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House Committee on Energy and Commerce
Subcommittee on Commerce, Trade, and Consumer Protection

Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007

May 2, 2007

Chairman Rush, Ranking Member Stearns, and Members of the Subcommittee, I am Scott Hemphill, an Associate Professor at Columbia Law School. My research and teaching focus upon the balance between innovation and competition established by antitrust law, intellectual property, and sector-specific regulation. I appreciate the opportunity to testify today about certain anticompetitive, "pay-for-delay" agreements between brand-name drug makers and their generic rivals. These remarks draw upon my ongoing academic research into the economic effects of these settlements and their appropriate legal treatment.[1]

I wish to make three points. First, the pay-for-delay settlement problem is large and longstanding. Second, courts have failed to provide an effective

[1] In particular, *Drug Patent Settlements Between Rivals: A Survey* (working paper 2007) [hereinafter *Survey*], *available at* http://ssrn.com/abstract=969492, which undertakes an empirical examination of settlements, with a view toward identifying a workable policy rule; and *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) [hereinafter *Paying for Delay*], which analyzes the competitive effects of certain settlements and their proper treatment under existing law.

response to the problem. And third, Congress can play a useful role in this area by passing legislation such as H.R. 1902 that prohibits settlements that combine payment with delay, while permitting exceptions to be made for settlements that can be shown not to result in consumer harm.

The pay-for-delay settlement problem

For more than twenty years, the Hatch-Waxman Act has provided a mechanism by which generic drug makers may introduce a competing version of a brand-name drug.[2] Frequently, the generic firm seeks to market its product prior to the expiration of a patent (or patents) claimed by the brand-name firm (or "innovator") to cover its product. Under the Act, the generic drug maker first asserts that the innovator's patent is invalid or not infringed by the generic product;[3] often, the innovator then files a suit in response alleging patent infringement. This form of pre-expiration litigation has become the norm with respect to the most important brand-name drugs. Moreover, these challenges often succeed in securing early entry by generic rivals. For example, of the ten

[2] Drug Price Competition and Patent Term Restoration Act of 1984, 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. *See* 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)).

[3] Technically, the pre-expiration challenge takes the form of an Abbreviated New Drug Application ("ANDA") with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000), or "Paragraph IV," that relevant patents are invalid or not infringed.

best-selling drugs of 2000, nine attracted pre-expiration challenges, of which at least four saw pre-expiration entry.[4]

In some cases the innovator, rather than take a chance that the generic firm might win the patent suit, settles the litigation. The parties dismiss the suit and agree to a particular date when the generic firm may enter the market. The entry date is the result of a hard-fought bargain between rivals. The innovator pushes for a later entry date by arguing that if the litigation proceeds to judgment, a court is likely to hold that the patent is valid and infringed. The likelier that judgment is, the later the entry date.

A settlement that relies solely upon the inherent strength of the patent is properly permitted. Such a settlement delays entry, to be sure, but the innovator is simply using its patent protection as leverage. The innovator's success in achieving a later date in this fashion defines the maximum extent of the patent right.

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[4] In 2000, the ten best sellers were Celebrex, Claritin, Glucophage, Lipitor, Paxil, Prevacid, Prilosec, Prozac, Zocor, and Zoloft. *See* Robert Pear, *Spending on Prescription Drugs Increases by Almost 19 Percent*, N.Y. TIMES, May 8, 2001, at A1. Of these, all but Glucophage attracted a pre-expiration challenge. CTR. FOR DRUG EVALUATION & RESEARCH, FDA, PARAGRAPH IV PATENT CERTIFICATIONS AS OF APRIL 23, 2007, http://www.fda.gov/cder/OGD/ppiv.htm. Of the nine challenges, Paxil, Prilosec, Prozac, and Zocor all resulted in pre-expiration entry. *See Paying for Delay*, *supra* note 1, at 1567 n.57.

The situation is different when an innovator makes a payment to its rival, rather than relying solely upon its prospects at trial. In that case the payment secures a later entry date than is warranted by the likely validity of the patent alone. That payment to a rival, made to secure additional delay—in effect, a privately-arranged patent term extension—is properly prohibited.[5] If the innovator paid a rival *after* patent expiration to abandon its effort to market a competing drug, that transaction would clearly be inappropriate. The same is true when the privately arranged extension postpones an entry date that is prior to patent expiration.

A payment to secure delayed entry undermines the existing balance between innovation and competition set by the Hatch-Waxman Act. The Act as written provides brand-name firms with important special protection for their innovative efforts, including patent term extension and a variety of nonpatent regulatory delays to generic entry. For example, if the innovator's approved drug contains a novel active ingredient, the Food and Drug Administration (FDA) must not accept any application to market a generic version for four years.[6] Once the generic application is accepted, and assuming that the innovator files a patent suit in response, the Act blocks FDA approval of the

[5] For a full analysis, see *Paying for Delay*, *supra* note 1.

[6] *See* 21 U.S.C. § 355(j)(5)(F)(ii) (Supp. III 2003). The delay is five years for ANDAs that do not contain a Paragraph IV certification. *Id.*

generic application for the first several years of the suit's pendency.[7] These provisions, taken together, can provide more than seven years of protected profits even if the patent protection is very weak.[8] A privately arranged term extension, then, is in addition to extensive protections already granted by Congress.

Pay-for-delay settlements are a longstanding issue. The very first blockbuster drug, the antiulcer medicine Zantac, had its effective patent protection extended by a pay-for-delay settlement.[9] One of the first settlements, a 1993 agreement involving the cancer drug tamoxifen, attracted an antitrust challenge that is only now, fourteen years later, pending as a petition for certiorari at the Supreme Court.[10]

Settlements are a major tool of lifecycle management. Figure 1 depicts, for selected drugs, the fraction of an innovator's exclusivity period covered by settlement. It is not uncommon for the settlement period to account for more

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[7] § 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.* The "thirty-month" stay can persist for more than three years. *See Paying for Delay*, *supra* note 1, at 1566 n.50. The stay resembles a preliminary injunction, but is superior from the innovator's standpoint, as there is no requirement that the innovator show a likelihood of success on the merits, and no obligation to pay damages if the innovator subsequently loses the patent case.

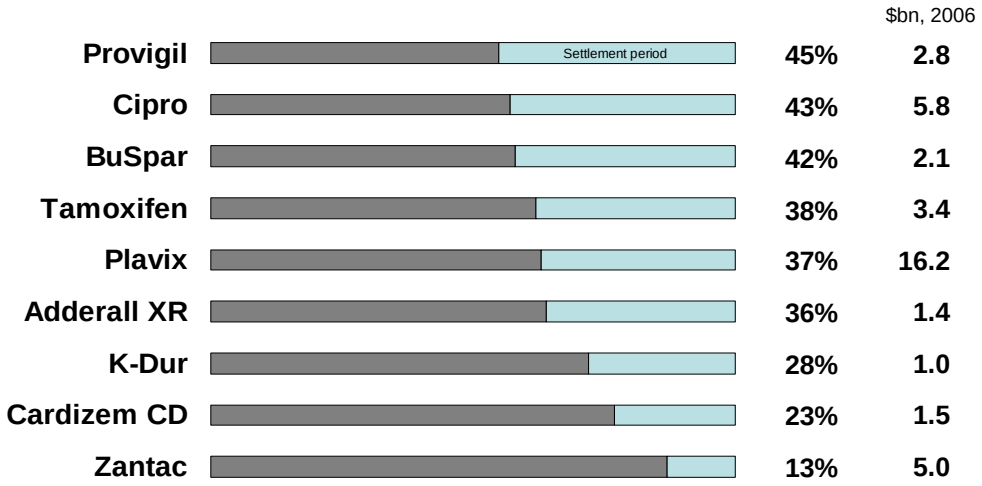
[8] If the patent case is decided before the expiration of the automatic stay, the period is shorter.

[9] For a fuller discussion, see *Survey*, *supra* note 1.

[10] Petition for Writ of Certiorari, *In re* Joblove, No. 06-830 (U.S. Dec. 13, 2006), 2006 WL 3694387.

than one-third of the time between brand-name product introduction and generic entry scheduled under the settlement. Percentages tell only part of the story. The dollar value is also large. Figure 1 includes an estimate of brand-name sales during the settlement period (in 2006 dollars).[11] This is the metric used by the maker of the wakefulness drug Provigil after settling four generic challenges. The firm's CEO quipped, "we were able to get six more years of patent protection. That's $4 billion in sales that no one had expected."[12]

Figure 1. Fraction of pre-entry period covered by settlement



[11] The estimates are based upon U.S. sales at the time of settlement, and assume that post-settlement sales remain constant in inflation-adjusted terms. That method underestimates the sales of some drugs—Provigil sales in 2006 exceeded sales in 2005, the benchmark year, by more than $200 million—and overestimates others. For each drug except Adderall XR, U.S. sales estimates were drawn from public sources as described in *Survey*, *supra* note 1. For Adderall XR, where only global sales were available, the figure in text reflects an assumption that U.S. sales were 60 percent of global sales.

The estimates do not coincide with the amount at stake for an innovator. An innovator would discount for the likelihood of success at trial and ignore that part of the settlement period where the generic firm would be unable to enter for another reason, such as the continued applicability of the stay.

[12] John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J., Mar. 17, 2006.

At least a dozen settlements have attracted pending antitrust suits or agency investigations.[13] Nine of these restrict generic entry associated with some $16 billion in sales, measured in 2006 dollars.[14] The figure excludes the sales that would have been covered by the failed Plavix settlement; that settlement, had it been fully implemented, would have restricted an additional $16 billion in sales. Not all important settlements have received antitrust scrutiny; the Zantac settlement, for example, restricted generic entry associated with about $5 billion in sales.

The settlements have occurred in two distinct waves. The first wave began in 1993 and ended in 2000 after the Federal Trade Commission (FTC) made clear its opposition to pay-for-delay settlements. The second wave began in 2005, after two appeals courts rejected antitrust liability for the settlements.[15] Figure 2 is a timeline depicting the two settlement waves, together with the two appeals court decisions, marked as solid diamonds.

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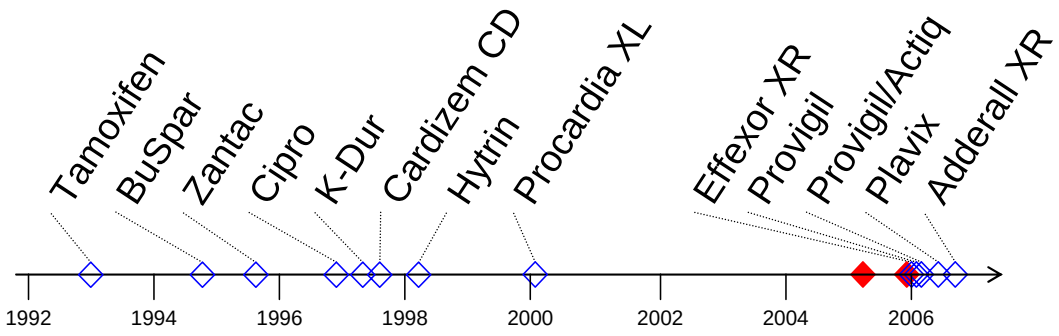
[13] The settlements are tamoxifen, Cipro, K-Dur, Hytrin, Provigil (four settlements), Actiq, Altace, Plavix, and Adderall XR. An innovator-generic agreement involving another drug, Ovcon 35, has attracted FTC and private antitrust attention, but there is no patent at issue there.

[14] The calculation omits three drugs listed in the previous footnote—Plavix (for reasons explained in the text), Altace, and Actiq. Altace, which had U.S. sales of approximately $700 million in 2003, is excluded due to the lack of clear public information about the terms of settlement. Actiq is omitted because that settlement did not directly delay entry but raises concerns in conjunction with one of the Provigil settlements.

[15] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005). The Second Circuit's ruling in *Tamoxifen* was handed down in 2005 but revised in 2006.

Figure 2. Two waves of settlement



Evolution and the failure of judicial intervention

The new wave of settlements is a direct response to the failure of federal courts to recognize and resolve the pay-for-delay issue.[16] When private parties and the FTC have challenged the settlements on antitrust grounds, courts have failed to recognize the illegality of the settlements. That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay.

In the earliest settlements, such as the tamoxifen, BuSpar, Zantac, and Cipro settlements, payment was a relatively straightforward affair. In exchange for the generic firm's delayed entry, the brand-name firm paid cash.[17] Modern

[16] The failure has not been uniform. One appeals court recognized liability on the somewhat unusual facts of that case. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003). A second appeals court considering the same facts reached a similar conclusion in dicta. Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809–12 (D.C. Cir. 2001).

[17] At least in part. Some of these early settlements also included alternative forms of payment, as explained below.

settlements also entail payment for delay, but the parties avoid a straight conveyance of cash, preferring instead to employ a variety of alternative forms of payment. Two are most important: *mispriced transfers* and *preserved exclusivity*.

Mispriced transfers are possible when the parties include more in their agreement than delay and a simple cash payment. For example, in many settlements the generic firm contributes not only delay but also something else, such as an intellectual property license. By overstating the contributed value of the generic firm, the parties can claim that the innovator's cash payment is in exchange for the contributed value, rather than for delay. The side deal thus provides a means to smuggle compensation to the generic firm.

Side deals take four principal forms, listed below, together with a few representative settlements that contain the term:[18]

- *Intellectual property and new product development*. The generic firm licenses its own intellectual property or agrees to develop new products for sale by the innovator. K-Dur, Provigil, Adderall XR.

- *Manufacturing and supply services.* The generic firm agrees to provide manufacturing services or supply product to the innovator,

[18] The settlements listed here for each provision are illustrative, not exhaustive. For listed drugs with multiple settlements, at least one settlement contains the term. For a detailed account of each settlement, see *Survey*, *supra* note 1.

or stands ready to do so upon the innovator's request. Provigil, Niaspan, Adderall XR, AndroGel.

- *Inventory*. The generic firm sells its existing stockpile of the drug. Provigil, Plavix.

- *Product promotion*. The generic firm agrees to promote the innovator's product at issue or an unrelated product. Niaspan, Adderall XR, AndroGel.

A second form of mispriced transfer is the flip side of an overpriced side deal. Rather than announcing a high price for value transferred from the generic firm to the innovator, the parties agree to a low price for value transferred from the innovator to the generic firm. The low price permits net payment from an innovator to a generic firm. Among the examples are the following:

- *Private label product*. The generic firm resells product licensed by the innovator in exchange for a fee to the innovator. Tamoxifen, Procardia XL.

- *Product lines*. The generic firm acquires the right to sell an older variant of the product at issue or an unrelated product. Effexor XR, Adderall XR.

From an outsider's perspective, it is not always possible to say with confidence whether a particular arrangement confers net compensation upon the generic firm. Public announcements of patent settlements frequently do not provide enough information—for example, by disclosing the price term of the deal—to perform an exact evaluation. The arrangements are very suspicious, however, to the extent that they tend to occur in the course of patent settlements but not otherwise. The FTC has noted, based upon observation of settlements during fiscal year 2006 and a review of settlements between 1993 and 2000, that side deals are common among settlement agreements that restrict entry but uncommon among those that do not,[19] a finding that supports the inference that the side deals are being used to confer payment.

An examination of multiple agreements also highlights a disadvantage of judicial decisionmaking, relative to agency review. Judicial decisionmaking focuses upon a single case, without examination of a larger sample of agreements. The latter is likely to provide useful insight as to the likelihood of anticompetitive activity in a particular case.

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[19] *See Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. 17 & n.41 (2007) (prepared statement of Federal Trade Commission), *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf; *see also* FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006, at 3 (2007), *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf (explicating this point for the fiscal year 2006 data).

Courts that have evaluated mispriced transfers, moreover, have failed to recognize their significance. One appeals court examined a side deal but wrongly concluded that the payment was for intellectual property licenses, not for delay.[20] The court ignored the extensive evidence offered by the FTC, which had challenged the settlement, that the payment was actually for delay.[21] Another appeals court considered a settlement containing a private label provision but misunderstood the opportunity for compensation.[22] It is therefore unsurprising that such terms have become a routine feature of modern settlement practice.

Preserved exclusivity. A second form of compensation avoids cash altogether. An important source of generic firm profits is a special exclusivity period, potentially available to a generic firm that is first to file a pre-expiration challenge. Such a firm may enjoy a 180-day exclusive right to market a generic version in competition with the innovator, effectively creating a duopoly during

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[20] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068–71 (11th Cir. 2005).

[21] See *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part IV (F.T.C. Dec. 8, 2003), which summarizes the evidence, including the fact that the payment was justified to the innovator's board of directors as a prerequisite to a settlement, given the generic firm's desire for cash to replace the lost income from generic entry, and that the innovator did an unusually haphazard job in assessing the value of the licenses to the firm.

[22] Indeed, the court wrongly thought that the deal *decreased* the amount of total compensation. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 215 (2d Cir. 2006). The point had been raised to the court by plaintiffs in that case. *See* Brief of Plaintiffs Appellants at 28, *available at* 2004 WL 3564422 ("As a newly-created partner with Zeneca in the tamoxifen monopoly, Barr enjoyed nine years of sales at 'branded' prices without generic competition.")

that period.[23] The exclusivity period is a valuable benefit to the generic firm worth hundreds of millions of dollars for a major drug.[24]

But exclusivity is not a sure thing, at least if the patent suit proceeds to judgment. If the first-filing generic firm loses the suit, it forfeits eligibility for exclusivity. Many settlements avoid this adverse outcome for the generic firm by preserving exclusivity, thereby insulating the generic firm from the risk of loss.[25] Settlement improves the generic firm's mere probability of enjoying exclusivity to a near certainty.[26] Preserving eligibility in this manner is a very valuable benefit conferred upon a generic firm. Indeed, the benefit is valuable even if the first-filing generic firm never actually enters the market. In the Zantac settlement, for example, the first-filing generic firm secured an additional cash payment from another generic firm by selectively waiving its entitlement to

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[23] 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

[24] 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. That large reward, moreover, came despite competition from an additional generic firm licensed by GlaxoSmithKline, Paxil's manufacturer. *Id.*

[25] For example, Zantac, K-Dur, Procardia XL, Effexor XR, Provigil, Plavix, and Adderall XR.

[26] The generic firm is not entirely certain of enjoying exclusivity because, for example, a later-filing generic firm might win a patent suit, triggering the first filer's exclusivity period prior to the first filer's FDA approval.

exclusivity, as the FDA permits a first filer to do, thereby permitting the later filer to enter.[27]

Some settlements take a further step to preserve exclusivity, by including a commitment by the innovator not to launch an "authorized generic" product. The authorized generic issue arises when an innovator, faced with generic competition, licenses a competing, unbranded version of the drug. Competition from an authorized generic product reduces the value of the first filer's exclusivity,[28] perhaps by half. Some settlements, including the Adderall XR and Plavix settlements,[29] include an agreement not to launch an authorized generic. Such an agreement again increases the value of exclusivity. It is another means to pay for delay.

So far as I am aware, no court has considered exclusivity preservation as a form of payment. Courts are unlikely to recognize this form of payment for delay, however, given both their prior refusal to prohibit settlements even when

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[27] *See* FDA, Response to Pfizer Citizen Petition at 4-5 & n.5, No. 2004P-0227 (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0227-pdn0001.pdf (explaining availability of selective waiver).

[28] Authorized generic entry is possible during the exclusivity period because exclusivity applies only to the approval of other ANDAs, not to entrants licensed under the innovator's own New Drug Application.

[29] There are two versions of the Plavix agreement. The initial agreement included the term, and the parties disagree about whether the revised agreement included the term. See *Survey*, *supra* note 1, for a fuller discussion.

the innovator pays cash and their demonstrated misconception of exclusivity as it shapes generic firm incentives.[30]

It is possible that the Supreme Court might step in to repair the errors made by lower courts. But the Court's previous refusals to review similar cases,[31] though they occurred before the practical importance of the settlement issue became quite so clear, leave that outcome very much in doubt. Even if the Court does enter the fray, moreover, its focus is likely to be limited to simple cash payments. That was the focus of the appeals court opinion that has given rise to a pending petition for certiorari. There is even less reason to expect that the Court will address the variety of ways in which innovators now pay for generic delay.

A new approach to pay-for-delay settlements

The current approach to pay-for-delay settlement is not working. Case-by-case judicial evaluation of individual settlements has failed to identify and

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[30] *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 214 (2d Cir. 2006) (taking the erroneous view that later filers had an incentive similar to the first filer's eligibility for the 180-day exclusivity period); Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (taking the incorrect view that a settlement "leaves the competitive situation unchanged"). For a further explanation of these errors, see *Paying for Delay*, *supra* note 1, at 1583–86.

[31] The Court has declined to review three such petitions. *See* FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006); Andrx Pharmaceuticals, Inc. v. Kroger Co., 543 U.S. 939 (2004); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 543 U.S. 939 (2004).

remedy the consumer harm. And the inadequacy of judicial resolution is likely to worsen, as payment increasingly takes alternative forms.

H.R. 1902 takes an important step toward identifying and deterring pay-for-delay settlement. Section 2(a) of the bill prohibits settlements that combine a delay in generic entry with an innovator's provision to the generic firm of "anything of value" beyond a negotiated entry date. Section 3 provides a process by which the FTC can create exceptions by rulemaking to the general prohibition of section 2. Taken together, the bill adopts an across-the-board prohibition of pay-for-delay settlements, coupled with rulemaking to flexibly identify exceptions to the general rule where they are practically justified.

A general prohibition, carefully limited by statute to those settlements that include a payment by the innovator and delay by the generic firm, is superior to case-by-case judicial scrutiny. That conclusion follows from two features of pay-for-delay settlement—first, that such settlements are frequently attempted and frequently successful, hardly a surprising result, given the parties' very strong incentives to enter pay-for-delay agreements. Second, courts have a demonstrated propensity to permit settlement behavior that properly ought to be condemned. Where, as here, anticompetitive activity is frequent and courts have difficulty distinguishing it, an across-the-board rule is justified.

Taken alone, this proposed rule will prohibit on occasion a competitively harmless settlement. That by itself is no critique of the rule. In price fixing and bid rigging, for example, two settings that pay-for-delay settlements resemble, a ban is well justified by the severe harm to consumer welfare, notwithstanding the possibility that the rule has a somewhat overinclusive effect. The real issue is whether any procompetitive justification for settlement is sufficiently important as a practical matter so as to justify an exception in a well-defined class of cases.

The FTC is ideally positioned to make such determinations in the pay-for-delay context—far better, certainly, than a generalist court. The agency sees the full range of cases, in contrast to the single-case purview of a court, due to its national enforcement scope. It augments its stock of knowledge by combining the analyses of staff economists with information gleaned from civil investigatory demands of market players. Perhaps most important, the FTC has access to the terms of all newly filed agreements, thanks to the foresight of Congress in 2003, which required drug makers to file such settlements with the agency.[32]

Suppose, for example, that the settling parties wish to defend a settlement that entails both delay by the generic firm and a side deal in which the innovator

[32] *See* Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003).

pays the generic firm for certain intellectual property licenses. That settlement is prohibited under section 2 of the bill because it includes both innovator payment and generic delay, subject to the exceptions created pursuant to section 3. If the settling parties wish to argue that the side deal has an important procompetitive effect, achievable only as part of this overall settlement, the FTC is in an excellent position to evaluate the practical heft of that claim, and to identify an exception if justified. This is a useful adjunct to its existing power to challenge anticompetitive settlements.

* * *

The pay-for-delay settlement problem appears to be worsening, as courts continue to decline to prohibit the settlements and as settlements evolve in a direction that makes effective judicial intervention increasingly unlikely. Congress has a vital role to play in establishing a broad prohibition of anticompetitive settlements, while maintaining agency flexibility to recognize exceptions where they are practically justified.

ARTICLES

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

C. SCOTT HEMPHILL*

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 limiting) opportunities for anticompetitive conduct as a

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

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3. *The Combined Effect of Tax and Subsidy* ..... 1610 R
C. *The Industry-Specific Case Against Pay-for-Delay Settlements* ..... 1612 R
CONCLUSION ..... 1616 R

> *"[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).

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

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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," 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).

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 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

[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.

case, but filed an unusual, contrary brief expressly disagreeing with the FTC approach.[14]

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

[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. § 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*

framed the cases as 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).

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 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.

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]

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

[20] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 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)).

[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.

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 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 com-

[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.

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

mentators 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.

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

[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).

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 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

[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.

[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.

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 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]

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[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").

[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).

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 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

[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).

[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).

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, 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]

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[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.

[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

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 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]

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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.

[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*

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] 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

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. 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.

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

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[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 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

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]

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.

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.*,

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] Federal antitrust enforcers

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

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 comple-

a district court adjudication of the infringement 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).

tion.[81] The conclusion that this loss gives rise to an antitrust violation depends upon 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.

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[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.

[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*).

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 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

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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.

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 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]

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[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 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).

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 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.

[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*

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 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

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 . . . .").

[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).

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 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,

[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) (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).

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] 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

[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).

[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.

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 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 chal-

[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.

[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.

lenge, 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 $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

[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 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 regu-

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 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 partic-

latory 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).

[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.

ular 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 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

[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.

[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,

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 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

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 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).

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]

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.

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[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 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.

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 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,

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[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").

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 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

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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.

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).

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 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

[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.

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]

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[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 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.

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 of negotiation. Consider a market served by an innovator,

[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 142–43 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.

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.

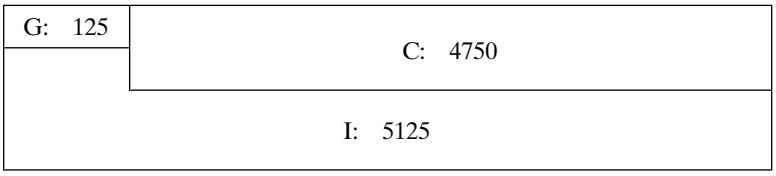
A few numerical assumptions ease the exposition. Suppose that under monopoly, the innovator receives 1000 each year, the generic firm and consumers nothing; that under duopoly, the innovator and generic firm each receive 500 per year, and consumers again nothing; and that under competition, consumers 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]

[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.

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 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.

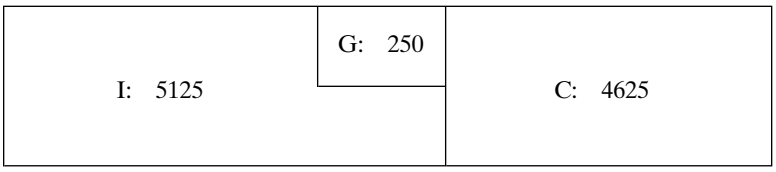
This can be depicted graphically. The length of the rectangle is ten years, and its height shows the division of expected benefits within a period:

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

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

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]

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.

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

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 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.

[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.

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 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 litiga-

[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.

tion 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 *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 enforce-

ment—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]

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

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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 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).

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 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

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[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).

[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).

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]

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

[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).

[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.

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 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

[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 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").

exception for restrictive practices that cover products not within the scope of the patent or that extend beyond its duration.[181]

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

[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—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).

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 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]

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[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 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.

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 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

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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).

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 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.

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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).

[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

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 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

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).

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").

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 (not ANDA submission) of three years.[204] Second,

[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.

[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 "experi-

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 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.

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mental 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.

[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.

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 would occur absent the

[209] For example, suppose that the patent is valid and infringed with probability *?*, 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 *?*. Entry is profitable provided $? < m'/m$.

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 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,

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 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.

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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.

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 benefit from subjecting these drugs to early competition

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

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 ben-

[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/intellectual property/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.

efits of innovation increase proportionately with 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.

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[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.

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 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

[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).

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.

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 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.

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[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 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.").

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 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 consid-

[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.

eration, 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]

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

[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 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).

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 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]

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[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].

[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.

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.

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.

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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.

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).

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 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

[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) (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).

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.

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[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)).

Drug Patent Settlements Between Rivals: A Survey

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Introduction

This survey classifies and analyzes patent settlements reached between innovator drug makers and their generic rivals over the past fourteen years, and the antitrust suits and investigations initiated in response. Thirty settlements involving twenty drugs fall within its scope. Several patterns emerge from the data.

Continued expansion in antitrust activity. Settlements involving ten drugs have attracted antitrust suits or Federal Trade Commission investigations that are currently pending—sixteen suits and three investigations in all, not counting multiple suits consolidated in a single jurisdiction. The first settlement, a 1993 agreement to delay entry and settle a patent dispute involving the cancer drug tamoxifen, attracted a challenge that is pending as a petition for certiorari at the Supreme Court.[1]

Not all settlements have antitrust challenges pending. Antitrust challenges to a few settlements have been resolved, and a few settlements never attracted an antitrust challenge. For example, the maker of Zantac, the first blockbuster drug, apparently paid $133 million to a generic rival, plus other consideration, to resolve a patent dispute. The Zantac settlement never invited antitrust attention, perhaps because the terms were not made public.

Emergence of repeat players. Of the seventeen innovators and eighteen generic firms that are party to the settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlements with respect to eight different drugs. Barr's first three settlements—tamoxifen, Cipro, and Ovcon 35—yielded antitrust suits that are pending as, respectively, a petition for certiorari, a Second Circuit appeal, and a district court suit. Its last three settlements—Adderall XR, Provigil, and Actiq—are the subjects of FTC investigations.[2]

Increased sophistication in second-wave settlements. The settlements have occurred in two distinct waves. The first wave occurred between 1993 and 2000.

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* Associate Professor, Columbia Law School. Akshay Deoras and Doug Geyser provided outstanding research assistance. This is a work in progress. Comments and corrections are welcome; please send them to hemphill@law.columbia.edu.

[1] This survey refers to each drug by its brand name, with the exception of Nolvadex, better known by its trade name tamoxifen.

[2] *See* Barr Pharmaceuticals, Inc., Quarterly Report (Form 10-Q), at 15-17 (Nov. 9, 2006) (link), which discusses the suits and investigations, with the exception of the Actiq investigation, which has been disclosed by Cephalon. See Part IV.A.4 *infra*.

FTC antitrust enforcement activity then halted settlements for a few years. But rulings adverse to antitrust liability by two federal appeals courts in 2005 and 2006[3] have led to a new wave of settlements.

The two waves share a basic structure: the innovator confers value upon the generic firm, and the generic firm agrees to delay entry. Second-wave settlements differ from first-wave settlements, however, in their sophistication. For example, second-wave agreements provide for generic entry prior to, rather than only after, patent expiration. Moreover, in many second-wave settlements the generic firm provides value to the innovator that is distinct from delayed entry. The additional value takes several forms, including intellectual property, product development, manufacturing, supply, inventory, and promotion. This contribution of additional consideration complicates antitrust evaluation. In addition, second-wave settlements lack restrictions on entry with respect to noninfringing products, one of the bases used to challenge first-wave settlements.

This survey is the first to offer a comprehensive account of the agreements and subsequent antitrust activity. It builds upon FTC reports in 2002, 2006 and 2007[4] that, unlike the present study, do not discuss individual agreements in detail or by name. For several settlements, this survey describes important settlement terms that can be inferred from FTC reports—for example, the size of the cash payment in the Zantac settlement.

The scope of the study is limited in several respects. First, it understates settlement activity due to its reliance on public information. Some settlements are clearly missing, judging from the settlement counts reported by the FTC. Second, some settlements have been omitted. For a drug to be included, an innovator must have entered into an agreement with a generic firm that was first to file an Abbreviated New Drug Application ("ANDA"). All but one[5] of the drugs in the study are protected by one or more patents, and the filed ANDA

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

[4] FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (2002) (link); 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 (link); FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 (link).

[5] The exception is Ovcon 35. See Part IV.B.1 *infra*.

asserts entitlement to offer the generic drug prior to patent expiration because every relevant patent is invalid or not infringed. Moreover, other practices in the pharmaceutical industry raising potential antitrust concern are outside the study's scope, including agreements between generic firms, "product hopping," and manipulation of the FDA citizen petition and Hatch-Waxman automatic stay processes. The study presumes familiarity with the complex regulatory structure of the Hatch-Waxman Act.[6]

The survey proceeds in four parts. Part I provides an overview of the agreements and subsequent antitrust activity. Part II analyzes the shift over time in the mechanisms of payment and delay. Parts III and IV describe in detail the particular agreements that compose each wave of settlement.

I. Settlements in summary

The following pages present innovator-generic agreements in tabular form. The agreements are organized by drug, in chronological order according to the date of agreement with the first filer. For each drug, the table indicates annual sales, the parties to and major terms of each settlement, and any antitrust activity.

[6] For an introduction, see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) (link).

Drug	US Sales	Parties	Agreement		Antitrust challenges
Nolvadex *Tamoxifen citrate*	$265 m	Zeneca-Barr	Mar. 1993	G $66 million G Private label sales G 180 days if revert I Neutralize first filer I Bottleneck I Vacate adverse ruling I Entry in Aug. 2002	Consumer/third party payor suit Pending petition for certiorari Below: CA2, NO
BuSpar *Buspirone HCl*	$288 m	Bristol-Schein	Dec. 1994	G $73 million I Neutralize first filer I Bottleneck I Entry in Nov. 2000	FTC consent decree MDL suit Dismissed in part as out of time (SDNY) Settlement
Zantac *Ranitidine*	$2150 m	Glaxo-Genpharm	Oct. 1995	G $133 million G 180 days G Licenses outside U.S. I Neutralize first filer I Entry in Aug. 1997	None
Cipro *Ciprofloxacin*	$680 m	Bayer-Barr	Jan. 1997	G $398 million G 180 days if revert I Neutralize first filer I Bottleneck I Entry in Dec. 2003	MDL purchaser suit Pending in CA2 Below: EDNY, NO State court suits in California, Florida, Kansas, New York, and Wisconsin All pending

Drug	US Sales	Parties	Agreement		Antitrust challenges
K-Dur *Potassium chloride extended release*	$190 m	Schering-Upsher	June 1997	G $60 million G 180 days I Neutralize first filer I Bottleneck I Entry in Sept. 2001 I Licenses to G's products I Other products excluded	FTC consent decree (as to ESI) FTC suit (as to Upsher) CA11, NO MDL purchaser suit Pending in DNJ (after denying dismissal)
		Schering-ESI (L)	Jan. 1998	G $30 million I Entry in Jan. 2004 I Licenses to G's products	
Cardizem CD *Diltiazem HCl controlled release*	$692 m	HMR-Andrx	Sept. 1997	G $90 million I Bottleneck I No launch at risk I Other products excluded	FTC consent decree Competitor suit Settled after CADC denied dismissal Purchaser suit $110 m settlement with direct purchasers $80 m settlement with indirect purchasers, states CA6, YES, as to nonsettling parties
Hytrin *Terazosin HCl*	$542 m	Abbott-Geneva	Apr. 1998	G $101 million I Bottleneck I No launch at risk I Other products excluded	FTC consent decree MDL suit Pending in S.D. Fla. after SJ for plaintiffs Prior: Remand from CA11 in *Valley Drug* Kaiser Foundation Health Plan suit Pending in CA9 Below: C.D. Cal, NO
		Abbott-Zenith (L)	Mar. 1998	G $45 million I Entry in February 2000 I Other products excluded	
Prozac *Fluoxetine HCl*	$2090 m	Lilly-Barr Lilly-Geneva	Mar. 1999	G $4 million G Quick appeal to CAFC I Dismissal of two claims I No launch at risk	None

Drug	US Sales	Parties	Agreement		Antitrust challenges
Naprelan *Naproxen sodium*	$59 m	Elan-SkyePharma	May 1999	G License G 180 days I Neutralize first filer I Bottleneck	Competitor suit Pending in S.D. Fla. on remand Prior: CA11, YES, denying dismissal Purchaser suit Pending in E.D. Pa., stayed for competitor suit
Procardia XL *Nifedipine extended release*	$311 m	Pfizer-Mylan	Feb. 2000	G Private label sales G 180 days I Neutralize first filer I Bottleneck	Competitor suit $9 m settlement after dismissal denied Purchaser suits Settled after class status denied, N.D. W. Va.
Ovcon 35 *Norethindrone and ethinyl estradiol*	$72 m	Warner Chilcott-Barr	Mar. 2004	G $20 million I Entry in May 2009 I Manufacturing	FTC suit Settled as to Warner Chilcott Pending in D.D.C. after denial of dismissal State attorneys general suits Pending Private plaintiffs suits Pending
Niaspan *Niacin extended release*	$380 m	Kos-Barr	Apr. 2005	G Cash G 180 days I Neutralize first filer I Bottleneck I Entry in Sept. 2013 I Promotion I Manufacturing	None
Effexor XR *Venlafaxine HCl extended release*	$2275 m	Wyeth-Teva	Dec. 2005	G New product line G 180 days I Neutralize first filer I Bottleneck I Entry in July 2010	None

Drug	US Sales	Parties	Agreement		Antitrust challenges
Provigil *Modafinil*	$476 m	Cephalon-Teva	Dec. 2005	G Part of $219 million G 180 days I Neutralize first filer I Bottleneck I Entry in October 2011 I Intellectual property I Manufacturing and supply	FTC investigation Purchaser suit Pending in E.D. Pa. Competitor suit Pending in E.D. Pa.
		Cephalon-Ranbaxy	Dec. 2005	G Part of $219 million G 180 days I Neutralize first filer I Bottleneck I Entry in October 2011 I Intellectual property I Supply	
		Cephalon-Mylan	Jan. 2006	G Cash G 180 days I Neutralize first filer I Bottleneck I Entry in October 2011 I Product development	
		Cephalon-Barr	Feb. 2006	G Part of $219 million G 180 days G Actiq-specific terms I Neutralize first filer I Bottleneck I Entry in October 2011 I Intellectual property I Inventory	
		Cephalon-Carlsbad (L)	Aug. 2006	I Entry in Apr. 2012	
Actiq *Oral transmucosal fentanyl citrate*	$395 m	Cephalon-Barr	Feb. 2006	G Earlier license G Share of sales in another product?	FTC investigation

Drug	US Sales	Parties	Agreement		Antitrust challenges
Alphagan *Brimonidine tartrate 0.15% ophthalmic solution*	$200 m	Allergan-Alcon	Mar. 2006	G Dismiss second suit I Entry in September 2009	None
Plavix *Clopidogrel bisulfate*	$3200 m	Bristol-Apotex	May 2006	G $40 million G 180 days G No authorized generic? G Breakup fee? G Launch-at-risk protection I Neutralize first filer I Bottleneck I Entry in Apr. 2011 I Inventory *Not fully implemented*	Department of Justice criminal inquiry Purchaser suit Pending in S.D. Ohio
Biaxin XL *Clarithromycin extended release*	$151 m	Abbott-Teva Abbott-Ranbaxy (L)	July 2006 July 2006	Unknown Unknown	None
Adderall XR *Mixed amphetamine salts, extended release*	$864 m	Shire-Barr Shire-Impax (L)	Aug. 2006 Jan. 2006	G $102 million G 180 days G No authorized generic G New product line I Neutralize first filer I Bottleneck I Apr. 2009 entry I Develop/supply other products G Cash I Entry in Jan. 2010 I Promote unrelated product	FTC investigation

Drug	US Sales	Parties	Agreement		Antitrust challenges
AndroGel *Testosterone gel 1%*	$330 m	Solvay-Watson	Sept. 2006	G Cash G 180 days by contract I Neutralize first filer I Entry in Aug. 2015 I Promotion	None
		Solvay-Par (L)	Sept. 2006	G $60 million I Entry in Feb. 2016 I Promotion I Backup manufacturing	

As the chart demonstrates, settlements occur in drugs with a wide range of sales. The study includes a few blockbusters, including Zantac ($2.2 billion in U.S. sales in 1995) and Plavix ($3.2 billion, 2005), a few quite minor drugs such as Naprelan ($59 million, 1999), and many in the sub-blockbuster range, that is, hundreds of millions of dollars in annual sales.[7] Several of the drugs are extended release or controlled release successors to existing drugs, such as K-Dur, Cardizem CD, Procardia XL, Effexor XR, Biaxin XL, and Adderall XR.

A wide range of firms have entered into the settlements, seventeen innovators and eighteen generic firms in all. The summary figures disguise some complications. For example, Kos and Abbott are counted separately, though Kos is now part of Abbott. Nor do the figures include multiple parties on one side of a transaction. As noted in the Introduction, a few generic firms appear repeatedly, particularly Barr.

For seven drugs, the innovator reached agreement with multiple generic firms. A few of these settlements are with multiple generic firms, each of which has first-filer status, and thus shares in potential entitlement to generic exclusivity. In the case of Provigil, for example, Cephalon settled with four different firms that each filed on the first possible day and therefore shared in potential entitlement to the exclusivity period. Other settlements are with a generic firm the filed later and thus lacked entitlement; these settlements are marked "(**L**)" in the chart.

The agreed-upon entry date varies widely. Many first-wave settlements, including tamoxifen, BuSpar, Zantac, and Cipro, provided for entry only upon expiration of the relevant patent protection. Second-wave settlements generally provide for a pre-expiration entry date. This was an innovation of the K-Dur settlements, part of the first wave, that has been widely adopted in second-wave agreements. For some settlements, the pre-expiration entry date is very close to expiration—in the case of the Plavix settlement, for example, eight months before. Others are earlier, as with Niaspan's agreed-upon entry in 2013, four years before patent expiration. Pre-expiration entry may nevertheless be at or after the end of the drug's period of profitability, due to the pre-expiration onset of generic competition in a competing therapy, the arrival of a superior,

[7] In most cases, the sales figure used is company sales in the United States in the year of settlement. In some cases, this figure was unavailable and a different estimate was used. See Parts III and IV for details.

competing brand-name drug, or the innovator's own plans to shift customers to a line extension or next-generation therapy.

Other settlement terms also vary widely, but their discussion is deferred to Part II; nevertheless, three clarifications of the chart may be useful. Terms benefiting the generic firm are marked "**G**", and those benefiting the innovator are marked "**I**". As for cash, where the public information indicates a range of cash payments, only the maximum is reported in the chart. Finally, in some settlements, the generic firm sells innovator-provided product under the generic firm's label. In others, the opposite occurs, and the generic firm provides product to the innovator. The term "supply agreement" is sometimes used to describe both practices. In this survey, only the generic firm's provision of product to the innovator is called a supply agreement; an innovator's provision of product to the generic firm is called "private label sales."

These settlements have attracted a great deal of antitrust activity, including private suits and agency investigations, consent decrees, and litigation. As noted in the introduction, ten drugs have pending activity. In a number of the challenges, a court has expressed a view about the merits, and this is indicated in the chart in a rough manner by "**NO**" (a ruling against antitrust liability) or "**YES**" (a ruling in favor of liability).

II. The mechanisms of payment for delay

The settlements share a basic structure. In each, a generic firm seeks to market a generic version of an innovator's drug prior to the expiration of the innovator's patent protection on the drug.[8] The innovator, rather than take the chance that it might lose the suit, agrees to confer compensation upon the generic firm. The generic firm agrees to abandon its challenge and to delay entry.

The settlements vary considerably, however, in the forms of payment and delay. This Part draws upon the detailed accounts of each settlement provided in Part III to explain the forms that compensation and delayed entry may take. In this discussion, two common settlement terms are ignored and not discussed further: provisions that accelerate the generic launch date if another generic firm enters the market, and royalties paid by the generic firm upon its negotiated launch date.

[8] With the exception of Ovcon 35, where no patent was at issue.

A. Compensation to the generic firm

The settlements in the study suggest three principal ways in which an innovator can pay a generic firm. It can pay cash, including overpayment for goods and services provided by the generic firm. It can act to preserve a first-filing generic firm's access to the lucrative 180-day period of generic exclusivity. And it can set a very low price for goods and services provided to the generic firm. Aside from these mechanisms, a few settlements may confer compensation that defies neat classification.

1. Cash and overpayment

The amount of cash paid varies greatly across the settlements. The Cipro settlement features the largest cash payment, $398 million. Other settlements with cash transfers exceeding $100 million[9] include Provigil ($219 million), Zantac ($133 million), and Adderall XR ($102 million).[10] Six more have cash payments in the $10 million to $100 million range, including BuSpar ($73 million), tamoxifen ($66 million), K-Dur ($60 million to the first filer and $30 million to a later filer), Hytrin ($45 million to a later filer), and Ovcon 35 ($20 million). In addition, the two "interim" settlements in the study included large cash payments.[11]

These figures must be used with care. The size of cash compensation is often absent in public data altogether or as to particular deal components. Moreover, focusing only on cash provides an incomplete and misleading picture of compensation. Such a single-minded approach ignores other important forms of compensation to a generic firm, including preservation of exclusivity and a low transfer price.

Focusing on cash also makes it tempting to rely upon economically incorrect "safe harbors." For example, the fact that a cash payment is smaller than the litigation expense saved by settling—even if none of the other forms of compensation is present—does not itself render a payment procompetitive.

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[9] The totals are for the year or years paid, so the figures are not precisely comparable. In some cases, the cash figure represents a maximum under the agreement. See Part III for details.

[10] The Provigil figure aggregates multiple agreements with first-filers. The Adderall XR figure is the net result of a complex set of transfer payments. See Part III for details.

[11] Interim settlements do not resolve the litigation but merely block entry pending its resolution. The Cardizem CD interim settlement provided for a $90 million payment. The Hytrin interim settlement with a first filer provided for a $45 million payment.

After all, *both* sides have litigation expense that they conserve by settling. Ordinarily, each party could simply pocket the saved expense, rather than one party paying the other. When the innovator pays the generic firm the entire amount of the innovator's saved expense, this can constitute payment for additional delay.

Evaluation of the cash component is complicated by the presence of simultaneous side deals. In first-wave settlements, such as tamoxifen, BuSpar, Zantac, and Cipro, the absence of a side deal made it relatively straightforward to conclude that the cash payment provided compensation for the generic firm's delayed entry. Second-wave settlements, by contrast, often feature a complex set of contemporaneous transactions in which the generic firm provides additional value, apart from the agreement to delay entry.

The earliest example of this development is actually a first-wave settlement, an agreement that drug maker Schering entered into with a generic rival with respect to the potassium replacement drug K-Dur. In exchange for cash, the first filing generic firm agreed both to delay entry and to supply licenses to other products.[12] The FTC's antitrust case challenging the agreement turned in part upon whether the cash payment made by Schering was consideration for the rival's delay or its licenses. One of the Eleventh Circuit's grounds for denying antitrust liability was its conclusion that the innovator's payment was consideration for the licenses.

It comes as no surprise, then, that side deals have been widely adopted in second-wave settlements. In general, the additional value provided by the generic firm is not something that the innovator had sought from the generic firm prior to the overall settlement, a signal that its value is low. Side deals take four principal forms.

Intellectual property and product development. The generic firm agrees to license its own intellectual property or to develop new products for sale by the innovator. The K-Dur settlement described above is an early example. Three of Cephalon's agreements with first-filing firms to settle Provigil patent suits include payments described as compensation for intellectual property. A fourth agreement includes a product development term. Similarly, one of the

[12] Schering subsequently reached a similar deal with a later filing generic firm. *See* Part III.A.5 *infra*.

agreements settling Adderall XR patent litigation includes a provision that the generic firm will help develop additional products.

Manufacturing and supply. The generic firm agrees to provide manufacturing services or supply product to the innovator. The Ovcon 35 and Niaspan settlements include such a term, as do two of the Provigil settlements (a manufacturing and supply term as to generic firm Teva, supply only as to Ranbaxy). In the Adderall XR settlement described above, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. One of two AndroGel settlements features a variation in which the generic firm provides "backup" manufacturing services.

Inventory. The generic firm agrees to provide its existing inventory of the drug. Agreements with inventory purchase terms include Cephalon's Provigil settlement with Barr and Bristol's Plavix settlement, never fully implemented, with Apotex.

Promotion. The generic firm agrees to promote the innovator's product. This is a term in the Niaspan settlement and both AndroGel settlements. In those settlements, the generic firm agreed to promote the product at issue in the litigation. In one of the Adderall XR settlements, the generic firm agreed instead to promote an unrelated product.

2. Preserving exclusivity

In many settlements, the generic firm retains eligibility for the 180-day exclusivity period, by agreeing to enter at a particular future date that is at least 180 days prior to patent expiration. Many settlements include this feature, including K-Dur, Naprelan, Procardia XL, Niaspan, Effexor XR, Provigil (as to each of four first-filers), Plavix, and Adderall XR.[13] Retained exclusivity is a form of compensation worth hundreds of millions of dollars for a major drug.[14]

The reason why retained exclusivity is valuable is somewhat subtle. Because the patent is never adjudicated, the generic firm does not risk the possibility that it might lose the patent suit. If the generic firm lost, it would be forced to wait until patent expiration—but more than that, it would lose the 180-day entitlement. By reaching an agreement on entry dates, the generic firm

[13] In a few cases, retained exclusivity cannot be confirmed based upon available public information.

[14] In addition, AndroGel appears to have retained exclusivity by contract.

retains the entitlement, turning the mere probability of enjoying it (if it won the patent suit) to a near certainty. The generic firm is not absolutely certain of enjoying exclusivity because, for example, a later-filing generic firm might win a patent suit, triggering the first-filer's exclusivity period prior to the first filer's FDA approval. But assurance of non-interference from the innovator is still very valuable to a generic firm.

A generic firm can even make money from the exclusivity period when it does not actually enter, by insisting upon compensation from a later-filing generic firm as a condition for relinquishing its exclusivity and permitting the later filer to enter. (This is a consequence of the "bottleneck"; see Part II.B.2 for a discussion.) The generic firm in the Zantac settlement, for example, made money in this way. Although the firm did not enter, it accepted payment in exchange for allowing another firm's entry.

A related source of compensation is for the innovator to agree not to launch an "authorized generic" version of the product. The authorized generic issue arises when an innovator, faced with 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 authorized generic reduces the value of the generic firm's exclusivity period. In some settlements, including Adderall XR and Plavix, the innovator agrees not to launch an authorized generic.[15] Such forbearance increases the value of exclusivity, potentially by a large amount. Thus an agreement to forgo an authorized generic, like retained eligibility itself, is a means to pay for delay.

Two other settlements, tamoxifen and Cipro, contain a weaker version of retained exclusivity. Both settlements provided that the generic firm would wait to enter until patent expiration, and the generic firm – in both cases Barr – altered its ANDA from paragraph IV to paragraph III.[16] But in each case, faced with the possibility of pre-expiration generic entry by other firms, Barr converted back from paragraph III to paragraph IV and asserted its continued entitlement to the exclusivity period.

Not all settlements include guaranteed exclusivity. This term may be missing for several reasons. First, the agreement may provide for no entry until

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[15] There were two Plavix agreements. The initial agreement included the term; the parties disagree about whether the revised agreement included the term. *See* Part IV.A.5 *infra*.

[16] In the tamoxifen settlement, there was limited generic entry in the form of private-label sales, as discussed in the next section.

patent expiration. Second, the agreement may not resolve the patent dispute, in which case the generic firm receives no assurance of being able to enjoy the exclusivity period. That was the case in the "incomplete" agreements—Hytrin, Cardizem CD, and Prozac—discussed in Part III.B. Third, some settling generic firms have no eligibility for exclusivity. This is true of later filers, such as the secondary settlements in Hytrin, K-Dur, Provigil, Adderall XR, and AndroGel. It is also true for first filers, where the applicable procedure provides no basis for exclusivity—for example, because there is no patent for the first filer to challenge, as in Ovcon 35, or because the particular procedure used for innovator approval does not allow for exclsuivity, as with Biaxin XL, or because the generic firm uses a procedure that does not provide for an exclusivity period, as with Alphagan. For a discussion of these settlements, see Part IV.B.

A final reason that might seem to undermine retained exclusivity turns out not to matter. The Medicare Modernization Act of 2003 limits the ability of a settling generic firm to retain eligibility by providing for forfeiture if the parties settle, but that provision does not apply to settlements resulting from ANDAs filed before the effective date of the Act.[17] Of the settlements in the survey in which the generic firm had potential eligibility for the exclusivity period, all but one are covered by the pre-MMA rules.[18] In the single exception, Actiq, the generic firm had no practical prospect of receiving the exclusivity period.[19]

3. Underpricing

Compensation may also be conferred by choosing a low price for goods transferred from the innovator to the generic firm. For example, the parties may arrange for private label sales, in which the innovator provides product that the generic firm sells under its own brand. The tamoxifen and Procardia XL

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[17] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat. 2066. The new forfeiture regime, 21 U.S.C. § 355(j)(5)(D) (Supp. 2004), applies only to ANDAs filed after December 8, 2003, where no previous ANDA-IV was filed earlier than December 8. See § 1102(b) of the Act, 117 Stat. 2460.

[18] Barr's ANDA in Actiq was filed after the new rules took effect. The forfeiture provisions do not apply to settlements for which the exclusivity period was never available. For settlements reached before MMA passage, the related ANDA filings occurred even earlier and are governed by the pre-MMA rules. Of the post-MMA settlements, all but Actiq had pre-MMA ANDA filings: Niaspan (October 2001 and March 2002); Effexor XR (March 2003); Provigil (December 2002); Plavix (November 2001); Adderall XR (November 2002); and AndroGel (May 2003).

[19] Barr's ANDA-IV in Actiq was filed sufficiently late as to leave little time to win a suit and enjoy the exclusivity period prior to patent expiration. See Part III for details.

settlements, for example, contain such a term. A private label deal, if it includes a low transfer price, permits net payment from an innovator to a generic firm. License terms are not public, so it is difficult to assess the extent of this practice.

Underpriced transfers are the flip side of overpriced side deals. For side deals, the concern is that the parties attribute an unrealistically high price to the value provided by the generic firm. For transfers, the concern is that the parties agree to an unduly low price for value provided by the innovator.

The transfer can extend to additional products not directly at issue, as in the Effexor XR and Adderall XR settlements. In both settlements, the innovator secured an agreement to delay entry in the newer extended-release version of the drug, but arranged for immediate generic use of the older immediate-release version. In the case of Effexor, this took the form of a product license; in Adderall, a sale of rights. Similarly, the private label sales in the Procardia XL settlement included dosage forms for which the generic firm was not the first filer. Again, the extent of compensation is difficult to evaluate with public information.

4. Additional channels

The innovator and generic firm may be adversaries in other disputes, the settlement of which can confer compensation upon the generic firm. For example, the Zantac settlement resolved patent litigation in other countries. Cephalon and Barr settled litigation involving two drugs, Provigil and Actiq, at the same time.

A further, unusual form of compensation is described in the most recent FTC settlement report (emphasis added):

> The remaining case also had no explicit restriction on generic entry. It involved a complex set of transactions in which the brand manufacturer granted the generic company a license to an authorized generic of the capsule form of the product that was the subject of the litigation; the brand company acquired a new tablet form of the product at issue; the brand agreed to pay the generic a royalty *on the sales of the acquired product*; and then the parties dismissed the litigation involving the capsule form of

the product. As one of the parties has disclosed, this set of transactions is under investigation by the FTC.[20]

If this description is correct, the innovator agreed to pay the generic firm a royalty on a different form—the new form—rather than the form actually at issue in the litigation. This unusual feature may have been a part of the Actiq settlement between Cephalon and Barr. (For further discussion, see Part IV.A.4.)

B. Delay in generic entry

The delay in generic entry takes four principal forms: by neutralizing the challenge by the firm most motivated to test the innovator's patent protection; by creating a bottleneck that prevents FDA approval of later filers; by heading off entry during the period while a patent suit is pending; and through application to products not directly at issue in the litigation.[21]

1. Neutralizing the first filer

In most settlements with first filers, the settlement has the effect of neutralizing the single firm with eligibility for exclusivity. 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 to the innovator's patents. The settlement removes from consideration the most motivated challenger, and the one closest to introducing competition.

2. Bottleneck

In some settlements, the entry of subsequent filers can be blocked entirely due to a statutory bottleneck created by the Hatch-Waxman regime. 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. 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 block is

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[20] FTC, FY 2006 Report, *supra* note 4.

[21] In one settlement, tamoxifen, the parties also agreed to vacate a ruling adverse to the innovator.

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.

In a few first-wave settlements, such as tamoxifen, BuSpar, and Cipro, the generic firm relinquished exclusivity eligibility by changing its certification from paragraph IV to paragraph III. In the case of tamoxifen and Cipro, however, this did not entirely remove the bottleneck, for upon the emergence of other potential generic entrants, the generic firm (in both cases, Barr) reasserted continued entitlement to the exclusivity period.

3. Interim delay

In two settlements (Cardizem CD and Hytrin), the delay in entry took the form of a commitment not to launch "at risk"—that is, after FDA approval of generic entry, but before complete certainty emerged that the patent was invalid or not infringed. For example, when an innovator sues a generic firm for patent infringement, an automatic stay is entered that prevents generic entry for thirty months or more. Sometimes, however, the automatic stay expires before the district court has decided the patent suit, in which case FDA approval may be granted and the product launched despite the absence of a ruling. In that event, a commitment by the generic firm not to launch at risk can be a valuable interim benefit to an innovator. Moreover, in Hytrin the generic firm agreed to stay out even after the district court ruled in its favor, and the risk had significantly subsided.

4. Agreement as to noninfringing products

In several settlements, the agreement prevented entry not only as to the product directly at issue in the generic firm's ANDA, but other competing products as well. This was true of one of the K-Dur settlements, the Cardizem CD settlement, and both Hytrin settlements. The FTC and courts attacked this term as clearly outside the scope of the innovators' patents. Second-wave settlements omit this term.

III. First-wave settlements

This Part and the next provide detailed accounts of each settlement, drawn from court filings, press releases, news accounts, and, in a few cases

where they have been made public, the actual agreements.[22] This Part describes first-wave settlements, organizing them according to whether the settlement fully resolves the underlying patent litigation. Settlements for seven drugs do so, and three do not.

A. Complete settlements

1. Tamoxifen

Tamoxifen citrate, sold by Zeneca under the brand name Nolvadex, is the "most prescribed cancer drug in the world."[23] Nolvadex's U.S. sales in 1992 totaled $265 million, which rose to $442 million in 2001, the last full year of sales prior to generic entry.[24]

Zeneca[25] and first-filer Barr reached agreement in March 1993.[26] Zeneca agreed to pay $66.4 million: $21 million to Barr, and $9.5 million immediately and $35.9 million over ten years to Barr's raw materials supplier Heumann. In addition to cash, Barr received compensation through profitable private-label sales. Zeneca allowed Barr to sell Zeneca-made tamoxifen under Barr's label. The licensed version sold at a 15 percent discount to Zeneca's version. Barr soon captured most of the market.

The amount of compensation provided by the private-label arrangement is difficult to determine using public information. Its value may be indicated, however, by the different course taken in the Cipro settlement. There, the innovator had the option to implement a similar supply agreement, but chose instead to simply make large cash payments.

Barr also retained potential entitlement to the exclusivity period, without fear of losing it by losing a patent suit. Barr initially changed its Paragraph IV

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[22] *See, e.g.*, Defendants' Notice of Submission of Zenith Settlement Agreement, Kaiser Found. v. Abbott Labs., No. 2:02cv2443 (C.D. Cal. Mar. 14, 2006) [hereinafter Hytrin Zenith-Abbott Agreement]; Barr Pharmaceuticals 10-Q, *supra* note 2, Exhs. 10.1, 10.2, and 10.3 [hereinafter Adderall XR Agreement]; Bristol-Myers Squibb, Quarterly Report (Form 10-Q), Exhibits 99.1, 99.2 (link) (Aug. 8, 2006) [hereinafter Plavix Agreement].

[23] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 193 (2d Cir. 2006).

[24] *See Zeneca Settles US Patent Dispute*, PHARMA MARKETLETTER, Mar. 22, 1993 (1992 sales); *Tamoxifen*, 466 F.3d at 193 n.1 (2001 sales).

[25] Zeneca succeeded to ICI's rights and later became part of AstraZeneca.

[26] *See Tamoxifen*, 466 F.3d at 193-96, 194 n.9.

certification to Paragraph III, thereby certifying that it would wait to enter until patent expiration. Yet Barr later reverted to a Paragraph IV certification, and asserted its continued entitlement to the 180-day exclusivity period when generic firm Mylan gained FDA's tentative approval to market a generic product.

From Zeneca's standpoint, the settlement neutralized the first-filer threat, by removing from litigation the single firm, Barr, with entitlement to the 180-day exclusivity period. The settlement also created a partial bottleneck, in the sense that Barr's reversion to a paragraph IV assertion limited the prospect for approval of later filers. Barr agreed to enter with its own ANDA product until August 2002, when a key Zeneca patent expired.[27] Generic manufacturers entered soon after the expiration of the patent. One further unusual feature of the agreement is that the parties agreed to seek vacatur of the district court's ruling that the relevant patent was invalid. The Federal Circuit granted vacatur.[28]

The tamoxifen settlement has attracted numerous antitrust challenges, including 33 purchaser class action complaints.[29] In 2006, the Second Circuit dismissed on the merits.[30] As of March 2007, a petition for certiorari was pending.[31]

2. BuSpar

Buspirone hydrochloride, sold by Bristol-Myers Squibb under the brand name BuSpar, is a widely prescribed antianxiety drug. BuSpar's U.S. sales in

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[27] U.S. Patent No. 4,536,516.

[28] Imperial Chem. Indus., PLC v. Heumann Pharma GmbH, 1993 WL 118931 (Fed. Cir. 1993).

[29] *See* Barr Pharmaceuticals 10-Q, *supra* note 2.

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

[31] Petition for Writ of Certiorari, Joblove v. Barr Labs, Inc., 2006 WL 3694387; see also Brief for 41 Professors of Economics, Business and Law as Amici Curiae in Support of Granting the Petition, 2007 WL 527488; Brief for the American Antitrust Institute as Amicus Curiae in Support of Petitioners, 2007 WL 518366; Brief for National Association of Chain Drug Stores as Amicus Curiae in Support of Petitioners, 2007 WL 518365. The petition is scheduled for consideration at Conference on Mar. 16, 2007; see Docket No. 03-7641 (link).

1995 totaled $288 million, which rose to more than $600 million in 2000, the year prior to generic entry.[32]

Bristol and first-filer Schein reached agreement in December 1994.[33] Bristol paid Schein $72.5 million in four installments. Retained exclusivity was not a source of compensation to Schein, as no entry was contemplated prior to patent expiration.

From Bristol's standpoint, the settlement neutralized the first-filer threat. The settlement also created a bottleneck: later ANDA-IV filers could not receive FDA approval until 180 days after entry of a first filer with exclusivity eligibility, so Schein's continued presence as a first filer blocked approval of later-filed ANDAs. Schein agreed to wait to enter with its own product until November 2000, when the key patent expired.[34]

The BuSpar settlement attracted numerous antitrust challenges. The FTC challenged the settlement, culminating in a consent decree in 2003 that covered this and other allegedly anticompetitive activities by Bristol.[35] (This consent decree played an important role in the later Plavix settlement; see Part IV.A.5.) A variety of private suits were filed and consolidated as multidistrict litigation in a New York district court. In 2002, the district court dismissed the suit as to competitors and in part as to purchasers, due to expiration of the limitations period.[36] In 2003, Bristol reached a settlement with state plaintiffs to resolve this and other claims.[37]

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[32] *See Annual Report: Top 100 Drugs: Antianxiety Medicines*, MED AD NEWS, May 1, 1996, *available at* 1996 WLNR 4441128 (1995 sales); FTC, Analysis to Aid Public Comment, *In re* Bristol-Myers Squibb Company (link) (2000 sales).

[33] *See* Analysis to Aid Public Comment; FTC report (noting payment in installments).

[34] U.S. Patent No. 4,182,763. This was not the end of the story; generic entry was delayed further by a dispute over a later-issued patent on metabolite.

[35] *In re* Bristol-Myers Squibb Co., No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003); *see also* Analysis to Aid Public Comment.

[36] *In re* Buspirone Patent Litig., 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (MDL-1410).

[37] The settlement reportedly totaled $100 million for consumers in most states and state agencies, and another $90 million for third-party payors and consumers in the remaining states. See Patrick E. Cafferty, Indirect Purchaser Class Action Settlements, American Antitrust Institute Working Paper No. 06-05 (June 2006).

3. Zantac

Ranitidine, sold by Glaxo under the brand name Zantac, is an antiulcerant. Zantac was the world's best-selling prescription medicine in 1995, with U.S. sales of $2.15 billion.[38]

To understand the settlement that resulted, it is necessary to review briefly the underlying patent suit. Two forms of ranitidine, "Form 1" and "Form 2," and two patents, are particularly relevant. At the time of the Zantac settlement, Form 1 ranitidine had never been made commercially and was considered relatively difficult to manufacture. Form 2 was the form actually used by Glaxo. The two forms are bioequivalent. Form 1 was protected by a patent that expired in July 1997.[39] Form 2 was protected by a patent that expired in December 2002.[40] First-filing generic firm Genpharm[41] sought to make a Form 2 product prior to patent expiration, and challenged not only the validity of the Form 2 patent, but also—and this was an unusual feature of the challenge—the validity of the basic Form 1 patent. The case was scheduled for a jury trial in October 1995.[42]

Glaxo and Genpharm reached agreement in October 1995, on the eve of trial.[43] Glaxo likely paid Genpharm $132.5 million, a figure not publicly disclosed but inferred from an FTC report.[44] Genpharm retained entitlement to

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[38] *See Annual Report: Top 100 Drugs: Histamine H(2) Receptor Antagonists*, MED AD NEWS, May 1, 1996, at 1, 36, *available at* 1996 WLNR 4446118.

[39] U.S. Patent No. 4,128,658.

[40] U.S. Patent No. 4,521,431. The original expiration was June 2002, but this was extended.

[41] Genpharm was and is a subsidiary of the E. Merck Generics Group of Merck KgaA.

[42] *See* Glaxo Wellcome PLC Further re Patent Litigation, July 10, 1995; cf. Granutec Inc. v. Shalala, 46 U.S.P.Q.2d 1398 (4th Cir. 1998) (describing the suit but erroneously asserting that Glaxo "prevailed," as opposed to settling, in October 1995). The relevant docket for the patent suit appears to be District of Maryland, Nos. 92-1831 and 93-4228.

[43] *See Granutec*, 46 U.S.P.Q.2d at 1403, 1405 (describing the waiver of 180-day eligibility, characterizing it as "quite lucrative," and noting entry); Press Release, Glaxo Wellcome PLC, Glaxo Wellcome PLC Re Genpharm Litigation (Oct. 23, 1995) (describing license in other markets).

[44] Zantac is likely Drug Product I in the 2002 FTC report. Product I is the only drug listed in the relevant FTC table whose sales (like Zantac's) exceeded $1 billion in the year of agreement. The agreement involving Product I included a delay of one year, nine months, which matches the delay between the Zantac agreement (in October 1995) and the expiration of the first patent in issue ('658, in July 1997). The agreement involving Product I resolved patent litigation in other countries, an unusual feature of the agreement. Similarly, the Glaxo-Genpharm pact settled Zantac litigation outside the United States. Drug Product I fits none of the other cases that have

the exclusivity period, without fear of losing it by losing a patent suit, and received compensation, including a profit-sharing agreement, when it later waived exclusivity in favor of subsequent filer Granutec.[45] A federal appeals court described the transaction as "quite lucrative." Glaxo granted Genpharm and related companies licenses and supply agreements to sell a generic version of Zantac in several other countries.

From Glaxo's standpoint, the settlement neutralized the first-filer threat. This was particularly important because Genpharm's challenge to the basic Form 1 patent was an unusual threat. The settlement did have a bottleneck potential, but Genpharm waived exclusivity in favor of Granutec in exchange for payment. Genpharm agreed to wait to enter with a Form 1 product until the Form 1 patent expired in July 1997 and to wait to enter with a Form 2 product until 2002.[46] The Form 2 restriction was significant because in 1995 it had not been established that a Form 1 product could be made without infringing the Form 2 patent, and Glaxo argued strongly (though ultimately unsuccessfully) to the contrary. Moreover, Form 1 had not yet been made in commercial quantities. Generic entry by Novopharm began in August 1997. The agreement also resolved patent litigation in other countries.

As the *Financial Times* described the Zantac settlement at the time, "With so much at stake, the fact that Glaxo is having to pay Genpharm to turn it from a competitor into a distributor is money well spent."[47] The settlement attracted no antitrust challenges.

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received antitrust attention from the FTC or private parties. At the time of the settlement, Glaxo described the amount of settlement as "not material," but a $132.5 million payment would not be considered material for a company as large as Glaxo. If Zantac is indeed Drug Product I, then the Zantac settlement, according to the FTC Report, entailed a payment of $132.5 million.

[45] Granutec, a subsidiary of Novopharm, expected $150 to $200 million in sales from a one-month lead (part of the exclusivity period had expired) before other generic firms entered. Sandra Rubin, *Novopharm Gets Zantac Deal*, FIN. POST, Aug. 5, 1997 ("'It's a major coup for us,' said Novopharm chairman Leslie Dan. 'In two weeks we can literally blanket the U.S. market. And history tells us that whoever enters the market first will usually end up as the major supplier of the product for many, many years.'"). Novopharm also paid Glaxo more than $70 million for a related license. *Id.*

[46] It appears that at the time of settlement, Genpharm had no ANDA filed on Form 1. *See* 46 U.S.P.Q.2d 1398 (noting 1996 filing of Genpharm ANDA-IV for Form 1).

[47] *See Soothing Glaxo's Ulcers*, FIN. TIMES, Oct. 24, 1995, at 20.

4. Cipro

Ciprofloxacin, sold by Bayer under the brand name Cipro, is an antibiotic. Cipro was the most widely prescribed quinolone in 1995, with U.S. sales in 1996 of $680 million.[48]

Bayer and first-filer Barr[49] reached agreement in January 1997.[50] Bayer paid Barr $398 million by December 2003: $49.1 million initially, followed by quarterly payments. Although the agreement provided for private label sales along the lines of the tamoxifen agreement, this provision was not implemented. Bayer exercised its option under the agreement to pay cash instead.

As with the tamoxifen agreement, Barr retained potential entitlement to the exclusivity period, without fear of losing it by losing a patent suit. Barr initially changed its Paragraph IV certification to Paragraph III, thereby certifying that it would wait to enter until patent expiration. Yet Barr later reverted to a Paragraph IV certification, and asserted its continued entitlement to the 180-day exclusivity period.

From Bayer's standpoint, the settlement neutralized the first-filer threat. The settlement also created a partial bottleneck, in the sense that Barr's reversion to a paragraph IV assertion limited the prospect for approval of later filers. Barr agreed to wait to enter until December 2003, when the relevant Bayer patent expired.[51]

The Cipro settlement attracted numerous antitrust challenges. Twenty-four class action complaints were consolidated in multidistrict litigation.[52] In 2005, the district court granted summary judgment to defendants. As of March 2007, appeal in the Second Circuit was pending. Defendants have moved that

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[48] *See Bayer Group Reports net earnings of $1.67 bil in 1995, up 21.5% vs 1994*, MED AD NEWS, Sept. 1, 1996 (most widely prescribed qunolone); *Glaxo's $5.8B in Revs Tops List of Drug Makers*, SELECT FEDERAL FILINGS NEWSWIRES, Feb. 14, 1997 (U.S. sales); *see also Cipro Global Sales of the Quinolone Cipro (Ciprofloxacin) Totalled $1.29 Bil in 1996, up 11.1% vs 1995*, MED AD NEWS, May 1, 1997 (worldwide sales of $1.29 billion).

[49] Barr recruited generic firm Rugby to share in the costs and profits of the litigation. Rugby was a subsidiary of Hoechst Marion Roussel at the time of the agreement, but was subsequently purchased by generic firm Watson.

[50] In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 519-20 (E.D.N.Y. 2005).

[51] U.S. Patent No. 4,670,444.

[52] *See id.*; notice of appeal filed, Nos. 05-2851, -2852 (2d Cir. June 7, 2005).

the litigation be transferred to the Federal Circuit, possibly because the Federal Circuit takes a relatively skeptical approach toward antitrust claims against patentees.

In addition, state court suits are pending in California (nine complaints), Florida (one), Kansas (one), New York (two), and Wisconsin (one).[53] In the Wisconsin case, oral argument in state supreme court was scheduled for December 2006.[54] In California and Kansas, litigation has been stayed pending resolution of the federal multidistrict litigation.

5. K-Dur

Potassium chloride in an extended-release form, sold by Schering-Plough under the brand name K-Dur, is a replacement for electrolytes lost from the body as a side effect of certain antihypertension drugs. U.S. sales of K-Dur in 1997, the year of settlement, totaled $190 million.[55]

Schering and first-filer Upsher-Smith reached agreement in June 1997.[56] Schering agreed to pay Upsher $60 million. Upsher retained eligibility for the exclusivity period and the expectation of enjoying it upon entry, without fear of losing it by losing a patent suit.

From Schering's standpoint, the settlement neutralized the first-filer threat. The settlement also created a bottleneck. Schering also received licenses to five Upsher products, including Niacor, a sustained-release niacin product. This grant was described as the basis for Schering's cash payment. Schering also agreed to pay milestone royalty payments and a percentage royalty on sales, but the project came to nothing and these payments were never made. Upsher agreed to wait to enter until September 2001, later than the likely entry date if Upsher had won but earlier than the expiration of the relevant patent in September 2006.[57] Upsher agreed to delay marketing not only the particular

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[53] *See* Barr Pharmaceuticals 10-Q, *supra* note 2.

[54] The issue in Wisconsin supreme court, Meyers v. Bayer AG, No. 03AP2840, is the scope of Wisconsin's state antitrust law.

[55] According to Schering's internal estimate. See In re Schering-Plough Corp., No. 9297, 2003 WL 22989651, Part II.B.2 (F.T.C. Dec. 8, 2003) (reporting Schering estimate for 1997, made in June 1997).

[56] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1059-60 (11th Cir. 2005).

[57] U.S. Patent No. 4,863,743.

drug at issue, but also any other "microencapsulated" extended release potassium chloride product.[58]

Schering and later filer ESI Lederle[59] reached agreement in January 1998.[60] Schering agreed to pay ESI $30 million, including a $5 million noncontingent payment, $10 million payment contingent on approval of ESI's generic product, and an additional $15 million for certain licenses. Exclusivity was not an issue because as a later filer, ESI had no eligibility. Schering also received licenses from ESI pertaining to generic enalpril and buspirone, grants described as the basis for some (but not all) of Schering's cash payments. ESI agreed to wait to enter until January 2004, later than the likely entry date if ESI had won the suit but (as with Upsher) earlier than the expiration of the relevant patent in September 2006.

The K-Dur settlements attracted several challenges. ESI entered a consent decree with the FTC in 2002.[61] Upsher chose to fight rather than settle with the FTC, and in 2003 the Commission concluded that defendants had violated antitrust law.[62] In 2005, the Eleventh Circuit set aside the Commission decision and vacated its cease and desist order,[63] and the Supreme court denied the FTC's petition for certiorari.

In addition, private antitrust suits have been consolidated as multidistrict litigation in a New Jersey district court. In 2004, the district court denied a motion to dismiss.[64]

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[58] The relevant agreement term stated: "Upsher-Smith agrees that it will not market in the United States its KLOR CON® M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." *See Schering*, 2003 WL 22989651, Part IV.A. Upsher-Smith contested this interpretation of the clause. *See* Upsher-Smith's Memorandum Addressing Complaint Counsel's Citations To The July 2002 FTC Study (filed Jan. 27, 2003) (link).

[59] ESI was owned by American Home Products Corp.

[60] *Schering*, 402 F.3d at 1060-61. Schering and ESI reached agreement in January 1998. The final agreement was dated June 1998.

[61] FTC, Agreement Containing Consent Order, Apr. 2, 2002 (link).

[62] *See Schering*, 2003 WL 22989651 (F.T.C. Dec. 8, 2003).

[63] *Schering*, 402 F.3d 1056.

[64] *In re* K-Dur Antitrust Litig., 338 F. Supp. 2d 517 (D.N.J. 2004).

6. Naprelan

Naproxen sodium, sold by Elan under the brand name Naprelan, is a non-steroidal drug used to manage pain, fever, and inflammation. U.S. sales of Naprelan in 1999, the year of the settlement, were $59 million.[65]

Elan and first-filer SkyePharma reached agreement in May 1999, the details of which are difficult to discern from publicly available information. Elan granted SkyePharma the right to manufacture, possibly under Elan's NDA. So far as appears, SkyePharma retained entitlement to the exclusivity period, without fear of losing it by losing a patent suit.[66]

From Elan's perspective, the settlement removed a first-filer threat, and appears to create a bottleneck. Terms of entry are unclear.

The Naprelan settlement has attracted several challenges. Generic competitor Andrx filed an antitrust suit in 2001.[67] In 2005, the Eleventh Circuit reversed the district court's dismissal, and the case remains pending on remand. A purchaser suit was filed in 2002 in the Eastern District of Pennsylvania, where it has remained on the suspense docket pending the outcome of the Florida case.[68]

7. Procardia XL

Nifedipine in an extended-release form, sold by Pfizer under the brand name Procardia XL, is a medication to reduce blood pressure and manage angina. U.S. sales of Procardia XL in 2000, the year of settlement, were $311 million.[69]

Pfizer and first filer Mylan reached agreement in February 2000. Pfizer granted Mylan a license to sell a private-label version of Procardia XL supplied

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[65] Elan Corporation, PLC, 2000 Annual Report, at 21 (link) (reporting U.S. Naprelan revenue for 2000 and 1999). U.S. sales in 2000 were $42 million.

[66] Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1231 (11th Cir. 2005).

[67] *See* SkyePharma PLC, Annual Report (Form 20-F) (June 24, 2006) (link) (reporting Andrx suit); *Andrx*, 421 F.3d 1227 (reversing district court's dismissal). The docket in the Southern District of Florida is No. 03-13605.

[68] *See* Action Alliance of Senior Citizens of Greater Phila. v. Elan Corp., No. 02-cv-2095 2003 WL 22358451 (E.D. Pa. Sept. 5, 2003).

[69] *See* Pfizer Inc., Consolidated Statement of Income, Jan. 24, 2001. U.S. sales in 1999 were $510 million.

by Pfizer. The license covered not only the 30 milligram dosage for which Mylan was the first filer, but also 60 and 90 milligram forms. It is not clear to what extent the private-label sales provided compensation to Mylan. Likely Mylan also had but declined the option, instead of private label sales, of a patent license agreement with a royalty on net sales.[70] So far as appears, Mylan retained entitlement to the exclusivity period, without fear of losing it by losing a patent suit. From Pfizer's perspective, the settlement removed the first-filer threat and created a bottleneck.

The Procardia XL settlement attracted several challenges. Competitor generic firm Mylan filed an antitrust suit, complaining in part of the bottleneck.[71] After the district court denied a motion to dismiss, Pfizer paid $9 million to settle the case. A set of purchaser suits were consolidated in a West Virginia district court.[72] After the district court denied class status in 2004, a settlement was reached dismissing some cases.[73]

B. Incomplete settlements

In the settlements in this section, the first-filing generic firm received no assurance of being able to enjoy the exclusivity period. The first two settlements, Cardizem CD and Hytrin, are interim settlements in which the innovator secured a delay in the first filing generic firm's entry pending resolution of the underlying patent dispute. (A second settlement involving Hytrin is not an interim agreement, but is included here for simplicity.) The third settlement, involving Prozac, resolved some but not all of the claims at issue.

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[70] The basis for this conclusion is that Procardia XL is likely the second "supply agreement" on p. 30 of the 2002 FTC study. As with Procardia XL, the supply agreement described by the FTC involved a drug with sales between $250 million and $500 million; was reached ten years, nine months before patent expiration (compare the February 2000 Procardia agreement and U.S. Patent No. 5,264,446, which expires in November 2010); took the form of an exclusive distribution deal; and covered strengths on which the generic firm had not filed an ANDA. If this analysis is correct, then, according to the FTC report, Mylan had but declined the option of choosing a patent license agreement with a royalty on net sales, instead of private label sales.

[71] Biovail Corp. v. Mylan Labs., Inc., No. 1:01CV66, 2002 U.S. Dist. LEXIS 6726 (N.D. W. Va. Mar. 22, 2002); Biovail Corporation Earnings Conference Call, July 29, 2003 (reporting $9 million settlement).

[72] Pfizer Inc., Quarterly Report (Form 10-Q) (Aug. 14, 2001) (noting Great Lakes Health Plan suit filed June 4, 2001, in E.D. Michigan); Pfizer, Quarterly Report (Form 10-Q) (May 15, 2002) (noting pendency of five suits in West Virginia district court).

[73] *See* Docket No. 01-cv-106 (N.D. W. Va.), Doc. 164 (filed Mar. 18, 2004) (denying class status); Doc. 169 (Apr. 2004) (settlement and dismissal as to Great Lakes Health Plan and Lotz).

1. Cardizem CD

Diltiazem hydrochloride in a controlled-release form, sold by Hoescht Marion Roussel under the brand name Cardizem CD, is a widely prescribed medication for hypertension.[74] U.S. sales of Cardizem CD in 1997, the year of settlement, were $692 million.[75]

Hoescht and first-filer Andrx[76] reached agreement in September 1997.[77] Hoescht agreed to pay Andrx $10 million per quarter, plus an additional $60 million per year if Hoescht lost the patent suit. Total payments equaled $89.83 million. As for the exclusivity period, Andrx retained its exclusivity entitlement, and agreed not to give it up. But the settlement did not provide relief from the prospect of losing the patent suit, which continued.

From Hoescht's standpoint, the "interim" agreement removed the risk that Andrx would launch immediately upon receiving FDA approval, though it did not resolve the patent suit. The settlement also created a bottleneck, since later ANDA-IV filers could not receive FDA approval until 180 days after entry of a first filer with exclusivity eligibility. Andrx agreed to delay marketing not only the particular drug at issue, but also other noninfringing products.

The Cardizem CD settlement attracted several challenges. An FTC consent decree was entered in 2001.[78] Generic competitor Biovail filed an antitrust suit, and after the D.C. Circuit denied dismissal in 2001, the parties settled in 2002.[79] Litigation by purchasers yielded several large settlements—$110 million for direct purchasers and $80 million for indirect purchasers and state attorneys general—and in 2003, the Sixth Circuit condemned the settlement as a violation of antitrust law.[80]

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[74] Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 803 (D.C. Cir. 2001).

[75] *1999: A Pivotal Year for Generics Pricing*, DRUG STORE NEWS, Feb. 15, 1999 (reporting U.S. sales of $691.7 million).

[76] Andrx is now part of Watson Pharmaceuticals.

[77] *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

[78] In re Hoechst Marion Roussel, Inc., No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001).

[79] *Andrx*, 256 F.3d 799; Andrx Corp., Annual Report (Form 10-K), at 5 (Mar. 31, 2003) (reporting July 2002 settlement with Biovail).

[80] In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Corp., Current Report (Form 8-K) (Oct. 31, 2002), Exh. 99.1, "Andrx Corporation Reports Financial Results for the Third Quarter of 2002." (direct purchaser settlement); Press Release, Office of the Att'y Gen., Attorney General Lockyer Announces $80 Million Settlement of Antitrust Case Against Drug Makers for Limiting Access to Generic Heart Medication (Jan. 27, 2003) (link) (indirect purchaser

2. Hytrin

Terazozin hydrochloride, sold by Abbott under the brand name Hytrin, is an antihypertension drug used to treat high blood pressure. U.S. sales of Hytrin in 1998, the year of settlement, were $542 million.[81]

To understand the settlement that resulted, it is necessary to review briefly the underlying patent suit. Two forms of terazosin hydrochloride, dihydrate and "Form IV" anhydrous, and two patents, are particularly relevant. Dihydrate was the form used by Abbott in Hytrin, protected by a patent expiring in February 2000.[82] Generic firm Geneva proposed to make a bioequivalent Form IV product, which would not infringe the dihydrate patent but would infringe a patent on Form IV not scheduled to expire until October 2014.[83] Geneva acknowledged infringement of the Form IV patent but argued, ultimately successfully, that this patent was invalid.

Abbott and first-filer Geneva reached agreement in April 1998.[84] Abbott agreed to make payments of up to $101 million. The formula was to pay $4.5 million per month until a district court judgment. If the generic firm won in district court, $4.5 million per month would go into escrow during appeal, payable if Geneva won. The agreement was scheduled to end at the earliest of the invalidation of the Form IV patent, another generic firm's entry, and February 17, 2000.[85] The latter date was the expiration of the *dihydrate* patent, not directly relevant to the litigation.[86] As for the 180-day exclusivity period, Geneva

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settlement). According to the release, $21 million was allocated to individual consumers, $4.5 million to state agencies, $15.6 million to plaintiffs' counsel, $2.5 million to state attorneys-general, and an additional sum to health plans.

[81] *See In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000).

[82] U.S. Patent No. 4,215,532.

[83] U.S. Patent No. 5,504,207. The description in text is of claim 4. The patent also claims making terazosin HCl dihydrate using Form IV as an intermediary.

[84] *See* In re Terazosin Hydrochloride Antitrust Litigation, 164 F. Supp. 2d 1340 (S.D. Fla. 2000); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).

[85] $4.5 million per month, applied to nine months of 1998, twelve months of 1999, and 1.61 months of 2000.

[86] The inclusion of the '532 dihydrate patent's expiration as a settlement term is initially puzzling, since this patent was not directly relevant to the ongoing dispute. A possible explanation is that Abbott understood that the last possible moment for exclusive Hytrin sales was February 2000—that after the '207 patent expired, generic firms would be free to sell a dihydrate version. The parties may have concluded that an expiration date for the agreement that extended beyond that point would raise an antitrust risk.

retained its exclusivity entitlement, and agreed not to give it up. But the settlement apparently did not provide relief from the prospect of losing the patent suit, which continued.

From Abbott's standpoint, the "interim" agreement removed the risk that Geneva would launch immediately upon receiving FDA approval—and even if Geneva won in the district court, during the pendency of appeal—though it did not resolve the patent suit. The settlement also created a bottleneck. Geneva agreed to delay marketing not only the particular drug at issue, but all terazosin hydrochloride products, even if noninfringing.

Abbott and later filer Zenith[87] reached agreement in March 1998.[88] Abbott agreed to pay Zenith up to slightly more than $45 million. The formula was $3 million up front, $3 million in the second quarter of 1998, $6 million per quarter for the last two quarters of 1999 and throughout 2000, and slightly more than $3 million for the prorated period between January 1 and February 17, 2000. (As with the Abbot-Geneva agreement, the latest end to the agreement was the expiration of the dihydrate patent.) If a generic firm entered, the payments would cease, except for $3 million per quarter during another firm's exclusivity period. Exclusivity was not an issue because as a later filer, Zenith had no eligibility. Unlike the Geneva agreement, this was a final agreement. Zenith agreed to enter no earlier than in February 2000, and to delay marketing of all terazosin hydrochloride products, even if noninfringing.

The Hytrin settlements have attracted several challenges. The FTC reached a consent decree as to the Abbott-Geneva agreement in 2000, apparently having taken no action with respect to the Zenith agreement.[89] A variety of antitrust suits were consolidated in multidistrict litigation.[90] Zenith reached a settlement. In 2003, the Eleventh Circuit ruled that the district court's conclusion of per se illegality as to the Geneva agreement had been "premature." The plaintiffs subsequently narrowed their case to the "appellate stay" period of the

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[87] Zenith became part of Ivax, which is now part of Teva.

[88] *See* Abbott-Zenith Hytrin Agreement, *supra* note 22; *Terazosin*, 164 F. Supp. 2d 1340; *Valley Drug*, 344 F.3d at 1300 (noting expiration in March 1, 2000).

[89] *In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (Geneva); *In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3946, 2000 WL 681849 (F.T.C. May 22, 2000) (same); *See* Ivax Corp., Annual Report (Form 10-K) (Mar. 30, 2000) (link) (noting FTC complaint against Abbott and Geneva but none against Zenith).

[90] *Valley Drug*, 344 F.3d 1294; In re Terazosin Hydrochloride Antitrust Litigation, 352 F. Supp. 2d 1279, 1286 (S.D. Fla. 2005). The docket number in the Southern District of Florida is 99-MDL-1317.

settlement, which prohibited entry during the pendency of the patent appeal—that is, after the district court's invalidation of the patent in September 1998, and before the Federal Circuit's affirmance in August 1999. On remand, the district court concluded that the appellate stay component violated antitrust law, and entered summary judgment for defendants. Most plaintiffs in the MDL litigation settled.[91]

One case that did not settle, brought by Kaiser Foundation Health Plan, returned to the Central District of California upon its release from MDL. In 2006, after a trial, the jury returned a verdict for defendants. Appeal in the Ninth Circuit is pending.[92]

3. Prozac

Fluoxetine hydrochloride, sold by Eli Lilly and Company under the brand name Prozac, is an antidepressant. U.S. sales of Prozac in 1999, the year of the settlement, were $2.09 billion.[93]

Two patents are particularly relevant to the subsequent settlement: the compound patent, which expired in August 2001,[94] and a follow-on patent on Prozac's administration to prohibit serotonin uptake, scheduled for expiration in June 2004.[95] Generic firms Barr and Geneva were each first to file on different strengths.[96] Lilly sued, and the district court ruled in favor of Lilly on two invalidity issues, obviousness-type double patenting and best mode. That left several other claims to resolve at trial.

In January 1999, on the eve of trial, Lilly reached agreement with Barr and Geneva as to the remaining claims.[97] Lilly paid Barr and Geneva $4 million in

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[91] The amount of settlement was reportedly $30,700,000. See Cafferty, supra, at 4.

[92] *See* Jury Verdict, Kaiser Found. v. Abbott Labs., No. 2:02cv2443 (C.D. Cal. Apr. 4, 2006). The Ninth Circuit appeal is docketed as Nos. 06-55687 and 06-55748. *See, e.g.*, Brief of Appellant, *Abbott Labs.* (Nov. 14, 2006), 2006 WL 3889913 (appellant's principal brief).

[93] Eli Lilly and Co., Annual Report (Form 10-K) (Mar. 30, 2000) (link).

[94] U.S. Patent No. 4,314,081. The August 2001 figure in text reflects pediatric extension. The focus was claim 5.

[95] U.S. Patent No. 4,626,549. The June 2004 figure in text reflects pediatric extension. The focus here was claim 7.

[96] Barr on 20 mg, Geneva, part of Novartis, on 10 mg. See Letter from FDA to Geneva Pharmaceuticals re: ANDA 75-049 (Aug. 2, 2001) (link).

[97] *See* David J. Morrow, *Lilly and 3 Rivals to Settle Prozac Suit for $4 Million*, N.Y. TIMES, Jan. 26, 1999, at C2; Eli Lilly and Co., Quarterly Report (Form 10-Q) (Nov. 14, 2000) (link); *Prozac, Eli*

total. By giving up the remaining claims, the generic firms appealed more rapidly the adverse summary judgment ruling. Lilly, for its part, avoided a trial on the claims, and avoided the prospect of a launch at risk upon the expiration of the automatic stay.

In May 2001, the Federal Circuit ruled the follow-on patent invalid.[98] Barr and Geneva entered in August 2001, upon expiration of the compound patent, each with exclusivity for different strengths.

IV. Second-wave settlements

This Part describes settlements in ten drugs reached since March 2004. For settlements involving seven drugs, the 180-day generic exclusivity period is potentially relevant. For three other drugs, exclusivity is not an issue because no generic filer has potential eligibility.

A. Settlements implicating exclusivity

1. Niaspan

Niacin in an extended-release form, sold by Kos[99] under the brand name Niaspan, is a medicine to manage cholesterol, primarily by raising HDL ("good") cholesterol. U.S. sales of Niaspan in 2005, the year of settlement, were $380 million.[100]

To understand the settlement that resulted, it is necessary to review briefly the underlying patent suit.[101] Two patents expiring in 2013 and 2017,

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Lilly and Co., MED AD NEWS, Mar. 1, 1999. See also Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007) (statement of Bruce Downey, Chairman and CEO of Barr Pharmaceuticals) (discussing the settlement). (The prepared testimony (link) does not discuss the payment.)

[98] A panel of the Federal Circuit initially reached this conclusion in August 2000, but that ruling was vacated and replaced with a second opinion reaching the same conclusion. *See* Eli Lilly & Co. v. Barr Labs., 222 F.3d 973 (Fed. Cir. 2000); 251 F.3d 955 (Fed. Cir. 2001).

[99] Kos is now part of Abbott.

[100] *See* www.drugs.com/top200.html (U.S. sales in 2005); see also Kos Pharmaceuticals, Annual Report (Form 10-K) (Mar. 16, 2006) (worldwide sales in 2005 of $435 million); Q4 Abbott Laboratories Earnings Conference Call, Jan. 24, 2007 (worldwide sales in 2006 of about $500 million).

[101] *See* Kos Pharmaceuticals, Quarterly Report (Form 10-Q) (Nov. 9, 2004) (link).

respectively, cover the product.[102] Barr filed an ANDA-IV with respect to these patents, and Kos sued. As new Kos patents issued beyond these two, Barr added new paragraph IV certifications to its ANDA, and Kos filed additional patent infringement suits in New York district court. The automatic stay was scheduled for expiration on March 30, 2005, whereupon Barr would be free to launch at risk. The trial was expected to occur in early 2006.

The challenged patents also protected Advicor, a second product marketed by Kos. Advicor is a tablet containing a mixture of Niaspan and lovastatin, a drug that lowers LDL ("bad") cholesterol. Worldwide sales of Advicor in 2005 were $116 million.[103]

Kos and first-filer Barr reached agreement in April 2005.[104] Kos agreed to pay Barr an undisclosed amount, described as compensation for helping to promote the drug. Kos also agreed to make payments initially and quarterly, described as compensation for manufacturing services. So far as appears, Barr retained entitlement to the exclusivity period, without fear of losing it by losing a patent suit.

From Kos's standpoint, the settlement neutralized the first filer and created a bottleneck. Under the agreement, Barr is scheduled to launch generic versions of Niaspan and Advicor, including line extensions, in September 2013, approximately four years earlier than the latest-expiring patent. Barr also agreed to co-promote Niaspan and Advicor (and line extensions) to obstetricians and gynecologists, to "stand ready" to produce Niaspan and Advicor for Kos, and (in exchange for additional payments) to actually produce the product if Kos wishes.

2. Effexor XR

Venlafaxine hydrochloride in an extended-release form, sold by Wyeth under the brand name Effexor XR, is an antidepressant. U.S. sales of 2005 of both Effexor XR and Effexor were $2.275 billion.[105]

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[102] U.S. Patent No. 6,080,428; U.S. Patent No. 6,129,930.

[103] *See Abbott Laboratories: Kos Pharmaceuticals a Wise Buy,* PHARMACEUTICAL BUSINESS REVIEW, Nov. 8, 2006 (reporting sales of $116 million).

[104] Kos and Barr Announce Definitive Co-Promotion, Manufacturing and Settlement Agreements (Apr. 13, 2005) (link).

[105] The U.S. sales figure is derived from net revenue figures reported by Wyeth: $576,131 in Q1 2005, $579,881 in Q2; $568,865 in Q3, and $550,244 in Q4. *See, e.g.*, Wyeth Q1 2006 Net

Wyeth and first filer Teva reached agreement in December 2005.[106] Wyeth granted Teva an exclusive license to sell Effexor starting in June 2006. This is a potentially lucrative source of compensation for a generic firm, depending upon the price of the license. (Teva must pay royalties, but their size is not disclosed.) Teva retained entitlement to the exclusivity period, without fear of losing it by losing a patent suit.

From Wyeth's standpoint, the settlement neutralized the first filer and created a bottleneck. Teva agreed to enter as to Effexor XR in July 2010. That date is later than entry if a generic firm won a patent challenge, but earlier than the expiration of Wyeth patents on extended-release formulations of venlafaxine HCl. (Teva did not challenge the compound patent, which expires in June 2008.)

3. Provigil

Modafinil, sold by Cephalon under the brand name Provigil, is a stimulant, "the first in a new class of wake-promoting agents."[107] U.S. sales in 2005 and 2006, during which the settlements were reached, were $476 million and $685 million, respectively.[108]

Cephalon reached agreement with four first filers in late 2005 and early 2006: Teva, Ranbaxy, Mylan, and Barr. Cephalon agreed to pay up to $136 million to Barr, Ranbaxy, and Teva, described as compensation for modafinil-related intellectual property. This compensation takes the form of upfront fees,

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Revenue Report (link) (reporting Q1 2005). See also Wyeth Pharmaceuticals, Wyeth Reports Earnings Results for the 2005 Fourth Quarter and Full Year, Jan. 31, 2006 (link) (reporting worldwide sales for both products of $3.5 billion).

[106] Wyeth Pharmaceuticals, Current Report (Form 8-K) (Jan. 13, 2006) (describing terms). Teva retains entitlement to the 180-day exclusivity period upon its entry in July 2010. *See* Event Brief of Q3 2005 Teva Pharmaceutical Earnings Conference Call, Nov. 8, 2005 (Teva taking view that it retains eligibility for the exclusivity period).

Agreement on principal terms was announced in October 2005. Agreement was actually reached in December 2005, and became "final" in January 2006. Press Release, Teva Pharmaceutical Industries, Ltd., Teva and Wyeth Announce Settlement of Effexor XR Litigation (Oct. 18, 2005) (link) (describing principal terms); Wyeth 2005 Financial Report (link) (noting date of actual agreement).

[107] Cephalon, *What is Provigil?* (link).

[108] Cephalon Reports Outstanding Financial Results for 2005, PR Newswire, Feb. 14, 2006 (reporting 2005 sales of $475,557); Milena Izmirlieva, *Cephalon's 2006 Revenues Jump 46% on Strong Provigil Sales*, GLOBAL INSIGHT DAILY ANALYSIS, Feb. 13, 2007 (reporting 2006 results).

royalties, and milestone payments.[109] Cephalon also agreed to pay $82.6 million for materials, beginning in 2006 and lasting for six years, to three unnamed "modafinil suppliers." The announcements of agreements with Teva and Ranbaxy explicitly mention supply agreements; likely they are two of the three suppliers. The agreement with Barr includes purchase of inventory, but it is unclear whether this is Cephalon's third supply agreement. The descriptions below assume that Teva, Ranbaxy, and Barr are the three suppliers. If the three suppliers are correctly identified, then Barr, Ranbaxy, and Teva share in payments of up to $218.6 million. In addition to these three agreements, Cephalon settled with Mylan, as described below. After these settlements, Cephalon's CEO stated that thanks to the agreements, "we were able to get six more years of patent protection. That's $4 billion in sales that no one had expected."[110]

The four settlements share certain features. The generic firm receives cash, described as consideration for value other than delay. The generic firm retains shared entitlement to the exclusivity period, without fear of losing it by losing a patent suit. From Cephalon's standpoint, the settlement neutralizes the first filer and creates a bottleneck (as to later firms, not the other first filers). The generic firm agrees to enter as of October 2011, or six months later if Cephalon secures a six-month pediatric extension. That date is later than entry if a generic firm won a patent challenge, but earlier than the October 2014 expiration of the patent at issue.[111]

Cephalon reached agreement with Teva in December 2005.[112] In that settlement, the cash is described as consideration for modafinil-related intellectual property and "certain arrangements . . . related to Teva's manufacture and supply" of modafinil to Cephalon. Cephalon also reached agreement with Ranbaxy in December 2005.[113] The visible terms are identical, with the omission of a manufacturing component; intellectual property and

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[109] Cephalon, Quarterly Report (Form 10-Q) (May 10, 2006) (link); Cephalon, Annual Report (Form 10-K) (Mar. 13, 2006).

[110] John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, Mar. 17, 2006.

[111] U.S. Patent No. RE37,516 (with pediatric extension, April 2015).

[112] Teva Announces Agreement with Cephalon Regarding Settlement of PROVIGIL Patent Litigation; Parties Also Agree to Business Arrangements Related to Modafinil, Business Wire, Dec. 9, 2005.

[113] Cephalon, Inc. Announces Agreement with Ranbaxy Laboratories Limited Regarding Settlement of PROVIGIL(R) Patent Litigation, Dec. 22, 2005 (link).

supply "certain arrangements . . . related to Ranbaxy's supply" are described as consideration for payment.

Cephalon reached agreement with Mylan in January 2006.[114] The agreement apparently includes no intellectual property licenses or supply agreement.[115] Instead, Mylan will receive payments (distinct from the payments described above) as part of certain product development collaboration agreements.[116]

Cephalon reached agreement with Barr in February 2006. In that settlement, the cash is described as consideration for intellectual property licenses and inventory. The agreement also addressed litigation between Cephalon and Barr over Actiq, an important antipain medication sold by Cephalon. The overall agreement expanded Barr's existing license to sell generic Actiq under very specific circumstances. It may also have granted Barr a fraction of Cephalon sales on an unrelated next-generation pain medication of Cephalon's. See Part IV.A.4 *infra*.

Cephalon also reached agreement with a later filer, Carlsbad, in August 2006. That agreement provided for entry in April 2012. Other terms have not been disclosed.

The Provigil settlements have attracted several challenges. The FTC requested information about the settlements in March 2006 and requested additional information in July 2006.[117] A purchaser suit was filed in Pennsylvania district court in April 2006.[118] Competitor Apotex also filed an

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[114] Cephalon, Inc. Announces Agreement with Mylan Pharmaceuticals Inc. Regarding Settlement of PROVIGIL(R) Patent Litigation, Jan. 10, 2006 (link) (making no mention of intellectual property or supply agreements).

[115] Cephalon's announced list of modafinil IP providers includes Teva, Ranbaxy, and Barr, but omits Mylan, and the announcements of the Mylan agreement omitted mention of intellectual property or supply.

[116] Cephalon Inc., Current Report (Form 8-K), at 2 (Jan. 9, 2006) (noting that parties had "entered into two product development collaboration agreements under which the companies will explore utilizing Mylan Technologies Inc.'s transdermal technology to address pain and certain central nervous system disorders. Under the arrangements, Cephalon will have an option to develop and commercialize the products in exchange for payment of milestones and ongoing royalties based on net sales of the products.").

[117] *See* Kristina Henderson, *Cephalon: FTC Seeks Info on Provigil Agreement*, DOW JONES CORP. FILINGS ALERT, July 13, 2006; Cephalon Inc., Current Report (Form 8-K) (July 13, 2006) (link) (reporting FTC's request for additional information).

[118] In re Modafinil Antitrust Litigation, No. 06-cv-01797 (E.D. Pa. Apr. 27, 2006).

antitrust suit, alleging that the bottleneck has blocked it from approval of its ANDA.

4. Actiq

Oral transmucosal fentanyl citrate, sold by Cephalon under the brand name Actiq, is a pain reliever delivered as a "lollipop," a lozenge attached to a handle. U.S. sales of Actiq in 2006, the year of settlement, were $545 million.[119]

To understand the resulting settlement, it is helpful to review the underlying patent suit. In August 2004, Cephalon granted Barr a license to market generic Actiq, starting in September 2006. This was due to the FTC's insistence that Cephalon grant a license as a condition for permitting its merger with Cima Labs, a company making a next-generation pain reliever.[120] Under the license, Barr's September 2006 entry would be accelerated if Cephalon received earlier approval of Fentora, its next-generation tablet antipain medication.[121] If Cephalon received a pediatric extension, entry would be pushed back to February 2007.

Notwithstanding the license, Barr filed an ANDA-IV for Actiq in October 2004, and Cephalon received notice in December 2004. Cephalon filed a patent suit in January 2005, triggering the 30-month stay.[122] The patent at issue, however, was set to expire in September 2006,[123] so the practical effect of the patent suit is unclear. At the time of the suit, Cephalon declared that it expected no change in the likely date of market entry.[124] The patent suit was unlikely to be resolved before patent expiration, and without a ruling the automatic stay would remain pending until then. It is possible that Barr thought it might win quickly,

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[119] Press Release, Cephalon Inc., Cephalon Reports Record Sales and Earnings for 2006 (Feb. 12, 2007) (link) (reporting U.S. sales, in thousands, of $475,557 for 2005 and $544,886 for 2006).

[120] *See* Barr Granted Rights to Generic of Cephalon's ACTIQ(R) Cancer Pain Treatments License and Supply Agreement Results from Cephalon, Inc. and CIMA LABS INC. Merger, PR Newswire, Aug. 10, 2004.

[121] In some filings, Fentora is referred to as OraVescent.

[122] *See* Barr Pharmaceuticals Inc., Barr Launches Generic ACTIQ Cancer Pain Management Product, Sept. 27, 2006 (link) (noting October 2004 ANDA-IV filing, December 2004 notification of Cephalon, and January 2005 suit).

[123] U.S. Patent No. 4,863,737. Cephalon Inc. v. Barr Laboratories, No. 05-29 (D. Del.). Document #37 is plaintiffs' opening brief on claim construction for Patent No. 4,863,737.

[124] Press Release, Cephalon Inc., Anticipated Generic ACTIQ Filing Occurs; Cephalon Expects No Change in Barr's Likely Date of Market Entry (Dec. 8, 2004) (link).

and secure early entry protected by exclusivity. A second possibility is that settlement of this suit provided a means for additional compensation from Cephalon to Barr in connection with the simultaneous settlement of Provigil litigation.

Cephalon and first filer Barr reached agreement in February 2006, in conjunction with settlement of the Provigil litigation. Barr secured a license to sell two months earlier, but only under particular circumstances. The change applied only if Cephalon secured pediatric exclusivity for Actiq but did not launch Fentora early. In that case, Barr would be entitled to a license in December 2006 rather than February 2007. This term was never triggered. Instead, Barr began to sell generic Actiq in September 2006 upon the FDA's early approval of Fentora.[125]

It is possible, however, that Barr receives a portion of Fentora sales. And if so, the Actiq litigation and settlement served to provide an additional means for Cephalon to make a payment to Barr. Recall the discussion in Part II.A.4, describing a particular settlement in which the brand-name firm paid royalties on a different version of the drug. The Actiq agreement fits this discussion in important respects, provided that "capsule" is understood to be a reference to the lozenge delivery mechanism of Actiq. As in the FTC account, Cephalon granted Barr a license to an authorized generic of the lozenge form; this lozenge form was the subject of the relevant litigation; Cephalon acquired a new tablet form of the product, that is, Fentora; and later, the parties dismissed the litigation involving the lozenge form. If the match is correct, then it can be inferred from the FTC report that one term of the settlement was for Cephalon to pay Barr a royalty on sales of Fentora.

The Actiq settlement has attracted an FTC investigation.[126]

5. Plavix

Clopidogrel bisulfate, sold by Bristol-Myers Squibb[127] under the brand name Plavix, is an anti-platelet drug used to prevent blood clots and the world's

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[125] Jonathan Goodall, *Barr Challenges Savient's Oxandrin Patents, Launches Generic Actiq*, GLOBAL INSIGHT DAILY ANALYSIS, Sept. 28, 2006.

[126] See Cephalon filing (noting FTC request for "certain information in connection with its review of this settlement").

[127] Sanofi-Aventis owns the '266 patent, and jointly markets Plavix with Bristol in the United States.

second bestselling medicine. U.S. sales in 2005, the year prior to the attempted settlement, were $3.2 billion.[128]

Any agreement between Bristol and first-filer Apotex 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 Bristol. Regulators rejected an initial agreement in March 2006, which led to a May 2006 revised agreement. The May 2006 version was rejected too, and in August 2006, Apotex launched at risk. In three weeks, Apotex flooded the market with more than a billion dollars of generic Plavix before a district judge halted further sales pending resolution of the patent suit.[129]

Upon the launch, certain provisions protecting Apotex took effect. Bristol had accepted a contractual delay in its ability to seek a preliminary injunction if Apotex launched at risk. Bristol also agreed that if Apotex launched a generic product and was later found liable for patent infringement, its damages would be capped at a reduced level.

Other provisions of the agreement never took effect.[130] For example, Bristol had agreed to pay Apotex $40 million, described as compensation for inventory. Apotex retained eligibility for the exclusivity period and the expectation of enjoying it upon entry, without fear of losing it by losing a patent suit. Two other sources of compensation were present in the March agreement, and Apotex alleges (and Bristol denies) that they were unwritten terms of the May revision: a commitment not to launch an authorized generic during Apotex's exclusivity period, and a breakup fee to Apotex if regulators rejected the deal. The breakup fee increased with the degree of delay in the regulators' response.

From Bristol's perspective, the settlement neutralized the first filer and created a bottleneck. Under the May agreement, entry by Apotex was permitted as of April 2011, or June 2011 if Bristol secured a pediatric extension. (Under the

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[128] *See* Val Brickates Kennedy, *Bristol-Myers CFO: Preparing for the Plavix Plunge*, MARKETWATCH, Feb. 14, 2007 (link).

[129] *See* Bristol-Myers Squibb, Annual Report (Form 10-K), at 31 (Feb. 26, 2007) (link) (estimating negative effects from Apotex inventory of $1.2 to $1.4 billion in 2006).

[130] *See* Plavix Agreement, supra note 22; John Carreyrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense of $4 Billion Drug*, WALL ST. J., Sept. 2, 2006; Bethany McLean, *Party Crasher*, FORTUNE, Feb. 5, 2007 (link); Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006) (noting November 2011 expiration of '265 patent).

March agreement, entry was permitted as of March 2011, or September 2011 if BMS secured a six-month pediatric extension.) That date was later than entry if Apotex won its patent challenge, but earlier than the November 2011 expiration of the patent at issue.[131] Apotex also agreed to transfer inventory to Bristol, described as consideration for Bristol's cash payment.

The failed Plavix settlement has attracted several challenges. In 2006, the Department of Justice opened a criminal inquiry into whether Bristol had misrepresented the content of its deal to regulators by omitting mention of the a breakup fee and a no-authorized-generic covenant. Also in 2006, purchasers filed an antitrust suit in an Ohio district court.[132]

6. Adderall XR

Adderall XR is the brand name for a mixture of amphetamine salts in an extended release form, sold by Shire and prescribed to treat attention deficit hyperactivity disorder. Worldwide sales of Adderall XR in 2006, the year of settlement, were $864 million.[133]

Shire and first-filer Barr reached agreement in August 2006.[134] Shire agreed to pay Barr a net amount of up to $102 million. That is, Shire agreed to pay a Barr subsidiary up to $165 million—$25 million immediately and up to $140 million over eight years—described as compensation for product development. And Barr agreed to pay Shire $63 million, described as compensation for transferring Shire's rights to Adderall IR (immediate-release) tablets.

Barr retained exclusivity eligibility without fear of losing it by losing a patent suit. Moreover, during the 180-day exclusivity period, Shire agreed not to compete with Barr through an authorized generic. (Barr will pay Shire a royalty during the exclusivity period; thereafter, the license is nonexclusive and royalty-

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[131] U.S. Patent No. 4,847,265.

[132] *See* Amended Complaint and Demand for Jury Trial, Kroger Co. v. Sanofi-Aventis, No. 06-00163 (S.D. Ohio July 31, 2006), 2006 WL 2503664.

[133] Shire PLC – Final Results, PR Newswire UK Disclose, Feb. 20, 2007 (2006 sales); see also Shire 2005 Annual Report (reporting worldwide sales of $731 million in 2005).

[134] *See* Barr Pharmaceuticals, Barr and Shire Sign Three Agreements (Aug. 14, 2006) (link); Barr Pharmaceuticals 10-Q, *supra* note 2 (discussing agreements); Adderall XR Agreement, *supra* note 22 (setting out, respectively, settlement, product development, and Adderall IR agreements, with some redactions).

free.)[135] Barr also received the rights to Shire's Adderall IR product and to purchase a supply of Adderall IR from Shire. It is unclear whether the deal price of $63 million or transfer price for supply permits significant compensation from Shire to Barr.

From Shire's standpoint, the settlement removed the first filer threat and created a bottleneck. Barr agreed to enter as of April 2009, a date later than if Barr had launched at risk or after winning a patent challenge, and earlier than the expiration of the last-to-expire patent.[136] Shire also received product development pertaining to six proprietary Barr women's health products, described as consideration for the $165 million payment. As to these products, there is also provision for Barr to supply product to Shire, in exchange for additional compensation.

Shire and later filer Impax reached agreement in January 2006.[137] Impax received cash, described as compensation for promotion of another drug. Exclusivity was not an issue because as a later filer, Impax had no eligibility. Impax agreed to enter in January 2010. Shire also received promotion for Carbatrol, a Shire epilepsy drug, described as consideration for the cash payment.

The Shire-Barr agreement has attracted an FTC investigation, opened in October 2006.[138]

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[135] Adderall XR Agreement, *supra* note 22, at Exh. 10.1, License Agreement (appended as "Exhibit A"), clause 3.7 ("Shire has not granted and will not grant a license . . . [or] other arrangement that allows any Third Party to market a Generic Equivalent before (i) the License Effective Date or (ii) the expiration of 180 days following Barr's launch of a Generic Product, [redacted]"); Event Brief of Q4 2006 Barr Pharmaceuticals, Inc. Earnings Conference Call, Aug. 15, 2006 (noting the no-authorized-generic provision).

[136] The patents at issue were 6,322,819 (expiring Oct. 2018), 6,605,300 (expiring Oct. 2018), and 6,913,768 (issued July 5, 2005, expiring Jan. 2023). See Shire, Annual Report (Form 10-K), at 20 (Mar. 1, 2007) (link). The '819 and '300 patents are listed in the Orange Book, but not the '768 patent. The press release described entry as nine years earlier than the last-to-expire patents in the Orange Book.

[137] *Shire, Impax Settle Adderall XR Lawsuits; Barr Still in Talks*, GENERIC LINE, Jan. 25, 2006.

[138] *See Barr Pharm: FTC Probing Shire Settlement Over Adderall XR*, DOW JONES CORPORATE FILINGS ALERT, Nov. 10, 2006; Barr Pharmaceuticals 10-Q, *supra* note 2 (reporting Oct. 3, 2006 notification by FTC of investigation).

7. AndroGel

Testosterone gel 1%, sold by Solvay under the brand name AndroGel, is a male hormone used in hormone replacement therapy. U.S. sales of AndroGel in 2005, the year before settlement, were about $330 million.[139]

Solvay[140] and first-filer Watson reached agreement in September 2006.[141] Solvay agreed to pay Watson an undisclosed amount, described as compensation for promotion. Watson forfeited its 180-day entitlement, but may expect to have 180 days of duopoly nevertheless: its licensed entry date is 180 days earlier than generic firm Par's entry date.[142]

From Solvay's standpoint, the settlement neutralizes the first filer, though it does not create a bottleneck thanks to the forfeiture. Aside from agreeing to enter in August 2015, Watson agreed to promote AndroGel to urologists.

Solvay and later filer Par[143] reached agreement in September 2006.[144] Solvay agreed to pay Par $60 million—$10 million per year for six years, paid quarterly—described as compensation for co-promotion. Solvay also entered a "backup" manufacturing deal, which may be a source of additional compensation. Par agreed to entry in February 2016. Par agreed to provide backup manufacturing services and, like Watson, to promote AndroGel.

B. Settlements not implicating exclusivity

For the three drugs in this section, no generic filer had potential eligibility to the exclusivity period, either because there was no patent for the first filer to challenge, as with Ovcon 35, or because the particular procedure used for innovator approval did not allow for it, as with Biaxin XL, or because the generic

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[139] *See* Watson Pharmaceuticals Receives FDA Approval for Testosterone Gel Product, PR Newswire, Jan. 30, 2006 (relying upon IMS Health figures).

[140] The agreements are with Unimed, a subsidiary of Solvay.

[141] *Solvay Settles Dispute with Par, Watson*, ASSOCIATED PRESS, Sept. 13, 2006; Watson and Unimed Pharmaceuticals, Inc. Settle Lawsuit Over AndroGel Testosterone Gel, Sept. 13, 2006 (notes forfeiture); Par Pharmaceutical Announces Agreement with Unimed Pharmaceuticals to Settle Androgel Patent Litigation.

[142] Compare August 31, 2015 and February 26, 2016.

[143] Par paid generic firm Paddock $6 million for rights to the ANDA of Paddock, another generic firm.

[144] Press Release, Unimed Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc. Settles AndroGel Litigation with Watson Pharmaceuticals, Inc. and Paddock Laboratories/Par Pharmaceutical Companies, Inc. (Sept. 13, 2006) (link).

firm used a procedure that does not provide for an exclusivity period, as with Alphagan.

1. Ovcon 35

Norethindrone and ethinyl estradiol, sold by Warner Chilcott[145] under the brand name Ovcon 35, is an oral contraceptive. Worldwide sales of Ovcon 35 in 2004, the year of settlement, were $71.5 million.[146]

Warner Chilcott and Barr reached agreement in March 2004.[147] Warner Chilcott agreed to pay Barr $20 million. No exclusivity period was at issue because Ovcon 35 is not protected by a patent. The major benefit to Warner Chilcott was that Barr agreed not to enter the market until May 2009.[148] Barr agreed to serve as a second supplier, in exchange for additional compensation.

The Ovcon 35 settlement has attracted several antitrust challenges. The FTC filed a complaint in 2005, leading to a settlement with Warner Chilcott and Barr's entry in 2006. Barr remained in the case, and in 2007 the district court denied Barr's motion to dismiss.[149] In addition, state attorneys general have brought suit, and eight private class action suits are pending.[150]

2. Alphagan

Brimonidine tartrate 0.15% ophthalmic solution, sold by Allergan under the brand name Alphagan, is a medication to treat glaucoma by lowering

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[145] Warner Chilcott was previously known as Galen Holdings PLC.

[146] For twelve months ending September 2004. See Complaint at 8, FTC v. Warner Chilcott Holdings Co. III, Ltd., 2006 WL 3302862 (D.D.C. 2006) (No. 1:05-cv-02179-CKK) (link) (noting $71.5 million in sales but not making explicit whether U.S. or worldwide); Warner Chilcott PLC Announces Strong Results for the Fourth Quarter Ended 30 September 2004, PR Newswire, Oct. 27, 2004 (noting total Ovcon sales, presumably including non-U.S. sales, of $71.5 million).

[147] Agreement reached in principle in September 2003. *See* Barr Pharmaceuticals 10-Q, *supra* note 2.

[148] According to the FTC complaint, the agreement was to not enter for five years. But the same document elsewhere describes a May 2009 entry date.

[149] FTC complaint, Dec. 2005 (link); Press Release, FTC, Consumers Win as FTC Action Results in Generic Ovcon Launch (Oct. 24, 2006) (link) (announcing generic launch after FTC settlement with Warner Chilcott); FTC v. Warner Chilcott Holdings Company III, Ltd., 2007 WL 158746 (D.D.C. Jan. 22, 2007) (denying motion to dismiss).

[150] *See* Barr Pharmaceuticals 10-Q, *supra* note 2.

intraocular pressure. U.S. sales in 2006 were around $200 million for Alphagan and related businesses.[151]

Two patent suits are relevant to the subsequent settlement.[152] In April 2004, Alcon filed a paper NDA with a paragraph IV certification. In August 2004, Allergan filed suit in the District of Delaware, asserting two patents against Alcon.[153] Allergan also filed a second suit in California district court asserting several patents pertaining to ocular antibiotics against the Alcon product.

Allergan and Alcon reached agreement in March 2006.[154] Alcon benefited from the dismissal of the second suit. As for the exclusivity period, Alcon had no entitlement to begin with because it filed a paper NDA rather than an ANDA.[155] Alcon agreed to enter in September 2009 as a "co-exclusive licensee." Entry is earlier if Allergan converts customers to two other products, a 0.1% solution and Combigan, rapidly enough.

3. Biaxin XL

Clarithromycin in extended release form, sold by Abbott under the brand name Biaxin XL, is an antibiotic. U.S. sales in 2006, the year of settlement, were $151 million (for both Biaxin XL and Biaxin).[156]

Teva filed an ANDA seeking to market Biaxin XL upon the May 2005 expiration of the compound patent.[157] Biaxin was approved under a statutory scheme, since repealed, that does not provide for a Paragraph IV certification, 30-month stay, or 180-day exclusivity period. In March 2005, Abbott filed an

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[151] Allergan Reports Fourth Quarter Operating Results, Jan. 31, 2007 ($295.9 million worldwide sales in 2006 for Alphagan P, Alphagan, and Combigan; $277.2 million in 2005; overall domestic sales, across all lines of business, were 67.4% and 67.5%, respectively; applying the overall domestic percentage yields $199.4 million and $187.1 million) (link). See also drugs.com (reporting $180 million in U.S. sales in 2005).

[152] *See* Allergan v. Alcon, No. 04-968, 2005 WL 3336535 (D. Del. Dec. 8, 2005); Letter from FDA to Alcon (May 22, 2006) (link) (approving drug, and noting Apr. 27, 2004 filing of paper NDA).

[153] U.S. Patent No. 6,673,337 and U.S. Patent No. 6,641,834

[154] Alcon, Alcon and Allergan Reach Agreement on Brimonidine 0.15% Patent Litigation, Business Wire, Mar. 9, 2006.

[155] FDA, Ctr. for Drug Eval. & Res., *Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 5 n.14 (Oct. 2004) (link).

[156] *See* Abbott Laboratories, Annual Report (Form 10-K) (Feb. 23, 2007) (link).

[157] U.S. Patent 4,331,803.

infringement suit in Illinois district court asserting two other patents.[158] (A similar suit was filed against Ranbaxy in December 2004.)[159] Trial was scheduled for March 2007.

A district court granted a preliminary injunction to Abbott, but in June 2006, the Federal Circuit vacated the injunction, concluding that Teva had raised substantial questions as to the validity of the patents.[160] In June 2006, Teva began selling generic Biaxin XL, then stopped when Abbott filed an emergency motion.

Abbott reached agreements with Teva and Ranbaxy in July 2006.[161] Settlement terms were not disclosed, except that Teva agreed not to enter "at this time."

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[158] U.S. Patent No. 6,010,718, for an extended release formulation; and U.S. Patent No. 6,551,616, a method of reducing certain side effects by using extended release.

[159] *See* Abbott, Annual Report (Form 10-K) (Feb. 22, 2006) (link).

[160] 452 F.3d 1331 (Fed. Cir. 2006).

[161] Teva, Abbott Settle Patent Lawsuit, Daily International Pharma Alert, Aug. 2, 2006; *See* Abbott Laboratories, Annual Report (Form 10-K) (Feb. 23, 2007) (link) (reporting that settlement occurred).