, 2000), http://www.fda.gov/ohrms/dockets/dailys/00/Aug00/081100/cp00001.pdf (alendronate sodium); Citizen Petition of Ranbaxy Laboratories Limited (F.D.A. May 13, 2003), http://www.fda.gov/ohrms/dockets/dailys/03/May03/052703/03P-0217-cp00001-01-vol1.pdf (modafinil sodium). An earlier response from the FDA to these petitions had apparently been unnecessary because ANDAs had not been approved for either drug prior to the FDA's response.

potentially delays the approval of subsequently filed ANDAs by operation of the 180-day exclusivity period,[123] an interpretation revisited and endorsed once again in 1999.[124] This is not the only plausible interpretation of the relevant statutory provision,[125] but it is a defensible one.[126] Amendments to the Hatch-Waxman scheme made in 2003 codified the FDA's interpretation.[127]

The singular availability of the bounty is underappreciated.[128] Most cases and commentary ignore or blur the difference between a successful first filer, which receives exclusivity, and a filer that is first to win a challenge, which may not receive exclusivity.[129] A recent federal appellate

123 *See* 21 C.F.R. § 314.107(c)(1)–(2) (1995) (identifying delay only with respect to "first application" and defining "first application"); *see also* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (proposed Aug. 6, 1999) (noting this aspect of 1994 regulation).

124 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. at 42,874.

125 Section 355(j)(5)(B)(iv) provides that if "a previous application has been submitted," a subsequent filer must wait until 180 days after the "first commercial marketing of the drug under the previous application" or a favorable court decision, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). In essence, the FDA concluded that the only "previous" application that triggers the delay is a *first* application. The alternative interpretation is that *any* previous application can be a source of delay, not just the first.

126 The FDA considered and rejected the alternative interpretation; though it did not explain its reasoning in detail, it did state that in the case where the first filer withdrew its application, its preferred interpretation was consistent with a goal of "encouraging prompt challenges." 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. at 42,875. A related policy justification is that having the first filer as a single "champion" encourages a potential challenger to file an ANDA as early as possible. Moreover, the reference in § 355(j)(5)(B)(iv) to "*the* previous application," *id.* (emphasis added), suggests contemplation of only a single previous filer, which supports the FDA view.

Likely the FDA also recognized that the alternative reading can produce anomalous results. If not only a first filer but also a second filer can be a "previous applicant," then the 180-day period, as enjoyed by a second filer, would not restrict the approval of a *first* filer (from the first filer's point of view, the second filer is not a "previous applicant" under any interpretation), making the subsequent filer's exclusivity into an entitlement of an oddly truncated sort.

It is possible that innovators and generic firms had doubts about the correctness of the FDA's interpretation, but provided that they attached at least some probability to its correctness, the analytical point in the text holds.

127 *See* 21 U.S.C. § 355(j)(5)(D)(iii) (Supp. III 2003) (stating that upon first applicant's forfeiture, no applicants are eligible for exclusivity period).

128 Though the point appears to have been ignored in the antitrust literature, several discussions of the Hatch-Waxman Act in academic journals provide passing mention. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 417 (1999) (noting that even if later filer wins its suit, it "would be compelled to wait 180 days before enjoying the fruits of its victory and would not receive any exclusivity of its own" because "under the language of the statute, the 180 days of exclusivity belong solely to the first challenger and not to the first winner"); *see also* Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, HEALTH AFF., Sept.–Oct. 2001, at 119, 123 (noting briefly that "[s]ubsequent challengers are ineligible for exclusivity").

129 Typical is this statement, contained in the Senate report accompanying a predecessor bill to the 2003 amendments: "The law as it stands gives temporary protection from competition to the

case, which rejected antitrust liability for a pay-for-delay settlement, provides a useful illustration.[130] There, the panel majority relied upon the erroneous view that bounty eligibility *does* cede to other filers. According to the majority, the innovator's settlement agreement with the first filer, by neutralizing the competitive threat of the first filer, "opened the [relevant] patent to immediate challenge by other potential generic manufacturers, which did indeed follow—spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit."[131] The majority apparently believed that, at least during the period of the FDA's successful defense interpretation (that is what the panel means by "at the time"), exclusivity eligibility ceded to a later filer.

How the Second Circuit panel reached this conclusion is not clear. No party or amicus brief argued that later ANDA filers might be eligible for the exclusivity. Other courts in similar circumstances have not reached this conclusion.[132] In support, the majority cited the district court opinion in another settlement case, but that opinion does not demonstrate the proposition.[133] Moreover, at another point the panel stated the correct rule.[134] The likeliest explanation is that the court simply repeated an incorrect assertion made by the district court below.[135]

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first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug." S. REP. NO. 107-167, at 4 (2002). From this ambiguous statement it is a short step to the erroneous statement that a second filer, if first in receiving FDA approval, could enjoy the exclusivity.

130 *In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244, at *22 (2d Cir. Aug. 10, 2006).

131 *Id.*

132 For example, a district court opinion considering the same settlement reflected the court's and parties' understanding that later filers were fighting to secure FDA approval, *not* exclusivity. *See generally* Mylan Pharm. Inc. v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000), *vacated as moot sub nom.* Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d 627 (D.C. Cir. 2002). Another case involving the same settling generic firm (Barr), settlement structure (a conversion upon settlement from Paragraph IV to Paragraph III), and timing (during the FDA's transition away from the authorized generic interpretation), also makes clear that subsequent filers sought access to FDA approval, not the exclusivity period. *See generally In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

133 *See Tamoxifen*, 2006 WL 2401244, at *22 (citing *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 242–43 (E.D.N.Y. 2003)). The cited discussion in *Cipro* merely notes the significance of the absence of a statutory bottleneck preventing FDA approval, an issue discussed in the next section.

134 *See Tamoxifen*, 2006 WL 2401244, at *2 (noting that during relevant period, exclusivity was available, provided successful defense was satisfied, "to the *first* ANDA filer to elect a paragraph IV certification" (emphasis added)).

135 The district court asserted that under the successful defense doctrine, "the ANDA filer which first successfully defended" would receive the bounty. *In re* Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 134 (E.D.N.Y. 2003). That statement is incomplete, since it omits the requirement that the filer be a *first* filer. From this statement, the court concluded that "[i]n

As a result, the court mistakenly attributed a nonexistent incentive to subsequent filers. That this error was apparently not challenged when first made in the district court, briefed or corrected during the appeals process, or noted by the panel's dissenting opinion, demonstrates that the singular availability of the bounty, and its significance for antitrust analysis, is poorly understood. The mistake is not merely technical, for a correct understanding of the exclusivity period is necessary to a proper understanding of generic firm incentives.

Generic firms other than the first filer will lag behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue a challenge. The subsequent filers' return on a challenge, aside from being smaller, depends upon the outcome of the first filer's suit (and possible settlement), providing a strategic motivation to slow down until that uncertainty is reduced.[136] It is therefore inaccurate to assert, as some cases have, that "[i]n a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market."[137] The settlement does secure an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition. Similarly, although it may be correct in a literal sense that a settlement "clear[s] the field,"[138] the implication is very different from that drawn by the Second Circuit: The most vigorous challenger has been removed from the field, thereby removing an important source of early competition.

3. The Approval Bottleneck

Settling with the firm that is closest to introducing competition and

other words," during the heyday of the successful defense requirement, "if [later-filing generic firms] had successfully defended against [the innovator's] patent infringement suit, the first one to do so would receive the 180-day exclusivity period pursuant to then-existing FDA regulations." *Id.* This latter statement flatly contradicts the consistent FDA view.

136 Another possible difference among generic firms is that one filer may have a claim that it is uniquely able to exploit. The private plaintiffs challenging the settlement in *Cipro* have made an assertion of this sort. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005). The subsequent filer retains *some* incentive even without the exclusivity period, particularly as winning may provide a head start in marketing. However, each filer benefits from favorable judgments in the others' suits, reducing the benefits from aggressive pursuit. A further complication is that a subsequent filer sometimes has an incentive for speed that the first filer lacks. The first filer receives the exclusivity whether it proceeds quickly or slowly (although the value of the exclusivity may decline over time); a subsequent filer receives a proportionately larger fraction of the rewards of normal generic entry by securing entry earlier.

137 Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); *see also Tamoxifen*, 2006 WL 2401244, at *23 n.28 (citing with approval quoted statement).

138 *Tamoxifen*, 2006 WL 2401244, at *8, *22 (quoting *Tamoxifen*, 277 F. Supp. 2d at 133, and noting that agreement "opened the [relevant] patent to immediate challenge").

has the greatest incentive to do so is a highly profitable opportunity, even if subsequent filers remain free to secure FDA approval. But in addition, the entry of subsequent filers can be blocked entirely in some instances, due to a statutory bottleneck created by the Hatch-Waxman regime.

As already noted, the 180-day exclusivity period operates by delaying FDA approval of a later-filing generic firm's ANDA-IV. In particular, the statute requires that a later-filed ANDA-IV not be approved until 180 days after the first filer's initiation of commercial marketing or a court determination of invalidity or noninfringement, whichever comes first.[139] A settlement between the first ANDA-IV filer and the innovator removes an opportunity for commercial marketing or a court determination. Without the occurrence of either triggering event, the later ANDA-IV filer is stuck, for the FDA lacks authority to approve the application.

The resulting delay is frequently emphasized in discussions of the pharmaceutical regime.[140] The degree of delay should not be overstated, however, since the block is incomplete. If a later ANDA filer wins a favorable court decision, that decision triggers the exclusivity period—that is, the *first* filer's exclusivity period. The subsequent ANDA filer could enter 180 days later.[141]

Nor is the bottleneck a pervasive feature of pay-for-delay settlements, for two reasons. First, the bottleneck applies only to settlements reached during a limited time period. The bottleneck did not arise until the demise of the successful defense requirement, for under that interpretation a *pending* suit between an innovator and first ANDA-IV filer, not yet having been successfully defended, was considered insufficient to block approval of a subsequent ANDA-IV filer.[142] Moreover, the bottleneck does not apply to filings made after December 2003. Due to a statutory change, to simplify greatly a complicated scheme, FDA approval of those later-filed

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139 *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

140 For analyses emphasizing the statutory bottleneck, see, for example, HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-31 (Supp. 2005); *id.* at 7-35, -37 (Supp. 2006); Brodley & O'Rourke 2002, *supra* note 15, at 54; Hovenkamp et al. 2003, *supra* note 15, at 1757; Hovenkamp et al. 2004, *supra* note 15, at 717 & n.23. The Hovenkamp et al. treatise does note that the removal by amendment of the statutory bottleneck, discussed *infra* note 143 and accompanying text, "reduces, but certainly does not eliminate, the gains from anticompetitive settlements." HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-36 (Supp. 2006). This apparent recognition that the bottleneck is not strictly necessary is not explicated.

141 However, if the innovator declined to sue the later filer, as often happens, it would be difficult to secure the necessary victory in court.

A further possibility is that there are no subsequent filers to be blocked. That, however, does not necessarily imply that there is no harm, since would-be filers may have been deterred by the futility of filing in light of the fact or likelihood of a blocking settlement.

142 During the heyday of the successful defense interpretation, however, doubts about its validity might have affected decisionmaking to some degree, in anticipation of its invalidity once tested. *See supra* note 126.

ANDA-IVs generally cannot be long delayed on account of a settlement between the innovator and a first-filing generic firm.[143] Second, some settlements do not take advantage of the bottleneck—for example, because the generic firm alters its filing in a way that removes the block.[144]

The approval bottleneck is sufficient but not necessary to demonstrate the feasibility of pay-for-delay settlement or the presence of allocative harm. And there is a downside to overreliance upon the bottleneck as the primary means to demonstrate the feasibility of a settlement that produces an allocative harm. The absence of an approval bottleneck can give the erroneous impression that there is no activity of competitive concern. Some courts have been distracted in just this manner.[145] Attention to limits on exclusivity eligibility, not just FDA approval, better identifies the extent of the allocative harm.

B. The Exclusivity Period as a Source of Compensation

1. The Value of a Guaranteed Bounty

The specific form of the bounty's implementation expands the potential for allocative harm in a second way. To see this effect, consider an ordinary patent validity suit with some probability of a judgment of invalidity.[146] To be concrete, suppose that the probability of a judgment of invalidity is fifty percent. If the parties see the litigation to conclusion, then consumers have a fifty percent chance of receiving the incremental benefits of competition, rather than facing a monopolist for the remainder of the patent term.

Two different kinds of settlement are just as good as litigation from a

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[143] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2)–(b), 117 Stat. 2066, 2458–60 (2003) (codified at 21 U.S.C. § 355(j)(5)(D) (Supp. III 2003)) (providing for forfeiture of entitlement to 180-day exclusivity period if parties settle).

[144] For example, one component of the settlements of patent suits involving Cipro, Nolvadex, and BuSpar was that the settling generic firm changed its certification from Paragraph IV to Paragraph III. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 519 (E.D.N.Y. 2005); *In re* Tamoxifen Citrate Antitrust Litig., No. 03-7641, 2006 WL 2401244, at *4 (2d Cir. Aug. 10, 2006); Complaint ¶ 32, *In re* Bristol-Myers Squibb Co., No. C-4076 (F.T.C. Apr. 14, 2003), 2003 WL 21008622. One complication that has occasionally arisen is lingering doubt about whether the conversion entirely removed the block. *See, e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 244 (E.D.N.Y. 2003) (discussing first filer's efforts, post-settlement, to continue to assert entitlement to exclusivity period); *Tamoxifen*, 2006 WL 2401244, at *4 (similar).

[145] *See, e.g.*, *Tamoxifen*, 2006 WL 2401244, at *19 (focusing upon proposition that although *this* competitor is excluded, settlement "would have no effect on other challengers" (quoting *Cipro*, 363 F. Supp. 2d at 534)); *Cipro*, 261 F. Supp. 2d at 242–43 (similar).

[146] Assume for now that launching a product "at risk"—that is, prior to a favorable judgment, but after the eventual expiration of the automatic stay—is not a significant factor. For a discussion of launching at risk, see *infra* Part III.B.2.

consumer's point of view. One settlement solution is simply to agree to decide by some random means, such as a coin flip, whether entry occurs. Another of equal effect is for the parties to divide up the remaining term in accordance with the probability of success. If the chance of success is fifty percent, then the patentee might agree to permit competition halfway into the remaining term. Consumers receive the full benefit of competition, but for one half of the period; that is equivalent to a fifty percent chance of enjoying the benefits of competition for the entire period, ignoring litigation costs and changes in market conditions. In this setting, each outcome—a lawsuit with a probabilistic outcome, a randomized settlement, and a settlement splitting entry in accordance with the probabilities—has the same effect upon expected patentee profits, entrant profits, and consumer welfare.

An agreement that divides up the remaining term into monopoly and competition periods fits the widely accepted rule that an agreement on entry dates raises no anticompetitive concern. The FTC, for example, has provided a safe harbor for agreements that set an entry date but include no cash payment from the innovator to the generic firm.[147] A term division solution has also been endorsed in commentary.[148] Economic modeling of pharmaceutical competition commonly accepts the same underlying view.[149]

[147] This view has been expressed in a major opinion of the Commission. *See In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part VII (F.T.C. Dec. 8, 2003) ("[W]e do not challenge agreements on entry dates, standing alone."); *see also id.* Part II(B)(4) ("A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent."). It has been referred to in a subsequent advisory opinion declining to challenge a settlement. *See In re* Bristol-Myers Squibb Co. (Teva Pharmaceuticals USA, Inc.), No. C-4076, FTC, at 2–3 (May 24, 2004), *available at* http://www.ftc.gov/os/caselist/c4076/040525advisoryc4076.pdf (advisory opinion under 2002 BMS consent, with respect to Carboplatin, explaining that absence of payment resolved antitrust concerns). The view is reflected in other settlement activity as well. For example, the consent decrees permit no-payment settlements, and the 2004 update to the FTC study noted with satisfaction that no settlement included a payment from the innovator to the generic firm. FTC STUDY UPDATE, *supra* note 70, at 4. Finally, the safe harbor was advocated in the FTC's briefing to the Supreme Court in *Schering*. *See* Petition for Writ of Certiorari, FTC v. Schering-Plough Corp., *supra* note 14, at 18 ("[S]ettlements that are beneficial or neutral to consumers are certainly possible. For example, if the parties simply compromise on an entry date prior to the patent's expiration, without cash payments, the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent."); *see also* Supplemental Brief for Petitioner at 6 n.5, FTC v. Schering-Plough Corp., No. 05-273 (U.S. June 12, 2006), 2006 WL 1647529 (settlement with compromise entry date but no cash payment does not "normally" raise antitrust concerns).

[148] *See, e.g.*, HOVENKAMP ET AL., *supra* note 7, § 7.4e, at 7-45 (Supp. 2005); Brodley & O'Rourke 2002, *supra* note 15, at 55–56; Hovenkamp et al. 2003, *supra* note 15, at 1762; Schildkraut, *supra* note 15, at 1043–44.

[149] For models that address pharmaceutical settlements without modeling the effect of the exclusivity period, see, for example, Leonard & Mortimer, *supra* note 114; Shapiro 2003a, *supra* note 15. See also Joseph Farrell & Carl Shapiro, How Strong Are Weak Patents? (Oct. 2005) (unpublished manuscript, available at http://faculty.haas.berkeley.edu/shapiro/weak.pdf), which

The model, however, fits pharmaceutical regulation poorly. In suits involving an ANDA-IV filer, a division-of-term settlement and a probabilistic lawsuit are not equivalent. Providing a generic firm with fifty percent of the remaining patent term is not the same thing as a fifty percent chance of winning the suit—not for the generic firm, innovator, or consumers. The key source of profits for a generic firm is the exclusivity period. Rather than monopoly followed by general entry, there is an intermediate stage of duopoly between the two. This feature is not reflected in the standard model.

Key to the difference is an important feature of the Hatch-Waxman regulatory arrangement: If the parties agree to a negotiated entry date, the generic firm enjoys the exclusivity period when it finally enters the market. This result follows directly from the approval bottleneck discussed in Part II.A.3. That section demonstrated how a first-filing generic firm could retain its exclusivity eligibility, despite settlement. One effect discussed there is that so long as the settling generic firm stays out of the market, later filers are denied FDA approval. In addition, once the generic firm *does* enter, it makes good on that eligibility, and enjoys the 180 days of exclusivity. This effect of the statute holds true in the same set of important though limited situations in which the approval bottleneck can delay FDA approval of later ANDA-IV filers.[150]

By making the bounty a certainty rather than a probability, the innovator confers value upon the generic firm. That opportunity to confer value disrupts the equivalence between litigation and a term-dividing settlement.[151] The disruption is most easily seen by considering two distinct aspects of the settlement negotiation.

First, it is costly to the innovator to allow the generic firm to enjoy the bounty with certainty rather than merely a probability. The innovator will accept a settlement only if the entry date is set late enough to compensate the innovator for the value thereby transferred to the generic firm. On average, that date leaves consumers with less benefit than they would receive through litigation.

To see this, it is helpful to consider a stylized model of the dynamics

offers a model explaining how a patentee can control the conduct of downstream oligopolists; though the model takes its motivation from the pharmaceutical settlement cases, it omits consideration of industry-specific features.

150 That is, those reached after the demise of the successful defense requirement, where the relevant ANDA was filed prior to the rule change of December 2003. *See supra* notes 142–143 and accompanying text. For settlements reached during the successful defense period, moreover, this feature might still be potentially relevant, if the anticipated demise of the successful defense requirement affected the terms of settlement. *Cf. supra* note 142.

151 For a brief analysis along similar lines, see Bulow, *supra* note 15, at 146–47. For an account of the potential harm from settlement that does not rely upon the particular role of an intermediate duopoly period, see generally Schrag, *supra* note 15.

of negotiation. Consider a market served by an innovator, who is equipped with a single patent granting ten years of exclusivity, and by generic firms, exactly one of which initiates a challenge to the patent. The innovator and the generic firm litigate or negotiate to determine the division of profits for the remainder of the patent term. If the parties litigate, there is a trial, and the patent is found valid and infringed with some probability—say, to continue with our maintained assumption, fifty percent. If the patent is found valid and infringed, the generic firm is barred from entry, and the monopolist enjoys monopoly profits for the remainder of the term. Otherwise the generic firm enters immediately, leading to two stages of competition: an exclusivity period set by statute, during which the innovator and generic firm each earn duopoly profits; and a residual period during which other firms can enter as well, and the two firms earn much lower profits.

The parties can choose to settle rather than litigate by agreeing upon the date of entry by the generic firm. Entry after negotiation resembles entry after litigation: There is a duopoly period followed by a residual period of competition. Entry after negotiation is certain, rather than probabilistic. Moreover, if the negotiated entry date is late enough, there is no final competition period, but instead monopoly followed by a truncated duopoly period. Suppose further that the parties decide whether to litigate or settle at the beginning of the ten-year period, and any agreement or trial is concluded instantaneously.

A few numerical assumptions ease the exposition. Suppose that under monopoly, the innovator receives 1000 each year, the generic firm and consumers nothing; that under duopoly, the innovator and generic firm each receive 500 per year, and consumers again nothing; and that under competition, consumers receive 1000 per year, and the innovator and generic firm each receive nothing. Think of each unit as a million dollars—$1 billion per year for the innovator under monopoly, and so forth—and the example roughly matches the magnitudes for a blockbuster drug.[152]

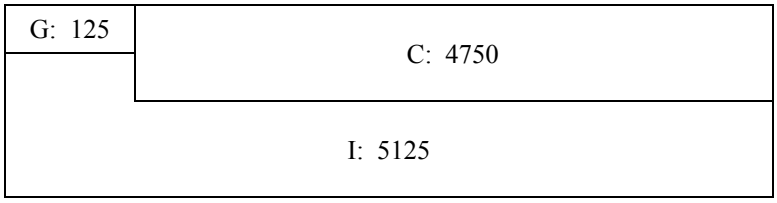
Under litigation, the innovator has a fifty percent chance of receiving 10,000 in monopoly profits and a fifty percent chance of receiving 250 in

[152] These assumptions are unrealistic in two respects. First, the model assumes that total duopoly profits equal monopoly profits. By contrast, under most models of competition, producer surplus drops under duopoly compared to monopoly, and consumer surplus rises. This is a variation on the point made in Part II.A.1, that duopoly profits are lower than monopoly profits. Pharmaceutical duopoly does tend to approximate monopoly profits, but the more important point is that the polar assumption serves to elucidate the effect presented in the text. Second, the model assumes that firms earn no profits once full entry commences. But as acknowledged in Part I, firms often enjoy some profits once the duopoly period has ended. These profits, if large enough, undercut the effect discussed in the text.

duopoly profits, an expected value of 5125. The generic firm has a fifty percent chance of receiving 250 and a fifty percent chance of receiving nothing, an expected value of 125. Consumers have a fifty percent chance of receiving 9500 (1000 per year for nine-and-a-half years; the first half-year is the duopoly period) and a fifty percent chance of receiving nothing, an expected value of 4750.

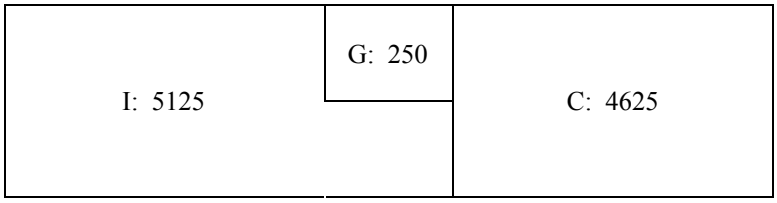
This can be depicted graphically. The length of the rectangle is ten years, and its height shows the division of expected benefits within a period:

LITIGATION



Now consider settlement. Under settlement, the generic firm receives 250 with certainty, because the bounty is now guaranteed. The additional 125 to the generic firm, compared to litigation, must come from somewhere. The innovator also receives 250 during the duopoly period. To be indifferent between settlement and litigation, the innovator must earn at least 4875 during the monopoly period. That level of profit can be earned provided that entry begins 4.875 years into the remaining patent term or later. Again depicting the result graphically:

SETTLEMENT: MINIMUM ACCEPTED BY INCUMBENT



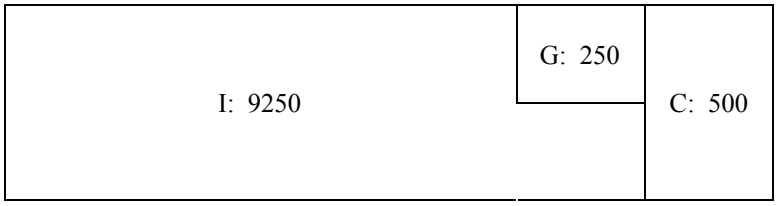
Consumers, in order to equal their benefit from litigation of 4750, require that the entry date be no later than 4.75 years; assuming that entry date, consumers begin to receive 1000 per year six months after entry, or beginning at year 5.25. If the entry date is 4.875 years, the level insisted upon by the innovator, consumers are worse off by 125 under settlement compared to litigation.

Moreover, the actual negotiated date of entry is likely to be substantially later than the threshold date that leaves the innovator

indifferent between litigation and settlement. The innovator will bargain with the generic firm over the gains conferred by making the bounty a certainty. Securing a later entry date is very important to the innovator. For the generic firm, an earlier entry date is better, given the higher present value of earlier payment, but only modestly so. Enjoying the exclusivity period with certainty is more important to a generic firm than its timing. In fact, if future market demand is anticipated to increase, a generic firm might *prefer* the later entry date, so long as the increase in projected profits exceeds the discount from the delay in their receipt.

The innovator is likely to bargain not for a settlement that perfectly matches its profits under litigation, but for a more profitable settlement—that is, one with a later entry date. The generic firm is likely to agree, so long as it secures the duopoly period with certainty rather than having to take its chances in litigation. Suppose, for example, that the innovator and generic firm agree to an entry date nine years into the remaining patent term—that is, a year before expiration. Now the innovator earns with certainty nine years of monopoly profits (9000) plus 250 from the duopoly period; the generic firm earns 250 with certainty; and consumers see competition only in the last six months, for a total benefit of 500. Again depicted graphically:

SETTLEMENT: RESULT OF BARGAINING



Indeed, this is not even the latest entry date to which the parties might agree.

The assumptions of the stylized model are unrealistic, particularly with respect to the generic firm, which normally earns some profit during the competition period, and hence has some reason to prefer earlier rather than later entry dates.[153] Yet the simple depiction here is sufficient to show the problem for consumers from no-payment settlements—an innovator will be unwilling to accept any entry date that would leave consumers at least as well-off, and the date the innovator actually chooses is even worse for consumers. Delayed entry can thereby align the incentives of the innovator and generic firm, a point generally overlooked.[154]

153 A formal, general model of the settlement game is the subject of work in progress.

154 For a contrasting view, see Hovenkamp et al. 2003, *supra* note 15, at 1762, which argues

2. The Complication of Litigation Expense

Considering litigation expense does not eliminate these allocative harms, and may, in fact, exacerbate them. To see why, it is useful to consider two respects in which saved litigation expense is thought to count in favor of settlement.

First, and as noted in Part I, saved litigation expense is thought to offset the allocative harm from the settlement. But although litigation expense is large in absolute terms, perhaps tens of millions of dollars, its size is dwarfed by the hundreds of millions or billions of dollars reallocated when parties enter a pay-for-delay settlement. The savings are insignificant except in the least important cases. Aside from its small role in any realistic assessment of the welfare effects of a settlement, saved expense is also an unlikely explanation of the parties' motivation for entering the settlement.

Second, even those who favor antitrust liability for pay-for-delay settlements make an exception for settlements with payments keyed to the size of litigation expense. In particular, as a matter of current practice the FTC effectively grants safe harbor to settlements in which the innovator makes a payment equal to or less than saved litigation expense.[155] This position has been endorsed by commentators.[156]

By differentiating pay-for-delay settlements that include large cash payments from those with payments that are equal to or less than saved litigation expense, the safe harbor usefully distinguishes those settlements likely to inflict the largest allocative harm. But the policy nevertheless permits some settlements that inflict allocative harm. That is true for two reasons. The first reason is an extension of the zero-payment settlement analysis of the previous section. Suppose, for example, that the innovator saves no litigation expense by settling. In that case an entry-splitting settlement that includes no cash payment is identical to the settlement discussed in the previous section. It fits within the safe harbor, yet entails an allocative harm.

Now suppose that the innovator saves some litigation expense by settling, but that the generic firm's bargaining power is such that it is able

that delayed entry "does not align the incentives of pioneer and generic litigants: Generics will want the delay to be as short as possible, and patentees to make the delay as long as possible."

155 *See In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part II (F.T.C. Dec. 8, 2003). Earlier orders had the same structure. *See* consent decrees cited *supra* note 67.

156 *See, e.g.*, HOVENKAMP ET AL., *supra* note 7, at § 7.4e, 7-39 (Supp. 2006) (allowing that settlements should be permitted where payment is "no more than the expected value of litigation and collateral costs attending the lawsuit," and provided that patentee's "ex ante likelihood of prevailing in its infringement lawsuit is significant"); *see also* Hovenkamp et al. 2003, *supra* note 15, at 1758–59 (same); Shapiro 2003b, *supra* note 15, at 76 n.10 ("[C]ash payments should be calculated net of the patent holder's avoided litigation costs.").

to extract all of the benefit from the innovator's saved expense. In that case, nothing has changed; a settlement that includes a payment equal to that saved expense is equivalent to the zero-payment settlement where there are no litigation savings.

If the innovator has some bargaining power, however, the safe harbor permits additional allocative harm. For in that case, the innovator will be able not only to retain part of the gain from saved litigation expense, but also to bargain for part of the generic firm's litigation savings. If the innovator has at least equal bargaining power, it should need to pay no more than *half* of the *difference* between the parties' saved litigation costs in order to secure a settlement. Allowing a larger payment, as the safe harbor does, permits the innovator to confer additional value upon the generic firm in exchange for additional delay, leading to additional allocative loss. Indeed, if the innovator has most of the bargaining power and the generic firm's saved expense is large enough (it need not be as large as the innovator's savings), the litigation savings component of the deal, considered alone, requires a net conferral of value from the generic firm to the innovator. In that case, the generic firm will not pay the innovator; instead, the parties will simply agree to a later entry date, thereby imposing a greater allocative harm.[157]

C. Assessing the Allocative Harm from Settlement

The foregoing analysis establishes that the allocative harm of settlement extends to a wider range of settlements than commonly supposed. Problematic settlements are feasible even where there is no formal bottleneck to FDA approval, because buying off the single firm with bounty eligibility carries a strong prospect of allocative harm. Settlements with small cash payments, moreover, can nevertheless entail payment for delay. Even where there is no cash payment, a term-dividing settlement provides the opportunity for an innovator to provide noncash compensation—the guarantee of the bounty itself—in exchange for delay.

Recognizing the true breadth of allocative harm from pharmaceutical settlements has implications for the choice of antitrust decision rule. It is further reason to think that the rule of effective per se legality fashioned by some courts is inappropriate. On the other hand, a rule of per se illegality is also too extreme: Particularly where the anticompetitive effect is modest or subtle, as when the settlement lacks an approval bottleneck or large cash payment, it may be important to provide defendants with an opportunity to offer a procompetitive justification for the settlement.

A better, middle route is the version of a rule-of-reason analysis

[157] The problem is compounded by the potential for manipulation, as the innovator could inflate its cost estimate in order to permit a larger payment insulated from antitrust scrutiny.

applied by the FTC in a recent case and endorsed by commentators,[158] expanded in scope to cover settlements with any cash payment or retention of exclusivity eligibility. A settlement that contains a cash payment or permits the retention of exclusivity eligibility raises a "red flag," and an accompanying presumption of illegality.[159] That presumption can be rebutted, however, by demonstrating that the settlement's provisions "are justified by procompetitive benefits that are both cognizable and plausible."[160] That procedure gives proper weight to the high likelihood of allocative harm arising from these settlements, while leaving space for defendants, the parties best positioned to come forward with justifications, to explain why the settlement is necessary to achieve some procompetitive end.

III
REGULATORY DESIGN AND CONGRESSIONAL JUDGMENT

Part II demonstrated how an industry-specific regulatory arrangement, here the Hatch-Waxman Act, alters the opportunity for collusive conduct. That analysis showed the various means by which the regulatory structure expands the opportunity for allocative harm from settlement. We must still contend with the important objections described in Part I—that the expected allocative losses from a pay-for-delay settlement ought to be tolerated. After all, these agreements settle litigation—and normally settlements are thought desirable, because they conserve litigation expense and benefit parties who are in the best position to arrange their own affairs. Moreover, the litigation settled is *patent* litigation, and patent policy favors innovation over consumer access; the interaction of patent policy with antitrust might be thought to permit allocatively harmful practices ordinarily condemned under antitrust law alone.

Here we come to the second effect of industry-specific regulation, its role as a congressional judgment about the proper balance between innovation and competition. This judgment, like the judgment about innovation policy reflected in the Patent Act, influences the scope and vigor of antitrust enforcement. For example, patent policy may contain a norm favoring innovation and favoring settlement that alters the antitrust treatment of practices involving patented goods. But even if patent policy

158 *See, e.g.*, *Schering*, 2003 WL 22989651, Parts I.C & II.B.1; Hovenkamp, *Sensible Rules*, *supra* note 15, at 26–31 ("[T]he Federal Trade Commission's approach in [*Schering*] seems about right."); *see also* Hovenkamp et al. 2003, *supra* note 15, at 1759–60 (suggesting burden-shifting approach).

159 *See Schering*, 2003 WL 22989651, Part II.B.4; Hovenkamp, *Sensible Rules*, *supra* note 15, at 30.

160 *See Schering*, 2003 WL 22989651, Part I.C; Hovenkamp, *Sensible Rules*, *supra* note 15, at 30.

generally contains such a norm, an industry-specific regulatory arrangement supplants that norm within its domain. To understand the alteration, it is necessary to understand in some detail how the regulatory regime differs in its effects from the usual effects of patent law.

This Part explains those differences and their relevance for antitrust enforcement. Part III.A presents the case for identifying, as a general matter of patent law and antitrust law, certain exceptions to the ordinary operation of antitrust law. Part III.B describes a key alteration, compared to patent law generally, wrought by the industry-specific regulatory regime in pharmaceuticals, which provides an effective tax for some drug development projects and a subsidy to others. Part III.C explains how Congress's industry-specific congressional judgment about the balance between innovation and competition undermines certain arguments against antitrust liability.

A. An Uneasy Case for Patent Exceptionalism

If patent policy depends upon above-cost pricing, and antitrust policy is suspicious of firm practices that defend and extend above-cost pricing, then there is a case to be made for a reconciliation of means in which antitrust gives way, and the patentee is allowed to employ certain practices that would otherwise be prohibited. To make headway, it is useful to consider first whether antitrust law of its own accord provides a special accommodation to the makers of innovative goods, and then to assess whether the Patent Act alters the baseline of enforcement for patented goods.

1. Innovation as an Internal Norm of Antitrust

A norm favoring innovation may at first seem foreign to antitrust law. After all, low prices are an important goal of antitrust enforcement—even, some have claimed, the primary goal.[161] And there are important areas of antitrust doctrine in which low consumer prices trump other efficiency-promoting values.[162]

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[161] *See, e.g.*, Aaron S. Edlin, *Stopping Above-Cost Predatory Pricing*, 111 YALE L.J. 941, 948 n.25 (2002) ("Despite the wish of economists and their fellow travelers that the goal of antitrust be to promote overall efficiency, neither case law nor legislative history stands for the proposition that overall economic welfare or wealth maximization trumps low prices.").

[162] For example, under current U.S. doctrine, cost savings achieved through a merger are generally not cognizable unless they are "sufficient to reverse the merger's potential to harm consumers in the relevant market, e.g., by preventing price increases in that market." U.S. Dep't of Justice & FTC, Horizontal Merger Guidelines § 4, 4 Trade Reg. Rep. (CCH) ¶ 13,104 (amended Apr. 8, 1997); *see also* FTC v. Staples, Inc., 970 F. Supp. 1066, 1088–90 (D.D.C. 1997) (applying Guidelines section 4). In addition, the Supreme Court has repeatedly invoked "consumer welfare" as the touchstone of antitrust analysis. *See, e.g.*, Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 221, 224 (1993); NCAA v. Bd. of Regents of

However, allocative efficiency does not exhaust the concerns of antitrust analysis.[163] Promoting innovation matters, too. Some innovation-promoting antitrust rules may have only a minimal conflict with allocative efficiency—for example, when an antitrust enforcement agency insists upon the maintenance of rivalrous research and development efforts as a condition of merger.[164] A greater conflict is posed by a policy that advocates market concentration as an inducement or (more controversially) a platform for innovation.[165]

Basic structures of antitrust doctrine reflect the need to provide a reward for "skill, foresight and industry"[166] in order to induce innovation, even at some expense of allocation. As a general matter, monopolies are subject neither to dissolution by government decree nor to a duty to provide access to rivals at a discounted rate.[167] Nor are product design decisions normally subject to disclosure to rivals, though disclosure would improve the rivals' ability to compete in the provision of complementary goods.[168] A contrary policy would lower prices in the short run but reduce the prospective incentive to invest in new and improved products and processes, an important engine of economic growth. This dynamic benefit of policies that preserve monopoly profits offsets their static allocative cost. As the Supreme Court recently explained, in rejecting a refusal-to-deal claim in the regulatory context of telecommunications law:

> The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts "business acumen" in the first place; it induces risk taking that produces innovation and

Univ. of Okla., 468 U.S. 85, 107 (1984) (quoting Reiter v. Sonotone Corp., 442 U.S. 330, 343 (1979) (citation omitted)).

163 *See, e.g.*, Town of Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (describing goals of both antitrust and regulation as "low and economically efficient prices, innovation, and efficient production methods").

164 *See, e.g.*, Michael L. Katz & Howard A. Shelanski, *Merger Policy and Innovation: Must Enforcement Change to Account for Technological Change?*, *in* 5 INNOVATION POLICY AND THE ECONOMY 109, 147–48 (Adam B. Jaffe et al. eds., 2005) (discussing conditions placed upon merger between Ciba-Geigy and Sandoz designed to preserve rivalrous research and development).

165 The canonical statement of concentration as an attractive platform for innovation is JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM & DEMOCRACY 87–106 (3d ed. 1950). As Katz & Shelanski explains, *supra* note 164, at 131–34, it remains an open question whether competition or concentration better promotes innovation.

166 United States v. Aluminum Co. of Am., 148 F.2d 416, 430 (2d Cir. 1945) (L. Hand, J.).

167 *See, e.g.*, Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415 (2004) (so holding, in context of telecommunications regulation).

168 *See, e.g.*, Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 281 (2d Cir. 1979) (holding that camera manufacturer had no obligation to predisclose information about new product design to competitors).

economic growth.[169]

Not all of the Court's opinions have gone this far, to be sure;[170] but it is fair to say that as an ordinary element of antitrust law consumer access is balanced against the incentive to create.

The difficult question is how far to push the argument for dynamic efficiency. The higher the producer profits allowed, the larger the dynamic benefits. An agreement with a rival to divide markets normally attracts condemnation under section 1 of the Sherman Act. But an innovator might argue that the additional profits induce enough incremental innovation to make the practice beneficial overall. The argument is fundamentally similar for patented and unpatented (though costly-to-create) goods. An innovator who builds a telecommunications network and one who designs a new drug are similarly positioned to argue that a certain profit-improving practice should be permitted, despite its adverse allocative consequences, in light of its salutary effect upon the incentive to innovate. The tradeoff inherent in providing incentives for creation while tolerating allocative distortion affects intellectual property and other assets alike.[171]

An argument favoring exemptions for innovative goods, however, likely fails as a matter of general antitrust law. It is difficult to establish convincingly that an exemption carries large benefits for future innovation.[172] Nor is a generalist court equipped to make the necessary fine-grained determinations of industrial policy, relaxing antitrust here and tightening it there, in accordance with its views about desirable innovation and acceptable deadweight loss. Certainly such case-by-case determinations of incremental innovation and incremental, deadweight loss are projects ill-suited to the capacities of a generalist court. There is, therefore, often good reason to limit attention to allocative efficiency in practice, even if one is committed to a full range of efficiency arguments—including dynamic efficiency—in theory.[173]

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169 *Trinko*, 540 U.S. at 407. The reference to "business acumen" comes from *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966).

170 *See, e.g.*, Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 483–86 (1992) (entertaining antitrust liability for manufacturer's refusal to sell parts to competitors in servicing).

171 This is a point recognized in Einer Elhauge, *Defining Better Monopolization Standards*, 56 STAN. L. REV. 253, 301–05 (2003) (noting that tradeoff between innovation and competition is not limited to intellectual property context).

172 Moreover, as Aaron Edlin has noted, "once one widens the scope of antitrust concerns beyond prices in order to evaluate overall social welfare, one confronts an impossible tangle of how to evaluate social welfare or societal wealth in a world rife with market failures." Edlin, *supra* note 161, at 948 n.25.

173 Resistance to recognizing cost savings as a basis for permitting a merger reflects similar concerns. *See, e.g.*, POSNER, *supra* note 8, at 29 ("Efficiency is the ultimate goal of antitrust, but competition a mediate goal that will often be close enough . . . ."); *id.* at 133–36 (discussing merger efficiencies).

2. The Patent Act as a Statutory Basis for Exceptionalism

The Patent Act provides a statutory foothold, external to antitrust law, for a patentee to insist upon a more innovation-protective antitrust policy than that available to innovators generally. There will not, of course, always be a conflict between antitrust law and patent policy. To the extent that the Sherman Act already reflects an acceptance of dynamic arguments, there may be no conflict in means. But often there *will* be a conflict, and in those cases the Patent Act provides a basis for seeking an exception to the ordinary operation of antitrust.

The high-water mark in judicial recognition of patent exceptionalism is the Supreme Court's holding in *United States v. General Electric* that a patentee may agree to a price-restricted license with its competitor.[174] The extent of or rationale for exceptionalism is often left undeveloped. This is a problem in *General Electric* and other old cases,[175] but the modern pay-for-delay cases fare little better. They are sprinkled with statements that, for example, antitrust liability should be withheld for "a rather simple reason: one of the parties owned a patent,"[176] and that "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition."[177] Such ipse dixit, if taken seriously, might justify a kind of naïve exceptionalism in which a court simply notes the conflict between antitrust and patent and concludes against antitrust liability without further analysis.

A more sophisticated version of exceptionalism ties the contemplated exception to a specific provision of the Patent Act or to a policy closely related to its provisions. Such statute-oriented specificity emerges from the Supreme Court's instruction in *Simpson v. Union Oil Co.*, explaining the rule of *General Electric*, that "[t]he patent laws which give a . . . monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*."[178] This version of *in pari*

174 272 U.S. 476, 488, 494 (1926) (holding that licensor patentholder may "impose the condition that [licensee] sales should be at prices fixed by the licensor and subject to change according to [the licensor's] discretion").

175 Typical is this statement from the Court's opinion in *United States v. United Shoe Machinery Co.*:

> Of course, there is restraint in a patent. Its strength is in the restraint, the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose. This strength is the compensation which the law grants for the exercise of invention. Its exertion within the field covered by the patent law is not an offense against the Anti-Trust Act.

247 U.S. 32, 57 (1918). The statement leaves unexplained what counts as "within the field" of the Patent Act.

176 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1064 (11th Cir. 2005).

177 *Id.* at 1065–66.

178 Simpson v. Union Oil Co., 377 U.S. 13, 24 (1964). *Simpson*, though not a case involving a patentee, is often cited as a statement of patent's relationship to antitrust. *See, e.g.*, *Schering*, 402

materia emphasizes that when two statutes govern the same activity, they must be reconciled by some means. In making that reconciliation, the Patent Act has a claim to primacy, as Congress's more specific take upon how best to balance innovation and consumer access with respect to patented goods.

Simpson refers to the *specific* rights provided by the Patent Act—the exclusion with respect to making, using, and selling, and a related right to license—not a general policy favoring patentee profit-taking.[179] The necessity of specific statutory support also is indicated by the Court's insistence elsewhere that exceptions created by the Patent Act must be "strictly construed."[180] Such constraints have prompted the recognition, for example, that a patentee enjoys no exception for restrictive practices that cover products not within the scope of the patent or that extend beyond its duration.[181]

F.3d at 1067; Miller Insituform, Inc. v. Insituform of N. Am., Inc., 830 F.2d 606, 608 (6th Cir. 1987); United States v. Westinghouse Elec. Corp., 648 F.2d 642, 646–47 (9th Cir. 1981); *In re* Indep. Serv. Orgs. Antitrust Litig., 989 F. Supp. 1131, 1142 (D. Kan. 1997).

179 The *Simpson* Court continues in a skeptical tone after the quotation: "That was the *ratio decidendi* of the General Electric case. We decline the invitation to extend it." *Simpson*, 377 U.S. at 24 (citation omitted). The continuation of the quotation suggests that the cases cited *supra* note 178 likely overstate the degree to which *Simpson* can be said truly to endorse an exceptionalist position.

180 United States v. Masonite Corp., 316 U.S. 265, 280 (1942) ("Since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed . . . ."); *see also* Lear, Inc. v. Adkins, 395 U.S. 653, 663 (1969) (noting, in course of rejecting licensee estoppel, that "the Sherman Act ma[kes] it clear that the grant of monopoly power to a patent owner constituted a limited exception to the general federal policy favoring free competition").

181 *See, e.g.*, Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1311 n.26 (11th Cir. 2003) (distinguishing *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907–08 (6th Cir. 2003), on ground that agreement contained restrictions broader than patent at issue); *In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1297 n.16, 1317 (S.D. Fla. 2005) (concluding that agreement contained restrictions broader than patent at issue, and indicating antitrust significance of that fact).

It is not always clear what to make of specific Patent Act provisions. For example, the Patent Act provides that "a patent shall be presumed valid." 35 U.S.C. § 282 (2000). This provision has been interpreted by the Federal Circuit to require that an invalidity defense to patent infringement must be established by clear and convincing evidence, rather than a mere preponderance. Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1549 (Fed. Cir. 1983); *see* 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.06(2)(d)(iii), at 5-793 n.103 (2003 & Supp. 2005) (collecting cases reciting standard). Some courts inclined against antitrust liability for pay-for-delay settlements have derived from this requirement an innocent-until-proven-guilty principle for antitrust: So long as invalidity has not been established by an authoritative adjudication, a patentee is free to act in ways that achieve the same degree of exclusion as a hypothetical patentee with a certainly valid patent. *E.g.*, *Schering*, 402 F.3d at 1066 (discussing presumption of patent validity as basis for exclusion of rivals, including exclusion by settlement); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 533 (E.D.N.Y. 2005) (rejecting probabilistic view of consumer entitlement to competition as contrary to statutory presumption of validity).

This interpretation of the validity presumption is doubtful, since the probability of losing the suit—the prospect that motivates a patentee to agree to make the payment in the first place—

Without an explicit statutory provision to rely upon, a patentee claiming an exception may instead seek refuge in the innovation-protective policy of the Act. Yet *every* profit-enhancing practice of a monopolist, however damaging to allocation because of its effect on prices, might be defended on the ground that it increases innovation. As a way to cabin such an argument, it is helpful to consider what we might call the innovation efficiency of the practice, the ratio of incremental innovation to incremental deadweight loss produced by the practice. Such a ratio has proved useful in commentary,[182] and gives shape to the Supreme Court's declaration that "we would not expect that any market arrangements *reasonably necessary to effectuate the rights that are granted* would be deemed a *per se* violation of the Sherman Act."[183] Where a practice produces a large deadweight loss without much benefit for innovation, it will be more difficult to understand the arrangement as reasonably necessary to effectuate the Patent Act's innovation policy, and the practice will be more vulnerable to antitrust condemnation.

The innovation interest is not limited to the patentee. An alleged infringer may be an entrant also engaged in innovative activity. Identifying and negotiating with every patentee that holds rights that are possibly relevant to the entrant's product is costly for the entrant, particularly in industries where innovation is cumulative.[184] Identifying relevant patents is discouraged in practice, moreover, by the specter of enhanced damages for willful infringement, an outcome thought to be made more likely by prior awareness of relevant patents.[185] The likely outcome is that an entrant will

already takes into account the allocation of proof. Calculations about settlement thus already reflect the probability that a generic rival would have been able to secure victory despite the heightened burden. *See* Shapiro 2003b, *supra* note 15, at 74. In addition, the presumption is probably best understood narrowly; it does not apply, for example, to the showing required to establish the likelihood of success necessary to secure a preliminary injunction. *See* New Eng. Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed. Cir. 1992) (presumption is "procedural device" for allocating burdens of production and persuasion at trial, not "evidence which can be 'weighed' in determining likelihood of success" at preliminary injunction stage).

182 *See* Kaplow, *supra* note 9, at 1829–34 (describing and applying ratio test); SCOTCHMER, *supra* note 31, at 109–12, 119–20 (similar); William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1659, 1707–19 (1988) (applying ratio test to copyright doctrine of fair use); Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113 (1990) (deriving optimal patent term and breadth, judged by ability to deliver fixed profit with minimum deadweight loss); Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON. 106 (1990) (similar).

183 Broad. Music, Inc. v. CBS, Inc., 441 U.S. 1, 19 (1979) (first emphasis added). This statement was made in the course of considering BMI's management of blanket copyright licenses.

184 For further discussion of cumulative innovation, see *supra* notes 30–33 and accompanying text.

185 *See* Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 BERKELEY TECH. L.J. 1085, 1100 (2003) ("[T]he willfulness game creates a strong incentive not to read patents."); *id.* at 1101 n.43 (collecting sources noting that employees are advised not to

frequently stumble into patent infringement suits in which it finds itself a defendant.

Seeing the litigation to conclusion is unlikely to be an attractive option for the defendant. Often, winning the litigation will be unrewarding for the entrant, due in part to a free-riding problem discussed in the next section. Yet a rule that prohibits all settlements that work an allocative harm will render some settlements unavailable. If all of the resulting confrontations must lead to a full adjudication of the patent, the result might be to reduce the supply of innovative entrants.[186] There is reason, therefore, to accept a certain amount of settlement, even settlement that works an allocative harm, in order to maintain incentives for a potential infringer's innovative entry.[187]

Patent exceptionalism has sharp critics. The concept runs contrary to the enforcement agencies' expressed view that "for the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property,"[188] and to the government's longstanding opposition to *General Electric*.[189] A forceful argument can be made, too, that patent law at most confers rights of exclusion and enjoyment that match but do not exceed those enjoyed by owners of tangible property, and if so, exceptionalism is unwarranted.[190] The present purpose is not to argue patent exceptionalism's merits, but merely to note its possible basis in statute and precedent. Provided that paying for delay

read patents if they can avoid it).

186 *Cf.* David Rosenberg & Steven Shavell, *A Solution to the Problem of Nuisance Suits: The Option to Have the Court Bar Settlement* 1 (John M. Olin Ctr. for Law, Econ. & Bus., Harvard Law Sch., Discussion Paper No. 489, 2004), *available at* http://ssrn.com/abstract=623285 (noting, in context of nuisance suits, that removing option to settle would reduce supply of plaintiffs).

187 Even when the resolution of the suit forces the alleged infringer to exit the market, the limited period prior to exit is a source of some consumer benefit.

188 U.S. DEP'T OF JUSTICE & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.0(a) (1995), *available at* http://www.usdoj.gov/atr/public/guidelines/0558.htm (making quoted statement one of three general principles guiding antitrust treatment of intellectual property licensing).

189 *See PTCJ Interview with Richard H. Stern, Chief, Intellectual Property Section, Antitrust Division, U.S. Department of Justice*, 377 PAT. TRADEMARK & COPYRIGHT J. (BNA) E-1, E-2 (May 4, 1978) (interview with antitrust official describing government's efforts to overturn or narrow *General Electric*). The United States has also opposed the idea, arguably advanced in the Federal Circuit's *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1327–28 (Fed. Cir. 2000), that refusals to license intellectual property are immune in nearly all circumstances from antitrust scrutiny. *See* Brief for the United States as Amicus Curiae at 10, CSU, L.L.C. v. Xerox Corp., No. 00-62 (U.S. Feb. 20, 2001), 2001 WL 34135314 (noting that if holding of that case were so understood, "we would have serious concerns . . . and would not be prepared to endorse it").

190 *See* A. Douglas Melamed & Ali M. Stoeppelwerth, *The* CSU *Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property Law*, 10 GEO. MASON L. REV. 407, 410–13 (2002) (making this argument and collecting evidence).

effectively supports a Patent Act policy, patent exceptionalism provides a potential, and to some courts a persuasive, basis for insulating the practice from antitrust attack.

B. A Tax-and-Subsidy Scheme for Pharmaceutical Innovation

The previous section identifies some statutory basis for treating patentees differently under antitrust law. But patent law and antitrust law are not the only means by which innovative monopolists are regulated. Antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. A reconsideration of the applicability of patent exceptionalism to pay-for-delay settlements in the pharmaceutical industry begins with an examination of the innovation and competition policy embodied in the Hatch-Waxman Act, compared to the treatment of patented goods generally.

That examination requires an investigation of the economic effects of the Act's principal components. That investigation receives no assistance from legislative history, which is too scant to provide even arguable use here. The main source of such history is a House report accompanying an early version of the Act, but the key 180-day exclusivity period became law without informative discussion in that report and without debate.[191] Moreover, it was apparently not contemplated at the time of passage that the regulatory scheme would facilitate collusion to the extent identified in Part II.[192]

1. The Bounty as an Innovation Tax

An important component of the innovation and competition policy of the Hatch-Waxman Act is the bounty provided by the 180-day exclusivity period. Without a bounty, the incentive to challenge patents is often much reduced. Normally, defensive nonmutual issue preclusion permits firms other than the original challenger to take advantage of a favorable legal judgment without repeating the time and expense of a suit.[193] If a favorable

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191 *See* H.R. REP. NO. 98-857, pt. 1, at 28 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. The House report mainly repeats the statutory language. There is no comparable Senate report.

192 This view has been captured in after-the-fact statements of members of Congress. *See* 148 CONG. REC. S7565, 7566 (daily ed. July 30, 2002) (statement of Sen. Hatch) (asserting that pay-for-delay settlements were unanticipated outcome); *see also* S. REP. NO. 107-167, at 4 (2002) ("Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . . .").

193 The leading case establishing defensive nonmutual issue preclusion is *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 349 (1971). As it happens, *Blonder-Tongue* is itself a patent case, but the doctrine is widely applied. *See* 18A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 4464 (2d ed. 2002) (collecting cases applying doctrine).

judgment is the only impediment to entry, then potential challengers will face a serious free-rider problem. Not only will a firm fail to internalize the full benefits of its challenge, since others can use the judgment as well, but in addition the gains will tend to be rapidly dissipated, as other firms enter and compete away the benefits of the favorable judgment.[194] This result has led commentators to conclude that patent challenges are underprovided, both in the decision to bring a challenge and in the incentive to pursue it vigorously.[195] The bounty provides a substantial boost to the incentive to challenge.

The bounty's importance as an inducement to challenge, however, varies with the type of challenge. Issue preclusion has an important effect where the absence of a favorable judgment is all that stands in the way of entry. This is true of an invalidity challenge, such as the recent challenge involving Plavix. It is true also of noninfringement challenges that establish a route of production available to many firms. For example, a district court might arrive at a narrow construction of patent claims, resulting in a clear, noninfringing, widely available route to offering a bioequivalent drug.[196] In other cases, however, the noninfringement route pursued by the generic firm is not readily available to other firms, because it is difficult to accomplish or separately patentable. In that event, the bounty, though still valuable to the generic firm, may be less necessary as an inducement to trigger suit.

Consider, for example, K-Dur, the drug at issue in an antitrust challenge brought by the FTC—the case mentioned in the Introduction to this Article that divided the agency and the Solicitor General. K-Dur is no

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194 Dissipation of the private benefits through post-judgment price competition is an important complication. With a pure public good, beneficiaries may agree in advance to contribute to its provision. Where post-provision rivalry is important, however, there must be in addition some way to limit the rivalrous use. *Cf.* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75, 89 (noting in passing that challengers might coordinate, but ruling out subsequent price coordination). An agreement on post-judgment prices raises antitrust concerns; it might also be ineffective if the incumbent remains within the market but outside the cartel.

195 *See* Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 687–88 (2004) (recognizing public-good characteristics of patent challenges); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 333 (same); *see also* Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 952 (2004) (noting resulting asymmetry in plaintiff and defendant incentives).

196 For an example demonstrating the close connection between invalidity and noninfringement in this context, see *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003), which offers alternative constructions: a broad reading, on which the patent was invalid, and a series of successively narrower readings, on which the generic firm's proposed drug did not infringe. As one would expect, *Blonder-Tongue*, 402 U.S. 313, applies to a noninfringement judgment. *See* Miller, *supra* note 195, at 729–30 & n.250 (collecting cases).

Plavix; its sales are measured in the hundreds of millions, not billions, of dollars.[197] Its active ingredient is an unpatented potassium salt used to replace an electrolyte lost from the body as a side effect of certain anti-hypertension drugs. K-Dur's advantage is a special patented coating that permits controlled release of the active ingredient.[198] Like Plavix, K-Dur is backed by a patent that, like any patent, is "probabilistic" and imperfect.[199] But the source of patent weakness is different. For K-Dur, there is a significant opportunity to argue noninfringement, rather than invalidity—assuming, that is, that the filer can in fact come up with an alternative, noninfringing means of achieving bioequivalence. This is exactly what happened with K-Dur; a generic rival concluded that it could manufacture a bioequivalent controlled-release product without infringing the patent.[200] The likelihood that *some* generic drug company will be able to do this may be fairly high; if it does so, it is *that* expertise, which may itself be protected by a patent, that forms part of the generic firm's ability to compete. This approach is less vulnerable to free-riding, less subject to a flood of profit-dissipating competitors, and less needful of the 180-day exclusivity to protect its bid for entry.

2. Entry Delays as an Innovation Subsidy

While the Hatch-Waxman regime promotes pre-expiration competition by means of litigation, a second set of provisions provides innovators with protection from pre-expiration competition.[201] First, if the innovator's drug contains a novel active ingredient, the FDA must not accept an ANDA-IV in the first four years after NDA approval.[202] This delay, sometimes referred to as data exclusivity, can be immensely valuable.[203] For other new drugs, there is an analogous delay of approval

197 $190 million annually at the time of the settlement. *See In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part II.B.2 (F.T.C. Dec. 8, 2003).

198 *See* U.S. Patent No. 4,863,743 (filed Sept. 5, 1989).

199 *See* Lemley & Shapiro, *supra* note 194, at 76 (emphasizing uncertain result of any patent challenge); *see also* Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 993 (1999) (noting importance of "probabilistic patents").

200 The generic firm contended that its product had a composition and viscosity different from that specified in the innovator's patent. *See* Schering Trial Brief, *supra* note 44, at 17–18.

201 A generic rival could in theory evade these regulatory delays by filing a full-blown NDA instead, including the safety and efficacy studies, but typically this will not be worth the time and expense.

202 *See* 21 U.S.C. § 355(j)(5)(D)(ii) (2000) (current version at 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003)). As discussed *supra* note 48, the delay is five years for ANDAs with Paragraph I, II, or III certifications. *Id.*

203 The delay would not be valuable if the drug holds so little future promise, as evaluated during the first few years of marketing, that a generic firm would not otherwise have sought to initiate a challenge earlier than the four-year point.

(not ANDA submission) of three years.[204] Second, ANDA submission triggers an initial, ministerial review by the FDA, normally completed within sixty days.[205] This is brief, but hardly trivial, since a single month's respite from competition may allocate hundreds of millions of dollars. Upon the completion of initial review, the generic firm sends notice of its filing to the innovator.[206]

If the innovator initiates a patent suit, further delays ensue.[207] One source of delay not unique to pharmaceuticals is the duration of the patent suit, which normally takes several years but can take longer, particularly in the hands of an innovator committed to drawing out the proceedings. The pharmaceutical innovator, compared to a patentee in another industry, receives additional protection during the pendency of the suit: the automatic stay of FDA approval introduced in Part I. The stay lasts for at

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204 The availability of this exclusivity depends upon the satisfaction of certain conditions discussed in THOMAS, *supra* note 35, at 352–53. As compared to the ordinary patent regime, the innovator's protection from ANDA filing and approval is a source of additional delay, though compared to the pre-1984 pharmaceutical regime, this provision arguably reflects a shift in the direction of increased competition. Prior to 1984, generic firms were not permitted to rely upon the innovator's clinical results establishing safety and efficacy. The necessity of repeating costly clinical tests, though not absolute, was a powerful deterrent to entry. *See* FTC STUDY, *supra* note 51, at 3–4 (discussing this problem).

The pre-1984 regime contained a further impediment that was swept away by the Hatch-Waxman Act. Even a generic manufacturer willing to undertake separate clinical studies was obliged to wait until patent expiration to commence their preparation, for such studies were held to be a "use" prohibited by the Patent Act. *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that generic firm's pre-expiration testing violates Patent Act). The Hatch-Waxman Act provides a statutory "experimental use" exemption from infringement. *See* 35 U.S.C. § 271(e)(1) (2000); Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2376–77 (2005) (applying § 271(e)(1)).

205 *See* 21 C.F.R. § 314.101(b)(1) (2006). The review is to confirm that the ANDA is sufficiently complete to permit substantive review. FDA regulations provide no deadline for completing this review, but as a matter of policy the FDA operates under the same sixty-day requirement applicable to NDAs. *See* § 314.101(a)(1) (establishing sixty-day deadline for NDAs). Upon completion of the review, the FDA notifies the ANDA-IV filer that its application has been received. *See* § 314.101(b)(2).

206 *See* 21 C.F.R. § 314.95(b) (2006) (explaining that applicant sends notice "when" it receives FDA's acknowledgement letter). As discussed *supra* note 120 and accompanying text, the generic firm must provide the NDA holder with a detailed statement of its factual and legal basis for its assertion of invalidity or noninfringement. 21 U.S.C. § 355(j)(2)(B)(iv)(II) (Supp. III 2003). The certification and statement is made with respect to each patent that the NDA holder (pursuant to FDA rule) associates with the drug in question, not only compositions of matter but also formulations and methods of use. § 355(b)(1) (2000 & Supp. III 2003). These are compiled in an FDA publication, *Approved Drug Products with Therapeutic Equivalence*, commonly known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A) (2000).

207 An additional process, running in parallel, is the FDA's evaluation of the ANDA to confirm compliance with its requirements. This process normally takes more than one year. James N. Czaban, Preserving and Leveraging Value from the IP/FDA Interface, http://www.buildingipvalue.com/n_us/154_157.htm (last visited Sept. 20, 2006) (estimating "two or more year FDA review time"). It does not normally delay the conclusion of an ANDA-IV challenge.

least the first thirty months after the innovator's receipt of notice, and under certain circumstances lasts longer.[208] If the suit drags on too long, the stay will expire. The stay superficially resembles the preliminary injunction ordinarily available to patentees, but the pharmaceutical innovator need not show irrevocable harm or likelihood of success on the merits, nor post a bond from which the alleged infringer's damages are paid if the patentee subsequently loses. As a result, not only is the stay automatic, but its expected cost is much lower than that of an injunction.

The several years' delay caused by the stay is an important source of profits where a generic firm would otherwise enter prior to the district court's judgment. A generic firm would sometimes prefer not to "launch at risk," even if permitted to do so; if a court eventually concluded that the innovator's patent was valid and infringed, the generic firm would be responsible for lost profits. But if the generic firm's likelihood of winning is sufficiently high and the discount at which it must sell to compete sufficiently slight, launching at risk will be an attractive strategy.[209] As matters stand, launches at risk do occur when the litigation has dragged on for so long that the stay expires, and such launches have brought early competition to Plavix[210] and other major drugs.[211] More launches at risk

208 The lengthening occurs as explained in note 50 *supra*, when the generic firm files an ANDA-IV less than five years after the innovator's FDA approval.

209 For example, suppose that the patent is valid and infringed with probability θ, and that entry takes the simple, unrealistic form of stealing share from the incumbent by selling at a discount. The incumbent earns a margin m on each unit; the entrant earns m'. Entry implies a gain of m' on each unit but damages of m, payable with probability θ. Entry is profitable provided $\theta < m'/m$.

This analysis does not factor in the bounty, which may incline a generic firm toward caution, since it can wait for the district court to rule, then enjoy the bounty with less risk of paying damages. (Eliminating the risk entirely requires waiting until the conclusion of the appeal.) Factors favoring earlier entry include the time value of money, the risk of a declining future market for the drug (particularly if a competing therapy is likely to become available), and the benefit of surprise in dealing with a threat from authorized generics (see the Conclusion for further discussion). Finally, a later ANDA filer may force the first filer's hand, for a later filer's victory triggers the first filer's exclusivity period.

210 Carreyrou & Lublin, *supra* note 72. The generic firm's Plavix launch was eased by two provisions of an innovator-generic agreement not subject to the consent decree discussed in note 72 *supra*: a limit upon the damages payable by the generic firm if it subsequently loses the patent infringement suit, and a contractual delay in the innovator's pursuit of an injunction. *Id.* After a short period in which the generic firm flooded the market with its product, a district judge preliminarily enjoined further distribution pending a trial on the merits of the infringement suit. *Id*.

211 Examples include Allegra, Neurontin, Paxil, and Wellbutrin SR. *See Barr Says Court Denies Preliminary Injunction to Halt Allegra Sales*, *supra* note 57 (noting launch of generic Allegra even before trial); Abboud, *supra* note 57 (describing launch at risk of generic Neurontin); *Apotex Launches Generic Paxil, Triggers GSK's Generic Version*, DRUG INDUSTRY DAILY, Sept. 10, 2003 (on file with the *New York University Law Review*) (reporting launch of generic Paxil before judicial proceedings concluded); *Eon Ships Generic Wellbutrin, Trips GSK's Authorized Generic*, GENERIC LINE, Jan. 28, 2004 (on file with the *New York University Law*

would occur absent the stay.[212]

Taken together, the delays set up by the Hatch-Waxman Act provide an important means for innovative drug makers to preserve the returns upon a new drug. For a new chemical entity backed by a patent, the delays provide about seven years of protection after the product is approved. Even if the drug were protected by *no* patent but had a new active ingredient, the delays would still secure about six years of protection.[213] A drug without a new active ingredient, like K-Dur, enjoys several years of protection, even if a challenge is immediate. Moreover, these figures understate the effect of delay enjoyed by an innovator. A drug must cross a certain threshold of profitability before a generic firm will find it worthwhile to prepare and file an ANDA-IV and then defend the ensuing patent suit. If a drug takes time to build demand, the generic firm will wait to file its challenge, and a substantial part of the delay is effectively held in reserve until that challenge occurs.

3. The Combined Effect of Tax and Subsidy

The combined effect of the tax and subsidy reflects contrary forces. Consumer access is promoted by the unique incentive to challenge patents. Innovation is supported by the term extensions, initial delay based upon data exclusivity, and automatic stay. But the two forces cannot readily be summed in an across-the-board manner that applies uniformly to all drugs. The combined effect is not functionally equivalent to a decrease or increase

Review) (reporting launch of generic Wellbutrin SR before court proceedings completed).

Such launches were formerly rare. *See* Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 198 (1999) (noting infrequency of launches at risk upon expiration of stay without district court decision). Launches at risk are underappreciated. Shapiro associates pharmaceuticals with the case in which there is no interim competition. *See* Shapiro 2003a, *supra* note 15, at 405 & n.22 (describing launching under threat as exception rather than rule); *id.* at 407–08 & n.28 (discussing entry-date settlements on assumption that challenger will not enter while litigation is pending, and noting that this assumption fits facts of pharmaceutical industry well). Hovenkamp and co-authors downplay this possibility as well. *See* Hovenkamp et al. 2004, *supra* note 15, at 715–16 ("Defendants are required by law to stay out of the market while patent litigation proceeds . . . .").

212 These are also the cases where an innovator would be least likely to secure a preliminary injunction, or would be responsible for the largest damages if it did secure an injunction and then lost the subsequent patent suit. A patentee's decision to secure a preliminary injunction (if it can) resembles an entrant's decision to launch at risk, in that each faces an expected penalty based upon the likelihood of losing the suit and the size of the other's damages that must be reimbursed in the case of a loss. The two are dissimilar, however, in the key respect that seeking a preliminary injunction is here always profitable. The innovator's profits saved are larger than the generic firm's profits foregone, so that even if the patentee thought its loss certain, a preliminary injunction would still be desirable from the patentee's standpoint. Ascertaining the proper level of damages, however, is a difficult question.

213 Without a patent to challenge, the generic firm cannot file an ANDA-IV, and therefore must wait five years before its ANDA is accepted, *see supra* note 202, and likely another year or more for FDA approval, *see supra* note 107.

in the patent term. Increased competition is the more important factor for some drugs, increased innovation the more important factor for others. The overall result is a pivot in the reward structure—a relative increase in the returns on some drugs and decrease on others.

The factors determining the balance for a particular drug are its market importance, the likelihood that an innovator's patent would be found invalid or not infringed if challenged, and the extent to which other challengers could take advantage of the judgment absent the exclusivity period. Plavix and K-Dur illustrate the alternatives. For some drugs, it is the increased threat from competition that predominates. This is likely the case for most blockbusters. For a popular drug with a patent covering a novel active ingredient, such as Plavix, an invalidity challenge is economically feasible due to the large bounty prospect, but otherwise would not be feasible on account of the free-rider problem and the low likelihood of success. The delays dampen the effect to a substantial extent,[214] but the overall effect is a reduction in reward. For other drugs, it is the increased protection from competition that predominates. For a drug faced with an infringement challenge not readily replicated by other generic firms, the bounty is less necessary to induce a challenge. If the challenge would have occurred in any event, the major effect of the regime is to protect the innovation for several rewarding years before subjecting it to potential competition.

The variation across different drugs may achieve in a rough manner an efficient balance between innovation and access across a range of drug development projects. With respect to a drug like K-Dur, increased protection may be a necessary inducement to invest, since such a drug is highly vulnerable to the noninfringing results of reverse engineering, which may be initiated once the drug's commercial success is established. The initial exclusivity period, slow adjudication, and the automatic stay protect the profits on such a drug for a limited period. The stay is particularly important, given the likely attraction of launching at risk. This protection helps justify the drug's development and approval expense.

With respect to blockbusters, patent-busting might be unusually beneficial to consumers, relative to patent-busting on other drugs. That would be true if blockbusters have an unusually large amount of demand at lower price levels, relative to other drugs.[215] In that event, the consumer

214 For example, a drug that earns the innovator $1 billion per year without competition and nothing otherwise, for which at least seven years of patent term are remaining upon its approval, and which has a fifty percent likelihood of losing its patent suit against a generic rival, has expected profits that are $3.5 billion ($1 billion per year *x* 7 years *x* 50 percent) higher than would be the case under immediate entry.

215 Such demand might result if popularity spawns widespread market awareness, or because treatments that manage chronic conditions—as most blockbusters do—have a large number of

benefit from subjecting these drugs to early competition is unusually high, and the decentralization of the challenge scheme is an attractive feature; entrusting the early-competition decision to the government would create a risk of capture by interested parties. The size and scope of the reduction in the incentive to innovate, moreover, depends upon the degree to which the innovator knows in advance whether the project, if successful, is likely to be a big success that would attract a challenge. If a drug maker never has any advance warning, then the dampening effect on innovative incentives will be spread thinly across all drug development projects. But to the extent the innovator *can* anticipate success,[216] the tax on innovation will be borne primarily by the projects that are prospective blockbusters. To the extent that such projects have not only a high value conditional on success but also a high expected value, the tax will have less deterrent effect upon innovation.

C. The Industry-Specific Case Against Pay-for-Delay Settlements

The particular shape of congressional intervention in the balance between innovation and access, together with important industry-specific features of the pay-for-delay problem in pharmaceuticals, serve to undercut the Patent Act–based case for an exception to the ordinary operation of antitrust law. The argument applies in different ways to the innovator-focused and infringer-focused arguments for an exception.

With respect to innovators, the practice in question is a poor fit with Patent Act policy, because permitting pay-for-delay settlements is a highly innovation-inefficient means of increasing the incentive to innovate. To see this, consider as a benchmark a competitive practice that had the effect of increasing the length of the patent term at no incremental expense to the patentee. Arranging a longer term might be expected to increase producer profits and consumer allocative losses in equal measure (assuming, among other things, that the producer faces the same demand curve in each period). If the social benefits of innovation increase proportionately with

low-valuing consumers. The argument assumes that the firm cannot easily price discriminate among consumers.

216 Some evidence of awareness of future promise is provided by the prevalence of multiple drug development projects, running in parallel, which exploit the same chemical pathway. This is true, for example, of cholesterol-lowering statins such as Lipitor, Zocor, and Pravachol, and antidepressant selective serotonin reuptake inhibitors such as Paxil, Prozac, and Zoloft. *See* Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry and the Timing of Development*, 22 PHARMACOECONOMICS (Supp. II) 1 (2004), *available at* http://www.who.int/intellectualproperty/submissions/Submission_DiMasi.pdf (describing parallel efforts to develop drugs in same therapeutic class, and characterizing these efforts as development race rather than process of post hoc imitation). This will tend to be the case when government or university research reveals the same promising pathway to multiple firms more or less simultaneously.

profits, then the ratio between innovation and deadweight loss is unchanged with respect to term length.

If instead, as is frequently presumed, additional profits have a *declining* impact upon the social benefits of incremental innovation, then a longer term entails a lower ratio—that is, less innovation "bang" for the additional deadweight loss "buck." Such a practice is difficult to justify by reference to Patent Act policy, for the reason introduced in Part III.A. Congress's selection of a particular patent term length implements a choice about the balance between innovation and acceptable deadweight loss. If Congress had chosen a longer term, it would have implemented a more innovation-protective policy with respect to patentees; but Congress did not do that. A "reasonable effectuation" of the Patent Act's innovation protectiveness does not require permitting a practice that is less innovation-efficient than, but otherwise identical to, a major innovation-protective term of the Patent Act. Therefore, to the extent that a privately-arranged term lengthening is less innovation-efficient than the current period of exclusivity, it cannot be insulated from antitrust attack by reference to the policies of the Patent Act.[217]

Pay-for-delay settlements resemble an increase in effective term length, but in an important respect they are even less innovation-efficient. In exchange for receiving a reprieve from competition, the patentee must make a sizable payment. This payment reduces its profits and hence the incremental innovation incentive gained by arranging for the extension.[218] This deficit in innovation efficiency makes the agreements more difficult to justify as a reasonable effectuation of the Patent Act. In short, the Patent Act's general policy of innovation protectiveness has, at best, a weak claim to insulating pay-for-delay settlements from antitrust attack.

Moving from the general case of patents to the specific case of pharmaceuticals further weakens the argument for insulation. As already noted, antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. Compared to the Patent Act, the

217 This argument resembles the strategy employed in Kaplow, *supra* note 9, at 1825–26, in taking a congressional choice with respect to some element of patent policy, comparing it to a practice under consideration, and rejecting the practice if it has a lower ratio than that of a congressional choice. The project here differs from Kaplow's, in that the ratio-based evaluation of innovation efficiency is made not to determine finally the antitrust treatment of a practice, but merely to see whether the Patent Act provides a basis for altering the ordinary result of antitrust law. Another difference is that in the special case considered here, there is no need to directly observe the ratio implied by the patent term and the ratio of the practice in question. Where policies are otherwise identical, the ratios are directly comparable on a relative basis even without knowing the size of either of them, and the practice can be unambiguously evaluated. A decisive comparison is unavailable, by contrast, where the practice has a *higher* ratio than that implied by the patent term, or is not readily comparable to an element of patent policy.

218 The point is general: Gains from a practice that must be shared among, say, cartel members, dampen the dynamic benefit of increased profits.

Hatch-Waxman Act provides within its domain a more specific and hence more relevant account of the congressionally implemented balance between innovation and competition.

The balance set by the Hatch-Waxman Act is a deliberate effort to promote consumer access through litigated challenges. For most drugs, the Hatch-Waxman Act is less innovation-protective than the Patent Act; as noted previously, the tax on blockbusters is a concession to consumer access at the expense of innovation. For a few drugs, it is actually more innovation-protective, thanks to the innovation subsidy provided by the industry-specific delays. In either case, the ordinary operation of the Act sets a particular balance between innovation and competition. The balance set for a particular drug is disrupted by a settlement favoring somewhat more innovation at the further expense of consumer access.

The disruption to the congressional balance caused by settlement, moreover, is difficult to understand in a way consistent with the Hatch-Waxman scheme. With the Patent Act, a general norm in favor of innovation might at least be relied upon; by contrast, the Hatch-Waxman Act provides a calibrated outcome for different types of drugs. The Patent Act is silent about the role of litigation and the extent to which litigation can be avoided in the interest of preserving profits. In the Hatch-Waxman Act, by contrast, the promotion and delay of litigation are central preoccupations of the regulatory regime. An open-ended permission for innovators to set innovation policy by self-help is less plausible, as Congress has taken explicit steps to fill those gaps. Since litigation is the *instrument* by which the regulatory arrangement accomplishes its ends, it is difficult to argue that an end-run on the instrument is consistent with the scheme. And given that the regime explicitly provides for innovation protection in certain cases—an effective lengthening of the patent term for certain drugs, but a limited one—it is implausible to attribute to that regime a tolerance for an additional, highly innovation-inefficient means to accrue additional profits.

The infringer's argument against antitrust liability is also weaker in the pharmaceutical context, compared to the general case. First, the generic firm lacks an innovator's interest. The generic firms simply make use of the Hatch-Waxman scheme to offer a bioequivalent drug. Even if a Patent Act policy favoring innovation helps some infringers, it cannot be thought to apply here.

Limiting the generic firm's ability to extract a benefit from unpromising litigation has some effect on an infringer's incentives, though not on its innovation incentives. To be clear, a limitation on settlement does not force the generic firm to see the litigation to completion—it can

simply walk away from the suit.[219] But a limitation on consumer-disregarding settlements does lower the value of the generic firm's abandonment option,[220] an option that matters most when a party develops new information about its prospects during the course of litigation. The difference in reward implies that some marginal challenges will not be brought. There is little reason, however, to think that preserving the full value of this option is necessary to effectuate a Hatch-Waxman Act policy of promoting challenges, not least because the incentive to challenge is already so large.

Second, and again unlike many infringers outside the pharmaceutical context, the generic firm has deliberately stepped, not stumbled, into the infringement controversy. It does not move in uncertain terrain filled with hidden patent dangers; the patents protecting pharmaceutical innovations are open and notorious, compiled in an FDA publication, *Approved Drug Products with Therapeutic Equivalence*, commonly known as the "Orange Book."[221] The generic firm volunteers for and seeks out the challenge by filing the Paragraph IV certification, which invites a lawsuit by the innovator.[222] Here, and unusually, Congress has recruited and offered to compensate generic firms to bring patent challenges. Far from being unwilling private attorneys general, generic firms have been deputized, in effect, to act on the public's behalf. The explicit use of litigation to achieve the balance undercuts the preference for settlement sometimes discerned in ordinary patent policy.

In summary, the analysis in this Part reinforces the conclusion from Part II that pay-for-delay settlements are properly accorded a presumption of illegality as unreasonable restraints of trade. It also undermines, in a domain-specific way, the patent policy arguments sometimes thought to justify a patent-based exception to antitrust as a general matter. Finally, the analysis offers industry-specific support for the proposition that *pharmaceutical* consumers do indeed have an entitlement to the average level of competition implied by litigation, a proposition more difficult to sustain as a general matter.

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219 It is possible to imagine a more aggressive rule, in which the generic firm is prohibited from abandoning a challenge once initiated; compared to the assumption in the text, this would increase the fraction of challenges that result in early competition, but at the expense of some challenges not being brought. This possibility resembles proposals sometimes made that a price cut, once initiated, must be maintained for a certain period in order to discourage predation.

220 For an illuminating discussion of abandonment options in litigation, see generally Joseph A. Grundfest & Peter H. Huang, *The Unexpected Value of Litigation: A Real Options Perspective*, 58 STAN. L. REV. 1267 (2006).

221 21 U.S.C. § 355(j)(7)(A) (2000).

222 *See* Hovenkamp et al. 2004, *supra* note 15, at 715–16 (emphasizing this feature).

CONCLUSION

Examining pay-for-delay settlements from the perspective of regulatory design yields two main results. First, the industry-specific bounty renders feasible an allocatively harmful settlement in a surprisingly wide array of circumstances. Because only the first-filing generic firm has potential access to the exclusivity period, an innovator has an especially strong incentive to pay to neutralize that source of potential competition. Because a guaranteed bounty is a valuable source of compensation to a first-filing generic firm, settlements that divide the remaining patent term confer a noncash payment for delay. Allowing an innovator to make multimillion dollar payments up to the amount of saved litigation expense exacerbates the allocative harm.

Second, the Hatch-Waxman Act produces a specific pattern of encouragement to and limitations upon innovative activity. That industry-specific pattern, rather than the arguably innovation-protective policy of the Patent Act, provides the basis for an *in pari materia* analysis with antitrust law. The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act, particularly in light of the inefficiency of pay-for-delay settlements as a means to provide additional reward to innovators.

Beyond the analysis of pay-for-delay settlements and other competitive practices in the pharmaceutical industry, a careful engagement with regulatory facts and economic theory within a specific industry is a promising method of antitrust analysis. The approach advanced here requires a close look at the economic effects of the regulation and the legislative instrument by which it achieves those effects. The project entails two distinct though related inquiries: an inquiry into industry economics, including the technology of innovation and the dynamics of competition, and an inquiry into the effects of industry-specific regulation.

Such an economically aware and institutionally informed examination is particularly important in industries that are in a process of deregulation. Such industries are an area of renewed interest in antitrust, as exemplified by their inclusion in the work of the commission recently set up by Congress to consider alterations to existing antitrust law.[223] Deregulation

[223] See Memorandum from Regulated Indus. Study Group, Antitrust Modernization Comm'n to All Comm'rs 1 (May 4, 2005) (available at http://www.amc.gov/pdf/meetings/regulated_industries_study_plan.pdf), which sets three questions for examination about the proper role of antitrust in regulated industries:

A. How should responsibility for enforcement of antitrust laws in regulated industries be divided between antitrust agencies and the regulatory agencies?

B. What is the appropriate standard for determining the extent to which the antitrust laws apply to regulated industries where the regulatory structure contains no specific antitrust

enlarges the domain of antitrust, as Herbert Hovenkamp has noted;[224] it does so in part by altering the contours of liability. In some industries, the process of deregulation has occurred in an incomplete fashion, and partial deregulation may give rise to heightened antitrust concern.

Under partial deregulation, the regulatory regime manages the balance between innovation and competition by decentralized mechanisms, rather than by the central command of price regulation. Under full regulation, there may be little role for antitrust, given its redundancy upon a regulator actively managing the antitrust function. Under partial deregulation, however, redundancy is less likely. The use of a decentralized mechanism by Congress risks nullification by unilateral or concerted action by self-interested firms, with allocatively harmful effects. Where the mechanism is not well preserved by the industry-specific regulatory agency, there may be a heightened role for antitrust intervention.

One virtue of an industry-focused approach is the presence of built-in limiting principles. An antitrust decisionmaker can resolve one set of cases without having to reconsider an entire category of conduct. For example, a court can resolve pay-for-delay settlements in the pharmaceutical industry—a set of cases of great theoretical significance and practical importance—without reconsidering the relationship of antitrust and patent generally. Another consequence, of course, is that we therefore lack an answer to broader questions—here, whether consumer-disregarding settlements of patent litigation in other industries are actionable as antitrust violations. But in an area of legal and economic inquiry so complex, and in which we lack even basic information about the facts on the ground in other industries, including the prevalence and structure of such settlements, this limitation is a virtue rather than a vice.

Approaching antitrust through deep investigation of the economic and regulatory structure of a single industry is not an entirely unfamiliar prospect. Economists and lawyers interested in competition policy often do focus upon an industry out of necessity, particularly where the presence of repeat defendants, and the resulting economies of scale, offer a natural basis for specialization; as with Alcoa in an earlier age, so with Microsoft today. But an industry-specific agenda runs counter to trends. The research agenda in antitrust is primarily driven on the one hand by work that cuts across many industries—for example that of industrial economists to understand the effects of a particular practice and efforts by legal

exemption and/or contains a specific antitrust savings clause?

C. Should Congress and regulatory agencies set industry-specific standards for particular antitrust violations that may conflict with general standards for the same violations?

224 HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE 230 (2005) ("As deregulation turns more decision making back to the regulated firms, antitrust takes a more important part.").

scholars to reconcile antitrust and intellectual property law—and on the other hand by lawyers and economists focused on the proper resolution of a specific case.[225]

The difficulty of making sense of an enactment's effects heightens the importance of deep industry expertise. The FTC's role in pharmaceutical enforcement is illustrative. About a quarter of the FTC's competition investigations are devoted to pharmaceuticals.[226] The Commission has produced comprehensive reports about industry competition[227] and, more generally, the intersection of patent and antitrust.[228] It has brought enforcement actions challenging a variety of industry practices[229] and explained in other cases why, after consideration, it had declined to do so.[230] It sees the full range of cases due to its national enforcement scope and augments its stock of knowledge by combining the analyses of staff economists with information gleaned from civil investigatory demands of market players.[231]

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225 For examples of the latter effort, see generally THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION, AND POLICY (John E. Kwoka, Jr. & Lawrence J. White eds., 4th ed. 2004).

226 Timothy J. Muris, Chairman, FTC, Remarks Before 7th Annual Competition in Health Care Forum: Everything Old Is New Again: Health Care and Competition in the 21st Century 3 n.13 (Nov. 7, 2002), *available at* http://www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf (noting that in 2001, twenty-five percent of new investigations involved pharmaceutical products).

227 *See, e.g.*, FTC STUDY, *supra* note 51.

228 See FTC, Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, http://www.ftc.gov/opp/intellect, which collects the results of twenty-four days of hearings in 2002. The results are summarized in FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf. *See also* William E. Kovacic & Andreas P. Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy*, 28 FORDHAM INT'L L.J. 1062, 1068–69 (2005) (advocating greater investment of resources in IP expertise for competition agencies working on issues at IP-antitrust interface).

229 In addition to pay-for-delay settlements, the challenged practices have included sham litigation, abusive Orange Book filings, and agreements among generic manufacturers. For a full account of recent FTC enforcement practices, see HEALTH CARE SERVS. AND PRODS. DIV., BUREAU OF COMPETITION, FTC, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (2006), *available at* http://www.ftc.gov/bc/0604rxupdate.pdf.

230 For example, Lilly, the manufacturer of Prozac, announced its intention to acquire a license from another company for a single-enantiomer version of Prozac (R-fluoxetine), in order to shift customers from regular Prozac, with respect to which generic competition loomed, to the single-enantiomer version. Sheila F. Anthony, Comm'r, FTC, Remarks Before the ABA "Antitrust and Intellectual Property: The Crossroads" Program: Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property (June 1, 2000), *available at* http://www.ftc.gov/speeches/anthony/sfip00060.htm. After an investigation, the FTC allowed the transaction to proceed unchallenged. *Id.* As the Commissioner subsequently explained, any case would have been premised upon a judgment about the relative efficacy of the two drugs, and the FTC declined to second-guess doctors and patients. *Id.*

231 *See, e.g.*, FTC STUDY, *supra* note 51. In addition, the 2003 amendments to the statutory

Such expertise is particularly important in dealing with the panoply of strategies employed by pharmaceutical firms. Apart from the settlement cases, the bulk of such strategies amount to beating competitors rather than joining them. Drug makers have displayed a great deal of ingenuity in preserving the profits from an innovative drug. The strategies include new-but-related drugs,[232] new patents on the same drug,[233] and new distribution and trademark-backed branding strategies. As one strategy is curtailed, others are introduced.[234] Some of the strategies are very difficult to justify by reference to a plausible consumer benefit. That is not to say that such techniques are all illegal or even troubling—new drugs and price-lowering distribution strategies, for example, potentially provide considerable consumer benefit. But the proliferation of such strategies does give rise to a bewildering array of choices for antitrust enforcers.[235]

An important test of that expertise comes in the current debate over "authorized generics." The basic idea is that an innovator, faced with

scheme require that industry settlements be filed with the FTC on an ongoing basis, which has provided continuing intelligence about industry practices. *See* Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003); FTC STUDY UPDATE, *supra* note 70.

232 A separately patentable alteration to an existing drug is profitable provided that doctors and patients can be convinced to switch over as protection on the old drug ends (due to expiration or successful challenge). The most famous transition is from the anti-heartburn drug Prilosec to Nexium, an enantiomer of Prilosec's active ingredient, omeprazole. *See* Malcolm Gladwell, *High Prices*, NEW YORKER, Oct. 25, 2004, at 86, 86 (describing transition).

233 For example, a firm may assert patents on metabolites (the compound a drug is converted to within the body), intermediates that appear during the production process, or alternative crystalline forms.

An important aspect of this strategy has involved an interaction with the regulatory system. As noted previously, an ANDA-IV must address every patent that is listed by the drug manufacturer in the Orange Book. 21 U.S.C. § 355(j)(7)(A) (2000). Adding additional patents after an ANDA-IV challenge has begun formerly obligated a generic challenger to amend its certification, which triggered further infringement challenges, which, in turn, was understood to trigger additional and later 30-month stays. The FTC criticized the practice in its study of generic competition, and 2003 legislation put an end to the practice of multiple stays. The filing of multiple stays by Bristol-Myers with respect to BuSpar was one of several activities that led to the consent decree discussed in note 72 *supra*. With respect to another drug, Paxil, indirect and direct purchaser class action suits resulted in settlements of $65 million and $100 million, respectively. *See* Nichols v. SmithKline Beecham Corp., No. Civ. A. 00-6222, 2005 WL 950616, at *1, *26–27 (E.D. Pa. Apr. 22, 2005) (indirect); Stop & Shop Supermarket Co. v. SmithKline Beecham Corp., No. Civ. A. 03-4578, 2005 WL 1213926, at *1 (E.D. Pa. May 19, 2005) (direct).

234 Such a "hydraulic" process is familiar from other areas of law. *See* Samuel Issacharoff & Pamela S. Karlan, *The Hydraulics of Campaign Finance Reform*, 77 TEX. L. REV. 1705 (1999) (describing how efforts to constrain political actors redirect, but do not eliminate, their activities); Tim Wu, *When Code Isn't Law*, 89 VA. L. REV. 679, 726–45 (2003) (describing responses to efforts to curtail file sharing).

235 One FTC Commissioner has colorfully analogized the FTC's task to a game of Whack-a-Mole. Jon Leibowitz, Comm'r, FTC, Remarks Before the Antitrust in Health Care Conference: Health Care and the FTC: The Agency as Prosecutor and Policy Wonk 9 (May 15, 2005), *available at* http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf [hereinafter Health Care and the FTC].

competition from a first-filing generic firm, recruits an additional generic firm to sell an unbranded version of the drug under the innovator's own license. The presence of an additional generic competitor, selling during and after the bounty period, lowers prices in the generic segment of the market.[236] Consumers benefit in the short run from lower prices, and the innovator enjoys incremental profits from the additional revenue stream; only the independent generic firm loses out. Over the last several years, an authorized generic product has become a familiar accompaniment to a pre-expiration launch by a generic firm.[237]

Generic drug makers complain that the use of authorized generics, in reducing the benefits of the 180-day exclusivity period, is contrary to the purpose of, and hence violates, the Hatch-Waxman Act.[238] This argument has failed on a textual reading of the Act, which merely excludes subsequent ANDA filers.[239] Generic firms have also argued that the use of authorized generics violates antitrust law by reducing generic profits to such an extent that a challenge is not worth pursuing, thus deterring generic entry. At least one court[240] and one FTC commissioner[241] have entertained the possibility of an antitrust claim.

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236 This effect on the generic segment of the market is typically a fifty percent discount on the innovator's price, compared to the thirty percent discount with just one generic firm. *See* QUANTIFYING THE IMPACT, *supra* note 116, at 4.

237 *See, e.g.*, Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1. A fighting-brand pharmaceutical is not a complete novelty. In the 1990s, innovator firms engaged in a certain amount of own-brand generic sales. Then, too, the activity raised antitrust concern. *See* Morton I. Kamien & Israel Zang, *Virtual Patent Extension by Cannibalization*, 66 S. ECON. J. 117 (1999); Catherine Yang, *The Drugmakers vs. the Trustbusters*, BUS. WEEK, Sept. 5, 1994, at 67. In the late 1990s the innovators for the most part exited the generics business, as they discovered that selling generic drugs was not their forte, and as they improved in their ability to shift customers from one product to its successor. *See* Milt Freudenheim, *Prescription Drug Makers Reconsider Generics*, N.Y. TIMES, Sept. 11, 1997, at D1. The resurgence of authorized generics may be attributable to three features: the patent expiration of a large number of blockbuster drugs, which creates an unusually large opportunity for generic competition; an increase in the number of exclusivity periods granted, particularly as evergreening strategies involving later-added, weak patents are successfully challenged by generic firms; and the increased penetration of generic entry, which creates a sizable profit opportunity for the innovator, provided that the additional entry does not affect pricing and volume too much in the branded segment of the market.

238 *See, e.g.*, Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 52–53 (D.C. Cir. 2005) (describing challenge to authorized generic for Neurontin); Mylan Pharm., Inc. v. FDA, No. Civ. A. 104CV242, 2005 WL 2411674, at *1 (N.D. W. Va. Sept. 29, 2005) (describing challenge to authorized generic for Macrobid); Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003) (describing challenge to authorized generic for Paxil).

239 *See Teva*, 410 F.3d at 53–55.

240 *See* Vicki Smith, *Mylan to Press Drug Complaint—Pharmaceutical Company Targets "Authorized Generics,"* SAN JOSE MERCURY NEWS, Aug. 31, 2004, at 2C (reporting District Judge Irene Keeley's view, expressed during oral argument, that Procter & Gamble's use of authorized generic for Macrobid raises significant antitrust issue).

241 *See* Health Care and the FTC, *supra* note 235, at 9–10.

The underlying antitrust concern is that the practice, though beneficial in its short-run allocative effect, will discourage future entry, ultimately leading to higher prices.[242] Acting to deter a rival's procompetitive actions is a general strategy analogous to, for example, the price-matching policies of large retail stores.[243] The structure of at least some authorized generic licenses provides for withdrawal should independent generic entry cease.[244] The authorized generic mechanism also has a unique feature that potentially enhances its deterrence. If the innovator licenses an outside firm, its contract is an observable commitment to entry, which may provide a source of credibility. Such an ability to precommit might make seeing through the threat unnecessary in practice—though the direct profitability of the additional distribution mechanism may, aside from lessening the antitrust concern, make precommitment unnecessary.

Unless authorized generics actually deter entry in practice, or—an important complication—slow the filing of ANDA-IVs or lessen the vigor of their pursuit, there is no basis for antitrust concern. Anecdotal evidence suggests that authorized generics have little practical effect on generic entry,[245] but substantial empirical work is needed to resolve the issue decisively. The necessary data about filings is out of reach, some of it confidentially lodged with the FDA[246] or scattered among the firms themselves. The FTC is uniquely positioned, due to its expertise and power, to collect and assess the relevant information, and it has indeed begun to do so.[247]

The underlying impulse to tailor innovation policy by industry resembles the parallel project by patent scholars to understand patent law in an industry-specific fashion.[248] In both contexts, the perspective implies

242 For discussions of the impact of authorized generics, see generally David Reiffen & Michael R. Ward, *"Branded Generics" as a Strategy to Limit Cannibalization of Pharmaceutical Markets* (Univ. of Tex. Dep't of Econ., Working Paper No. 05-004, 2005) and Ying Kong & James R. Seldon, *Pseudo-Generic Products and Barriers to Entry in Pharmaceutical Markets*, 25 REV. INDUS. ORG. 71 (2004).

243 *See generally* Aaron S. Edlin, *Do Guaranteed-Low-Price Policies Guarantee High Prices, and Can Antitrust Rise to the Challenge?*, 111 HARV. L. REV. 528 (1997) (discussing anticompetitive effects of price-matching policies).

244 *See, e.g.*, Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003) (describing authorized generic license, whereby authorized generic must leave U.S. market if independent generic exits).

245 For example, Apotex earned a large profit in its challenge to Paxil despite competition from an authorized generic. According to Apotex's own figures, its profits were reduced from the $530-to-$575 million range to the $150-to-$200 million range because of the authorized generic entry. *See* Comment of Apotex Corp., *supra* note 110, at 4.

246 The identity of an ANDA filer, for example, is confidential.

247 Press Release, FTC, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), *available at* http://www.ftc.gov/opa/2006/03/authgenerics.htm.

248 *See, e.g.*, Burk & Lemley, *supra* note 33, at 1576–80. *But see* R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003)

that a holding reached within a particular industry's factual setting is unlikely to have ready applicability to other industries. One important difference between the projects, however, is that the industry-specific approach in patent law operates primarily through judicial interpretation; it must necessarily do so, given the single statutory scheme that governs patent doctrine across most industries.

The approach here, by contrast, places more emphasis upon Congress and expert agencies. Congressional enactments govern the balance between innovation and competition, modulating the vigor of antitrust enforcement in an industry-specific fashion. The effect is to place the overall thrust of innovation policy more firmly in the hands of the legislative branch, perhaps quieting congressional complaints of "judicial circumvention" in other areas of competition policy.[249] The competition regulator, meanwhile, plays an important role in decoding the meaning of a legislative enactment as it bears upon industry economics and antitrust law. That role is particularly important where, as in pharmaceuticals and other industries, courts need help in recognizing and tailoring antitrust analysis to the "distinctive economic and legal setting"[250] of a regulated industry.

(providing critique of Burk and Lemley approach).

[249] *See, e.g.*, Press Release, U.S. House of Representatives Comm. on the Judiciary, Sensenbrenner and Conyers Introduce Legislation to Strengthen Competition in Telecom Marketplace: Legislation Will Reduce Telecom Prices and Expand Choices for Consumers (May 20, 2004), *available at* http://judiciary.house.gov/newscenter.aspx?A=309 (quoting House Judiciary Committee Chairman F. James Sensenbrenner, who described *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), as act of "judicial circumvention" and proposed its legislative overrule).

[250] *Trinko*, 540 U.S. at 411–12 (quoting Town of Concord v. Boston Edison Co., 915 F.2d 17, 22 (1st Cir. 1990) (citation and internal quotation marks omitted)).