

Aggregation, Antitrust, and Complex Collusion

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This Article examines the “aggregation deficit” in antitrust—the pervasive lack of information, essential to choosing an optimal antitrust rule, about the frequency and costliness of anticompetitive activity. It lessens the shortfall for an important, unresolved issue in U.S. antitrust policy, patent settlements between a brand-name drug maker and its generic rival. The analysis draws upon a new dataset of 142 settlements.

Taking an aggregate approach helps to set enforcement priorities, select a substantive liability standard, and identify the proper decisionmaker. The analysis uncovers a process of evolution in the means, including a variety of complex “side deals,” by which a brand-name firm can pay a generic firm to delay entry. The analysis supports a presumption of payment where a side deal is reached contemporaneously with delayed entry, and an expanded role for agencies, to take full advantage of non-public information. The aggregate perspective also sustains a pessimistic verdict on antitrust enforcement where, as here, firms can exploit regulatory complexity to disguise collusive activity.

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Introduction

Antitrust policymaking in the United States has a contradiction at its core. Its mission is to choose rules that minimize costly errors—false condemnations and false exonerations—even at the expense of accuracy in a particular case. Courts, as the actors charged with setting substantive antitrust policy, routinely make such choices. Unfortunately, courts lack the information needed to select a good rule.

Consider, for example, predatory pricing. Antitrust law permits price-cutting to exclude a rival, provided that the price does not fall below cost, on the view that a more aggressive rule yields too many false condemnations.¹ That lenient rule increases false exonerations, but these are unlikely, the Supreme Court has concluded, because predation is “rarely tried and even more

¹ Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 223 (1993) (declaring that such price cuts are “beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting”).

rarely successful.”² But how does a court come to know this? And is a court the right tool for uncovering the answer?

This Article identifies and examines an “aggregation deficit” in antitrust analysis: the troubling lack of information about the frequency and costliness of anticompetitive activity. Aggregation matters for both the substance and institutional structure of antitrust policy. In setting substantive antitrust rules, courts make rough guesses, informed by economic theory, about the distribution of real-world economic conduct. What a decisionmaker actually needs, I argue, is aggregate information, in order to identify a cost-minimizing substantive antitrust rule. In selecting an antitrust decisionmaker, moreover, we ought to favor the institution that has superior access to aggregate information.

As a laboratory for considering the substantive and institutional dimensions of aggregation, the Article focuses upon a single antitrust issue: patent settlements between a brand-name drug maker and its generic rival. Settlements result from a generic drug maker’s effort to market a competing version of a brand-name product. Although the product is protected by one or more patents, the generic firm asserts in patent litigation that the patent is invalid or not infringed by the proposed generic product. The brand-name firm, rather than take a chance that the generic firm might win that argument in court, settles the litigation by paying the generic firm to abandon the challenge and delay entry. Does this agreement violate antitrust law?

This question is the most important unresolved issue in U.S. antitrust policy, measured by economic importance and high-level judicial attention. As of November 2008, settlements insulate from competition more than \$_ billion in annual brand-name sales.³ The settlements include some of the world’s most important drugs.⁴ The importance and difficulty of the question has prompted the Supreme Court to seek the Solicitor General’s views three times since 2004.⁵

As a first step toward erasing this deficit, this Article draws upon a new dataset of drug patent settlements, developed from a wide range of public sources. The resulting dataset enables, for the first time, a vivid picture of the frequency and distribution of settlement activity. Viewing the settlements as a coherent whole, rather than piecemeal, permits new insights about enforcement priorities, the optimal substantive rule, and the choice of decisionmaker.

² *Brooke Group*, 509 U.S. at 226.

³ See Part II *infra*.

⁴ Settlements in 2008 included Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). See Pfizer Inc., 2007 Financial Report, at 18 (Lipitor sales).

⁵ See *Joblove v. Barr Labs., Inc.*, No. 06-830, 127 S. Ct. 1868 (2007); *FTC v. Schering-Plough Corp.*, No. 05-273, 546 U.S. 974 (Oct. 31, 2005); *Andrx Pharmaceuticals, Inc. v. Kroger Co.*, No. 03-779, 540 U.S. 1160 (Jan. 26, 2004).

The analysis reveals evolution in the terms of settlement. Whereas early settlements enacted a simple trade of cash for delay, modern settlements show sophistication in the means of both payment and delay. One example is the use of “side deal” arrangements, contemporaneous with delayed entry, in which the generic firm contributes unrelated value, such as a patent license. That tactic undermines reliable case-by-case determination: in a particular instance, it is difficult to tell whether the brand-name firm’s payment is consideration for delay, or for the unrelated value.⁶

An aggregate perspective permits us to approach the question in a different way. Side deals are frequently a component of settlements, but similar brand-generic deals are rare outside of settlement. Thus, the overall pattern of the arrangements suggests that they provide a disguised means to confer payment. The analysis supports the adoption of a presumption that a brand name firm’s payment to a generic firm, when contemporaneous with a generic firm’s agreement to delay entry, is consideration for delay, not for the content of the side deal.

The aggregate approach undermines the customary primacy of courts as an antitrust decisionmaker. A court is stuck with the facts of a particular case. It lacks the capacity to collect information about the distribution of activity in the economy. To be sure, parties can supply the court with aggregate analyses based upon public information, but public disclosures contain important gaps. Moreover, courts are likely to have trouble processing this information. Agencies have a decisive advantage in collecting and synthesizing aggregate information. Thus, the analysis sustains the conclusion that the Federal Trade Commission should do more to exploit its informational advantage as a plaintiff, amicus, and rulemaker.

Finally, the aggregate perspective provides a basis for predicting the success or failure of antitrust enforcement over time. As applied to settlements, the prediction is pessimistic. Settlement has continued to evolve—beyond side deals—in response to the enforcement emphases of courts and parties in particular cases. Settling parties have been able to achieve the same entry-delaying effect of the earliest settlements, while avoiding the particular formal characteristics that were the subject of previous suits. Existing antitrust institutions have trouble keeping up.

The Article proceeds in four parts. Part I introduces the pay-for-delay settlement problem, the aggregation deficit in antitrust, and the data collection effort. Part II outlines the scope and changing structure of entry-delaying settlements, and spells out how these features recommend

⁶ For example, in an important test case brought by the Federal Trade Commission, the case-specific approach produced divergent results at each level of review. *Compare* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (concluding that payment was value for licenses); *In re* Schering-Plough Corp., No. 9297, 2002 WL 1488085 (F.T.C. June 27, 2002) (opinion of administrative law judge reaching a similar conclusion; *with* *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003) (full Commission opinion concluding that payment secured delay).

making settlement an enforcement priority. Part III examines side deals from an aggregate perspective, and explains why they should be presumed to convey payment, when accompanied by an agreement to delay entry. Part IV shows why courts make poor aggregators, and how agencies can help fill the gap. That part also explains how the continuing evolution in settlement undermines a case-by-case approach.

I. Setting the Stage

The settlement issue has received a great deal of attention, but almost all of it has focused upon the theoretical issues raised by settlement cases, at the expense of important factual questions that also arise. Part I.A describes this neglect, and its connection to the larger problem of an aggregation deficit in antitrust. Part I.B outlines a first step toward remedying that deficit, an effort to collect publicly available data about settlements.

A. “Fact” Problems in Settlement Cases

Pay-for-delay settlements restrict a particular kind of competition between brand-name and generic firms. The process begins when a brand-name firm launches a new drug pursuant to the Hatch-Waxman Act, the industry-specific scheme that regulates pharmaceutical competition.⁷ In response, a generic firm seeks to launch a competing version of the same drug, asserting that any applicable patents are invalid or not infringed.⁸ The assertion is contained in an Abbreviated New Drug Application, or ANDA, that is filed with the Food and Drug Administration.⁹ If the filing is successful, the generic firm can launch a competing product without repeating the costly safety and efficacy studies that preceded the brand-name firm’s initial launch.

If the generic firm is the first file an ANDA, it is potentially entitled to a 180-day exclusive right to market a generic version in competition with the brand-name firm, effectively creating a duopoly during that period.¹⁰ In response to the ANDA, the brand-name firm may file

⁷ See 21 U.S.C. § 355(b) (2000 & Supp. III 2003) (providing for launch after a demonstration of safety and efficacy). This account is a simplification. For more details, see Hemphill (2006).

⁸ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000) (making a certification to the FDA, and notifying the rightsholder, that any applicable patents are invalid or not infringed).

⁹ The ANDA contains a so-called “Paragraph IV” certification that the applicable patent protection is invalid or not infringed.

¹⁰ 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003). The “duopoly” characterization ignores the effect of authorized generics, discussed *infra*.

a patent infringement suit to establish validity and infringement. This pattern—launch, challenge, sue—is typical for major drugs.¹¹

The litigation creates a powerful incentive to settle. A settlement in which the brand-name firm pays the generic firm, the parties dismiss the patent litigation, and the generic firm agrees to delay entry, is profitable for both firms. Entry hurts the brand-name firm more than it helps the generic firm, since entry lowers total producer profits, particularly as other generic firms are free to enter once the 180-day period ends.¹²

Such settlements, if they include payment, reduce expected static consumer welfare. Early competition benefits consumers through lower drug prices, sooner. The consumer benefit is probabilistic, since it is not certain that entry would occur; the brand-name firm might win the suit. Settlements without payment reflect the bargaining strength of the parties—for example, a generic firm’s fifty percent chance of success would yield, roughly speaking, an entry date halfway between immediate entry and patent expiration.¹³ Whether by settlement or litigation, the consumer sees half of the benefit of immediate competition. When the brand-name sweetens the bargain with a payment, by contrast, the payment shifts the entry date later, and consumer welfare falls.

As I have argued elsewhere, the consumer-disregarding effect of pay-for-delay settlements requires their condemnation as a violation of antitrust law.¹⁴ Settling parties have offered a variety of defenses, none of them persuasive—for example, that settlements do not violate antitrust law because the suppressed competition is merely probabilistic. To the contrary, the suppressed entry subject to antitrust regulation is almost always probabilistic.¹⁵ A second objection is that settlements in other industries are similarly consumer-disregarding, raising the specter of a widespread expansion of liability if these settlements are prohibited. However, the Hatch-Waxman Act denotes an industry-specific preference for competition, absent in other industries, to which antitrust should pay heed.¹⁶ A third objection, that prohibiting certain

¹¹ For example, of the fourteen best-selling drugs of 2005, twelve faced pre-expiration patent challenges. The two exceptions are Zocor and Advair Diskus. This calculation does not include biologic drugs not subject to the Hatch-Waxman regime.

¹² For details and caveats, see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006).

¹³ This is an oversimplification, due to some subtle but important effects of the exclusivity period. *See infra*; *see also* Hemphill, *supra* note xx.

¹⁴ *See* Hemphill, *supra* note xx.

¹⁵ “It would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.” *United States v. Microsoft*, 253 F.3d 34, 39 (2001) (en banc) (per curiam).

¹⁶ For an elaboration, see Hemphill, *supra* note xx.

settlements increases litigation costs, is overwhelmed by the billions of dollars in consumer welfare that are at stake.

The most important theoretical barrier to liability is the adoption of a maximalist view of the patent right. Most (though not all) appellate courts—including the Federal, Second, and Eleventh Circuits—have adopted the view that any settlement is permissible, provided it restricts no more entry than the nominal scope of the patent if valid and infringed.¹⁷ That view produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force. It allows innovators to buy private term extensions to their patents.¹⁸ This maximalist view of the patent right has been rejected by the Federal Trade Commission (FTC), senior officials of the Antitrust Division,¹⁹ and the Solicitor General.²⁰

The theoretical question of whether pay-for-delay settlements violate antitrust law has generated tremendous scholarly interest and a wide variety of responses.²¹ Beyond this theoretical question, there is a second, factual question that arises for many settlements. If settlement and delay occur as part of a larger set of transactions between the two firms, how do we know that the payment was made in exchange for delay, rather than some other value? Often, this is a difficult question. In the one case involving a side deal that has been fully litigated so far, the case-specific approach produced divergent results at each level of review.²² The factual question has been neglected so far.

This gap in our understanding of modern settlement practice exemplifies a general problem in antitrust enforcement. Given a theoretical model of anticompetitive behavior, true under specific factual circumstances, how do we establish with confidence that those

¹⁷ Compare *In re* Ciprofloxacin Hydrochloride Antitrust Litigation, No. 2008-1097, 2008 WL 4570669 (Fed. Cir. 2008) (declining to impose antitrust liability); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190 (2d Cir. 2006) (same), and *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) (same), with *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), and *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001) (reaching similar conclusion in dicta). Courts permitting settlement add the caveat that the patent suit must not be a sham.

¹⁸ This highly innovation-inefficient mechanism for increasing brand-name firm incentives is not a plausible interpretation of the Hatch-Waxman Act. See Hemphill, *supra* note xx.

¹⁹ David Meyer, speech, Oct. 31, 2007 (concluding that courts have gone too far in granting “carte blanche” to patentholders, and noting agreement of the Solicitor General in *Joblove* and *Schering*).

²⁰ *Joblove*.

²¹ More than thirty articles at last count, not including student notes. See Hemphill, *supra* note xx (collecting articles by John Bigelow, Joseph Brodley, Jeremy Bulow, Thomas Cotter, Daniel Crane, Herbert Hovenkamp, Mark Janis, James Langenfeld, Cristofer Leffler, Keith Leffler, Mark Lemley, Wenqing Li, Kevin McDonald, Maureen O’Rourke, Marc Schildkraut, Carl Shapiro, Joel Schrag, and Robert Willig).

²² See note xx *supra*.

circumstances are present in a particular case? If that determination is imperfect, how do we identify a cost-minimizing rule—that predation is “rarely tried, and even more rarely successful,” or that procompetitive uses of resale price maintenance are “infrequent or hypothetical,” a finding that might justify a per se ban?²³

Because a court lacks the independent capacity to collect this information, it relies upon others, including academics and other governmental institutions. In considering predation, for example, the Supreme Court has explicitly relied upon a “consensus among commentators” that the practice is rarely tried or successful.²⁴ If the external consensus changes, the Court suggests, so too may the substantive rule.²⁵ Agencies and Congress play a similar role. For example, Justice Breyer, in dissenting from the Court’s recent decision to end a longstanding per se ban on resale price maintenance, thought any change should await solid information about “how often are harms or benefits [from the practice] likely to occur,” and how easily the two can be distinguished: “[h]ow easy it is to separate the beneficial sheep from antitrust goats.”²⁶ Such information must be supplied by others: “both Congress and the FTC, unlike courts, are well-equipped to gather empirical evidence outside the context of a single case.”²⁷

Real-world evidence about the frequency and distribution of anticompetitive activity helps to build the requisite consensus among commentators. Such work has furthered our understanding of predation,²⁸ vertical contracting,²⁹ and other competitive practices. Industry-specific analyses, once a staple product of the FTC,³⁰ have been important too.³¹ This study

²³ *Leegin Creative Leather Products v. PSKS, Inc.*, 127 S. Ct. 2705 (2007).

²⁴ *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 589 (1986) (“there is a consensus among commentators that predatory pricing is rarely tried, and even more rarely successful”); *see also* *State Oil v. Khan*, 522 U.S. 3, 20 (1997) (noting the importance of “recognizing and adapting to changed circumstances and the lessons of accumulated experience”).

²⁵ Lower courts have taken that instruction seriously. *See, e.g.*, *U.S. v. AMR Corp.*, 335 F.3d 1109, 1114–15 (10th Cir. 2003) (“Recent scholarship has challenged the notion that predatory pricing schemes are implausible and irrational.”). In later predation cases, however, the Court has repeated the “rarely tried, rarely successful” language, without repeating the “consensus among commentators” qualifier. *Brooke Group BB*; *Weyerhaeuser BB*.

²⁶ *Leegin*, 127 S. Ct. at 2729 (Breyer, J., dissenting).

²⁷ *Id.* at 2737.

²⁸ *E.g.*, Patrick Bolton, Joseph F. Brodley & Michael H. Riordan, *Predatory Pricing: Strategic Theory and Legal Policy*, 88 *GEO. L.J.* 2239, 2244-49 (2000) (presenting evidence that casts doubt on the traditional assumption that predatory pricing is rare).

²⁹ *E.g.*, James C. Cooper et al., *Vertical Antitrust Policy as a Problem of Inference* (2005), available at <http://www.ftc.gov/speeches/froeb/050218verticalecon.pdf> (describing the interplay of evidence and theory to update prior beliefs over time; in the vertical context, that places a heavy burden on plaintiffs).

³⁰ [Examples of FTC studies; Scherer.]

³¹ *E.g.*, Peter Davis, *The Effect of Local Competition on Admissions Prices in the U.S. Motion Picture Exhibition Market*, 48 *J. L. & ECON.* 677 (2005) (identifying a significant but very small price

builds upon that work by adding a distinctive dimension, the effort to understand the evolution of a practice over time. Understanding that evolution provides evidence about how well existing antitrust instruments can be expected to cope. Frequent or rapid mutations in the practices of regulated firms raise doubts about whether common-law processes can effectively regulate the practices.

This is an apt moment to examine real-world evidence of settlements, while the rule remains in judicial and legislative flux. The Supreme Court has not weighed in on the settlement question, but if and when it does, its rule will be difficult to undo, thanks to the rareness of antitrust review, a cautious approach to *stare decisis*, and a fear of overturning reliance interests.³² Whether by legislative reform or a judicial rule, “[e]conomic policy must be contrived with a view to the typical rather than the exceptional,”³³ in George Stigler’s apt phrase. Both decisionmakers would benefit from a clear idea of how often settlements occur, in what forms, and with what prospect of effective judicial management. The next Part begins that examination.

B. Data Collection

To examine the frequency and evolution of brand-generic settlements since 1984, I collected a novel data set. The object is to identify and synthesize all public information about the frequency and terms of settlement. The effort drew upon press releases, trade and general interest publications,³⁴ financial analyst reports and analyst calls with management, conversations with practitioners, court filings of patent and antitrust litigation, SEC filings, FDA

reduction from local competition in motion picture exhibition, and little evidence that horizontal mergers in the industry caused price increases); *see also* Howard A. Shelanski, *Competition and Deployment of New Technology in U.S. Telecommunications*, 2000 U. CHI. LEGAL FORUM 85 (identifying a correlation between competition and innovation in a sample of new technology deployments in U.S. telecommunications networks, suggesting that strict enforcement of merger policy is unlikely to reduce welfare). And empirical methods are common in the analysis of particular case. *See, e.g.*, Jonathan B. Baker & Daniel L. Rubinfeld, *Empirical Methods Used in Antitrust Litigation: Review and Critique*, 1 AM. L. & ECON. REV. 386 (1999) [check]. Timothy F. Bresnahan, *Empirical Methods in Industries with Market Power*, in 2 HANDBOOK OF INDUSTRIAL ORGANIZATION _ (Richard Schmalensee & Robert Willig eds. 1989).

³² Transcript of Oral Argument at 11, *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, No. 06-480 (U.S. Mar. 26, 2007) (reporting Chief Justice Roberts’ concern that discount stores had developed in reliance upon a *per se* prohibition of resale price maintenance).

³³ George J. Stigler, *The Case Against Big Business*, FORTUNE, May 1952, at 123, 158.

³⁴ For example, a review of all articles in the Factiva database mentioning “settlement” and a “new drug application,” 3900 in all. The database includes newspapers, magazines, trade journals, press releases, company presentations at analyst conferences, and transcripts of calls between company executives and equity analysts. The search included linguistic variants of “settlement” and the abbreviations “NDA” and “ANDA.” The results of that search—3900 articles in all, many of them not responsive—identified all the settlements found by other means.

dockets, and FTC reports.³⁵ For eleven settlements, the actual settlement agreement was available.³⁶ In many cases, inconsistent information had to be reconciled.

This work yielded information for [142] settlements involving [98] brand-name drugs. For these drugs, at least basic information about settlement terms is available. Several checks confirm that the dataset is a substantially complete accounting of settlements that delay entry and settlements involving major drugs.³⁷ The resulting dataset is a new tool for examining the extent and evolution of settlement.

The data has significant gaps. Some settlements are missing. The omissions are likely to be concentrated in drugs that are minor, and hence left no public trace, or where settlement had no effect on entry. More importantly, for the identified settlements, limited public disclosure

³⁵ A 2002 report provided a detailed accounting of terms, with the drug name disguised. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* (2002). In December 2003, a new law required drug makers to file brand-generic agreements with the FTC. The FTC has presented summary information, with few details, in annual updates. 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*; 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*; 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 2007*.

³⁶ See Defendants' Notice of Submission of Zenith Settlement Agreement, *Kaiser Found. v. Abbott Labs.*, No. 2:02cv2443 (C.D. Cal. Mar. 14, 2006) [hereinafter Hytrin Abbott-Zenith Agreement]; Barr Pharmaceuticals 10-Q (date), 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 (Aug. 8, 2006) [hereinafter Plavix Agreement]; Andrx Corp., Annual Report (Form 10-K), Exhibit 10.109 (Mar. 16, 2006) [hereinafter Glucotrol XL Agreement]; Stipulation of Filing of Redacted Settlement Agreement, *Pfizer Inc. v. Zenith Goldline Pharmaceuticals*, No. 00-cv-0408, 01-cv-6007 (D.N.J. 2002) [hereinafter Zolofit Agreement]; Adams Respiratory Therapeutics, Inc., Quarterly Report (Form 10-Q), Exh. 10-1, May 15, 2007 [hereinafter Mucinex SE Agreement]; Kos Pharmaceuticals, Quarterly Report (Form 10-Q) (Aug. 9, 2005), exhs. 10.2 (co-promotion agreement), 10.3 (settlement and license agreement); 10.4 (license and manufacturing agreement) [hereinafter Niaspan Agreement]; Adams Respiratory Therapeutics, Inc., Quarterly Report (Form 10-Q) May 15, 2007), Exh. 10-1 [hereinafter Mucinex Agreement]; King Pharmaceuticals, Inc., Current Report (Form 8-K) (Jan 8, 2008), exh. 10.1 (termination agreement), exh. 10.2 (product agreement) [hereinafter Skelaxin Agreement]; King Pharm., Quarterly Report (Form 10-Q) (May 9, 2006), exh. 10.1 (distribution agreement), exh. 10.2 (product supply agreement), exh. 10.3 (application license agreement), exh. 10.4 (patent license agreement), exh. 10.5 (dismissal agreement) [hereinafter Altace Agreement]; Cephalon Inc., Quarterly Report (Form 10-Q), Exh. 10.1 (Nov. 8, 2006) [hereinafter Provigil Carlsbad Agreement].

³⁷ For example, the FTC catalogued 20 troubling settlements in 2002, but without naming names, of which this dataset contains at least 13. Of the eleven settlements in the 2005 update, I can account for eight, as well as 26 of 28 in the 2006 update and 20 of 33 in the 2007 update. Barr has stated that it reached settlements as to 14 drugs, cite, and I can account for all of them. Likewise, I can account for all ten settlements that Teva had entered by early 2007.

creates important gaps. In particular, price terms and other commercially sensitive details are normally omitted.

II. Enforcement Priorities

This Part elaborates an initial payoff from the aggregate approach: a clearer sense of the importance and nature of the settlement problem. Part II.A shows the magnitude and continuing importance of settlements with delayed entry. Part II.B describes three sources of evolution in the form of settlement, and their effects. Part II.C spells out several implications for enforcement.

A. Summary Statistics

[All figures preliminary:] Of the 98 drugs with settlements in the dataset, 43 drugs raise no pay-for-delay issue. (Here and elsewhere, I sometimes refer to the drug as shorthand for the relevant settlement.) Some include delayed entry by the generic firm, but without any compensation visible in the public record. These settlements merely reflect the relative bargaining strength of the parties. Their existence demonstrates that settlement without payment is feasible.³⁸ These drugs have average sales of \$631 million.

The remaining 55 drugs included both delay and possible contemporaneous provision of value by the brand-name firm. For 33 of the 55, the compensation was wholly or partly monetary.³⁹ Sometimes the payment was an open conferral of cash. For other drugs, the possible payment is buried within a more complicated transaction. The caveat, “possible,” is due to the fact that in many such cases, public information leaves it unclear whether the settlement included compensation. That issue is explored in more detail in the next Part. On average, these 33 drugs had annual U.S. sales of \$991 million.

The delay secured by payment is a significant component of life-cycle management. Figure 1 depicts the fraction of exclusivity covered by settlement for selected drugs.⁴⁰ Of these,

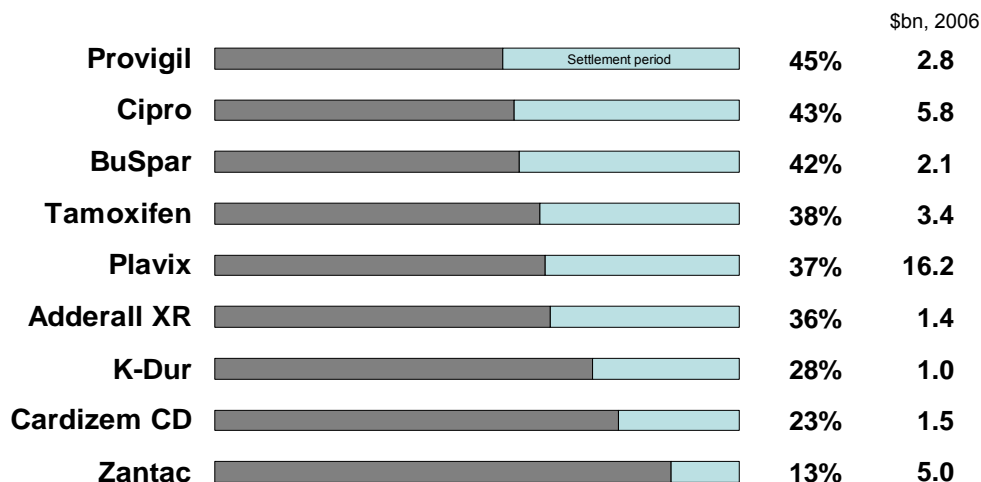
³⁸ Some of the 43 settlements tie up loose ends in litigation after entry has occurred, and do not make a similar demonstration. It should be noted, however, that the feasibility of settlement, without paying for delay, is not essential to the argument that settlement should be prohibited.

³⁹ This category includes “discounted product” settlements discussed in Part III.A.2.

⁴⁰ 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, Figure 1 reflects an assumption that U.S. sales were 60 percent of global sales.

all but Zantac attracted an antitrust suit or investigation. For many of the drugs, the settlement period accounts for between one-third and one-half of the time between brand-name product introduction and generic entry scheduled under the settlement.

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



The 33 drugs disproportionately include blockbusters such as Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). Nine drugs with annual sales exceeding \$1 billion account for about three-quarters of the total, measured by annual sales. This category also contains a disproportionate share of extended- and controlled-release versions of existing drugs.⁴¹

To give an idea of the potential effect of delayed entry, for a drug with a billion dollars in annual revenues, a one-year delay in generic entry is, under conservative assumptions, a transfer from consumers to producers of at least \$500 million.⁴² Thus, if each settlement delayed generic entry by one year, compared to a settlement without compensation, then the effect is a transfer from consumers to producers of about \$16 billion.⁴³

Estimating the transfer from pay-for-delay settlement is difficult, because it requires a prediction about what would have happened in each case absent the settlement. The particular

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.

⁴¹ For example, seven out of eleven drugs with a CD, XL, or XR suffix.

⁴² \$1 billion * 3/4 penetration * 2/3 price discount. That figure does not include additional deadweight loss.

⁴³ [Several complications to add.]

circumstances of a settlement can provide important indications of the likely alternative outcome. A weak patent, and likely early entry, might be identified by an analysis of the patent's validity and scope, or inferentially by a large payment. Another basis for inference is preparations by a generic firm to launch "at risk"—that is, to enter even before a court has ruled on invalidity or noninfringement.

For a few drugs, the expectations of financial analysts provide an estimate of the transfer. In the case of Provigil, for example, the drug maker's CEO said that due to settlements, the firm enjoyed "\$4 billion in sales no one expected."⁴⁴ That statement suggests a transfer of at least \$2 billion. In the case of Lipitor, the settlement delayed widely-anticipated entry by at least six months.⁴⁵ On a drug with annual sales exceeding \$7 billion, a six-month delay produces a transfer of about \$2 billion.⁴⁶ Extrapolating from these examples, the settlement data supports the conclusion that the overall transfer from monetary settlement totals tens of billions of dollars.

The remaining 22 drugs compensated the generic firm as part of an entry-delaying agreement, but the compensation was not monetary. Instead, compensation took the form of retained exclusivity. As explained in Part I, the 180-day period is valuable to the generic firm. 180 days of duopoly is worth hundreds of millions of dollars in the case of a blockbuster. The entitlement can also be sold to another generic firm.⁴⁷ The value of this opportunity, however, is discounted by the uncertainty that the generic firm might lose the litigation, and thus never enjoy the exclusivity period.⁴⁸ A brand-name firm's agreement to drop the patent fight—an

⁴⁴ x.

⁴⁵ Analysts projected entry in March 2010, upon the expiration of the one patent that was litigated successfully by Pfizer, or at the latest in June 2011, upon the expiration of a second patent that had been declared invalid by the Federal Circuit, but on which Pfizer sought reissuance. Entry by the generic firm is currently scheduled for November 2011.

⁴⁶ These calculations do not fully reflect the complexity of the 180-day period.

⁴⁷ A brand-name firm can either selectively waive its entitlement to a particular later filer, or relinquish it entirely. Selective waiver has been permitted for numerous drugs, including Zantac, Zoloft, and Wellbutrin XL. The FDA has insisted that selective waiver, as opposed to relinquishment, can occur only once the exclusivity has been triggered through a favorable court ruling or commercial marketing. *See* FDA, Response to Citizen Petition of Pfizer, Inc., at 4-5 & n. 5, No. 2004P-0227 (July 2, 2004); *see also* Boehringer Ingelheim Corp. v. Shalala, 993 F. Supp. 1 (D.D.C. 1997) (approving FDA interpretation allowing selective transfer); 64 Fed. Reg. 42873, 42881 (1999); Mylan Pharmaceuticals v. Shalala, 81 F. Supp. 2d 30, 42 (D. D. C. 2000) ("exclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price") (citing Granutec, 46 U.S.P.Q.2d at 1405).

⁴⁸ Other risks include the possibility that a later-filing generic firm wins a patent suit, triggering the first-filer's exclusivity period before the generic firm secures approval, or that the patent expires before the generic firm wins the suit.

arrangement that does not forfeit eligibility⁴⁹—is valuable to the generic firm because it raises the probability of enjoying the exclusivity.

The ability to settle with retained exclusivity disrupts the alignment of interest between the generic firm and consumers. Ordinarily, late entry dates are bad for consumers, but also bad for the alleged infringer, who can therefore be expected to fight for an earlier entry date. Here, by contrast, the generic firm cares more about enjoying the 180-day duopoly with near certainty, and less about *when* exactly that entry occurs. It is therefore willing to trade a later entry date in exchange for the better chance to enjoy the 180 days.⁵⁰

The preservation of exclusivity can take a second form. If the generic firm wins its patent challenge, it may trigger exclusivity prematurely. That may be the case if the generic firm declines to challenge a relevant patent (which thereby continues to block entry) or loses the challenge.⁵¹ A generic firm can avoid wasting its exclusivity by entering a settlement with delayed entry.⁵²

In addition to the drugs for which the only form of compensation is retained exclusivity,⁵³ some of the 33 settlements with monetary compensation also included this term.⁵⁴

⁴⁹ Settlement does not remove entitlement to the exclusivity period. *See infra*.

⁵⁰ For a full analysis, see Hemphill, *supra* note xx.

⁵¹ *See* DONALD O. BEERS, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* 4-43 (discussing situation where exclusivity is “effectively useless because a second patent, as to which a paragraph III certification had been made, had not yet expired when the 180-day exclusivity began to run.”).

⁵² Consider, for example, the Zolofit settlement. The generic firm challenged a secondary patent, but not a basic composition of matter patent scheduled to last for another six years. Had it seen the suit through to conclusion, at best it would have triggered exclusivity uselessly. Instead, it agreed to enter with exclusivity upon the expiration of the basic patent. *See* Stipulation of Filing of Redacted Settlement Agreement, Pfizer Inc. v. Zenith Goldline Pharmaceuticals, No. 00-0408, 01-6007 (D.N.J. 2002).

Barr’s challenge to Prozac raised a similar possibility. *See* Barr Laboratories, Inc., Annual Report (Form 10-K), at 10 (May 15, 2001) (noting possibility that 180-day period could be wasted if challenge succeeded, and exclusivity was triggered, while another patent blocked FDA approval). In the event, by the time exclusivity was triggered, the patent had expired, and applicable pediatric exclusivity had almost run. The premature triggering question was limited to the six-day overlap: was the 180-day period truncated by the overlap with pediatric exclusivity? Congress passed a statute providing for the full benefit of exclusivity in such circumstances, and generic entry was protected for the six days. Pub. L. No. 107-109 (2002), § 10; Press Release, Barr Laboratories, Inc., Barr Confirms Prozac Exclusivity Runs Until January 29 (Jan. 9, 2002) (announcing letter from FDA stating that BPCA “extends” exclusivity by the amount of the overlap, to January 29, 2002).

⁵³ This is true of many drugs, including Avandia and Valtrex. *See* Glaxo Annual Report 2007 at 153 (Avandia); Press Release, Ranbaxy Labs. Ltd, Ranbaxy and GlaxoSmithKline Enter Into an Agreement to Settle Valacyclovir U.S. Patent Litigation (July 26, 2007) (Valtrex) (noting Ranbaxy’s entry with exclusivity in late 2009).

Other settlements explicitly disclaim retained exclusivity,⁵⁵ trigger exclusivity,⁵⁶ or involve generic firms that are ineligible for exclusivity in the first place.⁵⁷ These 22 drugs had average sales of \$453 million.⁵⁸

The firms that have entered settlements with both payment and delay are quite diverse, 32 brand-name firms and 22 generic firms in all.⁵⁹ The most frequent brand-name settlers are Glaxo and Pfizer, with nine and four settlements, respectively, including three monetary settlements

⁵⁴ Many of the settlements already discussed have this feature, including K-Dur, Naprelan, Procardia XL, Estrostep, FemHRT, Lamictal, Niaspan, Effexor XR, Provigil (as to each of four first-filers), Plavix, and Adderall XR. In some cases, retained exclusivity cannot be confirmed based upon available public information.

⁵⁵ For example, Androgel. 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) [hereinafter Androgel Press Release]. The reason is to avoid antitrust attention, since retained exclusivity helps effectuate delay, as discussed in the next section.

⁵⁶ For example, Yasmin. Yasmin sales commenced by June 2008, see Bayer AG, Stockholders' Newsletter, at 43 (June 30, 2008), which suffices to trigger exclusivity under either Bayer's NDA or Barr's ANDA. See § 355(j)(5)(B)(iv) (2003) (exclusivity for post-MMA drugs triggered by "first commercial marketing," "including the commercial marketing of the listed drug"); Press Release, Barr Pharmaceuticals, Inc., Barr and Bayer Sign Supply and Licensing Agreements for Launch of Generic Yasmin and Yaz Oral Contraceptives (June 23, 2008) [hereinafter Yasmin Press Release].

For some settlements, such as Yasmin, retained exclusivity (and the accompanying bottleneck) are not necessary because exclusivity can be secured by other means. In the case of Yasmin, the brand-name firm sued the later filer on different patents. Answer, Affirmative Defenses, and Counterclaims, Bayer Schering Pharma AG v. Sandoz Inc., No. 08-3710, at 29-30 (S.D.N.Y. July 18, 2008) (alleging, inter alia, that Bayer's refusal to assert a patent asserted against Sandoz—the Barr litigation concerned a different patent—is part of a conspiracy that violates antitrust law).

⁵⁷ This is the case when the generic firm is not a first filer, as with subsequent settlements in Hytrin, K-Dur, Provigil, Adderall XR, and AndroGel, or when the brand-name drug does not give rise to exclusivity eligibility. Examples of the latter category include Paraplatin, Ovcon 35, Biaxin XL, and Alphagan.

⁵⁸ Preserved exclusivity can also be achieved by contract. A striking example occurs when a brand-name firm secures a six-month pediatric extension that is tacked onto the end of the patent term. Eligibility for the 180-day period expires when the relevant patent expires. A selective grant of a license during all or part of the pediatric exclusivity period is a valuable source of compensation that is employed in some settlements. For example, Imitrex and Lamictal. Press Release, Dr. Reddy's Laboratories Announces Settlement of Imitrex Litigation with Glaxosmithkline (Oct. 10, 2006) (noting expected launch under settlement in the fourth quarter of 2008, prior to expiration of pediatric exclusivity on February 6, 2009); Teva Launches Generic Lamictal Tablets in US, PHARMACEUTICAL BUSINESS REVIEW, July 23, 2008 (noting settlement provision that Teva has exclusive right to enter during pediatric exclusivity, which expires on January 22, 2009). Entry during pediatric exclusivity was not counted as retained exclusivity [check].

⁵⁹ Not accounting for mergers.

each.⁶⁰ Barr and Teva lead the generic-firm league tables, with 15 and 11 settlements, respectively. Barr has been more aggressive than Teva: 11 of its settlements, compared to just four of Teva's, have been monetary settlements. One generic firm, Ranbaxy, has played a role disproportionate to its settlement count, reaching settlements involving Lipitor and Nexium in the span of a few months in 2008. Although individual drug firms are repeat players, repeat negotiations between brand-generic pairs are rare—just three since the passage of the Hatch-Waxman Act.⁶¹

B. Sources of Evolution

Three factors have shaped a continuing evolution in settlement form: the waxing and waning of antitrust enforcement, a change in judicial interpretation of the Hatch-Waxman Act, and major statutory amendments to the Act in 2003.

1. Antitrust Challenges

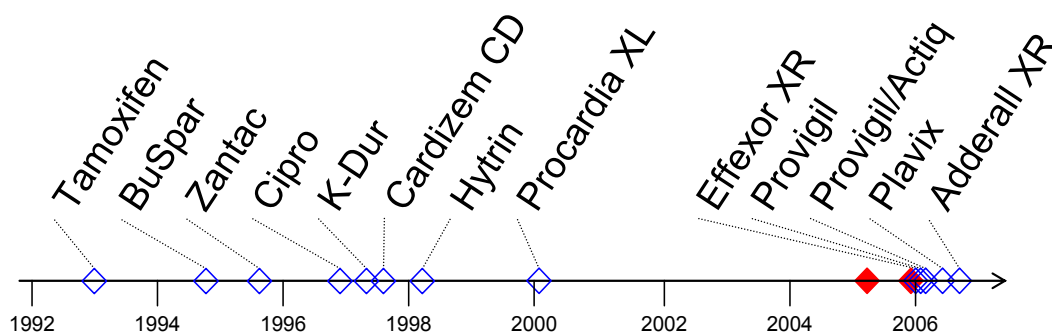
The form of settlement has varied significantly with the level of perceived antitrust risk, particularly as to monetary settlements. Figure 2 depicts the pattern. Monetary settlements occurred at a rate of one or two per year from 1993 through 1998, with a spike of three

⁶⁰ For Glaxo, see Press Release, TEVA Pharmaceuticals USA, Teva Announces Settlement of Lamictal Litigation with Glaxosmithkline (Feb. 17, 2005) (Lamictal; reporting settlement term permitting Teva to sell a second Glaxo product, a chewable version of Lamictal); Press Release, Mylan Labs., Inc., Mylan Announces Settlement of Paroxetine Hydrochloride Extended-Release Tablets with GlaxoSmithKline (Oct. 23, 2007) (Paxil CR); *Glaxo and Watson Settle Antidepressant Patent Case*, REUTERS NEWS, July 13, 2001 (Wellbutrin SR). For Pfizer, see Press Release, Pfizer Inc., Pfizer and Ranbaxy Settle Lipitor Patent Litigation Worldwide (June 23, 2008) (Lipitor; reporting additional settlement term “resolving” litigation over Accupril) [hereinafter Lipitor Pfizer Press Release]; Motion to Dismiss the Complaint at 5, No. 01-106 (N.D. W. Va. July 30, 2001) (Procardia XL); Stipulation of Filing of Redacted Settlement Agreement, Pfizer Inc. v. Zenith Goldline Pharmaceuticals, No. 00-0408, 01-6007 (D.N.J. 2002) (Zolofit).

⁶¹ The pairings are Bayer-Barr, Ortho-McNeil-Barr, and Glaxo-Teva. Bayer negotiated with Barr over Cipro, then Yasmin and Yaz. In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 519-20 (E.D.N.Y. 2005) (Cipro); Press Release, Barr Pharmaceuticals, Inc., Barr and Bayer Sign Supply and Licensing Agreements for Launch of Generic Yasmin and Yaz Oral Contraceptives (June 23, 2008) [hereinafter Yasmin Press Release] (Yasmin and Yaz). Barr negotiated with Ortho-McNeil over Ortho Novum 7/7/7, then Ortho Tri-Cyclen. Press Release, Barr Pharmaceuticals, Barr Laboratories Announces Agreement in Ortho-Novum 7/7/7 Patent Litigation (Oct. 29, 2001) (Ortho-Novum 7/7/7); Consent Judgment and Order, Ortho-McNeil Pharmaceuticals, Inc. v. Barr Labs., No. 00-2805 (D.N.J. July 23, 2003) (Ortho Tri-Cyclen). Glaxo negotiated with Teva over Lamictal, then Avandia, Avandaryl, and Avandamet. Teva Launches Generic Lamictal Tablets in US, *supra* note 58 (Lamictal); Glaxo Annual Report 2007 at 153 (Avandia, Avandaryl, and Avandamet). This statement ignores simultaneous or near-simultaneous settlement of multiple drugs, settlements that do not entail delayed entry, and cases that do not settle.

settlements in 1997. In 2000, the FTC initiated antitrust actions against several settlements,⁶² and monetary settlements fell. In 2005, plaintiffs suffered two important defeats in the Second and Eleventh Circuits. That year saw five monetary settlements, and in 2006, five more. Moreover, some settlements may be timed to correspond to a depletion in FTC enforcement capacity. In 2008, shortly after the FTC challenged one monetary settlement in February, there was a renewed flurry of monetary settlements, including Lipitor and Nexium.

Figure 2. Selected monetary settlements [to update]



Antitrust enforcement has affected not only the fact, but also the form, of monetary settlements. The first monetary settlements—including the first four depicted in Figure 2—blocked entry until patent expiration, and the brand-name firm paid cash.⁶³ Starting in 1997 and frequently after 2000, that basic form changed in two ways, both of them likely a response, in part, to increased pressure from antitrust enforcers.⁶⁴ First, settlements began to include some pre-expiration entry. That shift provides drug makers with the rhetorical opportunity to argue that the settlement guarantees some competition. Some entry looks better than no entry. From this perspective, the law has shifted in the drug makers' favor even further than they had hoped, given the prevailing view of appellate courts that it is fine to pay for settlements with no pre-expiration entry.

⁶² The [first] private suit was filed in 1998. See *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 903 (6th Cir. 2003) (noting that complaint was filed in August 1998).

⁶³ For example, Nolvadex, BuSpar, and Cipro. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Analysis to Aid Public Comment (BuSpar)*; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519-20 (E.D.N.Y. 2005). In Tamoxifen, there were authorized generic sales as well.

⁶⁴ The first such settlement, K-Dur, occurred in 1997, and predated increased antitrust pressure. Settlements shortly after K-Dur did not fully adopt the modern form. In addition, two settlements, Cardizem CD and Hytrin, were interim agreements raising somewhat different issues.

Second, the settlements began to include not only payment and delay, but also additional contractual terms that tend to obscure whether payment has occurred. The forms of these disguises, and their importance for case-by-case litigation, are discussed in the next Part.

2. Judicial Interpretation

The shift toward settlements with pre-expiration entry had a second cause. Prior to 1998, the FDA had insisted that, in order to enjoy the 180-day exclusivity period, a generic firm must successfully defend its pre-expiration challenge. In 1998, that view was defeated in the courts as contrary to the text of the Hatch-Waxman Act.⁶⁵ After that, a first-filing generic firm could expect to enjoy the exclusivity provided it did not lose the patent suit, and even if it settled. That made it possible to compensate using retained exclusivity, provided that entry occurred at least 180 days before patent expiration.

The end of the successful defense requirement also created a new form of delay with respect to non-settling firms. The result is due to a statutory quirk in the provision of the 180-day period: a later-filed ANDA may not be approved until 180 days after the first filer's initiation of commercial marketing or a court determination of invalidity or noninfringement. A settlement with the first filer eliminates the possibility of commercial marketing or a court ruling. The 180 days is never triggered, and the later ANDA filer is stuck, for the FDA lacks authority to approve the application, blocking subsequent entry.⁶⁶

This resulting “bottleneck” is incomplete: if a later ANDA filer wins a favorable court decision, that decision triggers the first filer's exclusivity period. The subsequent ANDA filer can enter 180 days later.⁶⁷ If the innovator declines to sue the later filer, as frequently occurs, then the later filer must bring a declaratory judgment suit challenging the patents, win that suit, and then wait 180 days.⁶⁸

⁶⁵ See *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d 1398 (4th Cir. 1998); *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); 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).

⁶⁶ [Number of settlements with bottlenecks.]

⁶⁷ In a few first-wave settlements, such as *Nolvadex*, *BuSpar*, and *Cipro*, the generic firm relinquished exclusivity eligibility by changing its certification from paragraph IV to paragraph III. In the case of *Nolvadex* 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.

⁶⁸ For some settlements, this route was blocked by the Federal Circuit's view that the generic firm lacked standing to bring suit, a roadblock that was later cleared by judicial interpretation. Cites.

Some but not all settlements after 1997 create a bottleneck.⁶⁹ Some settlements avoid the bottleneck just as they avoid retained exclusivity, by disclaiming or triggering exclusivity. Doing so reduces antitrust scrutiny, and has little effect on the brand name firm's exposure to competitive entry if there are other barriers to the entry of a later-filing firm.

3. Statutory Change

Statutory change offers a third possible source of evolution. In 2003, Congress enacted amendments to the Hatch-Waxman regime as part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).⁷⁰ These provisions were designed, in part, to curb anticompetitive settlements. The most important change was a new forfeiture procedure, which causes a generic firm to lose its entitlement to the exclusivity period under certain circumstances.⁷¹ The MMA's passage led some to conclude that the settlement problem had been solved. For example, the Solicitor General concluded that the statutory change lessened the need for Supreme Court review.⁷² We might expect, therefore, that after 2003, settlements with both payment and delayed entry would diminish or cease.

Five years after the MMA's passage, there is little evidence of that effect. As noted above, monetary settlements have been a frequent occurrence after 2003—if anything, they appear to have increased in frequency. Settlements without payment have diminished. And the incidence of blockbuster monetary settlements has increased. The most important settlements, preserving brand-name profits on blockbusters such as Lipitor, Nexium, and Plavix, occur after the statutory change. The only blockbuster settlement that predates the MMA is Zantac. That settlement, in 1995, predated FTC enforcement efforts and escaped antitrust scrutiny entirely.

One reason for the limited effect is that the new forfeiture regime has only prospective application. It applies only to drugs where the first ANDA was filed after December 2003.⁷³

⁶⁹ Two other settlements, Nolvadex and Cipro, contain a weaker version of the bottleneck. Both settlements provided that the generic firm would wait to enter until patent expiration, and the generic firm—in both cases Barr—altered its FDA filing to remove any asserted entitlement to pre-expiration entry. But in each case, faced with the possibility of pre-expiration generic entry by other firms [and court rulings that made retained exclusivity possible], Barr attempted to revert to the earlier status, and to assert its continued entitlement to the exclusivity period.

⁷⁰ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat. 2066.

⁷¹ 21 U.S.C. § 355(j)(5)(D) (Supp. 2004).

⁷² Brief for the United States as Amicus Curiae at 18, *Andrx Pharmaceuticals v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779), available at <http://www.usdoj.gov/osg/briefs/2004/2pet/6invt/2003-0779.pet.ami.inv.pdf>.

⁷³ To be more precise, December 8, 2008. See § 1102(b) of the Act, 117 Stat. 2460. [Describe the few provisions that apply retrospectively.]

Most drugs, however, are governed by the old regime. Patent litigation frequently takes four or five years to reach settlement. In Lipitor, for example, the first ANDA was filed in 2003, and settlement was reached in 2008. [All] of the settlements listed in Figures 1 and 2, and the blockbuster settlements in Lipitor, Nexium, and Plavix, were reached under the pre-MMA rules. Of the 98 settlements, only _ are subject to the new rules. In short, even if the pre-MMA regime is transitional, it is also massively important.

Moreover, the new forfeiture rules, when they eventually do have a large practical effect, may do little to curb pay-for-delay settlement. The new rules, like the old ones, permit a brand-name firm to neutralize the first filer’s challenge through settlement. That firm has the largest incentive to challenge the patent because only it is eligible to receive the 180-day reward. And the new rules, like the old ones, contain a bottleneck.⁷⁴ Forfeiture applies only upon the satisfaction of two statutory conditions.⁷⁵ The first condition is relatively easy to satisfy.⁷⁶ The second condition is triggered only if an appeals court rules that the relevant patents are invalid or not infringed, or if a settlement reaches a similar result.⁷⁷ The new bottleneck, like the old one, is incomplete. As before, a later-filing generic firm can break the logjam by winning its challenge, and then waiting—but now, it must wait until an appellate win before the exclusivity is triggered.⁷⁸

C. Setting Priorities

The foregoing survey has several implications for antitrust enforcement—first, to demonstrate that settlement is a first-order enforcement issue. The size of consumer welfare implicated, tens of billions of dollars, justifies vigorous FTC and private enforcement efforts,

⁷⁴ The FDA recently reached the same conclusion: “[I]nherent in the structure of the ‘failure to market’ forfeiture provisions is the possibility that a first applicant would be able to enter into a settlement agreement . . . in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without a forfeiture event under subpart (bb) occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability . . . could result in [approval delays of other ANDAs]. This potential scenario is not one for which the statute currently provides a remedy.” Response to Citizen’s Petition, Granisetron, <http://www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf>.

This is not the only possible interpretation, since a court might conclude, contrary to the FDA interpretation, that the application was not “properly maintained.”

⁷⁵ See (D)(i) (“later of” (aa) and (bb)). Aside from forfeiture for failure to market, there is also a provision for forfeiture in the case of certain “illegal agreements,” but that condition requires a successful antitrust suit against the settling parties.

⁷⁶ See (D)(i)(aa) (satisfied by “the earlier of” 75 days after the first filer’s effective date, and 30 months after application filing).

⁷⁷ See (D)(i)(bb). There is also a third possibility, that the brand-name firm withdraws the relevant patent information from the Orange Book.

⁷⁸ The details differ...

continued scholarly investigation of the evolution and effect of settlements, and a concerted effort by the FTC and Antitrust Division to reconcile their previously divergent view of settlements.⁷⁹

The survey also underscores the importance of prompt Supreme Court review. In practical importance, pay-for-delay settlement compares favorably to other antitrust issues on which the Supreme Court has granted certiorari. The issue likely affects more commerce, for example, than resale price maintenance, a practice that has long been avoidable for most well-counseled firms.⁸⁰

Moreover, settlement has become a patent issue, not only an antitrust issue. Although framed as an antitrust case by plaintiffs, the Federal Circuit and other appellate courts have taken the view that settlement is essentially a patent issue, governed by patent law—indeed, governed by Federal Circuit law⁸¹—and that patent trumps antitrust within the nominal scope of the patent. The settlement issue fits well with other patent cases on which the Court has taken certiorari in recent years, and is of a piece with the Court’s effort to combat hypertrophy in the claimed scope of patent protection.

The MMA provides no basis for postponing review. The “transitional” rules have proved to have long-lived impact, and will continue to do so. One of the first settlements concerned an ANDA filed in 1985; the certiorari petition pertaining to the resulting antitrust suit was filed 21 years later.⁸² Antitrust challenges regarding ANDAs filed in 2003 or earlier are likely to remain pending for quite some time. And, because post-MMA ANDAs are governed by similar rules, a Court ruling on a pre-MMA case largely controls the analysis for post-MMA cases as well.

The survey reveals a final advantage of prompt review. Antitrust challenges to early settlements are still making their way to the Court.⁸³ These contain payment and delay, but not much else. Later settlements, however, add contractual complexity. They add difficult factual questions—was there payment? was there delay?—atop the legal question of whether payment in exchange for delay violates antitrust law. For a Court that dislikes wading into factual complexity, the early cases provide a more attractive vehicle for setting a clear rule.

⁷⁹ 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. For evidence of convergence, see *supra*.

⁸⁰ Cf. cert grant in *Leegin*.

⁸¹ See *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 2008-1097, at *7-*10 (Fed. Cir. Oct. 15, 2008) (concluding that settlement did not violate antitrust law, apparently as matter of Federal Circuit law, not Second Circuit law).

⁸² Tamoxifen cert petition.

⁸³ For example, *Cipro*, which could yield petitions from both the Federal Circuit and the Second Circuit.

III. Substantive Policy

This Part examines how an aggregate perspective affects the choice of substantive antitrust rule. Part III.A singles out one element of the evolution in settlement, the rise of side-deals that disguise the fact of payment in a pay-for-delay settlement. Part III.B demonstrates that the content of the side deals, though common in settlements, is uncommon otherwise. Part III.C argues that the mismatch between settlement and non-settlement practice provides a basis for presuming that side deals are disguised payments for delay, not for value.

A. The Rise of Side Deals

As explained in Part II, the earliest settlements were a straightforward affair. The brand-name firm paid cash in exchange for the generic firm's delayed entry. The largest naked cash payment is nearly \$400 million, which Bayer agreed to pay Barr in settling litigation over Cipro, a major antibiotic.⁸⁴

Naked payments have given way to more complex arrangements, however, as antitrust scrutiny drove the payments underground. Today, side deals take two complementary forms: overpayment by the brand-name firm for value contributed by the generic firm, and underpayment by the generic firm for value provided by the generic firm.

1. Paying Too Much

In the most common type of side deal, the generic firm contributes, in addition to delayed entry, some further resource, such as an unrelated product license. The additional term provides an opportunity to overstate the value contributed by the generic firm, and claim that the cash is consideration for the contributed value, rather than delayed entry. In reviewing K-Dur, the earliest such settlement, the Eleventh Circuit accepted this factual assertion, which provided a basis for rejecting antitrust liability.

Side deals are now a regular feature of entry-delaying settlements. The contributed value covers a wide range of product development, manufacturing, and promotion services. In some

⁸⁴ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (Cipro) (\$398 million). Other naked payments include BuSpar (\$73 million), Zantac (\$133 million), and Nolvadex (\$66 million). FTC Report, matched against Hemphill (BuSpar); *id.* (Zantac); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (Nolvadex). Some of these settlements included other forms of payment too. In addition, "interim" agreements involving two drugs, Hytrin and Cardizem CD, included naked cash payments. See *In re Abbott Labs. & Geneva Pharm., Inc.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (Hytrin); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (Cardizem CD).

deals, the generic firm offers a product or patent license, or agrees to develop a new product.⁸⁵ In one variant, the generic firm develops a new formulation.⁸⁶ In other deals, it agrees to manufacture or supply the brand-name product to the brand-name producer,⁸⁷ or to provide inventory,⁸⁸ or even to provide “backup” manufacturing services.⁸⁹ Promotion may cover the product at issue or an additional or even unrelated product.⁹⁰

Some of these arrangements may seem suspect on their face. It may seem clear that the brand-name firm does not need a patent license that does not clearly cover its product, new product development that is unrelated to its current core business, a new source of raw material supply, backup manufacturing, or additional promotion.⁹¹ However, it is very difficult to say for sure without a deep and difficult inquiry into the business judgment of the two drug makers.

2. Charging Too Little

The brand-name firm, rather than paying too much, can charge too little. One mechanism involves “authorized generic” sales. These are sales made by a generic firm, under the brand-name firm’s product approval. The brand-name firm can supply the product to the generic firm at

⁸⁵ For example, K-Dur, Naprelan, Provigil, and Adderall XR. *See* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1059-60 (11th Cir. 2005) (K-Dur); *Andrx Pharm., Inc. v. Elan Corp.*, No. 00-3481, at *6 (S.D. Fl. Apr. 24, 2003) (Naprelan); *Federal Trade Commission v. Cephalon, Inc.* (D.D.C. Feb. 13, 2008) [hereinafter *Provigil Complaint*] (Provigil); *Adderall XR Agreement*, *supra* note 36.

⁸⁶ *See* *Altace Agreement*, *supra* note 36.

⁸⁷ The Ovcon 35 settlement includes 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). *See* Warner-Chilcott, Annual Report (Form 10-K), at 8 (Mar. 26, 2007) (noting that agreement with Barr provided a manufacturing source for Ovcon 35); *id.* at 12 (similar); *Provigil Complaint*, *supra* note 85. In the Adderall XR settlement, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. *Adderall XR Agreement*, *supra* note 36.

⁸⁸ For example, Provigil’s agreement as to Barr, and Plavix. *See* *Provigil Complaint*, *supra* note 85; *Plavix Agreement*, *supra* note 36.

⁸⁹ AndroGel’s settlement with Solvay has this feature. 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) [hereinafter *AndroGel Press Release*] (noting back-up manufacturing agreement as to Par). So does the Niaspan agreement. *See* *Niaspan Agreement*, *supra* note 36.

⁹⁰ Examples include Niaspan, both AndroGel settlements, and Adderall XR (as to an unrelated product). *See* *Niaspan Agreement*, *supra* note 36 (promotion of Advicor, a drug protected by same patents as Niaspan); *AndroGel Press Release*, *supra* note 89 (promotion of AndroGel); *Adderall XR Agreement*, *supra* note 36 (promotion of unrelated drug).

⁹¹ For example, in the case of a settlement involving the wakefulness drug Provigil, the brand-name firm, Cephalon, apparently was aware of one generic firm’s intellectual property for three years before showing any interest in seeking a license. *Provigil Complaint*, *supra* note 85, at 16.

a discount, which the generic firm can then resell under its own brand at a profitable price.⁹² The compensation is buried in the discounted price offered by the brand-name firm.

In several early settlements, the authorized generic product was launched at the time of settlement. This practice fell out of favor after a court concluded that the authorized generic sales triggered the 180-day period.⁹³ Some modern settlements avoid the trigger problem by providing for authorized generic sales only after another generic firm enters,⁹⁴ or on a drug other than the subject of the generic firm's ANDA filing.⁹⁵

A second form of discounted sales, which avoids the trigger issue, is for the brand-name firm to sell an entire product line to the generic firm. In one settlement, for example, the brand-name ended litigation involving an extended-release version of the drug, and the settlement included transfer (for a possibly discounted price) of the immediate-release version from the brand-name firm to the generic firm.⁹⁶ In another, more complicated set of deals, the brand-name firm sold the generic firm rights to one product, and the generic firm delayed entry in two other products.⁹⁷ Once again, the practical difficulty is that it is difficult for a decision-maker to know whether the transfer price provides compensation from the brand-name firm to the generic firm, and if so, how much.

B. Frequency Outside of Settlement

Outside of settlement, brand-name firms seldom seek out generic firms for help with the activities that form the basis of side deals. Indeed, as a general matter, brand-name firms and

⁹² For example, Tamoxifen and Procardia XL. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); Motion to Dismiss the Complaint at 5, No. 01-106 (N.D. W. Va. July 30, 2001) (Procardia XL).

⁹³ *See* FDA Response to Teva's Citizen Petition, Docket No. 00P-1446/CP1 (Feb. 6, 2001) (concluding that private-label sales triggered running of exclusivity period); Mylan Pharmaceuticals, Inc. v. Thompson, 207 F. Supp. 2d 476 (N.D. W. Va. 2001) (concluding that Teva was likely to prevail on that contention). The statutory basis for this conclusion is doubtful. Explain; Beers.

⁹⁴ *See infra*.

⁹⁵ For example, Propecia and Nexium. Press Release, Dr. Reddy's, Dr. Reddy's Launches Authorized Generic Versions of Proscar and Zocor (June 23, 2006) (noting January 2006 agreement to make Dr. Reddy's an authorized generic distributor); Letter from Mary Graham to Judge Gregory M. Sleet, Merck & Co. v. Dr. Reddy's Laboratories, No. 04-1313 (D. Del. Mar. 1, 2006) (reporting to judge that parties same had reached settlement as to Propecia); Merck, Annual Report (Form 10-K), at 34 (Feb. 28, 2007) (noting that settlement permits entry as to Propecia in 2013); Press Release, Ranbaxy Pharmaceuticals, Inc., Ranbaxy and AstraZeneca Reach Agreement in Esomeprazole Patent Litigation (Apr. 15, 2008). This was also true as to those strengths in Procardia XL for which the settling generic firm was not the first-filer.

⁹⁶ *See* Adderall XR Agreement, *supra* note xx.

⁹⁷ Cite.

generic firms seldom do deals of any kind outside the context of settlement. To evaluate this proposition, the annual securities filings of five major brand-name firms (AstraZeneca, Abbott, Bristol-Myers Squibb, Glaxo, and Pfizer) and five major generic firms (Barr, Mylan, Ranbaxy, Teva, and Watson) were examined. These ten firms yielded 25 possible brand-generic interactions. A review of these filings between 2002 and 2007 revealed just one set of business dealings by any brand-generic pair, outside the context of settlement.⁹⁸ Meanwhile, litigation and settlement figured frequently in these reports.⁹⁹ This evidence is not decisive: such non-settlement deals could exist, yet fall beneath the threshold of reporting. If so, however, they are apparently not of first-rank importance to the operations of the firm.

Further evidence about the firms' limited business dealings, outside of settlement, comes from a more detailed examination of a single type of side deal, namely co-promotion. Brand-name firms frequently have reason to enter co-promotion arrangements to augment their own promotion efforts—for example, to reach physicians that they could not otherwise reach with their own detailing team. The annual filings of Glaxo, for example, reveal a wide range of co-promotion and similar arrangements with a large number of firms. Deals with generic firms, however, are nowhere to be found, again with the single exception noted above. The filings of the other brand-name firms reveal a similar pattern.

This result is not surprising, considering the business of generic firms. Generally, they do not have a substantial promotion team, for they seldom have any branded drugs to promote. Their R&D capacity is limited too; this is not their core business. Nor do they have powerful manufacturing capacities such that they would be the obvious alternative supplier of choice.¹⁰⁰

The contrast is less severe when the side deal takes the form of brand-name firm value provided at a possible discount. It is quite common for a brand-name firm to set up an authorized generic arrangement with some generic firm. It does so to earn additional post-entry profits from the price-sensitive segment, and perhaps to discourage generic entry in the first place. Transfers of product lines to other drug makers are common as well.

C. Adopting a Presumption of Payment

Viewed in isolation, it is difficult to tell whether a side deal includes a payment for value, or instead amounts to disguised payment to the generic firm. A broader comparison of side deals

⁹⁸ Check; details; even authorized generics? An exception is Glaxo's unusual arrangement with Ranbaxy

⁹⁹ Details.

¹⁰⁰ For example, Cephalon agreed to buy active ingredient from a third generic firm, even though the firm had not manufactured the product and Cephalon already had an adequate source of supply. Complaint.

within settlements, versus outside, tells a different story. With respect to pay-too-much side deals, the lack of mutual interest in brand-generic deals outside of settlement is a strong reason to think that the deals are a way to pay for delay.

In such cases, it is appropriate to impose a presumption that the side deal provides disguised payment to the generic firm. That conclusion is not, by itself, enough to impose liability. It resolves the “fact” question, but does not address the “theory” question of whether payments, even if they induce delay to the end of the patent term, are permitted under patent and antitrust law.

Under this presumption proposal, the drug makers would be free to come forward with substantial evidence that their unusual deal was for value, and raises no anticompetitive issues. That burden is most appropriately placed upon them, as the least-cost providers of the necessary information. An alternative approach, also supported by the evidence from aggregation, would simply ban agreements with side deals altogether.

This proposal, like any aggressive antitrust rule, is potentially over-inclusive. It raises the probability of false condemnation—false positives, as they are sometimes called. But here, the rareness of such arrangements outside of settlement lowers the likelihood of false positives. The error cost analysis has a further component: how costly are false positives when they occur? Here, the answer is, not very costly, because the generic firm is seldom a distinctive source of the particular value in question.

The rule comports with the comparative rigor with which we treat collusive activity generally. Antitrust’s lenient approach to exclusionary conduct reflects an error cost calculation focused upon false positives.¹⁰¹ As noted in the introduction, decisionmakers think that true positives are rare and difficult to distinguish, and also that false positives are particularly costly, because they amount to condemnation of the “very conduct” that antitrust is supposed to protect.¹⁰² For collusion, by contrast, avoiding false negatives is the important goal, particularly where false positives are rare and low-cost, and where there are no significant equilibrating tendencies that tend to restore competition. That aggressive approach is shared even by “Chicago

¹⁰¹ See, e.g., *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (justifying stringent rule for predatory pricing as response to “intolerable risks of chilling legitimate price-cutting”); *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (justifying stringent rule for refusals to deal as response to costliness of false condemnations).

¹⁰² See, e.g., *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (“Mistaken inferences ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’”) (quoting *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)).

School” analysts, who support an enforcement emphasis upon collusion,¹⁰³ particularly given the absence of competition as a corrective against false negatives.¹⁰⁴

What about charge-too-little side deals? The likelihood of false positives is higher, compared to pay-too-much deals, because authorized generic arrangements and product transfers frequently occur outside the context of settlement. The cost of false positives remains low, however, due to the absence of distinctive value arising from *this* particular generic firm being the counterparty to the transaction. Here, the high cost of false negatives and low cost of false positives may be sufficient to support a presumption in the charge-too-little context, but this Article recommends a more cautious approach, which is to make the presumption applicable only on a going forward basis. That way, parties are on notice that they must reach charge-too-little deals, like pay-too-much deals, with parties with which they are not settling. Given the absence of distinctive value offered by the settling firm, that should not be too difficult.

IV. Institutional Structure

The analysis so far has remained agnostic about the choice of institutional actor. For example, a court could adopt the presumption of payment in deciding a side-deal arrangement, or an agency could promulgate a rule on the same basis, or Congress could amend substantive antitrust law. Part IV.A examines whether courts are the right tool for conducting antitrust policy in this area, arguing that courts are poor aggregators, compared to agencies. Part IV.B shows how the continuing evolution in settlement—beyond side deals to a wider range of tactics—makes enforcement difficult and perhaps possible given current institutional arrangements.

A. Aggregating Across Cases

Courts have two problems: they and their surrogates cannot observe non-public data about other settlements, and they have trouble absorbing the results of aggregate analysis supplied by parties or amici. Those problems suggest a shift in favor of agency-focused enforcement.

¹⁰³ Posner (2001) at 48 (noting that Reagan-era Antitrust Division, led by Bill Baxter, shifted enforcement focus from exclusionary to collusive practices).

¹⁰⁴ See *Premier Electrical Construction v. National Elec. Contractors Ass’n*, 814 F.2d 358 (7th Cir. 1987) (Easterbook, J.) (noting the heightened risk where no automatic mechanism exists to correct blunders); *In re High Fructose Corn Syrup Antitrust Litigation*, 295 F.2d 651(7th Cir. 2002) (Posner, J.) [?]; see also Posner’s view that oligopoly suffices for a section 1 violation.

1. Using Non-Public Data

An agency's superior powers of aggregation are a neglected source of authority and deference. An agency can collect and synthesize experiences from across the economy, which allows it to determine whether (say) predatory pricing is *really* "rarely tried and rarely successful," or whether collusive settlement between drug makers is frequently attempted and usually not subject to the disciplining effect of competition. This information can then be used to devise rules that reduce error costs.

Private plaintiffs have trouble figuring out the content of settlements. Some early settlements escaped notice entirely. More recent settlements have been protected by the difficulty of knowing how extensive pay for delay is, a fact usually not discernable from public information. That is one reason why few of the most recent settlements have been challenged.

This Article's analysis, far from escaping these information problems, actually demonstrates them. My data collection method often does not permit the determination, in an individual case, of whether the particular side deal imparts payment. The conclusions are only in the aggregate. The limited extent of public information puts an upper bound on the utility on a public aggregation analysis. Even with the information in Part II, courts and plaintiffs lack the full information they need to evaluate side deals and minimize error costs, and lack the necessary authority to generate better aggregate information.

The FTC is better positioned than courts or private parties—or academics—to undertake a comprehensive analysis of settlement practice. The FTC has unique access to the details of every settlement. Drug makers have a special statutory obligation to file all brand-generic settlements with the FTC.¹⁰⁵ Even without that specific authorization, the agency has general authority to require firms to divulge confidential information relevant to antitrust policymaking, including both the details of individual settlements and side deal-like agreements reached outside the context of settlement.

A related advantage is speed. A single court needs many years to develop a sense of the overall distribution of cases, as individual draws from the distribution appear only rarely. Pooling of this information—whether through the natural pooling of the appeals process (perhaps increased by centralizing all pay-for-delay appeals) or reading out-of-jurisdiction opinions—will help, but not by much.

¹⁰⁵ Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003). The Antitrust Division also receives a copy.

The aggregation advantage draws reinforcement from a second strength, the agency's superior expertise.¹⁰⁶ Expertise, as I intend the term here, means that the agency is better able to discern the competitive impact of a practice in a particular situation. Aggregation is a distinct virtue: the ability to infer what's going on in *this* case, based upon an understanding of what's going on in *other* cases. Expertise reinforces aggregation because the ability to accurately assess each data point in the distribution strengthens our confidence about the resulting inference. Often, aggregation is more important than expertise. A party to litigation can provide expertise, but it cannot fully supply aggregation.

A skeptical reader of this Article might conclude that the public survey results reported in Part II are too weak to justify a presumption of payment through side deals. The results would be stronger, for example, if the price terms of settlements were visible. If so, that strengthens the case for deploying the agency as an aggregator, to fill in the gaps, and better understand whether and exactly where compensation is conferred. In that sense, Part II is a rough draft for a more comprehensive, future agency report.

The FTC has not fully exploited its information advantage. In 2002, it published an important survey of settlements, drawing upon information about individual settlements that it obliged the drug makers to supply, combined with internal information lodged with the FDA. But the FTC has not undertaken a similarly comprehensive study of the evolution in settlement. Of the settlements in my dataset, fully [75] percent occurred after the end of the FTC's last major data collection effort. Although the FTC evaluates each individual agreement to determine whether further investigation is appropriate, it does not synthesize the resulting information, aside from very general annual summaries of settlement activity.

2. Processing Generalizations

The agency's aggregation advantage does not count out courts entirely. The court could simply draw upon an aggregate analysis made available by the agency in an amicus brief. [To come: an argument that courts have trouble processing cross-case generalizations.]

3. Agency Rulemaking

An administrative agency—here, the FTC—is well positioned to develop aggregate information. What should the FTC do with this information, once collected? One possibility,

¹⁰⁶ 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>; 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>.

noted above, is simply to supply it to courts. For example, the FTC could explain, in a particular case, that side deals are a frequent means of compensation in other settlements, and that side deals like those reached by these parties are unusual outside the context of litigation, either for these parties or for other brand-name and generic firms. This could be accomplished in an amicus brief—the FTC has filed many of these on other topics—or directly in the course of its own litigation.

A second option available to the FTC, and one made more attractive by the reluctance of courts to recognize the anticompetitive harm of pay-for-delay settlement,¹⁰⁷ would be to implement the outcome directly through a rulemaking. The rule would mirror the rule proposed for courts discussed above: a ban on or presumption against complex settlement.

The FTC possesses authority to promulgate substantive rules about competition policy. Prior to 1975, it was unclear whether the FTC had substantive rulemaking authority.¹⁰⁸ The D.C. Circuit recognized rulemaking authority in a controversial ruling,¹⁰⁹ which was later confirmed by statute.¹¹⁰ There remains some question about how far this authority extends, however, and the FTC has not undertaken any antitrust rulemaking thus far.

One seeming advantage of rulemaking is to reduce the need to prove the merits of each individual case. That advantage is smaller than one might expect, however, since parties subject to the prohibition are likely to bring judicial challenges. An important feature of rulemaking under the FTC Act is that, unlike private litigation, such rulemaking does not trigger treble damages. That feature should ease the fears of those who think treble damages are excessive, a fear that puts downward pressure upon the boundaries of liability. The argument against treble damages is strongest where the conduct is open and notorious. Here, the settlement is out in the open, but its content is not, suggesting that settlement is in this respect more like secret price fixing than like a monopolist's open refusal to deal.

¹⁰⁷ Not entirely more attractive. On the other hand, rulemaking might seem like an end-run on failure in the courts. That might undermine deference when court review occurred. The answer depends in part upon where review occurs.

¹⁰⁸ Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002).

¹⁰⁹ *Nat'l Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973) (requiring posting of octane ratings on gas pumps). Judge Skelly Wright's opinion has been criticized for ignoring that FTC's section 5 power was not accompanied by a sanction provision, whereas agencies in other contexts was so accompanied.

¹¹⁰ Magnuson Moss-Federal Trade Commission Improvement Act of 1975, Pub. L. No 93-637, 88 Stat. 2193. *See also* FTC Act § 6(g), 15 U.S.C. § 46(g).

B. Coping with Continued Evolution

Settlement practice continues to evolve to exploit regulatory complexity. Our maintained assumptions about settlement—that it entails an agreement, by which the cash or its equivalent is exchanged for entry, for an entry date that is constrained to be no later than patent expiration—are proving to be quite malleable. In fact, the moment of expiration, the forms of payment, and the fact for agreement are all manipulable. Here are a few examples from current settlement practice.

Fallback patents. If a brand-name firm has a large number of patents, no matter how weak, the moment of patent expiration is malleable. Consider, for example, Lipitor. Pfizer sued Ranbaxy, the first-filing generic firm, as to its two strongest patents: a composition of matter patent expiring in March 2010,¹¹¹ and a second patent expiring in June 2011.¹¹² Ranbaxy won its challenge to the June 2011 patent, and lost on the March 2010 patent.¹¹³

When the parties settled in June 2008, however, observers were surprised to discover that Ranbaxy's entry was set for November 2011, later than the expiration of either patent.¹¹⁴ The parties defended this result on the ground that Pfizer had two more patents, expiring in 2016,¹¹⁵ and had even taken the trouble to sue Ranbaxy on them in March 2008. These patents hardly provided any additional exclusionary force, however. Their only effect was to provide cover for the argument that the settlement fit within the nominal scope of the relevant patents.

Fallback patents help the drug makers in a second way. To see why, note that when Ranbaxy won one patent challenge, it triggered exclusivity prematurely, since the second patent prevented FDA approval. The combined result would have been to permit entry without exclusivity in March 2010. (The patents expiring in 2016 did not affect that result.) However, Pfizer had three more patents in reserve, on which it did not sue.¹¹⁶ Due to an interpretive quirk of the Hatch-Waxman Act (not applicable to post-MMA drugs), each patent provides a fresh

¹¹¹ '893. September 2009 expiration, extended by pediatric exclusivity to March 2010.

¹¹² '995. June 2011 includes pediatric exclusivity. These were the same two patents put at issue in UK litigation.

¹¹³ *Pfizer v. Ranbaxy Labs.*, 457 F.3d 1284 (Fed. Cir. 2006) (invalidating one patent and upholding one patent).

¹¹⁴ Pfizer Lipitor Press Release, *supra* note xx.

¹¹⁵ These patents were not listed in the Orange Book, that were the subject of a declaratory judgment action. Complaint, *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, No. 08-164 (D. Del. Mar. 24, 2008) (suing on '511 and '740, both expiring in July 2016) BB [check].

¹¹⁶ The patents were listed in the Orange Book, and Ranbaxy was first to file an ANDA with a paragraph IV certification as to them.

opportunity for exclusivity. By declining to sue Ranbaxy on these patents, Pfizer preserved Ranbaxy's exclusivity, despite the initial trigger, a preferable result for both parties.¹¹⁷

Payment by forswearing an authorized generic launch. As previously explained, retained exclusivity is a source of payment, and a source of compensation to a generic firm. That compensation is limited, however, by the likelihood that a brand-name firm will launch an authorized generic product to compete with the generic entrant. The brand-name firm can increase the generic entrant's profits from exclusivity by agreeing not to launch an authorized generic product. Many recent agreements include a "no authorized generic" term.¹¹⁸

Payment by forgiving probabilistic damages. Rather than pay the generic firm cash, a brand-name firm can forgive an existing debt. Lipitor is again exemplary. Pfizer and Ranbaxy had done battle on a second significant drug, Accupril. In 2004, Ranbaxy had launched a generic version of the drug "at risk," without waiting for a district court to rule whether Pfizer's patent was valid and infringed.¹¹⁹ Pfizer secured a preliminary injunction, which was affirmed by the Federal Circuit.¹²⁰ At this point, Pfizer's damages claim against Ranbaxy was, though probabilistic, large in expected value.¹²¹ The Lipitor settlement also "resolved" the Accupril dispute, likely by forgiving the accumulated expected damages.

¹¹⁷ The MMA replaced this "patent-by-patent" approach to exclusivity with a single opportunity for each product.

¹¹⁸ Examples include Adderall XR, Plavix, and Effexor XR. See Adderall XR Agreement, *supra* note 36, 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"); Event Brief of Q4 2006 Barr Pharmaceuticals, Inc. Earnings Conference Call, Aug. 15, 2006 (noting the no-authorized-generic provision); Plavix Agreement, *supra* note 36; Wyeth Pharmaceuticals, Current Report (Form 8-K) (Jan. 13, 2006) (Effexor XR) (noting that Teva's patent license is exclusive at first). There were two Plavix agreements. The initial agreement included the term; the parties disagree about whether the revised agreement included the term.

This source of payment to induce delay has attracted some attention of antitrust enforcement. That was one reason why antitrust enforcers rejected the Plavix agreement. See Hemphill, *supra* note xx. Logically, if a no-AG provision raises an antitrust problem, then so does retained exclusivity itself, for the effect of the no-AG provision is to raise the value of retained exclusivity.

¹¹⁹ Press Release, Teva Pharmaceutical Industries Ltd., Teva Launches Quinapril Hcl Tablets; Pursuant to Agreement with Ranbaxy, Dec. 16, 2004. Ranbaxy indemnified Teva as part of this launch. See Teva Pharmaceuticals Industries Ltd., Report of Foreign Private Issuer (Form 6-K), at 10 (May 10, 2007).

¹²⁰ Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1371 (Fed. Cir. 2005) (noting and affirming preliminary injunction entered March 29, 2005).

¹²¹ The rulings indicated a high likelihood that Pfizer would win on the merits. Accupril has annual sales of about \$400 million, so the expected damages were likely at least tens of millions of dollars.

The forgiveness strategy can be applied not only across several drugs, but also across several strengths of a single drug. For example, in Wellbutrin XL, the generic firm had challenged the patent applicable to several strengths of the drug. It launched at risk as to one strength but not as to a second strength. The subsequent settlement forgave accumulated damages on the first strength, and delayed entry on the second.¹²²

Avoiding Agreement. Through careful design, settling parties can arrange for delayed entry without any formal agreement as to delay. The parties can condition periodic payment upon non-entry, and make them a function of brand-name profits that depend upon non-entry—for example, a royalty paid on brand-name sales.¹²³ One settlement, involving the drug Altace, appears to have used a variant of this strategy. There, the brand-name firm acquired a new tablet formulation of the drug, and agreed to pay a royalty on sales of the tablet formulation. This gave the generic firm an incentive not to enter precipitously, as early entry might jeopardize the orderly transition to a new and more profitable formulation. In addition, periodic cash payments, purportedly in exchange for developing the new formulation, were made contingent on unspecified events. This may have been directly for non-entry or indirectly for a successful transition.

These examples demonstrate that parties are adept at achieving a particular substantive outcome—compensation from the brand-name firm to the generic firm, combined with delayed entry—while altering the form of settlement as necessary to evade the most obvious claims of liability. This evolution is taking settlement beyond the reach of existing antitrust institutions.

Courts are decreasingly likely to be an effective check on settlement, and not only because they are poor aggregators. Courts are fed cases by either a government agency or a private plaintiff. The FTC has limited enforcement capacity; practically speaking, it can bring at most a few pharmaceutical cases at a time, and they are likely to last for five years or more. The FTC is frankly overwhelmed by settlement volume. Private plaintiffs, meanwhile, are reluctant to bring cases. They have lost the simplest ones, so why take a chance on the complex ones?

Judges, meanwhile, have not shown much receptivity to even modest complexity. Consider the two major forms of complexity discussed in this Article, side deals and retained exclusivity, and the last two cases to reach the Supreme Court as petitions for certiorari. In one case, the FTC argued that retained exclusivity was troubling, but this argument went nowhere.¹²⁴

¹²² Press Release, Biovail, Biovail Announces Comprehensive Settlement Related to Wellbutrin XL (Mar. 5, 2007). The agreement was actually reached in February. Biovail Laboratories, Annual Report (Form 20-F), at 4 (Mar. 22, 2007).

¹²³ Naprelan adopted this strategy. *Andrx Pharm., Inc. v. Elan Corp.*, No. 00-3481, at *6 (S.D. Fl. Apr. 24, 2003). A promotion deal could be structured this way too.

¹²⁴ Schering.

In the other, a private plaintiff argued that authorized generic sales are troubling, but again this idea was not taken up.¹²⁵

Continuing evolution makes the crisis in case-by-case adjudication more acute for another reason. A single appellate or Supreme Court opinion imposing liability does not fully resolve liability for the newest settlements. A win on a simple case is a very helpful start, but only sets the stage in making sense of the more complicated cases. Thus, even if it were settled as a matter of theory that paying for delayed entry is prohibited, and settled as a matter of fact that side deals provide a disguised means to pay for delay, it is not straightforward to show that the newest settlements also violate antitrust law. On the other hand, if a court is forced to start with one of the most complex cases, without the benefit of affirmative precedent on the simpler cases, correctly identifying liability seems unlikely.

Can agencies or Congress fill this gap? The agency route is explored above. Congress, however, is quite vulnerable to gamesmanship on this issue. The MMA, for example, must be regarded as a failure so far as settlements are concerned. Though designed to eliminate the bottleneck, instead the MMA preserved it, and left in place retained exclusivity for settling parties. In an important sense it took a step back, by requiring a later filer, in its attempt to trigger a first-filer's exclusivity, to get a favorable *appeals* court ruling before entry would be possible. To be sure, it is possible Congress will get it right the second time around, but its failure so far provides strong grounds for pessimism.

Conclusion

Examining in detail the terms and effect of drug patent settlements uncovers several important points. Drug patent settlements remain an important—indeed growing—and unresolved problem in antitrust enforcement. The evolution in settlement structure makes it less likely that courts will correctly identify and condemn them. There is therefore much reason to fear a continuation and intensification of false negatives if the current policy is continued. Case-by-case evaluation is a failure and is likely to remain so, absent intervention by the Supreme Court. One partial response is to impose a presumption of payment where side deals accompany delayed entry.

The analysis supports several further measures. This study reveals persistent gaps in public knowledge about settlements, both in their existence and their terms. These are gaps that the FTC is uniquely positioned to fill. The agency should step in to collate the extensive information it already has, supplement it with additional fact-finding, and disseminate authoritative information of the type offered here. In that respect, this study can serve as a first draft for the FTC's future work. So long as settlements and their terms remain hidden, it will be

¹²⁵ Tamoxifen.

difficult to do integrative work of the kind suggested here, and difficult to develop the “consensus among commentators” that is a key step in discerning appropriate antitrust policy. The additional insight will help academics and policymakers in revising, if necessary, the emerging consensus to which this Article contributes—that pay-for-delay settlements are frequently tried and frequently successful.

Appendix: Settlements in Detail

This Appendix summarizes the major features of each of the brand-generic agreements in the dataset. The agreements are categorized by type, depending upon the degree to which the settlement raises a substantial pay-for-delay issue. Within each category, the settlements are listed by drug, in chronological order according to the date of the earliest brand-generic agreement.

Settling generic firms eligible for exclusivity at the time of settlement are listed in boldface, and ineligible firms are italicized. Where eligibility is not known, the firm is listed in plain type. In the interest of concision, some terms are omitted.¹²⁶

¹²⁶ For example, settlements with later filers remove a significant threat to the innovator's patent, but this implication is generally not noted. The nature of entry—whether it is ANDA-based (with a patent license) or a supply agreement—is also generally suppressed.

Brand name <i>Trade name</i>	U.S. Sales (\$m)	Innovator firm	Generic firm	Date	Terms
Nolvadex <i>Tamoxifen citrate</i>	265	Zeneca	Barr	Mar. 1993	<p>\$ Cash (\$66m) Authorized generic sales</p> <p>Δ Entry in August 2002 (patent expiration) <i>Delayed six months by pediatric extension</i> Remove primary threat to patent Bottleneck* Vacate judgment of invalidity</p> <p>* Uncertain whether settlement would forfeit 180 days</p>
BuSpar <i>Bupirone HCl</i>	288	Bristol	Schein	Dec. 1994	<p>\$ Cash (\$73m)</p> <p>Δ Entry in November 2000 (at patent expiration) Remove primary threat to patent Bottleneck</p>
Zantac <i>Ranitidine</i>	2150	Glaxo	Genpharm	Oct. 1995	<p>\$ Cash (\$133m) Remove threat to 180 days (payment for selective waiver) Extra sales in other countries</p> <p>Δ Entry in August 1997 Remove primary threat to patent</p>
Cipro <i>Ciprofloxacin</i>	680	Bayer	Barr	Jan. 1997	<p>\$ Cash (\$398m) Authorized generic sales at end of patent term</p> <p>Δ Entry in December 2003 (at patent expiration) <i>Delayed six months by pediatric extension</i> Remove primary threat to patent Bottleneck*</p> <p>* Uncertain whether settlement would forfeit 180 days</p>