

## ARTICLES

### AN AGGREGATE APPROACH TO ANTITRUST: USING NEW DATA AND RULEMAKING TO PRESERVE DRUG COMPETITION

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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. By synthesizing available information, the present analysis helps close the information gap for an important, unresolved issue in U.S. antitrust policy: patent settlements between brand-name drug makers and their generic rivals. The analysis draws upon a new dataset of 143 such settlements.*

*Due to the factual complexity of individual brand-generic settlements, important trends and arrangements become apparent only when multiple cases are examined collectively. This aggregate approach provides valuable information that can be used to set enforcement priorities, select a substantive liability standard, and identify the proper decisionmaker. The analysis uncovers an 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 Article proposes two solutions for such anticompetitive behavior, one doctrinal and one institutional: a presumption of (illegal) payment where a side deal is reached contemporaneously with delayed entry, and an expanded role for agencies, to gather and synthesize nonpublic information regarding settlements, and potentially to engage in substantive rulemaking. The aggre-*

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*gate approach also reveals the shortcomings of 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 tension at its core. Antitrust law “maintain[s] certain basic rules of competition” as a way to preserve low prices, efficient production, and robust innovation.<sup>1</sup> In regulating a particular type of behavior, a decisionmaker may choose a rule that minimizes 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 optimal rules.

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1. Michael D. Whinston, Lectures on Antitrust Economics 1 (2006).

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.<sup>2</sup> That lenient rule increases false exonerations, but the Supreme Court has concluded that these are unlikely, as predation is “rarely tried, and even more rarely successful.”<sup>3</sup> But how does a court come to know this? And is a court the right institution to uncover 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 and the facts of a specific case, about the distribution of real world economic conduct. What a decisionmaker actually needs is aggregate information on which to base 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, all else being equal.

As a vehicle for considering the substantive and institutional dimensions of an aggregate approach, this Article focuses on 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. The brand-name firm responds with a patent infringement suit that claims its product is protected by one or more patents, and the generic firm counters 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, thereby ending its monopoly on the product, 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. Recent settlements involve some of the world’s most important drugs.<sup>4</sup> The largest two settlements alone insulate from competition more than \$10 billion in annual brand-name sales.<sup>5</sup> The importance and difficulty of the question has prompted the Supreme Court to seek the

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2. *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”).

3. *Id.* at 226 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 589 (1986)).

4. Settlements in 2008 included Lipitor (more than \$7 billion in annual U.S. sales), Pfizer Inc., Annual Report (Form 10-K) exh. 13, at 18 (Feb. 29, 2008), and Nexium (more than \$3 billion), AstraZeneca PLC, Annual Report (Form 20-F), at 55 (Mar. 12, 2008).

5. See *supra* note 4.

Solicitor General's views three times since 2004.<sup>6</sup> As of early 2009, the Federal Trade Commission (FTC) is pursuing new litigation challenging settlements over two drugs,<sup>7</sup> new bills aiming to prohibit such settlements have been introduced in Congress,<sup>8</sup> and the President has included a ban on anticompetitive settlements in his annual budget proposal.<sup>9</sup>

Identifying the proper scope of liability, however, is not a simple task. Some settlements do not raise pay-for-delay concerns. For other settlements, it is difficult to tell whether a payment was made. Before an optimal antitrust rule can be developed, policymakers need accurate information regarding the scope and nature of the problem. As an initial step toward erasing this deficit, this Article assesses the problem of entry-delaying settlements by aggregating publicly available data about these settlements and considering the overall picture that emerges. This approach draws upon a new dataset of drug patent settlements, developed from a wide range of public sources. The resulting dataset provides, for the first time, a vivid picture of the frequency and distribution of settlement activity. Viewing the settlements collectively permits new insights about enforcement priorities, the optimal substantive rule, and the choice of decisionmaker.

The analysis reveals an evolution in the terms of settlement. Whereas early settlements simply traded cash for delay, modern settlements show sophistication in the means by which payment and delay are provided. One example is the use of side deals, consummated at the same time as settlement of the patent litigation, in which the generic firm contributes unrelated value, such as a separate patent license, ostensibly in exchange for payment. That tactic undermines reliable case-by-case characterization of settlements as collusive or not: In a particular instance, it is difficult to tell whether the brand-name firm's payment is consideration for delay, for the unrelated value, or both.<sup>10</sup>

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6. See *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 1868 (2007) (order requesting Solicitor General's opinion); *FTC v. Schering-Plough Corp.*, 546 U.S. 974 (2005) (same); *Andrx Pharms., Inc. v. Kroger Co.*, 540 U.S. 1160 (2004) (same).

7. Complaint, *FTC v. Watson Pharms., Inc.*, No. 09-598 (C.D. Cal. Jan. 29, 2009) [hereinafter *AndroGel Complaint*]; Complaint, *FTC v. Cephalon, Inc.*, No. 08-0244 (D.D.C. Feb. 13, 2008) [hereinafter *Provigil Complaint*].

8. *Preserve Access to Affordable Generics Act*, S. 369, 111th Cong. (2009); *Protecting Consumer Access to Generics Drugs Act of 2009*, H.R. 1706, 111th Cong. (2009).

9. Office of Mgmt. & Budget, *A New Era of Responsibility: Renewing America's Promise* 28 (2009) ("The Administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.").

10. For example, in an important test case brought by the FTC, the case-specific approach produced divergent results at each level of review. Compare *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1070-72 (11th Cir. 2005) (concluding that Schering's payment to Upsher-Smith was for value of licenses), and *Schering-Plough Corp.*, 136 F.T.C. 956, 1092, 1241 (2003) (opinion of administrative law judge) (same), with *Schering-*

An aggregate approach permits us to address the question in a different way. It reveals that these sorts of deals are a frequent component of settlements, but rare outside of settlement. Thus, the overall pattern suggests they provide a disguised means to confer payment. This 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 goods or services acquired in the side deal.

As an institutional matter, the aggregate approach undermines the case for courts as primary antitrust policymakers. A court is largely limited to 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, given their expertise, access to confidential information about regulated firms, and freedom to examine issues over a long period of time, outside the litigation context. Thus, the analysis suggests that the FTC 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—even beyond side deals—in response to the enforcement emphases of particular litigants and courts. Settling parties have been able to achieve the same entry-delaying effect of the earliest settlements, while devising new disguises for payment or even the very existence of agreement. As litigants respond dynamically to judicial scrutiny with new and complex settlement structures, existing antitrust institutions have trouble keeping up.

The Article proceeds in four parts. Part I introduces the pay-for-delay settlement problem and the aggregation deficit in antitrust. Part II draws upon the new dataset, outlining the scope and changing structure of entry-delaying settlements, and spells out how these features recommend making the settlement issue an enforcement priority. Part III examines side deals from an aggregate approach, explaining why they should be presumed to convey payment when accompanied by an agreement to delay entry. Finally, Part IV addresses the question of institutional choice. It first shows why courts make poor aggregators, and proceeds to consider how agencies can help fill the gap by aggregating data and promulgating rules.

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Plough Corp., 136 F.T.C. 956, 1019, 1051–52, 1055–56 (2003) (full Commission opinion) (concluding that payments secured delay).

## I. THE PAY-FOR-DELAY SETTLEMENT PROBLEM

Part I.A describes the pay-for-delay settlement problem. Although settlements have received a great deal of attention, almost all of it has focused upon the theoretical issues raised in individual cases, at the expense of important factual questions that also arise. Part I.B describes this neglect and its connection to the larger problem of an aggregation deficit in antitrust.

### A. *Why Settlements Violate Antitrust Law*

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.<sup>11</sup> Once the brand-name firm places a patented drug on the market, a generic firm may seek to launch a competing version of the same drug, asserting that any applicable patents are invalid or not infringed.<sup>12</sup> The assertion is contained in an Abbreviated New Drug Application, or ANDA, that is filed with the Food and Drug Administration (FDA).<sup>13</sup> If the filing is successful, the generic firm can launch a competing product without repeating the costly safety and efficacy studies that the FDA requires as a condition of brand-name approval.

The first generic firm to file an ANDA is entitled, upon FDA approval, 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.<sup>14</sup> For some drugs, multiple generic firms file ANDAs on the same day, and thus share the exclusivity entitlement.<sup>15</sup> For others, one generic firm files at least a day before the others.<sup>16</sup> In response to the

11. See 21 U.S.C. § 355(b) (2006) (providing for launch of new drug after demonstration of safety and efficacy). This account is a simplification. For more details, see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1564–66 (2006).

12. See § 355(j)(2)(A)(vii)(IV) (requiring certification to FDA and notification of rightsholder that any applicable patents are invalid or not infringed).

13. *Id.* The ANDA contains a so-called “Paragraph IV” certification that the applicable patent protection is invalid or not infringed. Not all ANDAs contain such a certification; often, the generic firm is content to wait until patent expiration before entering. FTC, *Generic Drug Entry Prior to Patent Expiration 10* (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (on file with the *Columbia Law Review*) [hereinafter FTC, *Generic Drug Entry*] (reporting ninety-four percent of the more than 8,000 ANDAs filed between 1984 and 2000 lacked a Paragraph IV certification). As a general matter, the ANDAs discussed in this Article contain Paragraph IV certifications.

14. § 355(j)(5)(B)(iv). The “duopoly” characterization ignores the effect of authorized generics, discussed *infra* Part III.A.2.

15. Ctr. for Drug Evaluation & Research, FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day 3–4* (2003), available at <http://www.fda.gov/cder/guidance/5710fnl.pdf> (on file with the *Columbia Law Review*).

16. Multiple first filers may result when the brand-name drug contains no “active moiety” already approved in another New Drug Application, or NDA. In that case, the

ANDA, the brand-name firm may file a patent infringement suit to establish validity and infringement. This pattern—launch, challenge, sue—is typical for major drugs.<sup>17</sup>

The two drug makers have a powerful incentive to settle. For a blockbuster drug with billions of dollars in annual sales, a brand-name firm has billions to lose from generic competition. Moreover, entry hurts the brand-name firm more than it helps the generic firm. Entry lowers total producer profits by introducing price competition, particularly once other generic firms are free to enter after the 180-day period ends.<sup>18</sup> There is therefore a large gain from trade for the two firms. A settlement in which the brand-name firm pays the generic firm, and the generic firm agrees to delay entry, is profitable for both firms. Because later filers generally have much less incentive to challenge a brand-name drug patent, including no eligibility for the 180-day period, buying off the first filer is an effective means to remove the most potent entry threat.<sup>19</sup>

Such settlements, if they include payment, reduce expected static consumer welfare. Early competition benefits consumers by lowering 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 perceived strength of the patent. 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.<sup>20</sup> That result is equal to the average result of litigation, in which the consumer has a fifty percent chance of enjoying the full benefit of immediate competition and a fifty percent chance of re-

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FDA must not accept an ANDA for four years after NDA approval. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b) (2006). Aside from giving the brand-name firm several years of protected sales before a generic challenge can commence, it also affords generic firms plenty of time to devise a workaround strategy. For other drugs, by contrast, the generic firms are in an immediate race to devise a plausible legal and pharmaceutical strategy, and the firms will usually differ significantly both in their assessment that the challenge is sufficiently promising to justify an investment, and in their skill and speed in developing a workaround.

17. For example, of the fourteen best-selling drugs of 2005, see Matthew Herper, *The Best-Selling Drugs in America*, *Forbes*, Feb. 27, 2006, at [http://www.forbes.com/2006/02/27/pfizer-merck-genentech-cx\\_mh\\_0224topsellingdrugs.html](http://www.forbes.com/2006/02/27/pfizer-merck-genentech-cx_mh_0224topsellingdrugs.html) (on file with the *Columbia Law Review*), twelve faced pre-expiration patent challenges: Lipitor, Nexium, Prevacid, Plavix, Zolof, Norvasc, Seroquel, Effexor XR, Zyprexa, Singulair, Protonix, and Risperdal. The two exceptions are Zocor and Advair Diskus. This calculation does not include biologic drugs not subject to the Hatch-Waxman regime.

18. For details and caveats, see Hemphill, *supra* note 11, at 1580–82.

19. See *id.* at 1585–86 (noting small incentive to file and vigorously pursue challenge); *id.* at 1605–06 (discussing free-rider problem among later filers resulting from nonmutual issue preclusion, particularly in invalidity challenges). In some instances, the settlement also creates a bottleneck for later filers, as discussed *infra* Part II.C.2.

20. This is an oversimplification, because it ignores the effect of the exclusivity period, which is a source of compensation for the generic firm. See *infra* notes 91–102 and accompanying text (describing use of exclusivity period in settlements); see also Hemphill, *supra* note 11, at 1588–94 (describing exclusivity period as source of compensation).

ceiving no benefit. By contrast, bargains that reflect not only perceived patent strength but also payments from brand-name to generic manufacturers will induce the generic firm to accept a later entry date, which decreases consumer welfare. Thus, a pay-for-delay settlement transfers wealth from consumers to drug makers, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm. The higher price also alters the purchase decisions of consumers and insurance providers, introducing an additional welfare loss.<sup>21</sup>

As I have argued elsewhere, the consumer-disregarding effect of pay-for-delay settlements requires their condemnation as a violation of antitrust law.<sup>22</sup> Allocating markets in this fashion is a restraint on trade in violation of section 1 of the Sherman Act,<sup>23</sup> and may also be condemned as illegal monopolization.<sup>24</sup> It is therefore no surprise that the FTC—the federal agency charged with antitrust enforcement in the pharmaceutical industry—has brought numerous cases, often together with state attorneys general, arguing that certain pay-for-delay settlements violate antitrust law.<sup>25</sup> Private parties have done so as well.<sup>26</sup>

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21. Assessing this welfare loss is complex. In an ordinary market, setting a price above marginal cost produces an allocative distortion and accompanying welfare loss for consumers, because consumers who value the good above its marginal cost, but below the prevailing price, are deflected to less desired substitutes. To the extent that public and private insurance secures the purchase of a drug, this distortion is reduced, though it is not eliminated (as insurance is incomplete). Moreover, the higher price produces new distortions (and hence inefficiency) in the decisionmaking process of the insurance provider, through decisions to charge higher premiums and not to reimburse drugs whose value exceeds their marginal cost. In a similar manner, the existence of incomplete insurance affects the assessment of the size of the transfer.

22. See Hemphill, *supra* note 11, at 1596.

23. 15 U.S.C. § 1 (2006); see *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49–50 (1990) (per curiam) (holding that competing bar review course providers illegally restrained trade by agreeing for one to withdraw from market in exchange for payments).

24. See 15 U.S.C. § 2 (prohibiting monopolization).

25. The FTC, alone or jointly with state enforcers, has challenged brand-generic settlements over Hytrin, Cardizem CD, BuSpar, K-Dur, Provigil, and AndroGel. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058–59, 1061–62 (11th Cir. 2005) (rejecting FTC challenge to K-Dur settlement); *Bristol-Myers Squibb Co.*, No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (describing BuSpar consent decree); *Hoechst Marion Roussel, Inc.*, No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (describing Cardizem CD consent decree); *Abbott Labs. & Geneva Pharms., Inc.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (describing Hytrin consent decree as to Abbott); *Abbott Labs. & Geneva Pharm., Inc.*, No. C-3946, 2000 WL 681849 (F.T.C. May 22, 2000) (describing Hytrin consent decree as to Geneva); *AndroGel Complaint*, *supra* note 7; *Provigil Complaint*, *supra* note 7. In addition, the FTC challenged a settlement over Ovcon that does not engage the Hatch-Waxman exclusivity provisions. See *FTC v. Warner Chilcott Holdings Co. III*, No. 05-2179, 2007 WL 158746 (D.D.C. Jan. 22, 2007) (denying motion to dismiss). The case later settled.

26. Aside from private litigation running in parallel with the FTC challenges discussed in note 25, purchasers or competitors have filed antitrust suits over Cipro, Naprelan,

Settling parties have offered a variety of defenses.<sup>27</sup> The most fundamental is that permitting settlement increases the brand-name firm's profit, and hence its expected reward for developing innovative drugs, the marketing of which provides great benefits to consumers. Put another way, the static harm of settlement from high prices today must be weighed against the dynamic benefit of more and better drugs in the future. The potential scope of this argument is extremely broad: *Any* practice currently prohibited by antitrust law, as practiced by innovators seeking to increase their profits, could be defended upon this ground. Even simple price fixing could be excused. In general, antitrust lacks any such exemption for collusive behavior.<sup>28</sup> The case for making an exemption is particularly weak where, as here, the increase in innovative incentive from delaying competition is partially offset by the necessary payments to the generic firm.<sup>29</sup>

Settling parties have offered several further objections. They assert that the suppressed competition is not cognizable because it is merely probabilistic.<sup>30</sup> That objection ignores the fact that the suppressed entry subject to antitrust regulation is almost always probabilistic.<sup>31</sup> 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.<sup>32</sup> It is true that market division through

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Nolvadex, Plavix, and Procardia XL settlements that the FTC has not challenged. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (Cipro); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (Nolvadex); *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227, 1231 (11th Cir. 2005) (Naprelan); *Biovail Corp. v. Mylan Labs., Inc.*, No. 01-66, 2002 U.S. Dist. LEXIS 6726, at \*8-\*9 (N.D. W. Va. Mar. 22, 2002) (Procardia XL); Amended Complaint and Demand for Jury Trial at paras. 1-2, *Kroger Co. v. Sanofi-Aventis*, No. 06-163, 2006 WL 2503664 (S.D. Ohio July 31, 2006) (Plavix). In addition, Sandoz, a later-filing generic firm, has alleged that the settlement between Bayer and Barr over Yasmin is part of an anticompetitive conspiracy. Sandoz alleges that Bayer and Barr agreed that Bayer would enforce a patent, which had not been asserted in litigation between Bayer and Barr, against other generic firms such as Sandoz. Answer, Affirmative Defenses, and Counterclaims at 29-30, *Bayer Schering Pharma AG v. Sandoz, Inc.*, No. 08-3710, 2008 WL 4486682 (S.D.N.Y. July 11, 2008).

27. For a detailed account, see Hemphill, *supra* note 11, at 1573-78 (describing justifications for paying for delay).

28. See *id.* at 1599-1600 (discussing why special exception for innovators is imprudent).

29. See *id.* at 1612-14 (making this point and arguing further that such "innovation inefficient" means of increasing brand-name drug maker incentives is unlikely interpretation of statutory balance between pharmaceutical innovation and competition).

30. Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, *Antitrust*, Spring 2003, at 68, 69.

31. "[I]t 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, 79 (D.C. Cir. 2001) (en banc) (per curiam).

32. For analyses expressing the worry that a restrictive settlement rule might spread to other industries, see, for example, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 *Antitrust L.J.* 1033, 1047-49 (2004).

patent settlement is a real possibility in other industries, and to that extent, antitrust liability may be warranted there too. In addition, the Hatch-Waxman Act reflects a specific effort to promote consumer access through litigated challenges, a feature that makes the case for prohibition particularly strong in this industry.<sup>33</sup> A third objection—that prohibiting certain settlements increases litigation costs—is overwhelmed by the much larger adverse effect on consumer welfare.

Courts have tended to reject antitrust liability for brand-generic settlements. These courts have accepted, as a doctrinal matter, a maximalist view of the patent right. Most appellate courts that have considered the issue 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.<sup>34</sup> As a result, brand-name firms are effectively permitted to buy private term extensions to their patents. The maximalist view thus produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force. Each can support a settlement that restricts generic entry until the nominal expiration date of the patent.

The maximalist perspective also ignores the fact that the nominal scope of the patents at issue, particularly the expiration date of the last-expiring patent, is highly malleable. A sophisticated brand-name drug maker can produce a steady stream of patents, with successively later expiration dates, which in turn support a settlement date that is even later than the expiration of effective protection. A settlement involving the blockbuster drug Lipitor, Pfizer's most important product, provides an example. Pfizer sued Ranbaxy, the first-filing generic firm, over Pfizer's two strongest patents, expiring in March 2010 and June 2011,<sup>35</sup> winning

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33. For an elaboration, see Hemphill, *supra* note 11, at 1604–16.

34. Compare *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (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 Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809–12 (D.C. Cir. 2001) (reaching similar conclusion in dicta). See also *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311–13 (11th Cir. 2003) (reframing analysis for district court to apply on remand, preserving possibility of liability); cf. *Kaiser Found. Health Plan v. Abbott Labs.*, 552 F.3d 1033, 1040–41 (9th Cir. 2009) (describing position staked out by *Valley Drug*). Courts permitting settlement add the caveat that the brand-name firm must not have engaged in fraud upon the patent office or sham litigation. See, e.g., *Cipro*, 544 F.3d at 1336; *Tamoxifen*, 466 F.3d at 208–09, 212–13; *Schering*, 402 F.3d at 1068.

35. See Duncan Bucknell, US Court of Appeal Invalidates Lipitor Patent Due to Improper Claim Dependency, Mondaq Bus. Briefing, Aug. 17, 2006, available at Factiva (noting March 2010 expiration, with periodic exclusivity, of U.S. Patent No. 4,681,893); Press Release, Pfizer, Inc., U.S. Patent and Trademark Office Accepts Pfizer's Reissue Application on Lipitor Enantiomer Patent (Jan. 6, 2009) [hereinafter Pfizer Lipitor Patent Press Release] (noting June 2011 expiration, with periodic exclusivity, of U.S. Patent No. 5,273,995). This and all other press releases cited in this Article are available through the Factiva electronic database, as were other sources noted in the footnotes. Each can be

as to the first patent but losing as to the second.<sup>36</sup> Analysts therefore expected entry in March 2010, or at the very latest in June 2011.<sup>37</sup> However, when the parties eventually settled, generic entry was set for November 2011, later than the expiration of either patent.<sup>38</sup> The parties defended this result on the ground that, shortly before settlement, Pfizer had also sued Ranbaxy on two minor patents that expire in 2016.<sup>39</sup> The main effect of the inclusion of these patents was to permit the parties to choose an entry date later than the expiration of the two main patents at issue.

Whether pay-for-delay settlements violate antitrust law has generated tremendous scholarly interest and a wide variety of responses.<sup>40</sup> The

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retrieved by executing a free text search for the document's title, across all available dates. All sources obtained from Factiva are on file with the *Columbia Law Review*.

36. See *Pfizer, Inc. v. Ranbaxy Labs.*, 457 F.3d 1284 (Fed. Cir. 2006). The court ruled for Pfizer on the basic composition of matter patent, *id.* at 1290, and invalidated the second patent on technical grounds, *id.* at 1292.

37. See, e.g., David Risinger, Merrill Lynch, Pfizer Inc.: Settlement Good News, at 1 (June 18, 2008) (on file with the *Columbia Law Review*) [hereinafter Merrill Lynch, Lipitor Settlement Report] (noting that prior to settlement, Merrill "had assumed U.S. generic competition in March 2010").

38. Press Release, Pfizer, Inc., Pfizer and Ranbaxy Settle Lipitor Patent Litigation Worldwide (June 18, 2008) [hereinafter Pfizer Lipitor Settlement Press Release].

39. The two patents at issue were not listed in the Orange Book, which contains listings of those patents, filed by the brand-name firm, that "count" for Hatch-Waxman purposes. Pfizer Sues to Protect Lipitor, Caduet Process Patents, *Drug Industry Daily*, Mar. 27, 2008, available at Factiva; see also Complaint at 1, 5–6, *Pfizer, Inc. v. Ranbaxy Labs.*, No. 08-164 (D. Del. Mar. 24, 2008) (suing for declaratory judgment of validity and infringement as to patents '511 and '740, both expiring in July 2016).

40. More than thirty articles or book chapters, not including student notes, address the issue. See Hemphill, *supra* note 11, at 1558 n.15 (collecting nineteen articles or book chapters through 2006 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, Joel Schrag, Carl Shapiro, and Robert Willig); see also Michael A. Carrier, Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law ch. 15 (forthcoming 2009); Robin Feldman, The Role of Science in Law 160–70 (2009); Reza Bagherian, The Preserve Access to Affordable Generics Act: Will Congress's Response to Reverse Payment Patent Settlements Enhance Competition in the Pharmaceutical Market?, 7 *J. Marshall Rev. Intell. Prop. L.* 150 (2007); Pamela J. Clements, The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law, 48 *IDEA* 381 (2008); Daniel A. Crane, Patent Settlements, in 3 *Issues in Competition Policy* 2109 (Wayne Dale Collins ed., 2008); Lucy Grace Dearce, Deconstructing and Recalibrating the *Valley Drug* Analysis of Reverse Payments, 47 *IDEA* 587 (2007); Christopher Fasel, Patent Term Limits, Anti-Trust Law, and the Hatch-Waxman Act: Why Defense of a Legally Granted Patent Monopoly Does Not Violate Anti-Trust Laws, 17 *Kan. J.L. & Pub. Pol'y* 109 (2007); A. Paul Heeringa, Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the "Reverse Payment" Dilemma, 5 *DePaul Bus. & Com. L.J.* 265 (2007); Christopher M. Holman, Do Reverse Payment Settlements Violate the Antitrust Laws?, 23 *Santa Clara Computer & High Tech. L.J.* 489 (2007); Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, 30 *Seattle U. L. Rev.* 377 (2007); James F. Ponsoldt & W. Hennen Ehrenclou, The Antitrust Legality of Pharmaceutical Patent Litigation Settlements, 2006 *U. Ill. J.L. Tech. & Pol'y* 37; Ronald W.

maximalist view of the patent right has been rejected by the FTC, senior officials of the Department of Justice Antitrust Division,<sup>41</sup> and the Solicitor General,<sup>42</sup> but they, like commentators, have a variety of views on the subject. Some take the view that all settlements that combine payment with delayed entry are per se violations of antitrust law.<sup>43</sup> Others would impose a presumption of illegality.<sup>44</sup> Still others say that the matter should be judged through a more detailed examination of the strength of the patent, compared to the details of the settlement.<sup>45</sup> The stronger the patent, the less troubling a long delay in entry would be.

Antitrust law is not the only way to address the pay-for-delay settlement problem. For example, Congress could modify or eliminate the 180-day exclusivity period, particularly for settling parties, or provide a means and incentive for drug purchasers, including the government, to challenge pharmaceutical patents. Such changes could address the incentives that give rise to the pay-for-delay settlement problem in the first place. As an alternative, settlements could be challenged at the moment they are reached, by requiring the court conducting the patent infringement case to approve the settlement using procedures akin to those employed in class actions to prevent collusive settlements. Private “objectors” or the FTC could be recruited to try to persuade the court that the settlement ought to be rejected.

Putting aside the question of political feasibility, however, such changes would not determine the legal status of the many settlements

Davis, Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal, Antitrust, Fall 2006, at 26.

41. David L. Meyer, Deputy Assistant Attn’y Gen., DOJ Antitrust Div., Speech at the George Mason University Law Review Symposium on Antitrust: We Should Not Let the Ongoing Rationalization of Antitrust Lead to the Marginalization of Antitrust 18 (Oct. 31, 2007) (prepared remarks available at <http://www.usdoj.gov/atr/public/speeches/227399.pdf> (on file with the *Columbia Law Review*)) (concluding that courts have gone too far in granting “carte blanche” to patentholders, and noting agreement of Solicitor General in *Joblove* and *Schering*).

42. Brief for the United States as Amicus Curiae at 9–12, *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), 2007 WL 1511527 [hereinafter Brief for the United States, *Joblove*]. Certiorari was denied. 127 S. Ct. 3001.

43. See, e.g., Cristofer Leffler & Keith Leffler, Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal, 21 Res. L. & Econ. 475 (2004).

44. The FTC, for instance, has held that:

If there has been a payment from the patent holder to the generic challenger . . . [then] [a]bsent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

*Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) (citations omitted).

45. See Brief for the United States, *Joblove*, supra note 42, at 12–15; see also *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 228 (2d Cir. 2006) (Pooler, J., dissenting) (favoring similar test).

that have already been reached. Thus, antitrust law is a necessary component of any complete resolution of the pay-for-delay issue.

### B. *Neglected “Fact” Questions*

Beyond this theoretical question—do pay-for-delay settlements violate antitrust law?—there is a set of factual questions that must be answered. For example, how frequently do pay-for-delay settlements occur? Knowing the answer is necessary to decide whether to make the settlement issue an enforcement priority. A second factual question arises in many modern 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 for some other valuable consideration? Often, this is a difficult question. In the only case involving a side deal that has been fully litigated so far, attempts to determine whether the particular settlement was anticompetitive produced divergent results at each level of review.<sup>46</sup> These factual questions have been neglected by scholars 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 circumstances are present in a particular case? If that determination is imperfect, how do we identify a cost-minimizing rule—for instance, that alleged predation is reviewed leniently because predation is “rarely tried, and even more rarely successful,”<sup>47</sup> or that resale price maintenance ought to be accorded rule of reason treatment because its procompetitive uses are not merely “infrequent or hypothetical”?<sup>48</sup>

Because a court lacks the capacity to independently collect the information necessary to develop an optimal rule, 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.<sup>49</sup> If the external consensus changes, the Court suggests, so too may the substantive rule.<sup>50</sup> Agencies and Congress play a similar role.

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46. See *supra* note 10 (describing litigation over agreement between Schering-Plough and Upsher-Smith).

47. See *supra* notes 2–3 and accompanying text.

48. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2717 (2007).

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

50. Lower courts have taken that instruction seriously. See, e.g., *United States 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 of

For example, Justice Breyer, 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."<sup>51</sup> He also questioned how readily the two can be distinguished; in other words, "[h]ow easy is it to separate the beneficial sheep from the antitrust goats?"<sup>52</sup> Such information must be supplied by others, if it is to be collected at all, since courts, unlike Congress and the FTC are not "well-equipped to gather empirical evidence outside the context of a single case."<sup>53</sup>

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,<sup>54</sup> vertical contracting,<sup>55</sup> and other competitive practices. Industry-specific analyses have been important too.<sup>56</sup> In addition to measuring the aggregate costs of a class of antitrust violation, this study adds a distinctive dimension: the effort to understand the evolution of a practice over time. Understanding this 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 those practices.

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*Matsushita*, without repeating the "consensus among commentators" qualifier. E.g., *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 323 (2007); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993).

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

52. *Id.*

53. *Id.* at 2737.

54. 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 traditional assumption that predatory pricing is rare).

55. E.g., James C. Cooper et al., *FTC, Vertical Antitrust Policy as a Problem of Inference* 17–23 (2005), available at [http://www.ftc.gov/speeches/froeb/050218vertical\\_econ.pdf](http://www.ftc.gov/speeches/froeb/050218vertical_econ.pdf) (on file with the *Columbia Law Review*) (describing interplay of evidence and theory to update prior beliefs over time which, in vertical context, places heavy burden on plaintiffs).

56. E.g., Peter Davis, *The Effect of Local Competition on Admission Prices in the U.S. Motion Picture Exhibition Market*, 48 *J.L. & Econ.* 677, 700–01 (2005) (identifying small price reduction from local competition in motion picture exhibition, but no evidence that horizontal mergers between exhibitors led to ticket price increases); see also Howard A. Shelanski, *Competition and Deployment of New Technology in U.S. Telecommunications*, 2000 *U. Chi. Legal F.* 85, 114–18 (identifying correlation between competition and innovation in sample of new technology deployments in U.S. telecommunications networks and suggesting strict enforcement of merger policy is unlikely to reduce welfare). And empirical methods are common in the analysis of particular cases. See, e.g., Jonathan B. Baker & Daniel L. Rubinfeld, *Empirical Methods in Antitrust Litigation: Review and Critique*, 1 *Am. L. & Econ. Rev.* 386, 386–91 (1999) (noting and offering explanations for increased use of empirical methods in merger cases); Timothy F. Bresnahan, *Empirical Studies of Industries with Market Power*, in 2 *Handbook of Industrial Organization* 1011, 1012–13 (Richard Schmalensee & Robert D. Willig eds., 1989) (assessing "new empirical industrial organization" model in which single or related industries are analyzed independently).

Whether by legislative reform or judicial decisions, “economic policy must be contrived with a view to the typical rather than the exceptional,”<sup>57</sup> to use George Stigler’s apt phrase. Both legislators and judges would benefit from a clear idea of how often and in what form settlements occur, and how effective we can expect judicial management to be. This is a fitting moment to examine real world evidence of settlements, before the Supreme Court or Congress establishes a new rule. 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 infrequency of antitrust review, the operation of *stare decisis*, and a fear of upsetting reliance interests.<sup>58</sup> The next Part begins the examination necessary to formulate an optimal rule for pay-for-delay settlements.

An agency such as the FTC is well positioned to fill these informational gaps. The agency has a statutory mandate to collect, study, and publish information about particular industries. It has general authority to require firms to divulge confidential information relevant to antitrust policymaking.<sup>59</sup> In the particular context of settlement, the FTC’s position is even stronger: It has unique access to the details of every brand-generic settlement since December 2003, due to drug makers’ special statutory obligation to file all such settlements with the agency.<sup>60</sup> This aggregate information complements other sources of FTC expertise developed and used in litigation, congressional testimony, and public hearings.<sup>61</sup>

The FTC sometimes uses this advantage to good effect. In 2002, the agency published an important survey of brand-generic drug competition, drawing upon information supplied by drug makers under FTC compulsion as well as information collected independently by the FDA.<sup>62</sup> That study indicated the importance of the pay-for-delay settlement problem and made a variety of policy recommendations. But there has been

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

58. See Transcript of Oral Argument at 11, *Leegin*, 127 S. Ct. 2705 (No. 06-480) (Roberts, C.J.) (expressing concern that discount stores had developed in reliance upon *per se* prohibition of resale price maintenance).

59. FTC Act, 15 U.S.C. §§ 46(b), 49, 57b-1(c) (2006).

60. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63. The Antitrust Division also receives a copy. *Id.* § 1112(c).

61. See *More than Law Enforcement: The FTC’s Many Tools—A Conversation with Tim Muris and Bob Pitofsky*, 72 *Antitrust L.J.* 773, 777–78 (2005) (using recent FTC action in health care industry to illustrate tools available to FTC); see also Health Care Servs. & Prods. Div., Bureau of Competition, FTC, *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* (2008), available at <http://www.ftc.gov/bc/0809rxupdate.pdf> (on file with the *Columbia Law Review*) (describing various enforcement actions taken by FTC in pharmaceutical industry).

62. FTC, *Generic Drug Entry*, *supra* note 13.

no follow-up to the 2002 study; more generally, industry studies—once a staple product of the FTC—have become less frequent.<sup>63</sup>

The FTC's conclusions, based on its aggregate information, can be deployed in a variety of policymaking settings. In the case of the 2002 study, the conclusions were used in amicus briefs, legislative advocacy, and litigation brought by the Agency.<sup>64</sup> But in each of these settings, the Agency is essentially supplying its information to an external decisionmaker.<sup>65</sup> The Agency has available to it a more aggressive option, however, which emphasizes the FTC's role as a decisionmaker in its own right: antitrust rulemaking.

The FTC possesses the power to promulgate rules with the force of law that are subject to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,<sup>66</sup> which imposes upon courts a "duty to defer to reasonable agency interpretations . . . [of an ambiguous] statute that an agency is charged with administering."<sup>67</sup> At first, this assertion may seem startling, because its power is seldom used. The Agency has promulgated just one such antitrust rule, and that was more than forty years ago.<sup>68</sup> Since then, the Commission has considered promulgating antitrust rules from time to time, but has never followed through.<sup>69</sup>

In Part IV, I argue that the FTC's aggregation advantage is a reason to favor antitrust rulemaking, and that pay-for-delay settlement is an attractive candidate for a rule. But first, I will lay out what an aggregate approach can tell us about drug patent settlements.

63. F.M. Scherer, *Sunlight and Sunset at the Federal Trade Commission*, 42 Admin. L. Rev. 461, 467–68, 470–79 (1990), describes a wide range of industry studies conducted by the FTC up until about 1980. Scherer attributes the falloff after that point to budget cuts and disinterest by FTC Bureau of Economics directors and staff, in part because "[i]ndustry case studies have fallen out of favor" in economics graduate programs. *Id.* at 484–85; see also Appendix I: *Investigations by the Commission, 1915–39*, 8 Geo. Wash. L. Rev. 708 (1940) (collecting wide variety of industry studies during early years of FTC).

64. All these routes were used after the issuance of the 2002 study. See, e.g., *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary, 108th Cong.* 41–42 (2003) (prepared statement of Timothy J. Muris, Chairman, Federal Trade Commission); *Brief for Federal Trade Commission as Amicus Curiae Supporting Appellant at 7, 20, In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097); *Petition for Writ of Certiorari at 5–6, 17, 21, 24, FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2005) (No. 05-273).

65. I say "essentially," because in the case of adjudication, the FTC makes an initial determination, which is then reviewed by an appeals court.

66. 467 U.S. 837 (1984). For a discussion of the FTC's authority, see *infra* Part IV.

67. Thomas W. Merrill & Kristen E. Hickman, *Chevron's Domain*, 89 Geo. L.J. 833, 833 (2001).

68. *Discriminatory Practices in Men's and Boys' Tailored Clothing Industry*, 16 C.F.R. pt. 412 (1968).

69. See, e.g., *FTC Staff Narrows Rulemaking Possibilities to Three Areas*, 1978 Antitrust & Trade Reg. Rep. (BNA) No. 884, at A-13 (Oct. 12, 1978) (noting FTC staff's search for suitable rulemaking subject).

## II. FILLING THE GAP: INTRODUCING AN AGGREGATE APPROACH

This Part introduces an aggregate perspective to the issue of settlements between brand-name and generic drug makers. Part II.A outlines the data collection effort. Part II.B shows the magnitude and continuing importance of settlements with delayed entry. It proceeds to describe three sources of evolution in the form of settlement, and the effects of each. Part II.C elaborates an initial payoff from the aggregate approach: a clear sense that settlements ought to be considered a top priority for antitrust enforcement.

### A. Data Collection

To examine the frequency and evolution of brand-generic settlements since 1984, I collected a novel dataset. The object was to identify and synthesize all public information about the frequency and terms of settlement. The effort drew upon press releases, trade publications, financial analyst reports, analyst calls with management, court filings of patent and antitrust litigation, SEC filings, FDA dockets, and FTC reports.<sup>70</sup> For nine settlements, the actual settlement agreement was available.<sup>71</sup> In addition to the terms of settlement, I recorded the annual sales

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70. The broadest search was a review of all articles in the Factiva database mentioning “settlement” and a “new drug application.” 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 Factiva search found a number of settlements that were not evident in other sources, such as analyst reports. In many cases, articles in Factiva filled in important settlement details.

The FTC’s 2002 report provided a detailed accounting of terms for the earliest settlements, with the drug name disguised. FTC, *Generic Drug Entry*, supra note 13. In December 2003, a new law required drug makers to file brand-generic agreements with the FTC. MMA, Pub. L. 108-173, § 1112, 117 Stat. 2066, 2461–63. 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* (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 2006* (2007); 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* (2008).

71. See *Stipulation of Filing of Redacted Settlement Agreement, Pfizer, Inc. v. Zenith Goldline Pharms., Inc.*, Nos. 00-0408, 01-6007 (D.N.J. June 14, 2002) [hereinafter *Zolof Agreement*]; *Adams Respiratory Therapeutics, Inc.*, Quarterly Report (Form 10-Q) exh. 10.1 (May 15, 2007) (*Mucinex*); *Andrx Pharm. Corp.*, Annual Report (Form 10-K) exh. 10.109 (Mar. 16, 2006) (*Glucotrol XL*); *Barr Pharms.*, Quarterly Report (Form 10-Q) exhs. 10.1–10.3 (Nov. 9, 2006) [hereinafter *Adderall XR Shire-Barr Agreement*]; *Bristol-Myers Squibb*, Quarterly Report (Form 10-Q) exhs. 99.1–99.2 (Aug. 8, 2006) [hereinafter *Plavix Agreement*]; *Cephalon, Inc.*, Quarterly Report (Form 10-Q) exh. 10.1 (Nov. 8, 2006) (*Provigil Carlsbad*); *King Pharms., Inc.*, Current Report (Form 8-K) exhs. 10.1–10.2 (Jan. 8, 2008); *King Pharms., Inc.*, Quarterly Report (Form 10-Q) exhs. 10.1–10.5 (May 9, 2006) [hereinafter *Altace Agreement*]; *Kos Pharms., Inc.*, Quarterly Report (Form 10-Q) exhs. 10.2–10.4 (Aug. 9, 2005) [hereinafter *Niaspan Agreement*].

figures at the time of settlement and noted whether the generic firm was eligible for the exclusivity period.<sup>72</sup> I also determined whether a major provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) applied to the settlement.<sup>73</sup> To be included in the set, the agreement must pertain to patent litigation resulting from an ANDA filing by a generic firm.<sup>74</sup> The search period extended from 1984, when the Hatch-Waxman Act was passed, through August 2008, and therefore ignores subsequent settlement activity.<sup>75</sup>

This work yielded information for 143 settlements involving 101 brand-name drugs. For 28 drugs, the brand-name drug maker settled with multiple generic firms. Multiple settlements can be the result of settlements with multiple first filers sharing the exclusivity entitlement,<sup>76</sup> or settlements with later filers who lack eligibility for the exclusivity period. Although the focus of the subsequent analysis is settlements with first filers, in some cases settlements with later filers can raise pay-for-delay issues as well.<sup>77</sup>

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72. To determine eligibility, I assessed whether the drug was subject to the exclusivity period, whether the settling generic firm was a first filer, whether any exclusivity eligibility had already been triggered at the time of settlement, and whether the settlement itself included a forfeiture of retained exclusivity. The second determination is the most difficult, because the FDA considers the identity of the first filer to be confidential information, and because there are often multiple first filers. I based the determination on FDA letters granting ANDA approval with exclusivity (which are not confidential), generic-firm press releases reporting presumed first filer status, and a comparison of complaints in patent suits with FDA reports of the *date* of a first ANDA filing, which is not confidential.

73. Pub. L. No. 108-173, 117 Stat. 2066 (2003). The relevance of this fact is discussed *infra* Part II.C.3.

74. This criteria rules out, for example, an agreement over Ovcon 35, which was not a patent dispute but did feature an agreement that was challenged as anticompetitive by the FTC. See *supra* note 25. It also omits drugs, such as Advicor, where a settlement as to another drug discouraged the filing of an ANDA in the first place. See, e.g., Niaspan Agreement, *supra* note 71 (providing eventual entry as to Advicor, a drug on which the generic firm had not yet filed an ANDA).

75. E.g., Associated Press, Teva, Barr Settle Patent Dispute with Sanofi, *Int'l Bus. Times*, Nov. 19, 2008, available at <http://www.ibtimes.com/articles/20081119/teva-barr-settle-patent-dispute-with-sanofi.htm> (on file with the *Columbia Law Review*) (reporting settlement of Allegra, Allegra-D, and Nasacort AQ litigation); Press Release, AstraZeneca, AstraZeneca Settles US Pulmicort Respules Patent Litigation with Teva (Nov. 25, 2008); Press Release, Medicis Pharm. Corp., Medicis and IMPAX Announce R&D Collaboration and Settlement (Dec. 1, 2008) (reporting settlement of Solodyn litigation); Press Release, Watson Pharms., Inc., Warner Chilcott and Watson Pharmaceuticals Announce Agreements on Loestrin 24 and Femcon Fe Patent Litigation (Jan. 12, 2009) (reporting settlement of Loestrin 24 and Femcon Fe litigation, as well as co-promotion, license, and supply agreements as to other Warner Chilcott products).

76. See *supra* note 16.

77. This applies, for example, to the settlements involving K-Dur, AndroGel, and Hytrin discussed *infra* note 105. In these cases, a later filer received an entry-delaying settlement in addition to the first filer.

Several checks confirm that the dataset contains nearly all significant settlements that delay entry.<sup>78</sup> The dataset oversamples settlements that restrict entry for important drugs. Important drugs receive more extensive coverage in public disclosures, and settlements that restrict entry tend to receive more attention. Thus, omitted settlements are likely to be for minor drugs, or settlements that had no effect on entry. For those settlements in the dataset, publicly available information contains significant gaps. In particular, price terms are normally omitted, and detailed settlement terms are sometimes missing. Even with these limitations, the new dataset is a useful tool for examining the extent and evolution of settlement; indeed, it may be the most comprehensive examination of brand-generic settlements until and unless the FTC uses its power of compulsion to produce a complete dataset.

### B. *A Typology of Settlements*

Of the 143 settlements in the dataset, 60 include both delayed generic entry and possible contemporaneous provision of value by the brand-name firm. The 60 settlements involve 51 out of the 101 drugs in the dataset. For an additional two drugs, the Hatch-Waxman dispute was resolved through acquisition: The generic firm bought out the brand-name firm's rights to the drug, thus ending the possibility of competition between the two.<sup>79</sup> (Neither deal was challenged by the FTC, however, suggesting that the firms lacked market power in the first place.) As to the remaining 48 drugs, my data collection effort identified no pay-for-delay issue, and so far as I know, the settlements raise none.<sup>80</sup> Some such

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78. For example, the FTC catalogued 14 troubling settlements in 2002, but did not name names: 8 cash or side deal settlements, 2 "supply agreements," and 4 retained exclusivity settlements. FTC, *Generic Drug Entry*, supra note 13, at 34. Of these, I can match 7, 2, and zero settlements, respectively, to my dataset. Of the 11 settlements in the 2005 update, I can account for 8, as well as 26 of 28 in the 2006 update and 20 of 33 in the 2007 update. See supra note 70. Barr has stated that it reached settlements as to 14 drugs. *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?*: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 23 (2007) (statement of Bruce L. Downey, Chairman and CEO, Barr Pharmaceuticals, Inc.). My data likewise contain 14 settlements as of the time of Barr's statement. Similarly, the data contain 10 Teva settlements by early 2007, which is identical to Teva's own statement. See *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 7* (2007) (prepared statement of Theodore C. Whitehouse, Partner, Willkie Farr & Gallagher LLP), available at [http://energycommerce.house.gov/cmte\\_mtgs/110-ctcp-hrg.050207.Whitehouse-Testimony.pdf](http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Whitehouse-Testimony.pdf) (on file with the *Columbia Law Review*).

79. The two drugs are Prefest and Mircette. Lewis Krauskopf & Martha McKay, N.J. Briefs: Barr Paying King \$15M for Rights to Prefest, Record (Bergen County, N.J.), Nov. 23, 2004, at L11; Press Release, Barr Pharms., Inc., Barr, Organon and Savient Finalize Mircette Settlement and Acquisition (Dec. 2, 2005).

80. Of the 81 settlements in this category, 67 pertain to 48 drugs whose settlements appear to raise no pay-for-delay issue. The remaining 14 settlements pertain to drugs in which the brand-name firm reached at least one other settlement that does raise a pay-for-

settlements include an agreement on the generic entry date, without any payment. These negotiated outcomes likely reflect the perceived strength of the relevant patents. Their existence demonstrates that settlement without payment is feasible.<sup>81</sup> Table 1 summarizes the three categories of agreement.

TABLE 1: TYPOLOGY OF SETTLEMENTS

Type	Drugs	Settlements
Payment and Delay	51	60
Acquisition	2	2
Other settlements	48	81
<b>Total</b>	<b>101</b>	<b>143</b>

For the 51 drugs raising pay-for-delay issues, payment and delay take a variety of forms. For 21 of the 51, the compensation was wholly or partly monetary.<sup>82</sup> Sometimes the payment was an open conferral of cash. For other drugs, the possible payment was embedded within a more complicated transaction. The caveat “possible” is used because in some cases public information leaves it unclear whether the settlement included compensation.<sup>83</sup> These 21 drugs are listed in Table 2, together with details about the various forms of payment, which are explained later in this Article. On average, they had annual U.S. sales, measured in the year of settlement and adjusted for inflation, of \$1.3 billion.

The 21 drugs include blockbusters such as Lipitor (more than \$7 billion in annual sales) and Nexium (more than \$3 billion). Five drugs with annual sales exceeding \$2 billion account for more than two-thirds of the total, measured by annual sales. More than half are new versions of existing therapeutic agents, whose patents are generally thought to be weaker because they tend to be obvious (and hence invalid) and are easily worked around.<sup>84</sup> Some of the settlements in Table 2 have lapsed, and generic entry has occurred, while others continue to block entry as of

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delay issue. To avoid double-counting, these latter settlements are not included in the number of drugs in this category.

81. See, e.g., Jon Leibowitz, Op-Ed., *This Pill Not to Be Taken with Competition: How Collusion Is Keeping Generic Drugs off the Shelves*, Wash. Post, Feb. 25, 2008, at A15 (pointing to feasibility of no-delay settlements as supporting conclusion that pay-for-delay settlements should be prohibited). Even if no-delay settlements were infeasible, however, the main reasons to condemn pay-for-delay settlements would still hold.

82. This category includes “underpayment” settlements discussed *infra* Part III.A.2.

83. This issue is explored in more detail *infra* Part III.

84. This group consists of Sinemet CR, K-Dur, Naprelan, Niaspan, Effexor XR, Propecia, Adderall XR, AndroGel, Wellbutrin XL, Nexium, and Aggrenox. Even for those drugs that are not new versions, some of the relevant patents are noticeably weak. For example, Altace was protected by a patent not on the basic compound, but an enantiomer, and was subsequently invalidated. *Aventis Pharma Deutschland, GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1295, 1303 (Fed. Cir. 2007). Provigil is protected not by a compound patent, which expired, but by a particle-size patent. *Provigil Complaint*, *supra* note 7, at 2.

TABLE 2: SETTLEMENTS WITH MONETARY PAYMENT

Year	Drug	Sales	Payment	Entry
1993	Nolvadex	400	Cash Authorized generic sales	9
1995	BuSpar	400	Cash	5
	Zantac	2950	Cash	2
	Sinemet CR	150	Cash	11
1997	Cipro	900	Cash	7
	K-Dur*	250	Retained exclusivity Side deal (product licenses)	4
1999	Naprelan	50	Retained exclusivity Side deal (intellectual property (IP))	3
2005	Lamictal	1100	Generic sales (Lamictal CD)	3
	Niaspan	450	Retained exclusivity Side deals (manufacturing (mfg), promotion) Generic sales (Advicor)	8
	Effexor XR	2750	Retained exclusivity (+ no authorized generic) Generic sales (Effexor IR)	5
2006	Provigil*	700	Retained exclusivity Side deals (IP, development, mfg, inventory) Generic sales (Actiq)	6
	Altace	700	Retained exclusivity Side deals (development, supply)	2
	Plavix	3400	Retained exclusivity (+ no authorized generic) Side deal (inventory) Deal sweeteners if settlement failed	5
	Propecia	150	Retained exclusivity Generic sales (Zocor, Proscar)	7
	Adderall XR*	900	Retained exclusivity (+ no authorized generic) Side deals (development, mfg, promotion) Generic sales (Adderall IR)	3
	AndroGel*	350	Side deals (mfg, promotion)	9
2007	Wellbutrin XL (150 mg)	850	Waived damages for 300 mg strength	1
2008	Nexium	3400	Retained exclusivity (+ no authorized generic) Side deal (manufacturing) Generic sales (Prilosec and Plendil)	6
	Lipitor	7200	Retained exclusivity Generic sales in Canada Waived damages (Accupril)	3
	Caduet	400	Joint with Lipitor	3
	Aggrenox	300	Retained exclusivity Side deal (promotion)	7

*Year*: Year of settlement; for Provigil, year of last settlement among four first-filers. *Drug*: \* indicates monetary settlements with multiple first filers (Provigil) or with both first filer and later filer (K-Dur, Adderall XR, AndroGel). *Sales*: Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or the twelve months preceding settlement, or where unavailable, the closest available year. Totals were adjusted to constant 2008 dollars using the monthly Consumer Price Index prepared by the U.S. Bureau of Labor Statistics, and rounded to the nearest \$50 million increment. *Payment*: “Retained exclusivity” is discussed later in this subsection. “No authorized generic” provisions are discussed *infra* Part IV.C. “Side deals” entail possible overpayment by the brand-name firm; see *infra* Part III.A.1. “Generic sales” entail possible underpayment by the generic firm; see *infra* Part III.A.2. “Waived damages” are discussed *infra* Part IV.C. *Entry*: Time between settlement and scheduled entry, rounded to the nearest year, except for Altace, where no date appears to have been disclosed. This figure does not include immediate authorized generic sales for Nolvadex, or unexpected six-month pediatric extensions for Nolvadex and Cipro. The details of each settlement are cited *infra*. For annual sales, the sources are on file with the *Columbia Law Review*.

March 2009. Ten drugs in the latter category account for about \$17 billion in annual sales.

The effect of delayed entry can be enormous. For the questionable settlements in Table 2, a one-year delay in generic entry represents, under conservative assumptions, a transfer from consumers to producers of about \$14 billion.<sup>85</sup> One of the 21 settlements, Plavix, never took full effect;<sup>86</sup> with Plavix removed, the transfer from a one-year delay is \$12 billion. Whether the one-year benchmark is an overestimate or an underestimate is often difficult to assess in a particular case using public information. Part of the total delay caused by settlement is attributable to the strength of the patent itself, rather than payment. Since the pre-expiration period covered by settlement is several years—the average period, weighted by sales (and excluding Plavix), is 4.1 years—the benchmark is likely conservative.

A more nuanced figure might be developed by offering a specific prediction about what would have happened in each case absent the settlement. The particular 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. Launches at risk suggest that the patent protection is weak, because the generic firm does not fear the prospect of damages (which would exceed the generic firm's profits if imposed) or a preliminary injunction (which would spoil the expensive preparations for a generic launch).

For some drugs, public statements by management or the expectations of financial analysts help to provide a specific measure of delay. In the case of Provigil, for example, the drug maker's CEO said that due to settlements, "We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected."<sup>87</sup> The CEO's statement reflects the firm's pre-settlement expectation of entry in 2006,<sup>88</sup> and set-

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85. Suppose generic entry achieves 75% penetration and that the generic product is priced at a two-thirds discount, relative to the brand-name drug. These figures are a simplification, because in reality, penetration and the discount (particularly during the 180-day period) are smaller at first, but quickly increase. Under these assumptions, the avoided transfer is one-half of annual sales, or \$661 million per drug. Across 21 drugs, the total is about \$14 billion. This figure does not include welfare losses caused by pricing distortions. See *supra* note 21.

86. See Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 31 (Feb. 26, 2007) (estimating negative effects from Apotex launch of \$1.2 to \$1.4 billion in 2006).

87. John George, *Hurdles Ahead for Cephalon*, *Phila. Bus. J.*, Mar. 20, 2006, at 1.

88. See, e.g., Q3 2005 Cephalon, Inc. Earnings Conference Call Transcript (Nov. 1, 2005), available at Factiva (statement of Frank Baldino, Chairman and CEO, Cephalon, Inc.) (providing earnings guidance for 2006, and assuming "generic versions of modafinil enter the market midyear").

tlements delaying entry until 2012.<sup>89</sup> In the case of Lipitor, the settlement delayed anticipated entry by nearly two years.<sup>90</sup> Overall, the \$12 billion benchmark estimate is likely to be conservative.

For settlements involving 25 drugs, the brand-name firm 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. One hundred eighty days of duopoly is worth hundreds of millions of dollars in the case of a blockbuster.<sup>91</sup> The entitlement can also be sold to another generic firm.<sup>92</sup> 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 pe-

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89. See Press Release, Cephalon, Inc., Cephalon Announces Agreement with Barr Laboratories, Inc. Regarding Settlement of Provigil and Actiq Patent Litigations (Feb. 1, 2006) [hereinafter Provigil Barr Press Release]; Press Release, Cephalon, Inc., Cephalon Announces Agreement with Mylan Pharmaceuticals, Inc. Regarding Settlement of Provigil Patent Litigation (Jan. 10, 2006); Press Release, Cephalon, Inc., Cephalon Announces Agreement with Ranbaxy Laboratories Ltd. Regarding Settlement of Provigil Patent Litigation (Dec. 22, 2005); Press Release, Cephalon, Inc., Cephalon, Inc. Announces Agreement with Teva Pharmaceutical Industries Ltd. Regarding Settlement of Provigil Patent Litigation (Dec. 9, 2005).

90. See, e.g., Merrill Lynch, Lipitor Settlement Report, *supra* note 37 (“We now expect an extra 20 months of U.S. Lipitor exclusivity (we had assumed U.S. generic competition in March 2010 and the Ranbaxy settlement delays generic launch until November 2011).”). Later, Pfizer succeeded in having the invalidated patent reissued. See Pfizer Lipitor Patent Press Release, *supra* note 38 (announcing U.S. Patent and Trademark Office’s acceptance of Pfizer’s correction of patent’s technical defect). Under the settlement, the generic firm will enter in November 2011. *Id.*

91. See *supra* note 85.

92. A generic firm can either selectively waive its entitlement in favor of a particular later filer, or relinquish it entirely. This is a profitable strategy where the firm with the entitlement has been unable to secure FDA approval—for example, due to difficulties in formulating or manufacturing the product—and a later filer is ready to go to market, but for the fact that it is “bottled up” behind the first filer. For a fuller explanation of this bottleneck, see *infra* notes 118–120 and accompanying text. Selective waiver has been permitted for numerous drugs, including Zantac, Zolof, and Wellbutrin XL. See *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 1–2 (D.D.C. 1997) (Zantac); Complaint at 5, *Teva v. Invagen*, No. 07-315 (S.D.N.Y. Jan. 12, 2007) (Zolof); Press Release, Teva Pharms., Teva Announces Launch of Generic Wellbutrin XL Tablets, 300 mg Under Agreement with Anchen and IMPAX (Dec. 18, 2006) (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., No. 2004P-0227, at 4–5 & n.5 (July 2, 2004); see also *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000) (citing *Granotec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1405 (4th Cir. 1998) (*per curiam*)) (“[E]xclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price.”); *Boehringer Ingelheim*, 993 F. Supp. at 2 (approving FDA interpretation allowing selective transfer); 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,881 (Aug. 6, 1999) (codified at 21 C.F.R. § 314.107 (2008)) (explaining FDA position that “applicant may selectively waive its exclusivity only after the 180-day exclusivity period has begun to run with the occurrence” of favorable court ruling or commercial marketing).

riod.<sup>93</sup> A brand-name firm's agreement to drop the patent fight—an arrangement that does not forfeit eligibility<sup>94</sup>—is valuable to the generic firm because it raises the probability of enjoying the exclusivity. These 25 drugs are listed in Table 3.<sup>95</sup>

TABLE 3: SETTLEMENTS WITH RETAINED EXCLUSIVITY

Year	Drug	Sales	Full?
2002	Zoloft	3000	*
2004	Femhrt	50	*
	Estrostep	50	*
2005	Lamictal CD	50	*
2006	Duoneb	250	*
	Imitrex tablets	900	
	Imitrex injection	250	
2007	Mucinex	150	*
	Diastat	100	*
	Valtrex	1350	*
	Adenoscan	350	*
	Avandia	1200	
	Avandamet	300	
	Avandaryl	100	
	Keppra	900	
	Paxil CR	350	*
	Flomax	1200	
	Cardizem LA	100	*
	Exelon	200	*
2008	Astelin	200	*
	Optivar	50	*
	Xopenex	500	*
	Miacalcin	150	*
	Depakote ER (500 mg)	700	*
	Mirapex	400	*

*Year and Sales:* As in Table 2. *Full:* Indicates whether the entry date was early enough to permit 180 days of sales prior to patent expiration.

The ability to settle with retained exclusivity disrupts the alignment of interests between the generic firm and consumers. Ordinarily, late en-

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

94. Settlement does not remove entitlement to the exclusivity period. See *infra* Part II.C.2 (discussing factors influencing settlements).

95. The list omits settlements where there was no delayed entry or where the available data was ambiguous about continued entitlement to the exclusivity period. Entry as to one drug on the list, Exelon, was not disclosed, but was assumed to be at least 180 days prior to patent expiration. This list is underinclusive. For example, my data collection identified none of the four early retained exclusivity settlements discussed in the FTC report. See *supra* note 78 (comparing this Article's dataset with that of the FTC report).

try dates are bad for consumers, but also bad for the alleged infringer, whose profits are a function of the amount of time on the market, and who therefore can be expected to fight for an earlier entry date. Here, by contrast, the generic firm cares more about protecting its 180-day duopoly entitlement, and less about *when* exactly that entry occurs. It is therefore willing to trade a later entry date for the better chance to enjoy the 180 days.<sup>96</sup> Meanwhile, consumers and taxpayers finance the continued sale of drugs at the higher, brand-name price.

This argument has an important limit. If the generic firm's pre-expiration entry lasts for less than 180 days, then its profits are, roughly speaking, linearly increasing as it pushes for an earlier entry date. In that case, the alignment between the generic firm and consumers is more nearly maintained. Of the 25 drugs listed in Table 3, 7 have entry dates so late that they have less than 180 days of exclusive sales.<sup>97</sup> For the remaining 18 drugs, the misalignment critique applies.

The 25 drugs have average annual sales of \$580 million. Of these, the 18 drugs with "full" exclusivity have average sales of \$442 million. If guaranteed exclusivity induces a delay of one year for each of these drugs, the transfer, using the same calculus described above, would be about \$4 billion.

The preservation of exclusivity can take a second form. In some cases, a generic firm wins a patent challenge, but is blocked from approval by a second patent that the generic firm either did not challenge at all, or challenged unsuccessfully. In such a case, the generic firm "wastes" the exclusivity resulting from that partial victory, which is triggered and expires while the generic firm is blocked from entering by the second patent.<sup>98</sup> Once the second patent expires, the generic firm enters, but without exclusivity. A generic firm can avoid wasting its exclusivity by abandoning its challenge, and agreeing to enter with exclusivity upon the expiration of the second patent.<sup>99</sup> This benefits the brand-name firm, and harms consumers, for the same reason: Prices are higher

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96. For a detailed analysis, see Hemphill, *supra* note 11, at 1588–94.

97. Frequently, this occurs when a brand-name firm secures a six-month pediatric extension that is tacked onto the end of the patent term. 21 U.S.C. § 355a(b), (c) (2006); see, e.g., Press Release, Dr. Reddy's Labs., Dr. Reddy's Laboratories Announces Settlement of Imitrex Litigation with GlaxoSmithKline (Oct. 10, 2006) (noting expected launch of generic Imitrex under settlement in fourth quarter of 2008, prior to expiration of pediatric exclusivity on February 6, 2009).

98. See Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* § 4.02[H], at 4–43 (7th ed. 2008) (discussing situation where exclusivity is "effectively useless because a second patent, as to which [the generic firm had declined to challenge validity or infringement], had not yet expired when the 180-day exclusivity began to run").

99. The Zolofit settlement between Pfizer and Zenith is an apt example. Pfizer had two patents on Zolofit: a strong patent expiring in 2006, and a weak patent expiring in 2013. In 1999, Zenith challenged the 2013 patent but not the 2006 patent. Winning as to the 2013 patent would have wasted the exclusivity, unless that happened after the expiration of the 2006 patent. (Patent suits are slow, but not that slow.) Instead, Zenith

during the (preserved) duopoly exclusivity period than with full competition from other generic firms.

In addition to the drugs for which the only form of compensation is retained exclusivity, most of the drugs in Table 2, after the first five, have secured an assured 180 days of generic sales.<sup>100</sup> Other settlements explic-

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agreed to enter with exclusivity upon the expiration of the basic patent. See Zolof Agreement, *supra* note 71.

Barr's challenge to Prozac raised a similar possibility. See Barr Labs., Inc., Amendment to a Previously Filed 10-K405 (Form 10-K405/A), at 10–11 (May 15, 2001) (noting that 180-day period could be wasted if challenge to one patent succeeded, triggering the generic firm's exclusivity as to it, while a second patent blocked FDA approval of the generic drug). As it turned out, the patent had expired by the time exclusivity was triggered, and only six days remained of the associated pediatric exclusivity period. 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. Best Pharmaceuticals for Children Act (BPCA) § 10, 21 U.S.C. § 355a(k) (2006); Press Release, Barr Labs., Inc., Barr Confirms Prozac Exclusivity Runs Until January 29 (Jan. 9, 2002) (announcing letter from FDA stating that BPCA "extends" exclusivity by amount of overlap, in this case to January 29, 2002).

The Lipitor settlement appears to contain another variant. When Ranbaxy won its challenge to one patent in the Federal Circuit, this triggered exclusivity, but prematurely, since the other valid and infringed patent prevented FDA approval. *Pfizer, Inc. v. Ranbaxy Labs.*, 457 F.3d 1284, 1290–92 (Fed. Cir. 2006). The combined result would have been to permit entry without exclusivity in March 2010. (The patents expiring in 2016 were never listed in the Orange Book, and did not affect that result.) However, Pfizer had three more Orange Book-listed patents in reserve, on which Ranbaxy was likely the first ANDA filer but Pfizer did not sue. Under pre-MMA law, each patent provided a fresh opportunity for exclusivity. See *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 72–74 (D.D.C. 2006), *aff'd per curiam*, 226 F. App'x 4 (D.C. Cir. 2007) (granting *Chevron* deference to FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) (2000), to provide separate exclusivity for separate patents). By declining to sue Ranbaxy on these patents, Pfizer preserved Ranbaxy's exclusivity despite the initial trigger, a preferable result for both parties. The MMA replaced this "patent-by-patent" approach to exclusivity with a single opportunity for each product. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2006) (making exclusivity available only to "first applicant"); *id.* § 355(j)(5)(B)(iv)(II)(bb) (defining "first applicant" by reference to drug, not patent); see also John. R. Thomas, *Pharmaceutical Patent Law 367* (2005) (explaining post-MMA scheme).

100. The first five settlements included no pre-expiration entry, for reasons discussed *infra*. In the case of Lamictal and AndroGel, the preserved exclusive sales is a synthetic construct achieved by contract. For Lamictal, the 180-day period expires when the relevant patent expires, and the generic firm is granted a license during the pediatric exclusivity. Teva Launches Generic Lamictal Tablets in US, *Pharmaceutical Bus. Rev.* Online, July 23, 2008, at [http://www.pharmaceutical-business-review.com/article\\_news.asp?guid=3B55AC72-6DFA-4112-8CAA-A81234A9C2C3](http://www.pharmaceutical-business-review.com/article_news.asp?guid=3B55AC72-6DFA-4112-8CAA-A81234A9C2C3) (on file with the *Columbia Law Review*) [hereinafter *Lamictal Press Release*] (noting settlement provision that Teva has exclusive right to enter during pediatric exclusivity, which expires on January 22, 2009). In the case of AndroGel, the first-filing generic firm disclaimed exclusivity. Press Release, Unimed Pharms., 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 presumably to avoid antitrust attention, since retained exclusivity helps effectuate delay, as discussed in the next section. However, the settlement is structured to preserve exclusive sales in practice: First filer

itly trigger exclusivity,<sup>101</sup> or involve generic firms that are ineligible for exclusivity in the first place.<sup>102</sup>

Five pay-for-delay settlements fit neither of these categories. Three are “interim” agreements, which restrict entry while the patent infringement suit is pending but do not resolve the suit. After such agreements were targeted for antitrust enforcement in the late 1990s,<sup>103</sup> parties turned to the monetary and retained exclusivity settlements discussed above. The remaining two settlements are supply agreements in which the generic firm did not retain exclusivity eligibility.<sup>104</sup> A summary of the four categories of pay-for-delay settlements appears in Table 4. Again, the number of settlements is larger than the number of drugs, because—for a few drugs—the brand-name firm entered multiple settlements.<sup>105</sup>

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Watson’s negotiated entry date, August 31, 2015, is 180 days earlier than later filer Par’s entry date of February 26, 2016. See *Solvay Settles Dispute with Par, Watson, Associated Press*, Sept. 13, 2006, available at Factiva (reporting entry dates for both filers).

101. For example, Yasmin sales commenced by June 2008, see Bayer AG, *Stockholders’ Newsletter* 43 (July 30, 2008), which sufficed to trigger exclusivity under either Bayer’s NDA or Barr’s ANDA. See § 355(j)(5)(B)(iv) (triggering exclusivity for post-MMA drugs upon “first commercial marketing,” “including the commercial marketing of the listed drug”); Press Release, Barr Pharms., Inc., *Barr and Bayer Sign Supply and Licensing Agreements for Launch of Generic Yasmin and Yaz Oral Contraceptives* (June 24, 2008) [hereinafter *Yasmin Press Release*].

For some settlements, such as Yasmin, contracting for retained exclusivity (and the accompanying bottleneck) is not necessary because delay can be secured by other means. In the case of Yasmin, the brand-name firm sued the later filer on different patents, thus depriving the later filer of the benefit of the earlier litigation. For an argument that this tactic is anticompetitive, see Answer, *Affirmative Defenses, and Counterclaims* at 29–30, *Bayer Schering Pharma AG v. Sandoz, Inc.*, No. 08-3710 (S.D.N.Y. July 11, 2008).

102. This is the case when the generic firm is not a first filer, or when the brand-name drug does not give rise to exclusivity eligibility.

103. Interim settlements were reached for Cardizem CD and Hytrin (tablets and capsules), which led to the FTC consent decrees cited in note 25 supra.

104. The drugs are Procardia XL and Wellbutrin SR. In the case of Procardia XL, the generic firm received an immediate license not only on the 30-milligram strength for which it was the first filer, but on two other strengths as well. Defendant Pfizer, Inc.’s Motion to Dismiss the Complaint at 4–6, *Great Lakes Health Plan, Inc. v. Pfizer, Inc.*, No. 01-106 (N.D. W. Va. July 30, 2001). In the case of Wellbutrin SR, the generic firm relinquished any eligibility for the 180 days, and received a license to sell not only the 100-milligram strength for which it was first filer, but also a second strength. See FDA Memorandum in Opposition to Motion for Preliminary Injunction at 11, *Andrx v. Thompson*, No. 03-23171 (S.D. Fl. Dec. 11, 2003) (referring to “Company X,” which filed a substantially complete ANDA after Andrx’s incomplete ANDA of June 18, 1999, but before Andrx’s sufficiently complete ANDA on August 12, 1999); Complaint at 10–12, *Andrx*, No. 03-23171 (S.D. Fl. Nov. 26, 2003) (discussing Andrx’s understanding that first filer, in FDA’s view, was Watson).

105. Provigil entered monetary settlements with four first filers. See supra note 89 (identifying settlements). In addition, the drugs K-Dur, Adderall XR, AndroGel, and Hytrin had monetary settlements with generic firms that filed ANDAs with Paragraph IV certifications, but were not first filers. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060–61 (11th Cir. 2005) (K-Dur); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1346 (S.D. Fla. 2000), rev’d on other grounds, 344 F.3d 1294 (11th Cir. 2003) (Hytrin); AndroGel Press Release, supra note 100; Press Release, Shire PLC, Shire

TABLE 4. PAY-FOR-DELAY SETTLEMENTS SUMMARIZED

Type	Drugs	Settlements
Monetary	21	28
Retained exclusivity only	25	27
Interim agreement	3	3
Supply agreement	2	2
<b>Total</b>	51	60

The firms that have entered settlements with both payment and delay are quite diverse: 28 brand-name firms and 25 generic firms in all.<sup>106</sup> The most frequent brand-name settler is Glaxo, with 2 settlements in Table 2 and 8 in Table 3.<sup>107</sup> Teva and Barr are the most frequent generic settlers, with 11 and 9 settlements, respectively. Barr has been more aggressive than Teva: 6 of its settlements, compared to 4 of Teva's, appear in Table 2.<sup>108</sup> One generic firm, Ranbaxy, has played a role disproportionate to its settlement count, reaching settlements involving the blockbusters Lipitor<sup>109</sup> and Nexium<sup>110</sup> in the span of a few months in 2008. Although many individual drug makers enter into multiple brand-generic settlements, repeat negotiations between brand-generic pairs are rare.<sup>111</sup>

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and Impax Settle All Pending Litigation Concerning Adderall XR (Jan. 19, 2006) (Adderall XR) [hereinafter Adderall XR Shire-Impax Press Release]. In Table 4, to avoid double counting, Hytrin is included in the count for interim settlement drugs, but not monetary settlement drugs. Exelon had retained exclusivity settlements with three first-filing generic firms. Press Release, Dr. Reddy's Labs., Dr. Reddy's Announces Settlement of Exelon ANDA Litigation with Novartis (Jan. 22, 2008); Press Release, Sun Pharm. Indus., Sun Pharma Announces Settlement of Litigation over Generic Exelon (Dec. 6, 2007); Press Release, Watson Pharms., Inc., Watson and Novartis Settle Lawsuit over Exelon Patent Litigation (Dec. 6, 2007).

106. Accounting for mergers, the set of generic firms falls to 20. Teva and Barr are considered separately, though they merged in December 2008. Press Release, Teva Pharm. Indus. Ltd., Teva Completes Acquisition of Barr (Dec. 23, 2008) [hereinafter Teva Merger Press Release].

107. In Table 2, Zantac and Lamictal. In Table 3, Lamictal CD, Imitrex (both tablets and injection), Valtrex, Avandia, Avandamet, Avandaryl, and Paxil CR.

108. For Barr, Nolvadex, Cipro, Niaspan, Provigil, Adderall XR, and Aggrenox. For Teva, Lamictal, Effexor XR, Provigil, and Wellbutrin XL. In addition, Barr has three settlements in Table 3 (Estrostep, Femhrt, and Mirapex), and Teva has six (Zoloft, Adenoscan, Avandamet, Avandaryl, Avandia, and Lamictal CD). The Zoloft settlement was reached with Ivax, which Teva later acquired.

109. See Pfizer Lipitor Settlement Press Release, *supra* note 38.

110. See Press Release, Ranbaxy Pharms., Inc., Ranbaxy and AstraZeneca Reach Agreement in Esomeprazole Patent Litigation (Apr. 15, 2008) [hereinafter Nexium Press Release].

111. Of the settlements in Tables 2 and 3, Glaxo negotiated with Teva over Lamictal, then Avandia, Avandaryl, and Avandamet. GlaxoSmithKline PLC, Annual Report 2007 (Form 20-F), at 152-53 (Feb. 29, 2008) (Avandia, Avandaryl, and Avandamet); Lamictal Press Release, *supra* note 100. Glaxo settled with Genpharm over Zantac, then settled with Genpharm's successor, Mylan, over Paxil CR. See, e.g., Eric Reguly, Shares in Glaxo Rise as

### C. *The Evolution in Settlement*

Three factors have shaped a continuing evolution in the structure and content of brand-generic settlements: (1) the waxing and waning of antitrust enforcement, (2) a change in judicial interpretation of the Hatch-Waxman Act, and (3) major statutory amendments to the Act in 2003. This evolution poses challenges when choosing an optimal substantive antitrust rule and antitrust decisionmaker, topics taken up in Parts III and IV, respectively.

1. *Antitrust Challenges*. — The form of settlement varies significantly with the level of perceived antitrust risk, particularly as to monetary settlements. Table 2 depicts this pattern. Monetary settlements occurred at a rate of about one per year from 1993 through 1999. In 2000, the FTC initiated antitrust actions against several settlements,<sup>112</sup> and monetary settlements subsided. In 2005, the government and private purchaser plaintiffs lost antitrust suits in the Eleventh and Second Circuits, respectively.<sup>113</sup> That year saw monetary settlements as to three drugs, and in 2006, six 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, there was a renewed flurry of monetary settlements, including Lipitor and Nexium.

The intensity of antitrust enforcement affects not only the fact, but also the form, of monetary settlements. The first monetary settlements—including the first five listed in Table 2—blocked entry until patent expiration, and the brand-name firm paid cash.<sup>114</sup> Starting in 1997, and with

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Lawsuit Is Settled—Glaxo Wellcome, Times (London), Oct. 24, 1995, available at Factiva (Zantac); Press Release, Mylan, Inc., Mylan Announces Settlement of Paroxetine Hydrochloride Extended-Release Tablets with GlaxoSmithKline (Oct. 23, 2007) (Paxil CR).

Looking beyond the tables, Bayer negotiated with Barr over Cipro, then later reached settlements over Yasmin and Yaz, settlements in the dataset but not part of either table. In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1328 (Fed. Cir. 2008) (Cipro); Yasmin Press Release, *supra* note 101 (Yasmin and Yaz). Barr negotiated with Ortho-McNeil over Ortho Novum 7/7/7, which may be a retained exclusivity agreement, then Ortho Tri-Cyclen. Consent Judgment and Order, Ortho-McNeil Pharm., Inc. v. Barr Labs., No. 00-2805 (D.N.J. July 23, 2003) (Ortho Tri-Cyclen); Press Release, Barr Labs., Inc., Barr Laboratories Announces Agreement in Ortho-Novum 7/7/7 Patent Litigation (Oct. 29, 2001) (Ortho-Novum 7/7/7).

112. The first private suit I am aware of was filed in 1998. See In re Cardizem CD Antitrust Litig., 332 F.3d 896, 903 (6th Cir. 2003) (noting that complaint was filed in August 1998).

113. In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005), amended and superseded by 466 F.3d 187 (2d Cir. 2006) (upholding agreement between Zeneca and Barr); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1070–72 (11th Cir. 2005) (upholding Schering's agreements with Upsher-Smith and ESI Lederle).

114. These include Nolvadex (\$66 million), BuSpar (\$73 million), Zantac (\$133 million), Sinemet CR (unknown), and Cipro (\$398 million). See *Ciprofloxacin*, 544 F.3d at 1328–29 (Cipro); *Tamoxifen*, 466 F.3d at 193–94 (Nolvadex); Bristol-Myers Squibb Co., 135 F.T.C. 444 (2003) (FTC Analysis to Aid Public Comment), available at 2003 WL 1092114 (BuSpar); Hemphill, *supra* note 11, at 1570 n.69 (inferring size of BuSpar settlement from

increasing frequency after 2000, settling firms changed the standard form of settlements in two ways, both likely responses to increased pressure from antitrust enforcers.<sup>115</sup> 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 may have anticipated, given the prevailing view of appellate courts that it is fine to pay for settlements with no pre-expiration entry.<sup>116</sup>

Second, starting in 1997, settlements frequently included 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 Part III.

2. *Judicial Interpretation.* — The shift toward settlements with pre-expiration entry has 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, on the ground that it was contrary to the text of the Hatch-Waxman Act.<sup>117</sup> After that, a first-filing generic firm could expect to enjoy exclusivity provided it did not lose the patent suit, even if it settled. That made it possible to compensate using retained exclusivity, provided that entry occurred before patent expiration.

The end of the successful defense requirement also created a new form of delay with respect to nonsettling firms. This is due to a statutory quirk in the 180-day exclusivity provision: A later-filed ANDA may not be approved until 180 days after either 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

FTC, *Generic Drug Entry*, supra note 13, at 32 tbl.3-3; id. at 1569 & n.63 (inferring same for Zantac); Faulding Inc., Annual Report (Form 10-K), at 9 (Sept. 27, 1996) (Sinemet CR). In addition, "interim" agreements involving two drugs, Cardizem CD and Hytrin, included naked cash payments. See *Cardizem*, 332 F.3d at 902-03 (*Cardizem CD*); *Abbott Labs. & Geneva Pharms., Inc.*, No. C-3945, 2000 WL 681848, ¶¶ 25-27 (F.T.C. May 22, 2000) (*Hytrin*).

115. The first such settlement, *K-Dur*, was negotiated in 1997, and predated increased antitrust pressure. See *Schering-Plough*, 402 F.3d at 1059-61.

116. See cases cited supra note 34.

117. See *Granotec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998) (discussing clarity of statute's language); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), aff'd, 140 F.3d 1060 (D.C. Cir. 1998) ("The language of the statute . . . is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation."); 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/2576fml.pdf> (on file with the *Columbia Law Review*) (stating that "FDA will not enforce the 'successful defense' provisions" and "intends to formally remove" them from Code of Federal Regulations).

later ANDA filer is stuck, for the FDA lacks authority to approve the application, blocking subsequent entry.<sup>118</sup>

This resulting “bottleneck,” however, is defeasible. If a second generic firm files an ANDA, is sued by the brand-name firm, and wins the patent suit, that decision triggers the first filer’s exclusivity period. The second ANDA filer can enter 180 days later.<sup>119</sup> To avoid that outcome, the brand-name firm may decline to sue the second generic firm, in which case the generic firm must bring a declaratory judgment suit challenging the patents,<sup>120</sup> win that suit, and then wait 180 days.

3. *Statutory Change.* — Statutory change represents a third possible source of evolution, but here, the actual change has been unexpectedly small. In 2003, as noted above, Congress amended the Hatch-Waxman regime as part of the MMA.<sup>121</sup> 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 described below.<sup>122</sup> The MMA’s passage led some to conclude that the settlement problem had been resolved.<sup>123</sup>

118. Of the 21 monetary settlements described in Table 2, at least 11 appear to create a bottleneck. As for the others, the first 5 settlements predated the demise of the successful defense requirement, and so their effect, at least as of the date of settlement, is debatable. Four recent settlements—Wellbutrin XL, Nexium, Caduet, and Aggrenox—are governed by the new rules, considered below. In the remaining settlement, AndroGel, the first filer abandoned any claim to the bottleneck. Of the 25 drugs described in Table 3, 9 appear to create a bottleneck under the old rules. The remaining 16 are subject to the new rules discussed *infra*.

119. In several early settlements, the generic firm disavowed exclusivity eligibility by changing its certification from Paragraph IV to Paragraph III. See *Ciprofloxacin*, 544 F.3d at 1328–29 (Cipro); *Tamoxifen*, 466 F.3d at 193–94 (Nolvadex); *Bristol-Myers*, 135 F.T.C. at 453–54 (FTC Analysis to Aid Public Comment) (BuSpar). In the case of Nolvadex, however, the generic firm reasserted its continued entitlement to exclusivity, after other potential generic entrants emerged and the successful defense requirement was held invalid. *Tamoxifen*, 466 F.3d at 195–96; see also *Cipro*, 544 F.3d at 1340 n.14 (considering and dismissing plaintiffs’ contention that later filers were discouraged by belief that first filer retained exclusivity).

120. 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. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 n.11 (2007) (identifying problems with Federal Circuit’s “reasonable anticipation of suit” test); *Caraco Pharm. Labs., Ltd., v. Forest Labs., Ltd.*, 527 F.3d 1278, 1288 (Fed. Cir. 2008) (noting Court’s rejection of reasonable anticipation of suit test); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007) (“In light of the Supreme Court’s recent decision . . . we reverse.”).

121. Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of U.S. Code, including 21 U.S.C.).

122. 21 U.S.C. § 355(j)(5)(D) (2006).

123. See, e.g., Kent S. Bernard, *The 2008 EC Sector Inquiry Regarding Pharmaceuticals: What Does It Mean from a Research-Based Company Perspective?*, GCP: Online Mag. for Global Competition Pol’y, Nov. 2008, at 8, available at <http://www.globalcompetitionpolicy.org/index.php?id=1466&action=907> (on file with the *Columbia Law Review*) (“In the U.S., the evil of paying the first challenger was that he could block any

Five years after the MMA's passage, however, there is little evidence that settlements featuring both payment and delayed entry have become less popular. As noted above in Figure 2, monetary settlements have been a common occurrence after 2003; if anything, they appear to have increased in frequency. And the incidence of monetary settlements for blockbuster drugs has increased. The most important settlements, preserving brand-name profits on blockbusters such as Lipitor, Nexium, and Plavix, occurred after the statutory change. The only blockbuster settlement that predates the MMA is Zantac. That 1995 settlement also preceded significant antitrust enforcement efforts and avoided antitrust scrutiny.

One reason for the limited effect is that the new forfeiture regime only applies prospectively. It is limited to drugs for which the first ANDA was filed after December 2003.<sup>124</sup> Most drugs, therefore, are governed by the old regime. Patent litigation frequently takes four or five years to reach settlement. In the Lipitor litigation, for example, a generic firm first filed an ANDA in 2003, but the firms did not settle until 2008. All but 4 of the 21 monetary settlements depicted in Table 2, and 9 of the 25 retained exclusivity settlements in Table 3, were reached under the pre-MMA rules. In short, even if the pre-MMA regime is only transitional, it remains important.

Moreover, even when fully applicable, the new forfeiture rules do little to curb pay-for-delay settlement. Like the old rules, they permit a brand-name firm to neutralize the first filer's challenge through settlement. That first filer still has the largest incentive to challenge the patent because only it is eligible to receive the 180-day reward. And the new rules still contain a bottleneck.<sup>125</sup> Forfeiture applies only upon the satis-

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others, so that a single settlement could block all generic competition on a compound. The law has since changed on this point, and the bottleneck is no longer an issue.”); see also Brief for the United States as Amicus Curiae at 18, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779), 2004 WL 1562075 [hereinafter Brief for the United States, *Andrx*] (concluding that MMA's passage lessened need for Supreme Court review).

124. To be more precise, December 8, 2003. MMA § 1102(b)(1), 117 Stat. at 2460. An exception is that one basis for forfeiture, an unappealed or unappealable determination that the agreement violates antitrust law, 21 U.S.C. § 355(j)(5)(D)(i)(V), applies also to “old” ANDAs, MMA § 1102(b)(2), 117 Stat. at 2460.

125. The FDA recently reached the same conclusion:

Inherent 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.

Letter from Gary J. Buehler, Dir., Office of Generic Drugs, FDA, to Marc A. Goshko, Executive Dir., Teva N. Am. 5 n.6 (Jan. 17, 2008), available at <http://www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf> (on file with the *Columbia Law Review*). This is not the only possible interpretation, since a court might conclude instead

faction of two statutory conditions.<sup>126</sup> The first condition is relatively easy to satisfy.<sup>127</sup> The second 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.<sup>128</sup> The new bottleneck, like the old one, is defeasible; a later-filing generic firm can break the logjam by winning its challenge and waiting 180 days. The post-MMA rules make the relevant condition for defeasement an appeals court win, rather than a district court win—a condition now applicable to both post-MMA and pre-MMA drugs.<sup>129</sup> This change delays further the moment of generic entry.

#### D. *Setting Enforcement Priorities*

The foregoing survey has several implications for antitrust enforcement. First, it demonstrates that the settlement issue is a first-order enforcement question. The size of the buyer overcharge from pay-for-delay settlements likely exceeds \$16 billion.<sup>130</sup> The large implications for consumer welfare justify vigorous FTC and private enforcement efforts, continued scholarly investigation of the evolution and effect of settlements, and a concerted effort by the FTC and Antitrust Division to reach a full convergence of their historically divergent views of settlements.<sup>131</sup>

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that the certification asserting patent invalidity or noninfringement was not “lawfully maintained.” § 355(j)(5)(D)(i)(I)(bb).

126. See § 355(j)(5)(D)(i)(I) (triggering forfeiture when “later of” (aa) and (bb) occurs). 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 government antitrust suit against the settling parties. § 355(j)(5)(D)(i)(V).

127. See § 355(j)(5)(D)(i)(I)(aa) (requiring satisfaction by “the earlier of” 75 days after the first filer’s effective date, and 30 months after application filing).

128. See § 355(j)(5)(D)(i)(bb). There is also a third possibility, that the brand-name firm withdraws the relevant patent information from the Orange Book. § 355(j)(5)(D)(i)(I)(bb)(CC).

129. Prior to the MMA, a generic firm’s district court win triggered the running of the exclusivity period. *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 47 (D.D.C. 2000); Court Decisions, ANDA Approvals, and 180-Day Exclusivity, 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (codified at 21 C.F.R. § 314.107 (2008)). The FDA had previously taken the view that the generic firm could wait until an appeals court ruling without triggering exclusivity, in order to avoid the choice between launching at risk and losing exclusivity. 21 C.F.R. § 314.107(e)(1) (1999), repealed by 65 Fed. Reg. 43,233 (July 13, 2000). The MMA restores the appeals court trigger for pre-MMA ANDAs. Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (2003) (codified as a note to 21 U.S.C. § 355). For new ANDAs, the rule is analogous. Forfeiture (rather than triggering) of exclusivity occurs 75 days after a generic firm’s appeals court win, § 355(j)(5)(D)(i)(I)(bb)(AA) (setting failure to market trigger), and provided that the “easy-to-satisfy” condition discussed *supra* note 127 is also satisfied.

130. The one-year benchmark measures discussed in Part II, \$12 billion for monetary settlements and \$4 billion for retained exclusivity settlements, imply a total \$16 billion transfer from buyers to sellers. Again, that figure leaves out any effect from increased utilization due to competitive prices.

131. Compare Petition for Writ of Certiorari at 3, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2005) (No. 05-273), 2005 WL 2105243 (arguing that pay-for-delay settlements violate antitrust law), with Brief for the United States as Amicus Curiae at 11–12, *Schering-*

The survey also underscores the importance of prompt Supreme Court review.<sup>132</sup> In terms of their practical importance, the impact of drug patent settlements is at least comparable to other antitrust issues on which the Supreme Court has granted certiorari. By way of comparison, resale price maintenance, the subject of a recent major Supreme Court case, has long been avoidable for most well-counseled firms.<sup>133</sup>

Moreover, settlement has become a patent issue, not only an anti-trust issue. Although framed as an antitrust case by plaintiffs, the Federal Circuit has embraced the view that settlement is essentially a patent issue, governed by patent law—indeed, arguably governed by Federal Circuit law<sup>134</sup>—and that patent law trumps antitrust doctrine 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 perceived hypertrophy in the claimed extent of patent protection.<sup>135</sup>

The MMA provisions targeting anticompetitive settlements provide no basis for postponing review. The “transitional” pre-MMA rules continue to have a significant impact. One of the first pay-for-delay settlements concerned an ANDA filed in 1985; the certiorari petition in the resulting antitrust suit was filed 21 years later.<sup>136</sup> 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

*Plough*, 548 U.S. 919 (No. 05-273), 2006 WL 1358441 (raising doubts about FTC position). For evidence of convergence, see Meyer, *supra* note 41, at 18 (expressing agreement of DOJ Antitrust Division official with FTC position that courts are too lenient toward settlements).

132. The courts of appeals have varied in their treatment of settlements, see *supra* note 34 (collecting and comparing cases). The Solicitor General, assessing the cases prior to the most recent *Cipro* decision of the Federal Circuit, took the view that these cases do not create a true circuit split. Brief for the United States, *Joblove*, *supra* note 42, at 15–16.

133. See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2722 (2007) (describing practice of avoiding discussions of pricing policy on advice of “counsel knowledgeable of the intricacies of the law”).

134. In the Federal Circuit's recent opinion rejecting antitrust liability, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), the court does not consistently rely upon the law of the relevant regional court of appeals—the Second Circuit, as the appeal was from a district court in that circuit. After an initial, general statement that the overall rule of reason method should be employed as a matter of Second Circuit law, *id.* at 1332, the court's detailed analysis gave no privileged place to Second Circuit analysis, see *id.* at 1332–36, and cited only its own cases at several points, see *id.* at 1333–34. The court's conclusion was presented as its own independent judgment, rather than as a view about what the Second Circuit would have concluded. *Id.* at 1336.

135. See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741–43 (2007) (rejecting, as too low a bar, Federal Circuit test for patent nonobviousness); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393–94 (2006) (rejecting Federal Circuit rule that permanent injunctions must be issued against patent infringement, absent exceptional circumstances).

136. *Petition for a Writ of Certiorari, Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), 2006 WL 3694387.

rules, a Court decision about a pre-MMA case largely controls the analysis for post-MMA cases as well.

This aggregate survey reveals a final advantage of prompt review. Antitrust challenges to early settlements are still making their way to the Court.<sup>137</sup> These contain payment and delay, but not much else. Later settlements, however, add contractual complexity. They add difficult factual layers—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.

### III. DEVELOPING SUBSTANTIVE POLICY FROM AGGREGATE DATA

This Part examines how an aggregate approach affects the choice of a substantive antitrust rule. Part III.A highlights one particularly troubling element of the evolution in settlements: the rise of side deals that disguise the fact of payment in a pay-for-delay settlement. Part III.B demonstrates that the exchanges seen in these side deals, though common in settlements, are uncommon otherwise. Part III.C argues that the absence of similar deals outside the settlement context 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.B, the earliest settlements were straightforward affairs. The brand-name firm paid cash in exchange for the generic firm's delayed entry. The largest naked cash payment was nearly \$400 million, which Bayer agreed to pay Barr in settling litigation over Cipro, a major antibiotic.<sup>138</sup>

In the wake of increased antitrust scrutiny, naked payments have given way to more complex arrangements. 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 brand-name firm.

1. *Overpayment by the Brand-Name Firm.* — In the most common type of side deal, the generic firm contributes—in addition to delayed entry—some further value, 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 for delayed entry. In reviewing K-Dur, the earliest settlement with this type of side deal, the Eleventh Circuit accepted such a factual assertion, which provided a basis for rejecting antitrust liability.<sup>139</sup>

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137. An example is Cipro, which could yield petitions from both the Federal Circuit and the Second Circuit. See *supra* notes 26, 111, 114, 134 (describing Cipro litigation).

138. See *supra* note 114 and accompanying text.

139. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1070–71 (11th Cir. 2005).

Side deals are now a regular feature of entry-delaying settlements. The contributed value can include a wide range of product development, manufacturing, and promotional services. In some deals, the generic firm offers a product or patent license, or agrees to develop a new product.<sup>140</sup> In one variant, the generic firm develops a new formulation of the brand-name drug.<sup>141</sup> In other deals, it agrees to furnish manufacturing services to the brand-name producer,<sup>142</sup> or to provide inventory,<sup>143</sup> or even to provide “backup” manufacturing services.<sup>144</sup> In some cases, the generic firm provides promotional services as to the product at issue, related drugs, or unrelated products.<sup>145</sup> For some drugs, the brand-name firm reaches entry-delaying settlements with multiple generic firms, each with side deals.<sup>146</sup>

Some of these arrangements are 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 drug development that is unrelated to its current core business, a new source of raw material supply, backup

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140. For example, K-Dur (two settlements), Naprelan, Provigil (four settlements), and Adderall XR (two settlements) all involved a license or product development agreement. See *Andrx Pharm., Inc. v. Elan Corp.*, No. 00-3481, slip op. at 6 (S.D. Fl. Apr. 24, 2003) (order granting motion for judgment on the pleadings) (Naprelan); Schering-Plough Corp., 136 F.T.C. 956, 961–62 (2003) (K-Dur settlements as to Upsher-Smith and ESI Lederle); Provigil Complaint, *supra* note 7, at 16–20 (patent licenses as to Teva, Ranbaxy, and Barr, and product development as to Mylan and Barr); Adderall XR Shire-Barr Agreement, *supra* note 71, exh. 10.1; Adderall XR Shire-Impax Press Release, *supra* note 105.

141. See King Pharms., Inc., Quarterly Report (Form 10-Q), at 10 (Aug. 7, 2007) (noting that generic firm has responsibility for providing new formulations).

142. The Nexium settlement and two of the Provigil settlements include such a term. Provigil Complaint, *supra* note 7, at 16–18 (describing supply terms included in agreements with Teva and Ranbaxy); Nexium Press Release, *supra* note 110. In one of the Adderall XR settlements, the generic firm agreed to provide manufacturing as to products that might emerge from the development agreement. Adderall XR Shire-Barr Agreement, *supra* note 71, exh. 10.2. The Altace settlement included manufacturing of a new formulation by the generic firm. Altace Agreement, *supra* note 71.

143. E.g., Provigil Complaint, *supra* note 7, at 19–20 (describing Cephalon’s agreement with Barr); Plavix Agreement, *supra* note 71, exh. 99.1.

144. AndroGel’s settlement as to Par has this feature. AndroGel Press Release, *supra* note 100 (noting back-up manufacturing agreement as to Par). So does the Niaspan agreement. See Niaspan Agreement, *supra* note 71, exh. 10.4, at 1.

145. Examples include Niaspan, Adderall XR (one settlement), both AndroGel settlements, and Aggrenox. See Niaspan Agreement, *supra* note 71, exh. 10.2, at 1 (promotion of Advicor, a drug protected by same patents as Niaspan); Adderall XR Shire-Barr Agreement, *supra* note 71, exh. 10.1 (promotion of unrelated drug); AndroGel Press Release, *supra* note 100 (promotion of AndroGel); Press Release, Barr Pharms., Inc., Barr Announces Agreements to Settle Mirapex and Aggrenox Patent Challenges (Aug. 12, 2008) (co-promotion agreement for Aggrenox).

146. This is the case for four of the drugs discussed *supra* note 105: Provigil (as to multiple first filers), Adderall XR (as to both a first filer and a later filer), AndroGel (same), and K-Dur (same). See *supra* notes 140–145.

manufacturing, or additional promotion.<sup>147</sup> However, not all such settlements are facially absurd. In some cases, the generic firm has plausible expertise in the subject of the side deal.<sup>148</sup> It is very difficult to be certain that a deal is collusive without a deep and complex inquiry into the business judgment of the two drug makers.

2. *Underpayment by the Generic Firm.* — 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 FDA approval. The brand-name firm supplies the product to the generic firm at a discount, which the generic firm then resells under its own label at a profitable price. 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.<sup>149</sup> This practice fell out of favor after a court concluded that the authorized generic sales triggered the 180-day period.<sup>150</sup> Some modern settlements avoid the trigger problem by providing for authorized generic sales only after another generic firm enters, or of a drug other than the subject of the generic firm’s ANDA filing,<sup>151</sup>

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147. 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 7, at 16.

148. See, e.g., Adderall XR Shire-Barr Agreement, *supra* note 71 (describing Barr investments in drug delivery technology, to be exploited in new product development by brand-name firm as part of settlement). The agreement was later terminated, with substantial payments to Barr. Shire PLC, Current Report (Form 8-K), at 1.01 (Mar. 2, 2009) (reporting reimbursement of up to \$30 million in expenses, one-time payment of \$10 million, and \$25 million in foregone revenue from license for authorized generic supply).

149. For example, Nolvadex and Procardia XL involved authorized generic sales. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193–94 (2d Cir. 2006) (Nolvadex); Defendant Pfizer Inc.’s Motion to Dismiss the Complaint at 5, *Great Lakes Health Plan, Inc. v. Pfizer, Inc.*, No. 01-106 (N.D. W. Va. July 30, 2001) (Procardia XL).

150. This conclusion was reached as to Procardia XL, one of the two supply agreements discussed *supra*. See Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation and Research, FDA, to Deborah A. Jaskor, Senior Dir., Teva Pharms., Regarding Docket No. 00P-1446/CP1, at 1 (Feb. 6, 2001) (on file with the *Columbia Law Review*) (concluding, in response to Teva’s citizen petition, that private-label sales triggered running of exclusivity period); see also *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001) (concluding that Teva was likely to prevail on that contention).

151. For example, in settling Nexium litigation, AstraZeneca made Ranbaxy an authorized generic distributor of Prilosec and Plendil. See Nexium Press Release, *supra* note 110. The Effexor XR settlement granted the generic firm an early license to sell an immediate-release version of Effexor. Wyeth Pharmaceuticals, Current Report (Form 8-K) (Jan. 13, 2006). The Niaspan settlement provided a license as to Advicor. Niaspan Agreement, *supra* note 71, exh. 10.3. The Propecia settlement appears to be a fourth example. There, Merck made Dr. Reddy’s an authorized generic distributor of Proscar and Zocor around the same time that the parties settled litigation over Propecia. See 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 authorized

or in another country.<sup>152</sup>

In a related form of discounted sale, which avoids the trigger issue, the brand-name firm sells an entire product line to the generic firm. One settlement involving an extended-release version of a drug, for example, transferred (for a possibly discounted price) the immediate-release version to the generic firm.<sup>153</sup> In a more complicated set of deals, a brand-name firm may have sold a generic firm rights to one product, and the generic firm delayed entry in two other products.<sup>154</sup> (A further variant of this strategy, simultaneous settlement of multiple drugs with uneven entry terms, is considered in Part IV.C.) Once again, it is very difficult as a practical matter for a decisionmaker to know whether the transfer price provides compensation from the brand-name firm to the generic firm, and if so, how much.

### B. *Infrequency Outside of Settlement*

Outside of settlement, brand-name firms seldom contract with generic firms for help with the activities that form the basis of side deals. Indeed, as a general matter, brand-name and generic firms seldom execute major deals outside the settlement context, with the exception of authorized generic arrangements, which necessarily are reached between a brand-name firm and a generic firm.

A review of the annual securities filings of settling drug makers supports this proposition. To examine the extent of business dealings outside of settlement, five major brand-name firms<sup>155</sup> and five major generic firms<sup>156</sup> were chosen based upon their frequency of settlement activity and economic importance. For each brand-name firm, annual fil-

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generic distributor); Letter from Mary Graham to Judge Gregory M. Sleet, Regarding Merck & Co. v. Dr. Reddy's Labs., No. 04-1313 (D. Del.) (Mar. 1, 2006) (on file with the *Columbia Law Review*) (reporting to judge that parties had reached settlement as to Propecia).

152. For example, in settling Lipitor litigation, Pfizer made Ranbaxy an authorized generic distributor of Lipitor in Canada. Q2 2008 Ranbaxy Laboratories Ltd. Earnings Conference Call (July 29, 2008), available at Factiva (noting particularly significant authorized generic opportunity for Ranbaxy in Canada, triggered by another firm's entry as to Lipitor).

153. See Adderall XR Shire-Barr Agreement, *supra* note 71, exh. B.

154. Galen sold Barr rights to Loestrin, and Barr delayed entry as to two other products, Estrostep and Femhrt. Brian Lavery, Galen and Barr Make Deal on Drug Rights and Patents, N.Y. Times, Sept. 12, 2003, at W1. This transaction is not included in Table 2 because the Loestrin sale was completed first. Compare Barr Acquires Galen's Loestrin Under Final Agreement, Drug Industry Daily, Mar. 26, 2004, available at Factiva, with Press Release, Barr Pharms., Inc., Barr Announces Agreement with Galen Resolving Outstanding Patent Challenges on Estrostep and Femhrt (Apr. 27, 2004). That ordering limited the degree to which a Loestrin sale could confer compensation upon Barr, in exchange for delayed entry on Estrostep and Femhrt, because Barr could simply walk away with its Loestrin "quid" without providing an Estrostep/Femhrt "quo."

155. Abbott, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, and Pfizer were selected as brand-name firms.

156. Barr, Mylan, Ranbaxy, Teva, and Watson were the selected generic firms.

ings between 2000 and 2007 were searched for the names of the five generic firms.<sup>157</sup> Each resulting “hit” led to further examination, to see whether the discussion indicated a business relationship between the two firms, as opposed to, say, a description of litigation or competition. The business transactions were examined further using articles in the trade press and other materials. The same exercise was performed for each of the generic firms, as to each of the five brand-name firms.<sup>158</sup>

The resulting inquiry into twenty-five total brand-generic business dealings—each of five brand-name firms, with each of five generic firms—produced just two responsive business arrangements, both of them involving Ranbaxy: an unusual drug development deal with one brand-name firm,<sup>159</sup> and a purchase of rights to a set of minor dermatology drugs from another brand-name firm.<sup>160</sup> Several other business arrangements do not match the terms of the side deals discussed above.<sup>161</sup> This evidence is not decisive; such non-settlement deals could exist, yet be too insignificant to report in an annual filing. 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, is revealed by one specific type of side deal known as co-

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157. Form 10-K, in the case of Abbott, Bristol, and Pfizer; Form 20-F, in the case of AstraZeneca and GlaxoSmithKline.

158. Form 10-K, in the case of Barr, Mylan, and Watson; Form 20-F, in the case of Teva; and detailed annual reports filed under Indian securities law, in the case of Ranbaxy.

159. Glaxo and Ranbaxy have an unusual drug development initiative, in which Ranbaxy takes “hit” molecules from Glaxo that show initial promise, and helps develop and winnow them into “candidates” for further development by Glaxo. Ranbaxy Labs. Ltd., Annual Report 2003, at 30 (on file with the *Columbia Law Review*); Ranbaxy, GSK in R&D Pact, *Hindustan Times*, Oct. 23, 2003, available at Factiva. In 2006, the agreement was expanded to permit Ranbaxy to participate in development beyond the candidate stage, to the point of a new investigational new drug application in India. Ranbaxy Labs. Ltd., Annual Report 2006, at 16 (on file with the *Columbia Law Review*) [hereinafter Ranbaxy, 2006 Annual Report]; see also Ranbaxy Seeks Nod for Human Clinical Trials, *Fin. Express* (India), Oct. 14, 2008, available at Factiva.

160. See Ranbaxy Labs. Ltd., Annual Report 2007, at 13 (on file with the *Columbia Law Review*) (describing purchase from Bristol-Myers Squibb); Alicia Ault, Ranbaxy Buys BMS Derm Brands, *Skin & Allergy News*, July 1, 2007 (listing the products).

161. For example, Bristol agreed to commercialize EmSam, a patch treatment for depression, after it was already developed by a Mylan-Watson joint venture, and ready for FDA approval. B-MS and Somerset in EmSam Distribution Deal, *Pharma Marketletter*, Jan. 3, 2005, available at Factiva. Bristol and Barr have had complex marketing arrangements on several products, but this is the accidental result of an antitrust settlement between DuPont and Barr, inherited by Bristol when it bought DuPont’s drug business. Rick Mullin, Bristol-Myers Untangles Barr-DuPont Agreements, *Chemical Wk.*, May 8, 2002, at 27, available at Factiva. Ranbaxy bought Glaxo’s generic drug operations in Spain and Italy. Ranbaxy, 2006 Annual Report, *supra* note 159, at 5. In 1999, Watson paid Glaxo to acquire the rights to Androderm, a testosterone patch, but this was a reacquisition of rights to a product developed by a company later acquired by Watson. Taren Grom, *Generics: Best Years to Come*, *Med Ad News*, Oct. 1, 1999, available at Factiva (describing Watson’s acquisition of TheraTech); Watson Rights, *Chain Drug Rev.*, June 28, 1999, available at Factiva (announcing reacquisition of Androderm rights).

promotion. Brand-name firms frequently enter co-promotion arrangements to augment their promotion efforts—for example, to reach physicians that their own detailing team does not visit. In a second search, the same annual filings were reviewed for mentions of promotion, and those mentions which pertained to product promotion were examined further. That search produced many examples in which a brand-name firm recruited other brand-name firms to help promote a drug, but no significant examples, outside the settlement context, in which the brand-name firm recruited a generic firm to promote a brand-name drug.<sup>162</sup> On the other hand, generic firms do occasionally have significant branded drugs, and the search did reveal instances when they have hired brand-name firms to help market the drug.<sup>163</sup>

This result is not surprising, considering the business of generic firms. Generally, they do not have substantial promotion teams, for they seldom have major branded drugs to promote. The absence of generic provision of other services, outside the settlement context, is equally unsurprising. Although some generic firms have made efforts to develop a brand-name drug business,<sup>164</sup> as a general matter, their research and development capacity is limited; this is not their core business. Nor do they have powerful manufacturing capabilities such that they would be the obvious and efficient alternative supplier for a brand-name firm.<sup>165</sup> The contrast is less severe in side deals featuring transferred assets. It is quite common for a brand-name firm to set up an authorized generic arrangement with some generic firm. 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 represents payment for value or disguised payment for delayed generic entry. A broader comparison of side deals in conjunction with settlements, versus brand-generic deals outside this context, tells a different story. At least with respect to overpayment side deals, the absence of brand-generic

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162. A minor exception is promotion efforts outside the United States. In particular, Ranbaxy promotes a Sanofi vaccine in India. See Ranbaxy to Market Aventis Vaccines, Bus. Line, Oct. 6, 2002, available at Factiva (describing agreement to market six vaccines); see also Aventis Arm in Vaccine Tie-Up with India's Ranbaxy, Reuters News, Oct. 4, 2002, available at Factiva (describing marketing agreement).

163. For example, Teva recruited a predecessor of Sanofi-Aventis to help sell its multiple sclerosis drug Copaxone. Sanofi-Aventis, Annual Report (Form 20-F), at 61 (Mar. 7, 2008); Teva Pharmaceutical Industries Ltd., Annual Report (Form 20-F), at 20 (Mar. 31, 2001). Another example is the EmSam deal discussed *supra* note 161.

164. See, e.g., Teva Pharms. Inc., Innovative Research & Development, at <http://www.tevapharm.com/research> (on file with the *Columbia Law Review*) (describing efforts to develop innovative drugs that have yielded two products, Copaxone and Azilect).

165. For example, Cephalon agreed to buy Provigil's 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. Provigil Complaint, *supra* note 7.

deals outside of settlement is a strong reason to suspect that the deals are used 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. Under this pay-for-delay presumption, drug makers would be free to come forward with evidence that their unusual deal was for value and therefore 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 supportable by the evidence from aggregation, would make this presumption conclusive.

That conclusion is not, by itself, enough to impose liability. It resolves the “factual” question of whether a settlement containing a side deal constitutes payment for delay, but not the “theoretical” question of whether pay-for-delay settlements violate antitrust law.<sup>166</sup>

This proposal, like any aggressive antitrust rule, is potentially overinclusive. It raises the probability of false condemnation. But here, the rarity 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? Not very costly, as it turns out, 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.<sup>167</sup> 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” (competitive price cuts) that antitrust is supposed to protect.<sup>168</sup> As other commentators have noted, false negatives are an important countervailing problem.<sup>169</sup> For collusion, by contrast, avoiding false negatives is the important goal, particularly where false positives are rare and low-

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166. See *supra* Part I.A.

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

168. See, e.g., *Trinko*, 540 U.S. at 414 (“Mistaken inferences and the resulting false condemnations ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’” (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986))).

169. See, e.g., Andrew I. Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, 72 *Antitrust L.J.* 3, 5 (2004) (arguing that lenient rule toward exclusion creates substantial false negative risk); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 *Antitrust L.J.* 311, 346 (2006) (arguing that “profit-sacrifice test” for exclusionary conduct creates substantial false negative risk); see also Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 *Minn. L. Rev.* 101, 179 (2006) (arguing that passive

cost, and where no significant equilibrating factors tend to restore competition. That relatively aggressive approach is shared even by “Chicago School” analysts, who support an enforcement emphasis upon collusion.<sup>170</sup>

What about underpayment side deals? The likelihood of false positives is higher, compared to overpayment 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 dealing with this particular generic firm, which happens to be locked in a patent suit with the brand-name firm, as the counterparty in a transaction with this particular brand-name firm.

The high cost of false negatives and low cost of false positives support a presumption in the underpayment context, just as in the overpayment context. A more conservative alternative would be to make the presumption applicable only to future settlements. That way, parties have ample notice that they must not reach underpayment deals with parties with which they are settling. Given the absence of distinctive value offered by the settling firm, that route places at most a minimal burden upon parties that wish to reach authorized generic or asset transfer arrangements.

This policy suggestion could be implemented by several routes. For example, it could be adopted by a court considering a particular case, using the federal courts’ common lawmaking authority under the Sherman Act. Alternatively, it could be instituted through new congressional legislation, or promulgated as an agency rule by the FTC. The next Part considers the strengths and weaknesses of these alternative routes.

#### IV. EXPANDING THE FTC’S ROLE AS AGGREGATOR

This Part turns to the institutional question of who should employ this aggregate approach to antitrust questions. Part IV.A explains why an agency—here, the FTC—is better positioned to collect and synthesize aggregate information, relative to courts. Part IV.B argues that this advantage in wielding aggregate information favors a shift in substantive policymaking authority from courts to agencies.

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possession of invalid patents serves to exclude competitors which, if permitted, creates false-negative costs).

170. See, e.g., *Premier Elec. Constr. Co. v. Nat’l Elec. Contractors Ass’n*, 814 F.2d 358, 369 (7th Cir. 1987) (Easterbrook, J.) (noting heightened risk where “[n]o automatic mechanism corrects blunders”); Richard A. Posner, *Antitrust Law* 48 (2d ed. 2001) (noting that Reagan-era Antitrust Division, led by Bill Baxter, shifted enforcement focus from exclusionary to collusive practices); Richard A. Posner, *Oligopoly and the Antitrust Laws: A Suggested Approach*, 21 *Stan. L. Rev.* 1562, 1562 (1969) (suggesting that section 1 of Sherman Act reaches both explicit and tacit collusion in oligopoly).

*A. Information Gathering and Synthesis*

A court establishing antitrust policy faces the fundamental problem that it has little capacity to collect aggregate data. The disadvantage of a court as a fact-finder is a familiar idea from the literature on institutional choice.<sup>171</sup> The problem is particularly acute here. At best, a single court needs many years to develop a sense of the overall distribution of cases, as antitrust cases appear only rarely on its generalist docket. The Supreme Court is in a slightly better position, since it is exposed to appeals from all over the country. But many instances of anticompetitive behavior are never litigated, and courts have particularly limited ability to observe non-public data about settlements outside the case at bar.

Private parties cannot entirely fill the gap. These plaintiffs struggle to learn the content of settlements, with some early agreements escaping notice entirely.<sup>172</sup> Later settlements have been shielded from scrutiny due to the difficulty of discerning, from public information, the extent of pay-for-delay deals. This information gap partially explains why so few of the most recent settlements have been challenged.

This Article helps fill the gap, but it is not a complete solution. My data does not include nonpublic details that would help build confidence about whether a side deal conveys payment. For example, how much did the brand-name firm agree to pay for a co-promotion agreement? How much did a generic firm pay for a product transfer? Is payment conditioned on successful performance by the other party? Was a particular product development deal a long-felt need of the firm, which shopped for alternative sources? How was the service provided valued internally by the payor? Public data for most settlements lack these details.

Outside the context of side deals, two other issues are important. First, do the parties expect the generic firm to retain exclusivity when it enters the market? In some cases, one or both parties divulge their view publicly, but in other cases they do not. Second, how often does the brand-name firm contract with this counterparty and other generic firms

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171. For an excellent discussion of this literature, see Margaret H. Lemos, *The Commerce Power and Criminal Punishment: Presumption of Constitutionality or Presumption of Innocence?*, 84 *Tex. L. Rev.* 1203, 1251–57 (2006) (reviewing argument that courts are weak fact-finders, limited by lack of expertise, investigative capacity, and access to facts beyond those of single case before them). Among the many sources cited there, see, e.g., Benjamin Cardozo, *The Growth of the Law* 116–17 (1924) (“Some of the errors of courts have their origin in imperfect knowledge of the economic and social consequences of a decision, or of the economic and social needs to which a decision will respond.”); Cass Sunstein, *The Partial Constitution* 147 (1993) (“Courts are rarely experts in the area at hand. Moreover, the focus on the litigated case makes it hard for judges to understand the complex, often unpredictable effects of legal intervention. Knowledge of these effects is crucial but sometimes inaccessible.”); William W. Buzbee & Robert A. Schapiro, *Legislative Record Review*, 54 *Stan. L. Rev.* 87, 143 (2001) (observing that courts “are not well-suited to gather the evidence necessary to assess the magnitude of complex social practices . . .”).

172. See, e.g., *Reguly*, *supra* note 111, at 25 (reporting Zantac settlement).

outside the context of settlement? Reciprocally, what is each generic firm's experience with brand-name firms outside the context of settlement? Public information of the type collected in Part II paints only an incomplete picture of the frequency of particular arrangements outside the settlement context. With details such as these, an inference of payment for each case could be strengthened, and—more importantly—the inference of payment across cases could be strengthened as well.

The FTC already has in place all the tools it needs to perform this task. As noted in Part I.B, it receives information about each settlement and has statutory authority to require firms to produce additional information of the types discussed above.<sup>173</sup> That authority ought to be used to collect two types of information. First, the Agency should seek full details about each settlement—at least enough information to answer the questions listed above. Some of these questions may be answerable by examination of the agreement itself. To the extent they are not, the gaps could be filled using voluntary questionnaires or, if necessary, compulsory process. Second, the Agency should collect from each brand-name firm a detailed catalogue of its dealings with generic firms, and vice versa for generic firms.

This information would be the key input in a comprehensive study of side deals. It would provide a firm basis for the Agency to endorse or reject the conclusion offered in Part II, based upon public information, that contemporaneous side deals should possess a presumption of payment. If the information is sufficiently lopsided, error cost minimization might suggest the more aggressive rule should be instituted, making the presumption of illegality conclusive and effectively banning contemporaneous side deals.

In this respect, the analysis in Part II provides a rough draft for a more comprehensive, future agency report. The public data presents a *prima facie* case that something is amiss regarding the increasing utilization of side deals. For skeptical readers of this Article, who may think that the survey results reported in Part II are too weak to justify a presumption of payment through side deals, the case for deploying the agency as an aggregator should be even stronger; agency action is necessary to fill these informational gaps and better explain whether and when compensation is conferred for delay.

The FTC has not fully exploited its information gathering advantage. Of the drugs with monetary settlements in Table 2, two-thirds occurred after the end of the FTC's last major study in 2002. Moreover, all of the retained exclusivity settlements in Table 3 post-date the study. To be sure, the FTC evaluates each individual agreement to determine whether further investigation is appropriate, and no doubt it asks some of the questions detailed above in considering its response. But it does not synthesize the resulting information, aside from very general annual summa-

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173. See *supra* notes 59–60 and accompanying text.

ries of settlement activity. As this Article reveals, only through such an aggregate approach can we expect to generate a useful picture of—and rule for—brand-generic settlement.

### B. *Antitrust Rulemaking*

The previous section advocates a focused increase in the FTC's "competition policy research and development."<sup>174</sup> If the FTC accepted the suggestion, it would eventually reach a firm, empirically grounded conclusion about the optimal policy for side deals, and thus either confirm or reject the conclusion reached in Part II. That conclusion could be deployed in a variety of policymaking settings, including litigation brought by the Agency, amicus practice, and advocacy for congressional legislation. This section considers a further possibility, that a comprehensive aggregate study of settlement practice could form the basis for substantive policymaking by the Agency in the form of rulemaking.

There is of course an enormous literature on the choice of courts versus agencies, adjudication versus rulemaking, and rules versus standards, and this Article does not engage the full complexity of those debates. My goal here is simply to suggest how the virtues of an aggregate perspective on settlement practice shift the balance in a way that favors agency rulemaking. In other words, the settlement issue highlights certain advantages of moving away from a court-centered model of antitrust law.

Why bother with rulemaking? Even if the expert agency is better than a court at arriving at a correct policy conclusion, thanks to its superior capacity for aggregation, it does not necessarily follow that the agency ought to set policy. It could instead simply furnish the information to a court or Congress, which might then implement the same conclusion, with some of the same benefits—for example, efficiency compared to case-by-case adjudication, and certainty for businesses about the range of acceptable practices.

Put another way, why would we care whether the agency itself makes policy in the first instance, rather than acting as an input to a court? The question suggests a bureaucratic version of the Coase Theorem. If there is no friction in communicating an expert policy conclusion from the agency to the court, then it does not matter which of the two has policymaking authority. If, on the other hand, the agency's message arrives garbled or is ignored by the court, that provides reason to prefer that the agency reach a substantive policy judgment of its own, rather than merely furnishing advice to the court.

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174. Timothy J. Muris, *Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy*, 2003 *Colum. Bus. L. Rev.* 359, 403–04.

One reason to expect the court to do a less effective job is that courts have trouble correctly identifying anticompetitive strategic behavior,<sup>175</sup> particularly in a setting as complex as the Hatch-Waxman Act. That view is borne out by a recent appeals court opinion about settlement. The court relied, as a reason to deny antitrust liability, upon the mistaken idea that a settlement with one generic firm would spur other generic firms to action, and that these firms would have the large incentive provided by the exclusivity period.<sup>176</sup> In fact, later filers are ineligible for the exclusivity period. This error was unforced; the point does not appear to have been argued below. The same court took comfort in the view that often there is more than one generic challenger, and the court concluded that multiple challengers are difficult to buy off.<sup>177</sup> In fact, however, multiple settlements do happen.

Courts have also had trouble evaluating the facts of particular cases. For example, in the case discussed above, the plaintiff had argued that the brand-name firm compensated the generic firm not only with cash, but also through authorized generic sales.<sup>178</sup> The court ignored this idea entirely.<sup>179</sup> In a second case focused on side deals, the appeals court essentially ignored the extensive evidence that the payment was for delay, rather than the separate value offered by the generic firm.<sup>180</sup> This pattern is likely to continue, given the evidence of complexity discussed in Part III.A.

An expert agency, essentially by definition, is less likely to make mistakes identifying the strategic behavior of parties. To be sure, this information could be communicated to a court. But as a practical matter, courts have not welcomed the information about settlements supplied by the FTC. In a key case brought by the FTC, the appeals court largely ignored the analysis employed by the Agency, granted essentially no deference to its findings of fact, and indeed berated the Agency for failing to

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175. See Herbert Hovenkamp, *The Antitrust Enterprise* 47 (2005) (“[T]here is relatively little disagreement about the basic proposition that often our general judicial system is not competent to apply the economic theory necessary for identifying strategic behavior as anticompetitive.”); Christopher R. Leslie, *Rationality Analysis in Antitrust*, 158 U. Pa. L. Rev. (forthcoming 2009) (manuscript at 3, on file with the *Columbia Law Review*) (arguing that “courts are generally not effective arbiters of whether alleged business conduct is implausible”).

176. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 214 (2d Cir. 2006).

177. See *id.* at 211–12 (noting “possibility” of settlements with multiple challengers but “doubt[ing], however, that this scenario is realistic”); see also Brief for the United States, *Andrx*, *supra* note 123, at 18 (concluding that shared exclusivity would cause settlements to subside).

178. Brief for Plaintiffs Appellants at 7, 28, *Tamoxifen*, 466 F.3d 187 (2d Cir. 2004) (No. 03-7641), 2004 WL 5261441.

179. *Tamoxifen*, 466 F.3d at 215–16.

180. See generally *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

follow the appeals court's earlier rule.<sup>181</sup> For the most part, courts have also ignored the results of the FTC's extensive 2002 study and its subsequent annual summary updates, as well as its amicus recommendations based on this data.<sup>182</sup>

A second reason to expect courts to be less effective than the FTC is that antitrust courts are obliged to impose treble damages when they condemn behavior as a violation of the Sherman Act. The large measure of damages may strike a court as excessive, particularly where the conduct seems ambiguous or complicated, such that the parties might not be expected to know that their behavior violated antitrust law.<sup>183</sup> That impression may be reinforced where the conduct is out in the open, rather than hidden, so that a usual justification for a damages multiple—the difficulty of detection—is missing. The combined effect is to make a court gun shy, and to cause it to select a deliberately underinclusive antitrust rule.<sup>184</sup> And indeed, courts rejecting antitrust liability for settlements have repeatedly adverted to treble damages in their analysis.<sup>185</sup>

The FTC is less constrained. Its substantive conclusions would be made under the Federal Trade Commission Act's prohibition of "unfair

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181. See *id.* at 1068 n.18, 1075 n.26, 1076 (11th Cir. 2005); Daniel A. Crane, *Technocracy and Antitrust*, 86 *Tex. L. Rev.* 1159, 1201 (2008) [hereinafter Crane, *Technocracy*] (describing *Schering-Plough*).

182. See, e.g., Brief of Federal Trade Commission in Support of Appellants, In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), 2008 WL 644394 (favoring antitrust liability for brand-generic settlement, a position rejected by appeals court); Brief of Federal Trade Commission in Support of Plaintiffs-Appellants, *Tamoxifen*, 466 F.3d 187 (No. 03-7641), 2005 WL 3332374 (same); see also Brief of Federal Trade Commission in Support of Appellant, *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir. 2004) (No. 04-1186), available at <http://www.ftc.gov/os/2004/04/040331amicusbrieftevapfizer.pdf> (on file with the *Columbia Law Review*) (arguing that generic firm has Article III standing to challenge brand-name firm's patent in declaratory judgment action, in part because that result would improve industry competition, a position rejected by appeals court).

183. In other contexts, courts are thought to narrow substantive rights when the consequence of their violation is believed to be too severe. See, e.g., Akhil Reed Amar, *Fourth Amendment First Principles*, 107 *Harv. L. Rev.* 757, 799 (1994) ("The exclusionary rule renders the Fourth Amendment contemptible in the eyes of judges and citizens. Judges do not like excluding bloody knives, so they distort doctrine, claiming the Fourth Amendment was not really violated.").

184. See Margaret H. Lemos, *The Other Delegate: Judicially Administered Statutes and the Nondelegation Doctrine*, 81 *S. Cal. L. Rev.* 405, 464–68 (2008) (describing factors that might lead courts to adopt underinclusive antitrust liability rules). This argument embraces both substantive rules, as discussed in the text, and procedural rules. See *Bell Atl. Corp. v. Twombly*, 127 *S. Ct.* 1955, 1964–66 (2007) (interpreting pleading standard for antitrust suits); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 *U.S.* 574, 585–88 (1986) (describing summary judgment standard for antitrust suits).

185. See *Tamoxifen*, 466 F.3d at 204 (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 *F. Supp. 2d* 514, 529 (E.D.N.Y. 2005)) (asserting that treble damages might chill settlements); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (stating that treble damages would discourage settlements).

methods of competition,”<sup>186</sup> rather than under the Sherman Act. The Supreme Court has stated repeatedly that the FTC Act’s prohibitions are broader than those of the Sherman Act.<sup>187</sup> Thus, behavior that constitutes unfair competition does not necessarily also violate the Sherman Act’s prohibitions of unreasonable restraints of trade or monopolization.

This conclusion is resisted by some observers, who think it is “no longer tenable” to treat the FTC Act as broader than the Sherman Act.<sup>188</sup> However, the Supreme Court’s rejection of strict equivalence can be justified on an eminently pragmatic ground. The argument for equivalence rests upon the proposition that, as Richard Posner puts it, “the Sherman and Clayton Acts have been interpreted so broadly that they no longer contain gaps that a broad interpretation of Section 5 of the FTC Act might be needed to fill.”<sup>189</sup> But to the extent that the Sherman Act as actually interpreted by courts contains important gaps, as exemplified by the lack of liability for pay-for-delay settlements, the quoted statement does not hold. Where, as here, courts are reaching incorrect conclusions about liability, distinguishing the two statutes is useful, because it allows the FTC to enjoin settlements without being automatically reversed by a court equipped with the (erroneous) view that antitrust law does not extend so far.

Moreover, nonequivalence is particularly useful where, as here, treble damages lead courts to constrict the scope of liability. Even if it is appropriate for courts to constrict liability to compensate for the heightened false-positive risk created by treble damages, it does not follow that the FTC must adhere to the same path. The FTC seeks injunctive relief, not treble damages. That difference reduces concerns about false positives and overdeterrence. Put another way, the FTC’s optimal scope of liability may well be broader than the courts’. Nonequivalence allows the FTC to take advantage of that difference, compared to the Sherman Act, which applies a harsher penalty to a narrower class of activity.<sup>190</sup>

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186. FTC Act § 5(a)(1), 15 U.S.C. § 45(a)(1) (2006).

187. See, e.g., *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 454 (1986) (holding that section 5 covers “not only practices that violate the Sherman Act and other antitrust laws, but also practices that the Commission determines are against public policy for other reasons” (citations omitted)); *FTC v. Brown Shoe Co.*, 384 U.S. 316, 321 (1966) (holding that section 5 reaches “practices which conflict with the basic policies” underlying antitrust law, as well as incipient violations of antitrust law); *FTC v. R.F. Keppel & Bros., Inc.*, 291 U.S. 304, 310 (1934) (“It would not have been a difficult feat of draftsmanship to have restricted the operation of the Trade Commission Act to those methods of competition in interstate commerce which are forbidden at common law or which are likely to grow into violations of the Sherman Act . . .”); see also *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972) (noting that FTC must “consider[ ] public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws”).

188. Richard A. Posner, *The Federal Trade Commission: A Retrospective*, 72 *Antitrust L.J.* 761, 766 (2005) [hereinafter Posner, *Retrospective*].

189. *Id.*

190. For an argument along similar lines, see Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 *Antitrust L.J.* 337,

A third advantage of the FTC is that it is less subject to the constraint of *stare decisis*. Lower courts are bound by their own or Supreme Court precedent.<sup>191</sup> The Supreme Court, for its part, is not quick to revisit antitrust doctrine,<sup>192</sup> and frequently feels constrained to follow its own previous views.<sup>193</sup> The FTC is freer to change course, provided that the new interpretation is a reasonable understanding of the FTC Act.<sup>194</sup>

One way for the FTC to exploit these advantages is to promulgate a legislative rule—that is, a rule having the force of law and entitled to *Chevron* deference by a court.<sup>195</sup> FTC rulemaking has been suggested periodically by commentators as a way to shift decisionmaking authority to the FTC and fill gaps in the coverage of other antitrust statutes.<sup>196</sup> The

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384–85 n.285 (2000) (“While the FTC cannot afford compensation to the private parties favored by non-Chicagoans, it may be more likely than the current federal judiciary to prohibit the practices that concern Chicago’s critics.”). The nonequivalence provides an answer to the understandable concern, raised by Daniel Crane, that the shared authority of the Antitrust Division and FTC over antitrust matters might undermine the FTC’s claim to *Chevron* deference. Crane, *Technocracy*, supra note 181, at 1209. Crane points out that the FTC has characterized its powers as being co-extensive “for the most part” with the Sherman Act, id. at 1209 n.269 (quoting FTC’s opinion in *Schering-Plough*, see supra note 10), and suggests that it might be necessary to combine the two enforcers before granting *Chevron* deference, id. at 1209. But the quoted language also underscores the non-identity of the two statutes, consistent with the Supreme Court’s long-held view.

191. See, e.g., *Khan v. State Oil Co.*, 93 F.3d 1358, 1363 (7th Cir. 1996) (“[T]he Supreme Court has told the lower federal courts, in increasingly emphatic, even strident, terms, not to anticipate an overruling of a decision by the Court; we are to leave the overruling to the Court itself.”), vacated, 522 U.S. 3, 20 (1997) (“The Court of Appeals was correct in applying that principle despite disagreement with *Albrecht*, for it is this Court’s prerogative alone to overrule one of its precedents.”).

192. Compare *Dr. Miles Med. Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911), with *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705 (2007) (overruling *Dr. Miles*).

193. See, e.g., *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 9 (1984) (“It is far too late in the history of our antitrust jurisprudence to question the proposition that certain tying arrangements pose an unacceptable risk of stifling competition and therefore are unreasonable ‘per se.’”).

194. See, e.g., Jerry L. Mashaw, Norms, Practices, and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation, 57 *Admin. L. Rev.* 501, 505–14 (2005) (discussing this aspect of agency flexibility).

195. Some commentators use the term “substantive rules” instead of “legislative rules” for the rules I have in mind, but the choice of terminology is unimportant for my purposes. See, e.g., Jacob E. Gersen, *Legislative Rules Revisited*, 74 *U. Chi. L. Rev.* 1705, 1710 (2007) (“[I]t has become commonplace to use the terms legislative rules and substantive rules interchangeably.”).

196. See, e.g., Jonathan B. Baker, Two Sherman Act Section 1 Dilemmas: Parallel Pricing, the Oligopoly Problem, and Contemporary Economic Theory, 38 *Antitrust Bull.* 143, 207–19 (1993); David Balto, Returning to the Elman Vision of the Federal Trade Commission: Reassessing the Approach to FTC Remedies, 72 *Antitrust L.J.* 1113, 1117–19 (2005); Philip Elman, Comment, Rulemaking Procedures in the FTC’s Enforcement of the Merger Law, 78 *Harv. L. Rev.* 385 (1964); William E. Kovacic, Antitrust Policy and Horizontal Collusion in the 21st Century, 9 *Loy. Consumer L. Rep.* 97, 107–08 (1997); see also Crane, *Technocracy*, supra note 181, at 1206–09 (raising possibility of FTC rulemaking, but also raising doubts about its use).

rulemaking route, though not without controversy, is an attractive and feasible means to take full advantage of the aggregate approach to settlement.

The FTC possesses the power to promulgate rules with the force of law that are subject to *Chevron* deference. As noted in Part I.B, the FTC has already promulgated one such antitrust rule,<sup>197</sup> which was issued and eventually rescinded after notice and comment.<sup>198</sup> The FTC's rules and operating procedures do not deny the agency's possession of this authority, to be administered under ordinary notice-and-comment procedures, but neither do they fully spell it out.<sup>199</sup>

The FTC's rulemaking power arises from its general rulemaking authority,<sup>200</sup> which the D.C. Circuit interpreted in *National Petroleum Refiners Ass'n v. FTC* as a grant to make rules with the force of law.<sup>201</sup> Although the *Petroleum Refiners* result is doubtful as an original matter,<sup>202</sup> it is currently relatively settled that an ambiguous statute, such as the FTC Act, suffices to confer that authority. Similar rulings have been made for

197. Discriminatory Practices in Men's and Boys' Tailored Clothing Industry, 16 C.F.R. pt. 412 (1968). The rule was promulgated pursuant to sections 2(d) and 2(e) of the Clayton Act, 15 U.S.C. § 13(d), (e) (2006).

198. Trade Regulation Rule: Discriminatory Practices in Men's and Boys' Tailored Clothing Industry, 58 Fed. Reg. 35,907 (July 2, 1993) (providing notice of proposed rulemaking to rescind rule). The rule appears never to have been used by the agency in law enforcement. Notice of Repeal of Rule, 59 Fed. Reg. 8527-28 (Feb. 23, 1994) (providing notice of repeal of rule).

199. According to the FTC's Operating Manual, "the Commission has statutory authority under FTCA § 6(g) to promulgate rules respecting unfair methods of competition." FTC, Operating Manual ch. 7, at 33, available at <http://www.ftc.gov/foia/ch07rulemaking.pdf> (on file with the *Columbia Law Review*) [hereinafter FTC, Operating Manual]. The Rules of Procedure accommodate antitrust rulemaking too. See 16 C.F.R. § 1.22(a) (2008) ("For the purpose of carrying out the provisions of the statutes administered by it, the Commission is empowered to promulgate rules and regulations applicable to unlawful trade practices."). The closest they come to acknowledging legislative rulemaking authority is to note that *Petroleum Refiners*, discussed *infra* note 201, gives the FTC "authority to promulgate rules with substantive effect." FTC, Operating Manual, *supra*, at 2-3. On the applicability of ordinary notice-and-comment procedures, see *id.* at 33 (describing rulemaking under 5 U.S.C. § 553 (2006), and spelling out that "[w]hether to provide an opportunity for oral presentation of data, views, and arguments remains discretionary with the agency").

200. 15 U.S.C. § 46(g) (granting FTC authority to "make rules and regulations for the purpose of carrying out the provisions of this subchapter").

201. 482 F.2d 672, 698 (D.C. Cir. 1973) (upholding rule requiring posting of octane ratings on gas pumps). The FTC has two distinct missions, consumer protection and antitrust, and *Petroleum Refiners* specifically dealt with a consumer protection rule, not an antitrust rule. But the relevant statutory language covers both consumer protection and antitrust rules, and the applicability of the court's ruling to both types of rules is fairly implied in its opinion. See, e.g., *id.* at 684-85, 693, 694.

202. See Thomas W. Merrill & Kathryn Tongue Watts, Agency Rules with the Force of Law: The Original Convention, 116 Harv. L. Rev. 467, 493-509 (2002) (arguing that when Congress passed FTC Act and other statutes, its intent to deny legislative rulemaking authority was evidenced by lack of sanction for rule violation).

other statutes,<sup>203</sup> and overruling *Petroleum Refiners* today would jeopardize rulemaking in these other contexts, including the grant analyzed in *Chevron* itself.<sup>204</sup> These prudential considerations, and a later congressional enactment,<sup>205</sup> tend to confirm the viability of rulemaking authority. Although the FTC reportedly sought candidates for antitrust rulemaking after *Petroleum Refiners*,<sup>206</sup> it has not yet found any. A rulemaking focused on settlements is an attractive candidate if this procedural route is pursued again.

Rulemaking is not the only way to shift substantive policymaking authority from courts to the FTC. The FTC can bring individual cases through agency adjudication,<sup>207</sup> reviewed in a court of appeals of a respondent's choosing,<sup>208</sup> or directly in an action in district court. The FTC has taken both routes in attacking settlements. The agency adjudication route resulted in an appeals court loss; two cases in district court are pending.

Rulemaking has significant, familiar advantages over the adjudicatory route. Rulemaking permits affected parties to test aggregate data in an open way, with ample opportunity for rebuttal.<sup>209</sup> The opportunity

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203. See, e.g., *In re Permanent Surface Mining Regulation Litig.*, 653 F.2d 514, 523–25 (D.C. Cir. 1981) (en banc) (holding that general language in Surface Mining Control and Reclamation Act suffices to grant legislative rulemaking powers); *Nat'l Ass'n of Pharm. Mfrs. v. FDA*, 637 F.2d 877, 887 (2d Cir. 1981) (reaching similar conclusion as to section 701 of Food, Drug, and Cosmetic Act); *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873–74 (D.C. Cir. 1979) (reaching similar conclusion as to Clean Air Act); see also *Merrill & Watts*, supra note 202, at 557 n.484, 563–65 (discussing these cases).

204. See *Merrill & Watts*, supra note 202, at 587–90 (describing this “*Chevron* paradox”).

205. After *Petroleum Refiners*, Congress authorized legislative rulemaking in the consumer protection sphere, while preserving whatever antitrust rulemaking authority already existed. See 15 U.S.C. § 57a (authorizing rulemaking regarding “unfair or deceptive acts or practices in or affecting commerce”). This legislative action took place against the backdrop of both *Petroleum Refiners* and the previously promulgated antitrust rule. The decision not to disturb these indications of antitrust rulemaking authority, while altering the contours of consumer protection rulemaking authority, is arguably a ratification of the FTC and D.C. Circuit's views. On the other hand, an examination of the legislative history paints a more skeptical view. See Einer Elhauge & Damien Gerardin, *Global Antitrust Law and Economics* 5 n.11 (2007) (concluding, based upon legislative history, that Congress came to no considered view about existence or absence of antitrust rulemaking authority when it passed Magnusson-Moss Act).

206. FTC Staff Narrows Rulemaking Possibilities to Three Areas, supra note 69, at A-13 (noting FTC staff's interest in rulemaking about “delivered pricing in the cement industry, physician influence over health insurance payments, and mergers”).

207. FTC Act § 5(b), 15 U.S.C. §45(b).

208. *Id.* § 5(c). The chosen court of appeals must be one in which the condemned practice was used, or in which the respondent does business. In the settlement context, that means as a practical matter that the administrative ruling will be reviewed in a court of appeals already known to be hostile to liability.

209. See, e.g., Arthur Selwyn Miller & Jerome A. Barron, *The Supreme Court, the Adversary System, and the Flow of Information to the Justices: A Preliminary Inquiry*, 61 *Va. L. Rev.* 1187, 1211–18 (1975) (assessing problems that result when judges use data “not subject to test or challenge by the losing party”).

for input and testing tends to produce superior policy.<sup>210</sup> The resulting rule thus has a superior claim to judicial deference, compared to judicial review of a single case: The rule has been thoroughly vetted under notice and comment, after a broad, deep review of the full terrain of behavior by regulated parties. It is this superior breadth and greater vetting, rather than the doctrinal force of *Chevron* itself,<sup>211</sup> that presents the strongest reason to think that a rule might succeed where adjudication has failed.

Rulemaking helps in another way. The FTC Act is broader than the Sherman Act, as noted above, but the degree of its additional breadth has been a subject of controversy. Some lower courts have regarded with skepticism the FTC's efforts to regulate behavior not already governed by the Sherman Act.<sup>212</sup> A powerful way for the FTC to overcome this skepticism would be to support its claim to authority with aggregation, buttressed by notice-and-comment rulemaking. In this manner, the FTC could combine, in a mutually reinforcing manner, the two ways in which its authority stands out relative to ordinary, judicial antitrust policymaking: in having a statute with broader reach than the Sherman Act, and in possessing the power to collect information beyond the reach of the judiciary.

Rulemaking has a further effect: It attracts congressional attention to an important policy issue where adjudication may not. The FTC's first controversial foray into rulemaking was the Cigarette Rule,<sup>213</sup> a consumer protection rule promulgated in 1964 that governed the advertising and labeling of cigarettes. One powerful effect of the rule was to focus Congress on the question, in part because the industry argued that the FTC had usurped congressional prerogatives. The rule was withdrawn the following year, replaced by a watered-down statute.<sup>214</sup>

A modern antitrust rule might be expected to create a similar provocation. Whether that is an argument in favor of rulemaking is less cer-

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210. See, e.g., Richard J. Pierce, Jr., Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 Duke L.J. 300, 308 ("Rulemaking yields higher-quality policy decisions than adjudication because it invites broad participation in the policymaking process by all affected entities and groups, and because it encourages the agency to focus on the broad effects of its policy rather than the often idiosyncratic adjudicative facts of a specific dispute.").

211. William N. Eskridge, Jr. & Lauren E. Baer, The Continuum of Deference: Supreme Court Treatment of Agency Interpretations from *Chevron* to *Hamdan*, 96 Geo. L.J. 1083, 1120-36 (2008) (presenting evidence that *Chevron* is less important than commonly thought).

212. See, e.g., *Ethyl Corp. v. FTC*, 729 F.2d 128, 136 (2d Cir. 1984) (interpreting FTC Act's scope as similar to Sherman Act's); *Boise Cascade Corp. v. FTC*, 637 F.2d 573, 577 (9th Cir. 1980) (same).

213. Trade Regulation Rule on Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, Statement of Basis and Purpose, 29 Fed. Reg. 8324, 8325 (July 2, 1964), withdrawn, 30 Fed. Reg. 9484 (July 29, 1965).

214. Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. § 1331-1341 (2006)).

tain. In the case of cigarette regulation, congressional action preempted the FTC's rule in key respects.<sup>215</sup> However, the FTC stayed deeply engaged in congressional debates on the issue, and played an important role in promoting further statutory change.<sup>216</sup> Increased congressional attention might therefore be regarded as a modest positive overall, or at least not a negative.

At the same time, some of agencies' distinctive disadvantages seem less pronounced here. A shift from courts to agencies raises concerns about an agency's comparatively greater vulnerability to capture by regulated parties.<sup>217</sup> As applied to the FTC, this concern finds some support in the early history of the Agency, where a protectionist attitude toward small businesses in certain industries can be plausibly attributed to capture.<sup>218</sup> Moreover, the settlement issue is currently of concentrated interest only to the pharmaceutical industry, making the capture concern particularly salient, although one could imagine insurers and other drug purchasers providing a counterweight.

On the other hand, the modern FTC is a much more effective organization today than the agency that received so much criticism several decades ago, and has erased the taint of the earlier capture critique.<sup>219</sup> Its newfound success can be attributed in part to a bipartisan consensus about the role of economic analysis in modern antitrust law. That consensus has had a further effect, which is to help neutralize a second attribute of agencies, namely their sensitivity to political changes over time.<sup>220</sup> In any event, whatever the general merits of this characterization, it seems inapplicable to the settlement issue, where FTC commissioners

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215. See *id.* § 5 (preempting FTC authority as to "statement[s] relating to smoking and health" on packaging and advertising, and otherwise leaving its authority unchanged).

216. For an account of these changes, see Sidney M. Milkis, *The Federal Trade Commission and Consumer Protection: Regulatory Change and Administrative Pragmatism*, 72 *Antitrust L.J.* 911, 918–19 (2005) ("Eight years after Congress rejected the FTC's regulation of cigarette advertising the agency's policies were adopted in their entirety.").

217. Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 *Colum. L. Rev.* 1, 12–25, 34–56 (1998) (reviewing literature applying public choice theory to agencies). Some observers of agency behavior doubt the explanatory power of capture arguments. See, e.g., *id.* at 52–56 (noting that "empirical evidence [supporting public choice theory] is far from overwhelming"); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and "Empirical" Practice of the Public Choice Movement*, 74 *Va. L. Rev.* 199, 238–68 (1988) (offering skeptical review of claimed examples of capture).

218. Richard A. Posner, *The Federal Trade Commission*, 37 *U. Chi. L. Rev.* 47, 83 (1969) (offering capture-based explanation for poor FTC performance).

219. See Posner, *Retrospective*, *supra* note 188, at 764–65 (revising earlier negative views).

220. Cf. Matthew C. Stephenson, *Legislative Allocation of Delegated Power: Uncertainty, Risk, and the Choice Between Agencies and Courts*, 119 *Harv. L. Rev.* 1035, 1038 (2006) (depicting choice of agency versus court as providing relative stability across issues and instability over time).

across the political spectrum have been unanimous in their view that settlements raise serious competitive concerns.

C. *Responding to Novel Forms of Regulatory Avoidance*

Settlement practice continues to evolve to exploit regulatory complexity. The usual assumptions about settlement are that it entails an agreement, by which cash or its equivalent is exchanged for entry, for an entry date that is constrained to be no later than patent expiration. In fact, the forms of payment and even the fact of agreement are manipulable. The following examples from recent settlement practice bear this out.

1. *Multiple Settlement with Uneven Entry.* — In some instances, the brand-name and generic drug makers settle several disputes at the same time, affording the brand-name firm an opportunity to pay the generic firm for delayed entry on one drug by granting early generic entry on a second drug. Consider, for example, Lamictal, a blockbuster epilepsy treatment that is offered in both chewable and nonchewable forms. A generic firm launched a pre-expiration challenge to each form; both centered upon the same patent.<sup>221</sup> In the joint settlement of both disputes, the generic firm received a license to the chewable version that permitted entry three years before entry on the nonchewable version.<sup>222</sup>

Uneven entry does not automatically raise pay-for-delay concerns. For example, a one-year delay as to one drug might exactly offset a one-year acceleration of entry on a second drug of equal importance. More generally, if a generic firm's interests are aligned with consumer interests, there is little to worry about, because a generic firm will insist upon early enough entry (and increased consumer welfare) on one drug to compensate for the reduced generic entry (and consumer welfare) on the other drug. Of course, in such a situation, it is difficult to see why the parties would bother with uneven entry. The explanation is that the drug with early entry is one on which the parties expect comparatively little incremental entry from other generic firms. In the case of Lamictal, the nonchewable version is far more important than the chewable version; in fact, the chewable version had low enough sales as to be unlikely to attract additional generic challengers.<sup>223</sup>

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221. Letter from Gary Buehler, Dir. of Office of Generic Drugs, FDA, to Philip Erickson, Teva Pharms. USA (Aug. 30, 2006) (on file with the *Columbia Law Review*) (describing patent dispute over Lamictal); Letter from Gary Buehler, Dir. of Office of Generic Drugs, FDA, to Philip Erickson, Teva Pharms. USA (June 21, 2006) (on file with the *Columbia Law Review*) (describing patent dispute over Lamictal CD).

222. Press Release, Teva Pharms. USA, Teva Announces Settlement of Lamictal Litigation with GlaxoSmithKline (Feb. 17, 2005) (describing entry for Lamictal CD in 2005 and for Lamictal in 2008).

223. U.S. sales of Lamictal and Lamictal CD were \$825 million and \$47 million, respectively, in 2004. *Id.* A second example is Barr's settlement of Provigil litigation, wherein Cephalon granted a slightly earlier entry date as to another drug, Actiq, on which Barr already had a license providing for entry under certain circumstances. See Press

2. *Probabilistic Payment.* — A special case of the strategy arises when entry as to one of the drugs has already occurred, and there are accrued damages—probabilistic, as the patent suit has not yet been resolved—that the brand-name firm can forgive as part of the settlement. Lipitor is again exemplary. Pfizer and Ranbaxy had done battle on a second significant drug, Accupril. Ranbaxy had launched a generic version of Accupril without waiting for a district court to rule whether Pfizer's patent was valid and infringed.<sup>224</sup> Pfizer secured a preliminary injunction, which was affirmed by the Federal Circuit.<sup>225</sup> At this point, Pfizer's damages claim against Ranbaxy, although probabilistic, was large in expected value.<sup>226</sup> The Lipitor settlement also "resolved" the Accupril dispute, likely by forgiving the accumulated expected damages. The residual uncertainty about the terms of this settlement helps illustrate why the FTC's role is so important.

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 two different strengths of the drug. It launched at risk as to only one strength. The subsequent settlement forgave accumulated damages on the first strength, and delayed entry on the second.<sup>227</sup>

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Release, Barr Pharms., Inc., Barr Granted Rights to Generic of Cephalon's ACTIQ Cancer Pain Treatments (Aug. 10, 2004), available at <http://www.medicalnewstoday.com/articles/12020.php> (on file with the *Columbia Law Review*) (describing initial Barr license); Provigil Barr Press Release, supra note 89 (describing earlier Actiq license). A third possible example is Optivar and Astelin, which had first filer challenges that pertain to the same patent. Meda AB, Interim Report, at 6 (May 6, 2008), available at [http://www.meda.fi/english/news/year\\_2008/interim\\_report\\_january-march\\_2008.pdf](http://www.meda.fi/english/news/year_2008/interim_report_january-march_2008.pdf) (on file with the *Columbia Law Review*). The settlement as to both drugs permits entry as to Optivar, the less important drug, three months earlier than Astelin. *Id.* at 6–7 (noting settlement terms); see also Meda AB, 2007 Annual Report, at 19 (Feb. 26, 2008) (reporting that Astelin and Optivar had U.S. sales of \$188 million and \$37 million, respectively, in 2007), available at [http://www.meda.se/english/news/year\\_2008/2007\\_year-end\\_report.pdf](http://www.meda.se/english/news/year_2008/2007_year-end_report.pdf) (on file with the *Columbia Law Review*).

224. See *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1371 (Fed. Cir. 2005); see also Press Release, Teva Pharms. Indus., Teva Launches Quinapril HCl Tablets; Pursuant to Agreement with Ranbaxy (Dec. 16, 2004) (announcing partnership by which Teva would distribute quinapril manufactured by Ranbaxy pursuant to its ANDA). Ranbaxy indemnified Teva as part of this launch. See Teva Pharms. Indus., Report of Foreign Private Issuer (Form 6-K), at 10 (May 10, 2007).

225. *Pfizer*, 429 F.3d at 1371, 1383 (noting and affirming preliminary injunction entered March 29, 2005).

226. 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. Press Release, Par Pharm. Cos., Par Pharmaceutical Companies, Inc. Receives Final Approval to Market Generic Accupril Tablets (Dec. 22, 2004).

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

The logical next step is a launch followed by waiver for a single drug.<sup>228</sup>

3. *“No Authorized Generic” Provisions.* — As previously explained, retained exclusivity is a source of compensation to a generic drug maker.<sup>229</sup> That compensation is reduced, however, if a brand-name drug maker launches an authorized generic product to compete with the generic entrant, in addition to the brand-name firm’s existing branded product. The brand-name firm can increase the generic entrant’s profits from exclusivity by agreeing not to launch an authorized generic product. This decision is costly to the brand-name firm, which foregoes extra profits from its own authorized generic competitor. Numerous recent agreements include a “no authorized generic” term.<sup>230</sup>

4. *Avoiding Agreement.* — Through careful design, settling parties can arrange for delayed entry without any formal agreement as to timing. The parties can condition periodic payment upon nonentry, and make payment a function of brand-name profits that depend upon nonentry—for example, a royalty paid on brand-name sales.<sup>231</sup> One settlement, in-

228. For a possible example, see Jonathan D. Rockoff, *Democrats Target Deals to Delay Generics*, Wall St. J., Mar. 31, 2009, at A3, which describes the March 2009 settlement of patent litigation over Solodyn (referred to in the article as “a Medicis acne drug”). There, the generic firm launched at risk, then agreed to cease sales until 2011, in exchange for a damages waiver.

229. See *supra* text accompanying notes 92–96.

230. Examples include Adderall XR, Plavix, Effexor XR, and Nexium. See Adderall XR Shire-Barr Agreement, *supra* note 71, exh. 10.1, cl. 3.7 (“Shire has not granted and shall 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 . . . .”); Q4 2006 Barr Pharms., Inc. Earnings Conference Call (Aug. 15, 2006), available at Factiva (noting “no authorized generic” provision); Plavix Agreement, *supra* note 71, exh. 99.1 (permitting generic manufacturer “to sell its Plavix brand product, but not to launch an authorized generic”); Wyeth, Current Report (Form 8-K), at 1.01 (Jan. 13, 2006) (noting that Teva’s patent license for Effexor XR is exclusive at first); Nexium Press Release, *supra* note 110 (describing Nexium generic entry as “exclusive”); see also Lamictal Press Release, *supra* note 100 (describing grant of entry in Lamictal settlement, in which generic firm entered during pediatric exclusivity period, as “exclusive”).

This source of payment to induce delay has attracted some antitrust enforcement attention. The clause was reportedly one reason why antitrust enforcers rejected the Plavix agreement. See John Carreyrou et al., *FBI Raids Offices at Bristol-Myers over Plavix Deal*, Wall St. J., July 28, 2006, at A3 (reporting that FTC opposition to “no authorized generic” clause caused rejection of initial agreement); see also Declaration of Bernard Sherman at 10–12, *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2006) (No. 02-2255) (declaring that Sanofi orally offered to secretly include “no authorized generic” term in revised deal, after initial agreement containing that term was rejected by regulators). Logically, if a “no authorized generic” provision raises an antitrust problem, then so does retained exclusivity itself, for the effect of the provision is to raise the value of retained exclusivity.

231. Napreelan adopted this strategy. See *Andrx Pharms., Inc. v. Elan Corp.*, No. 00-3481, slip op. at 6 (S.D. Fl. Apr. 24, 2003) (order granting motion for judgment on the pleadings) (describing royalty on brand-name sales, but finding allegation insufficient to survive dismissal on the pleadings). A promotion deal could be structured this way too.

volution of 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 its sales.<sup>232</sup> 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 nonentry or indirectly for a successful transition; it is impossible to tell based on the limited data available.

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These examples demonstrate that drug makers are adept at achieving a particular substantive outcome—brand-name compensation of generic firms, combined with delayed generic entry—while altering the form of settlement to evade the most obvious risks of antitrust liability. The continuing shift in strategy here resembles the economics of tax shelters. As a regulatory prohibition becomes more stringent, the cost of noncompliance rises. Some regulated parties will give up and simply comply, resulting in a welfare gain. Others will continue to avoid regulation, and instead shift to new strategies. These strategies are more costly to the firm, for otherwise they would have been chosen in the first place; this shift represents a social loss.<sup>233</sup> Thus, whether an increase in enforcement is warranted depends upon the amount of residual noncompliance and the increase in social costliness of the new behavior.<sup>234</sup>

The review of settlement behavior in this Article paints a mixed picture. To be sure, this process of continuing evolution threatens the ability of existing antitrust institutions, particularly courts, to keep pace. Courts are increasingly unlikely to be an effective check on settlement. In part, this is because they are poor aggregators. In addition, courts must be fed cases by either a government agency or a private plaintiff. The FTC has limited case-by-case enforcement capacity; practically speak-

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232. King Pharms., Inc., Quarterly Report (Form 10-Q), at 10 (Aug. 7, 2007) (describing King's exercise of previously secured option to buy Cobalt's tablet NDA, and to pay Cobalt to manufacture and supply the tablet form). A royalty on sales for the acquired tablet product does not appear in the parties' disclosure of the agreements, but it is mentioned in the FTC's 2006 update describing a "complex set of transactions" that fit the Altace transactions. FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006, at 6 (2007).

233. See Louis Kaplow, Optimal Taxation with Costly Enforcement and Evasion, 43 J. Pub. Econ. 221, 230–33 (1990) (providing model of costly evasion in response to increased enforcement); David A. Weisbach, An Economic Analysis of Anti-Tax-Avoidance Doctrines, 4 Am. L. & Econ. Rev. 88, 99–101 (2002) (assessing shift by taxpayers, in response to increased enforcement, to more costly shelters).

234. This account is incomplete; also important are the cost of administering the system itself and costs resulting from overinclusion—for example, restricting some value-increasing side deals. For a discussion of why the latter cost is likely small, see *supra* Part III.C.

ing, it can bring at most a few pharmaceutical antitrust cases at a time, and they are likely to last for five years or more. That capacity is small, compared to the frequency of pay-for-delay settlements—although a successful enforcement action or two would likely reduce the frequency.<sup>235</sup> Private plaintiffs, meanwhile, are reluctant to bring cases. Having lost the simplest cash-for-delay agreements, why should they take a chance challenging more complex settlements?

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 theoretical matter that paying for delayed entry is prohibited, and settled as a factual matter that side deals provide a disguised means to pay for delay, it does not necessarily follow that the newest settlements also violate antitrust law. Given the malleability of side deals, even an on-point judicial decision imposing liability would not preclude firms from arguing that their arrangements were conceptually or factually distinct. 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 less likely.

Here, too, FTC rulemaking can help. As to new forms of payment, for example, the FTC could set a rule stating that *any* conferral of value by a brand-name firm, if made contemporaneously with a generic firm's agreement to delay entry, will be considered to exchange payment for delay. Probabilistic damages would clearly fit within that definition. Agreements to preserve exclusivity, whether simply by agreeing not to contest ANDA approval or by an affirmative agreement not to launch an authorized generic product, would also be included, as just another form of payment. In these examples, the aggregation approach helps to identify and respond to emergent settlement practices before they become more prevalent. For settlements without formal agreement, moreover, FTC rulemaking would be even more effective, because the applicability of the FTC Act, unlike section 1 of the Sherman Act, is not conditioned on the existence of an agreement.<sup>236</sup>

Agency rulemaking is not the only possible route for implementing a broadly applicable rule. If a court can be persuaded to think broadly about the implications of settlement, it may adopt a similarly broad ruling, though the considerations above tend to make that less likely. Legis-

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235. See *supra* text accompanying note 112 (describing hiatus in pay-for-delay settlements during period of successful FTC enforcement).

236. Compare 15 U.S.C. § 1 (2006) (prohibiting “contract[s], combination[s] . . . [and] conspirac[ies], in restraint of trade”), with *id.* § 45(a)(1) (declaring that “[u]nfair methods of competition in or affecting commerce . . . are hereby . . . unlawful”). But see the lower court cases cited *supra* note 212, which suggest that the FTC Act requires agreement to the same extent as the Sherman Act.

lative action is also a possibility. The MMA closed some loopholes, though it preserved others, including the bottleneck and retained exclusivity. Its requirement that an appeals court trigger exclusivity also worsened the delays in an important respect, through a provision buried seven steps deep in the statutory structure: 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

Thus, although Congress could directly implement any of the presumptions or rules discussed above, its ability to do so quickly and correctly is open to significant doubt. These difficulties also suggest a re-framing of the legislative project. Rather than closing identified loopholes with another new layer of complexity, it would be better to remove existing complexity—in particular, by ending retained exclusivity. Simply put, if a generic firm ends its litigation against a brand-name firm, it should no longer be eligible for the exclusivity period.

In a sense, this provision would offer a partial return to the FDA's original view that a generic firm must earn exclusivity by winning a patent suit.<sup>237</sup> It would reduce both the amount of payment conferred in a settlement, and the extent to which a settlement delays entry. The provision should apply to both new and existing settlements, like other statutory provisions that have been given retrospective effect. Finally, the political economy of such a statutory change is attractive. If, as some observers might argue, retained exclusivity is not a valuable form of compensation for delay, then its omission from the settlement equation will not be missed, and there is little reason for drug makers to resist this statutory change.

A rule directed to all contemporaneous conferrals of value by a brand-name firm would appear to resolve the pay-for-delay issue, closing the avenue for escape to yet further forms of regulatory avoidance. This appears to be true even as to informal contemporaneous understandings reached between parties, as in the Altace example above. In tax planning, informal alternatives to contract greatly expand the opportunity for avoidance.<sup>238</sup> That problem is less severe for drug patent settlements, where repeat interactions are much less frequent,<sup>239</sup> and the negative

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237. See *supra* note 117 and accompanying text.

238. See, e.g., Alex Raskolnikov, *The Cost of Norms: Tax Effects of Tacit Understandings*, 74 U. Chi. L. Rev. 601, 613–30 (2007) (describing contractual norms relevant to tax planning); Alex Raskolnikov, *Relational Tax Planning Under Risk-Based Rules*, 156 U. Pa. L. Rev. 1181, 1205–13 (2008) (describing avoidance strategies by which tax planners enter implicit agreements).

239. See *supra* note 111 and accompanying text. One ground for caution is a trend of continuing industry consolidation. See, e.g., Andrew Ross Sorkin & Duff Wilson, *In Tight Market, \$68 Billion Deal Is Reported for Pfizer and Wyeth*, N.Y. Times, Jan. 26, 2009, at A1; Teva Merger Press Release, *supra* note 106. Further consolidation, as it reduces the number of industry players, could increase the frequency of repeat play, and hence the opportunity for informal arrangements. It would also raise the cost of overinclusion, by reducing the number of available alternative counterparties with which to conduct business arrangements for non-settlement purposes.

consequence of curtailing brand-generic interactions—of tolerating an overinclusive ban on the content of side deals—is small. Eliminating continued entitlement to the exclusivity period, despite settlement, would also simplify consideration of any arrangement reached by the brand-name and generic firms. Thus, it seems unlikely that effective avoidance would survive the promulgation of a strong rule. If that judgment is incorrect, the agency's ability to respond flexibly, without being subject to *stare decisis*, may prove to be a significant advantage.

#### CONCLUSION

Examining in detail the terms and effects of drug patent settlements reveals several important points. Drug patent settlements that restrict generic competition are an increasingly important, 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 persists. Case-by-case evaluation is a failure and is likely to remain so, at least absent intervention by the Supreme Court. One partial response is to impose a presumption of payment where side deals accompany delayed entry. This would force firms to explain their increasingly questionable side deals, and would potentially discourage such complex dealmaking in the future.

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 factfinding, and disseminate authoritative information of the type offered here. In that respect, this study represents a *prima facie* case that additional information gathering is necessary, and can serve as a first draft for the FTC's future work. So long as settlements and their terms remain hidden, it will be difficult to do integrative work of the kind suggested here, and difficult to develop the "consensus among commentators" that is a key step in developing appropriate antitrust policy. The additional insight will help academics and policymakers in revising, if necessary, the initial conclusion presented here that pay-for-delay settlements are frequently tried and frequently successful.