The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph iv Patent-Litigation Decisions

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Abstract

In paragraph iv pharmaceutical cases, a patent-litigation decision often determines whether a brand-firm monopoly continues or generic entry occurs. Using unique patent-litigation data and an event-study approach that accounts for probabilistic district court decisions and an appellate process, we estimate that brand-firm stakes in such cases average $4.3 billion while generic-firm stakes average $204.3 million. After the *Schering-Plough v. FTC* decision in 2002 that upheld a settlement in which the brand firm paid the generic firm in return for delayed entry, we find that settlement is more likely and stakes are significantly lower, despite greater average brand sales for the drugs in the cases. On the basis of this evidence, we conclude that pay-for-delay settlements led to less within-market competition after 2002.

1. Introduction

The 1984 Hatch-Waxman Act attempts to strike a balance between promoting innovation of new brand drugs (to enhance dynamic efficiency) and facilitating generic entry (to enhance allocative efficiency) in the United States. One key provision, paragraph iv certification and the abbreviated new drug application (ANDA) process, uses patent challenges to help achieve this balance. In particular, the US Food and Drug Administration (FDA) permits generic firms to rely on brand-firm data on safety and efficacy in seeking approval to sell copies of brand drugs but does not grant early entry unless and until the generic firm successfully challenges all brand-firm patents covering the active ingredient and formulations of the drug in question. To encourage such challenges, the first generic

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firm to file for an ANDA and win a successful patent challenge receives a 180-day marketing exclusivity.

In its essence, paragraph iv certification and the ANDA process seek a level of competition that should be characterized by earlier generic entry when the brand firm's patents are weak and later when the brand firm's patents are strong. If firms settle patent challenges out of court and agree to delay generic entry, however, brand firms may retain monopoly power even with weak patents. In many notable cases, brand firms have paid generic firms as part of such settlements, and such pay-for-delay settlements are quite controversial (Shapiro 2003; Bulow 2004; FTC 2010).

In this paper, we contribute an analysis of paragraph iv ANDAs filed during 1985–2010 and their outcomes. We introduce a model in which generic firms choose to attempt entry, brand firms choose to file a patent-infringement suit to block entry, and both firms choose whether to litigate or settle. Firms' decisions depend on patent strength, monetary stakes in the case, and antitrust scrutiny. On the basis of this model and a variety of empirical evidence, we argue that a wider scope for pay-for-delay settlements led to less within-market competition after 2002.

The centerpiece of our analysis is a novel adaptation of the event-study framework, which we use to estimate the size of the stakes in paragraph iv ANDA filings that reach a district court decision. For each decision, we first estimate abnormal returns in publicly traded brand and generic firms' stock-market valuations. This basic event-study analysis indicates that firms tend to gain significant value when they win and lose significant value when they lose. For brand wins, the brand firm's value rises by an average of about 2.1 percent, and the generic firm's value falls by an average of about 1.6 percent. For brand losses, the brand firm's value falls by an average of about 2.4 percent, and the generic firm's value rises by an average of about 3.1 percent.

We also estimate ex ante probabilities of district court wins and losses and appellate reversals, which we interpret as investors' beliefs about the strength of brand-firm patents. In estimating those beliefs, we control for factors influencing the decision odds and selection into litigation. For each firm-decision pair, we use the estimated probabilities to make a multiplicative adjustment of the abnormal return, which yields an estimate of the stakes for the firm in the case.[1] Incorporating these beliefs, we estimate that average stakes for brand firms are about $4.3 billion, while average stakes for generic firms are about $204.3 million (all values are in 2010 dollars). This difference highlights the massive payoff that firms may reap by reducing within-market competition. In a simple ordinary least squares regression of stakes on drug sales, we show that our model's estimates are sensible. We find that $1 of additional yearly sales of the drug increases the brand's stakes by about $7.55 and increases the generic's stakes by about $.12. The effect on the brand's stakes equals slightly more than recent sales times re-

[1] See Ramdas, Williams, and Lipson (2013) for a similar framework that models beliefs in an event-study framework.

maining patent life. The effect on the generic's stakes—roughly 25 percent of 180 days' sales—is consistent with a 180-day Cournot duopoly payoff.

To shed light on the effects of pay-for-delay settlements, we analyze paragraph iv outcomes before and after the closely watched 2002 decision in *Schering-Plough v. FTC* (136 F.T.C. 1092 [2002]) that upheld a pay-for-delay settlement.[2] These comparisons highlight numerous dramatic changes that suggest reduced within-market competition after *Schering-Plough*.

First, the frequency of settlement rose from the 1990s to the 2000s and was highest during 2006–10. This trend reflects primarily substitution of cases out of completed litigation and into settlements, though the frequency of uncontested generic entry also fell slightly across time. In our model, the raw trends in settlement frequency are consistent with firms expecting relaxed antitrust scrutiny of settlements in the 2000s.

Second, cases that do go to trial include stronger patents after *Schering-Plough*. While our model predicts that more frequent settlement could occur for cases with either weak patents or high-sales drugs, we find that patent strength is the key margin of substitution into settlement. After *Schering-Plough,* the brands win 60 percent of cases versus just 40 percent in prior years. Hence, decisions after *Schering-Plough* include stronger patents on average, which suggests that settlements induced by relaxed antitrust scrutiny tend to include weaker patents.

Third and perhaps most important, the estimated monetary stakes in district court decisions (which adjust for beliefs about patent strength) are lower after *Schering-Plough*. The average brand stakes fell 65 percent after *Schering-Plough,* from about $8.8 billion to about $3.1 billion, while the average generic stakes fell about 69 percent, from $473.8 million to $146.6 million. This occurred despite average drug sales being nearly twice as high for drugs in decisions after *Schering-Plough*. Intuitively, when firms expect an anticompetitive settlement after a brand loss at the district court level, the stakes connected to that decision are lower. Notably, our data indicate a drop in the rate of appeal of brand losses after *Schering-Plough*—from 100 percent to 70 percent.

Our work contributes primarily to the literature on the economics of pay-for-delay settlements.[3] Our econometric approach and results complement papers using event studies to estimate the effects of resolution of paragraph iv litigation. Using slightly different sample-selection criteria, Panattoni (2011) conducts an event study of 37 brand-firm paragraph iv litigation events during 1984–2007. Like us, she finds large effects of district court decisions on firms' value. She does not study generic firms. Drake, Starr, and McGuire (2014) study settlement announcements of paragraph iv patent litigation and capture indication of pay

[2] The administrative law judge's decision (40 LEXIS 244 [F.T.C. 2002]) upheld the settlement, and the 11th Circuit Court of Appeals eventually upheld it as well (402 F.3d 1056 [11th Cir. 2005]).

[3] For arguments using case discussions that such settlements are both harmful and unanticipated by the Hatch-Waxman Act, see Hovenkamp, Janis, and Lemley (2003), Hemphill (2006, 2009), Elhauge and Krueger (2012), and Edlin et al. (2013). See, in contrast, Willig and Bigelow (2004), Yu and Chatterji (2011), and Harris et al. (2014) for conditions under which pay-for-delay settlements are not necessarily anticompetitive.

for delay. They find that brand-firm value rises an average of 6 percent in pay-for-delay settlements but does not increase for other settlements. McGuire et al. (2016) argue that such event studies are potentially useful in showing that pay-for-delay settlements are anticompetitive. None of these papers incorporate investors' beliefs, nor do they estimate the stakes in the cases.

Our work also relates to papers using alternative methods to study paragraph iv cases. Branstetter, Chatterjee, and Higgins (2016) study paragraph iv cases for hypertension drugs. Using a random-coefficients logit model, they estimate that paragraph iv entry yields a static gain to consumers of $42 billion and a loss to brand firms of $32.5 billion. Helland and Seabury (2016) use variation in circuit court decisions on the legality of pay-for-delay settlements to estimate the effects of paragraph iv challenges on entry. They conclude that pay-for-delay settlements effectively nullify the procompetitive effect of the paragraph iv process on entry.

Finally, our work contributes methodologically to the literature on market entry. Generally, the lack of exogenous reasons for the end of monopolies complicates estimation of the value of entry and deterrence. To circumvent this, researchers often make difficult-to-test behavioral and parametric modeling assumptions. The models typically take the form of either a complete-information binary game (Bresnahan and Reiss 1990, 1991; Berry 1992) or a dynamic Markov-perfect equilibrium framework (Ericson and Pakes 1995; Gedge, Roberts, and Sweeting 2013). However, in some industries, the regulatory environment generates exogenous variation that permits more direct inference (Snider and Williams 2015). In this spirit, we show how an event-study framework, with minimal structure and assumptions, can be used to infer the size of stakes in cases in which entry is on the line and provide insights into US pharmaceutical firms' incentives to settle disputes. In addition, by relying on private investors' valuations, our approach notably avoids problems with pricing data in pharmaceuticals in which unobservable rebates and discounts or insurance co-pays may pose a problem.

2. Innovation and Entry in the US Pharmaceutical Industry

For a brand firm, drug development is long and costly. After testing a new molecule to determine its toxicity (typically in animals), a researcher (often financed by a pharmaceutical firm) files an investigational new drug application to start trials in humans. In the clinical trials, the applicant must prove safety and efficacy.[4] If successful, the applicant files a new drug application (NDA) with the FDA; once approved, the applicant may sell the product in the United States.

Firms pioneering new drugs typically seek patents to cover active ingredients, formulations, methods of use, devices, and processes as they develop the innovations. To approve a generic version of an NDA, the FDA requests that the generic applicant certify whether the active-ingredient and formulation patents could prevent such approval under the Hatch-Waxman Act (Korn, Lietzan, and Shaw

[4] Trials follow a strict, costly, three-phase process. See Bradford, Turner, and Williams (2018) for further details.

2009). The Hatch-Waxman Act permits generic sponsors to bypass clinical trials by filing an ANDA. The regulations lead frequently to scenarios in which the outcome of patent litigation determines whether a brand firm maintains a status quo monopoly or first-time generic sponsors can enter.

In the most common scenario, the FDA grants a 5-year new chemical entity (NCE) exclusivity to a pioneer drug. After the NCE exclusivity is no longer in effect, other firms may seek to enter (see 21 C.F.R. 314.108 [b]). The Hatch-Waxman Act encourages entry prior to patent expiration by granting a 180-day marketing exclusivity to the first generic applicant to file for and successfully obtain ANDA approval.[5] To earn exclusivity, a successful entrant must provide in its ANDA to the FDA (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355 sec. 505[j][2][A][vii][IV]) the following:

> (A) a certification, in the opinion of the applicant and to the best of his [or her] knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under Paragraph (i) or subsection (c) of this section,
>
> (i) that such patent information has not been filed;
>
> (ii) that such patent has expired;
>
> (iii) of the date on which such patent will expire, or
>
> (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
>
> (B) if with respect to the drug for which investigations described in Paragraph (i)(A) were conducted information was filed under Paragraph (i) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The four types of certifications are known as paragraph i–iv certifications. Paragraph i–iii certifications lead to entry but no patent litigation. Some paragraph iv ANDAs may also lead to entry without litigation, but if the brand monopoly initiates litigation, the FDA does not grant final marketing approval to such an ANDA until the infringement lawsuit is resolved or the respective patents expire. In some cases, tentative approval is granted pending the outcome of the litigation for full approval.

The FDA's Orange Book lists three basic types of patents: active ingredient, formulation, and method of use (21 C.F.R. 314.53; see also the proposed rules at 67 Fed. Reg. 65,448–65). Under section B, the generic applicant can often satisfy the FDA's requirement for granting the ANDA, with respect to method-of-use patents, by specifying that it will not sell the drug for the patented methods. Active ingredients in pharmaceutical patents are typically claimed by their chemical structure. To receive an ANDA approval, a generic must essentially copy this chemical structure in its drug. Hence, active-ingredient patents are nearly always

[5] Sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the Federal Food, Drug, and Cosmetic Act regulate the 180-day marketing exclusivity.

found to be infringed in paragraph iv patent litigation. However, a generic firm may still win a patent lawsuit against an active-ingredient patent by successfully arguing that it is invalid. For patents covering formulations, by contrast, the generic firm may win by proving either invalidity or noninfringement.

After receiving notice that a generic firm is pursuing a paragraph iv ANDA, a brand firm has 45 days to initiate a lawsuit. If the brand firm sues within this window, the FDA's approval of the ANDA is stayed until the earliest of the following: the patents expire, the court decision is issued, or the 30-month stay expires (FTC 2002). Note that the 30-month stay is important because it gives incumbent firms incentive to initiate litigation even in cases in which the probability of winning is low; thus, settlements tend to occur after initiation of a lawsuit.[6] The FTC reports that the FDA usually takes over 25 months to approve the ANDA even when no litigation occurs.[7] By filing the first paragraph iv ANDA, a generic firm can delay entry of another generic firm even when the first one has not succeeded in a litigation case but the second firm has (Korn, Lietzan, and Shaw 2009).[8]

Through 2000, there were at least nine settlements in which the brand firm made a payment to the generic firm, which suggests anticompetitive motives (FTC 2002; Shapiro 2003; Bulow 2004). Beginning in 2000, the FTC prosecuted pharmaceutical firms over four settlements: Hoechst and Andrx (Cardizem), Abbott and Geneva (Hytrin), Bristol and Shein (BuSpar), and Schering-Plough and Upsher-Smith (K-Dur). The first three settlements included maximal entry dates (that is, set at patent expiry) and anticompetitive stipulations that were clearly outside the scope of the patents: for example, agreements by generics not to enter with any product using the brand's active ingredient and agreements that the generic would not give up or trigger the 180-day exclusivity (Bulow 2004). Each of the three cases resulted in a consent decree. Schering-Plough and Upsher-Smith, whose settlement over K-Dur did not include anticompetitive measures outside the scope of the (hypothetically ironclad) patent and which negotiated entry dates prior to patent expiry, instead contested their cases. The FTC's actions sharply reduced reverse-settlement activity during the pendency of the K-Dur case (FTC 2010).

However, despite the FTC's efforts to curtail pay-for-delay settlements, on June 27, 2002, an administrative law judge upheld the Schering-Plough–Upsher-

[6] Prior to 2003, different abbreviated new drug application (ANDA) filings for different patents of the same drug caused multiple 30-month stays when litigated. Furthermore, since 1998, a court decision of dismissal, a certified settlement, or noninfringement or invalidity of patents can trigger approval and the 180-day exclusivity. Prior to 1998 only a successful decision (patents invalid or not infringed) triggered approval (Korn, Lietzan, and Shaw 2009).

[7] In March 2000, the FDA also issued guidelines for what constitutes a triggering court decision. For cases in which the FDA approves a paragraph iv ANDA because of the expiration of the 30-month stay, most generic firms wait until the district's court decision to begin marketing; if they market before an adverse court decision, they may be liable for lost profits to the brand firm if they lose the case.

[8] The decision in *Mova Pharmaceutical Corp. v. Shalala* (955 F. Supp. 128 [D.D.C. 1997], aff'd, 140 F.3d 1060 [D.C. Cir. 1998]), which invalidated the successful defense requirement, established this precedent.

Smith settlement. Although the decision was appealed and reversed by the full commission, the 11th Circuit Court of Appeals eventually upheld the settlement (*Schering-Plough v. FTC,* 402 F.3d 1056 [11th Cir. 2005]). In this and two subsequent cases in other circuits (*In re Tamoxifen Citrate Antitrust Litigation,* 466 F.3d 187 [2d Cir. 2006]; *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* 544 F.3d 1323 [Fed Cir. 2008]; see also Elhauge and Krueger [2012, pp. 285–87] for discussion of the reasoning), the appellate courts endorsed a scope-of-the-patent test for whether the agreements were anticompetitive. Under this test, if the agreement is permissible conditional on an ironclad patent, then it is not anticompetitive. The Supreme Court declined to hear any of the cases, and surge in pay-for-delay settlements ensued (FTC 2010). Later settlements have typically avoided the type of aggressive stipulations found in the early agreements, and firms have often obscured the existence and size of the reverse payment.

In 2012, the Third Circuit Court of Appeals rejected the scope-of-the-patent test and found the *Schering-Plough* settlement anticompetitive in an antitrust case brought by various purchaser groups (*In re K-Dur Antitrust Litigation,* 686 F.3d 197 [3rd Cir. 2012]). This created a circuit court split, which prompted the Supreme Court to engage the reverse-settlement question. In a June 2013 decision over a reverse settlement for the drug Androgel (*FTC v. Actavis, Inc.,* 133 U.S. 2223 [2013]), the Supreme Court remanded the case to the 11th Circuit Court of Appeals and instructed courts to apply a rule-of-reason analysis whenever a settlement includes a large and otherwise unexplained payment from the brand to the generic (Hovenkamp 2014).

3. Theoretical Model

As a framework for our empirical analysis, we introduce a model of the paragraph iv process for attempted generic entry. Suppose there is a drug that has been approved for marketing by a risk-neutral brand firm (B) operating as a monopolist. Suppose further that all nonpatent exclusivities that block entry by a risk-neutral generic firm (G) have expired. The brand firm owns patents that protect the compound and/or formulations of this drug.

Figure 1 highlights the process. First, the generic firm decides whether to seek FDA approval to enter this market. If it chooses not to seek approval, the brand firm continues to enjoy a monopoly (case A). If it chooses to seek approval, then the brand firm next decides whether to contest entry. If the brand firm does not contest entry, then the generic firm enters, and oligopoly competition ensues (case B). If the brand firm does contest entry, then it sues the generic firm for patent infringement.

If the brand firm sues to block entry, then the firms either settle the litigation out of court or litigate to a decision in court.[9] If they settle out of court, the terms of the settlement include agreement on the (delayed) timing of generic entry (relative to the case of uncontested entry). This is case C. If they litigate, then the

[9] The generic firm could also launch "at risk," a rare occurrence that we ignore in this paper.

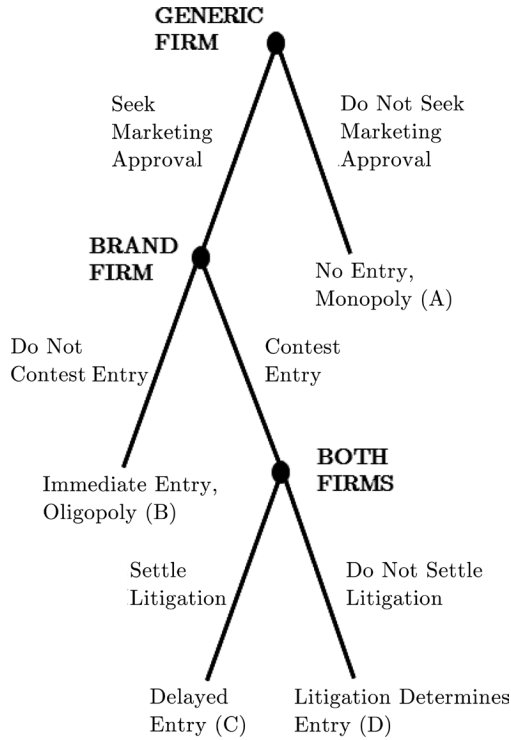

Figure 1. Paragraph iv certification process

outcome of the trial determines whether entry occurs (case D). If the brand firm is ultimately successful, the generic firm cannot enter, and the brand firm's monopoly continues. If the brand firm is unsuccessful, the generic firm can enter, and the brand firm's monopoly ends.

Figure 2 shows a tree of the litigation subgame. At the top of the tree, firms and investors form expectations of future payoffs prior to any decisions. Then the litigation process determines whether the brand or generic firm wins the case at the district court level. Let α be the probability that the brand firm wins. Just after the district court's decision, firms and investors update their expectations of future payoffs. Then, in subsequent (appellate) review, nature determines whether the district court's decision stands or is reversed. Let β_B be the probability that the brand firm's win is upheld, and let β_G be the probability that the generic firm's win is upheld.

To conserve on notation, we do not explicitly model a decision to appeal. Implicitly, β_B includes the probability of all scenarios such that the district court's decision is not overturned. This group includes decisions of the generic firm not to appeal the decision and cases in which the generic firm does initiate an appeal but the appellate case is dismissed, settled, or decided in favor of the brand.

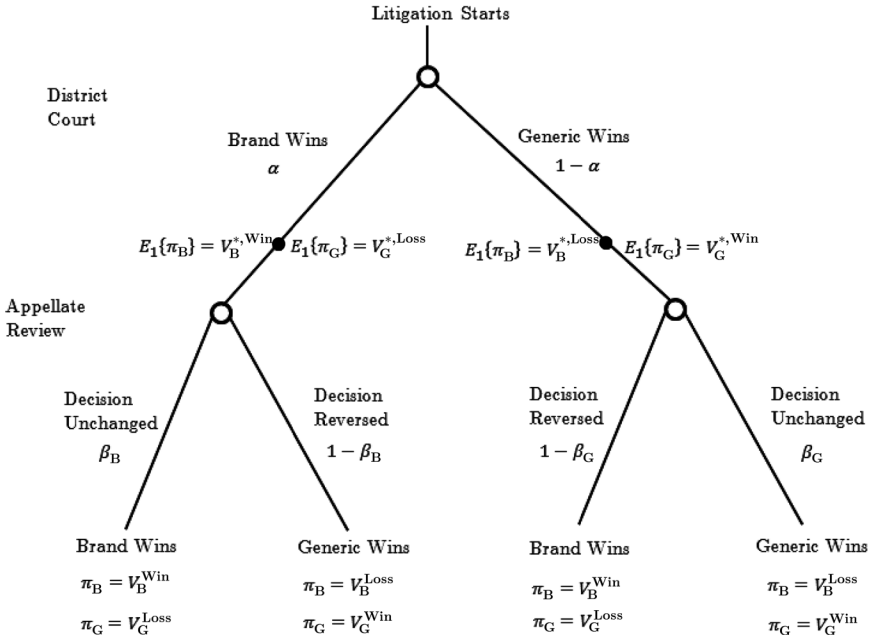

Figure 2. Paragraph iv patent litigation

Let the ultimate profit π_i for firm $i \in \{B, G\}$, net of litigation costs, be the following:

$$\begin{aligned} &\text{Brand wins:} \quad \pi_B = V_B^{Win} \quad \pi_G = V_G^{Loss} \\ &\text{Generic wins:} \quad \pi_B = V_B^{Loss} \quad \pi_G = V_G^{Win}. \end{aligned}$$

The dispute value $V_i^{Win} - V_i^{Loss}$ gives the stakes in the case for firm i: $V_B^{Win} - V_B^{Loss}$ for the brand firm and $V_G^{Win} - V_G^{Loss}$ for the generic firm. We assume that both dispute values are positive and increasing in the brand firm's predispute sales. We also assume that joint profits are higher when the brand firm wins, $(V_B^{Win} + V_G^{Loss}) - (V_B^{Loss} + V_G^{Win}) \geq 0$, and that this difference is increasing in the brand firm's predispute sales. Payoffs are realized only at the conclusion of the dispute.

Suppose first that settlement is impossible at any stage of litigation. If the brand firm wins, then the monopoly is preserved, and $V_B^{Win} + V_G^{Loss}$ is the joint profit under monopoly. If the generic firm wins, then entry occurs, and $V_B^{Loss} + V_G^{Win}$ is the joint profit under entry. In that environment, the dispute values have very clean interpretations. For the generic firm, $V_G^{Win} - V_G^{Loss}$ is the value of entry. For the brand firm, $V_B^{Win} - V_B^{Loss}$ is the value of deterring entry.

These values are not directly observed but can be inferred using the impact of the district court's decision on firm value along with the market's expectations re-

garding the outcome of the district court's decision and the subsequent appellate process. Denote the expected payoffs after the district court's decision, but before any appeal,

$$\begin{aligned} &\text{Brand wins:} \quad E_1\{\pi_B\} = V_B^{\star,\text{Win}} \quad E_1\{\pi_G\} = V_G^{\star,\text{Loss}} \\ &\text{Generic wins:} \quad E_1\{\pi_B\} = V_B^{\star,\text{Loss}} \quad E_1\{\pi_G\} = V_G^{\star,\text{Win}}. \end{aligned}$$

These are shown in Figure 2 just above the appellate-review nodes. From the tree, we see that for a brand firm,

$$V_B^{\star,\text{Win}} = \beta_B V_B^{\text{Win}} + (1-\beta_B)V_B^{\text{Loss}}$$

and

$$V_B^{\star,\text{Loss}} = \beta_G V_B^{\text{Loss}} + (1-\beta_G)V_B^{\text{Win}}.$$

Now consider the expected value of the brand firm at the very top of the tree,

$$E_0\{\pi_B\} = \alpha V_B^{\star,\text{Win}} + (1-\alpha)V_B^{\star,\text{Loss}}.$$

Rearranging terms, we can write

$$0 = \alpha(V_B^{\star,\text{Win}} - E_0\{\pi_B\}) + (1-\alpha)(V_B^{\star,\text{Loss}} - E_0\{\pi_B\}). \tag{1}$$

Denote $V_i^{\star,\text{Win}} - E_0\{\pi_i\}$ the decision impact of a win and $V_i^{\star,\text{Loss}} - E_0\{\pi_i\}$ the impact of a loss for firm i. Then, the first term in equation (1) is the decision impact when a brand firm wins a paragraph iv lawsuit, weighted by the probability of a brand-firm win. Correspondingly, the second term reflects the decision impact when a brand firm loses the case. This implies the following relationship between the decision impact and the dispute values for $i \in \{B, G\}$, conditional on the district court's decision:

Brand win:

$$\begin{aligned} &\text{Effect on B:} \quad \overbrace{V_B^{\star,\text{Win}} - E_0\{\pi_B\}}^{\text{Event Study}} = \overbrace{(1-\alpha)(\beta_B + \beta_G - 1)}^{\text{Nearest Neighbor}}\overbrace{(V_B^{\text{Win}} - V_B^{\text{Loss}})}^{\text{Dispute Value}} \\ &\text{Effect on G:} \quad V_G^{\star,\text{Loss}} - E_0\{\pi_G\} = -(1-\alpha)(\beta_B + \beta_G - 1)(V_G^{\text{Win}} - V_G^{\text{Loss}}) \end{aligned} \tag{2}$$

Brand loss:

$$\begin{aligned} &\text{Effect on B:} \quad V_B^{\star,\text{Loss}} - E_0\{\pi_B\} = -\alpha(\beta_B + \beta_G - 1)(V_B^{\text{Win}} - V_B^{\text{Loss}}) \\ &\text{Effect on G:} \quad V_G^{\star,\text{Win}} - E_0\{\pi_G\} = \alpha(\beta_B + \beta_G - 1)(V_G^{\text{Win}} - V_G^{\text{Loss}}) \end{aligned}$$

These equations form the basis of our methodology. For each district court decision in our sample, we observe two events—one firm wins and one loses. For each event (for example, Pfizer win) for which the firm is publicly traded, we complete the following steps. We first estimate the decision impact (left side of the equation), using an event-study routine described in Section 5.1. Then, we estimate the decision probabilities α, β_B, and β_G using a nearest-neighbor tech-

nique described in Section 5.2. Together, these results and the structure of the model reveal the dispute value $V_i^{\text{Win}} - V_i^{\text{Loss}}$.

3.1. Settlement

Now suppose that settlement is possible. If the firms settle, they engage in Nash bargaining over the terms of the settlement. In a completely unconstrained settlement, the firms would maximize the joint surplus by achieving joint profit $V_{\text{B}}^{\text{Win}} + V_{\text{G}}^{\text{Loss}}$. In such a settlement, the firms increase total profit by the difference between the joint profit and the expected joint surplus under litigation. Thus, for a settlement that occurs prior to the district court decision, the bargaining surplus S_{Barg} is

$$S_{\text{Barg}} = [\alpha(1-\beta_{\text{B}}) + (1-\alpha)\beta_{\text{G}}][(V_{\text{B}}^{\text{Win}} + V_{\text{G}}^{\text{Loss}}) - (V_{\text{B}}^{\text{Loss}} + V_{\text{G}}^{\text{Win}})], \tag{3}$$

net of any litigation costs.

Such a settlement is highly anticompetitive, however, and firms will typically face antitrust constraints. To capture this idea, let parameter $\theta \in [0, 1]$ index the level of antitrust scrutiny. Suppose further that if the brand and generic firms capture share ω of S_{Barg}, then the cost of a bargain is

$$C_{\text{Barg}}(\omega, S_{\text{Barg}}, \theta) = C_{\text{Barg}}^0 + \phi(\omega, \theta)S_{\text{Barg}},$$

where C_{Barg}^0 is the direct transaction costs of negotiating a settlement. Assuming that monopoly profit is constant across time, an appropriate interpretation of ω is that it is the amount of additional delay earned past the expected entry date, as a fraction of the maximum possible amount of delay. The function $\phi(\omega, \theta)$ captures the effect of antitrust scrutiny. Let it be continuously differentiable, increasing in both arguments and strictly convex in ω whenever $\theta > 0$. Furthermore, let $\phi(0, \theta) = \phi(\omega, 0) = 0$. Let litigation costs similarly be C_{Lit}^0.

Then the optimal settlement solves the following problem:

$$\max_{\omega} \ \omega S_{\text{Barg}} - C_{\text{Barg}}(\omega, S_{\text{Barg}}, \theta).$$

The term $\omega^\star$ is the optimizer. Firms then settle if and only if

$$S_{\text{Barg}} \geq \frac{C_{\text{Barg}}^0 - C_{\text{Lit}}^0}{\omega^\star - \phi(\omega^\star, \theta)}.$$

Straightforward comparative statics analysis shows that lower antitrust scrutiny leads to a higher probability of settlement.[10] Intuitively, firms in high-S_{Barg} cases

[10] This occurs at the margin when $C_{\text{Barg}}^0 - C_{\text{Lit}}^0 > 0$, while settlement is optimal for all values of S_{Barg} when $C_{\text{Barg}}^0 - C_{\text{Lit}}^0 < 0$. In civil litigation generally, it is more natural to imagine that $C_{\text{Barg}}^0 - C_{\text{Lit}}^0 < 0$, so that cases typically settle. There are many reasons why this need not be so in paragraph iv cases, however. First, the 30-month stay gives brand firms a strong incentive to proceed with litigation (and continue to enjoy monopoly profit) for some period of time, even if they intend to settle later. Moreover, most cases are appealed, and generic firms rarely enter until after the resolution of an appeal. This may stretch the brand firm's monopoly past the 30-month stay, even in a case that it loses. These forces significantly raise the relative cost of bargaining. Firms may also gain reputational benefits from defending their patents.

have a stronger incentive to enter into a settlement that secures a higher value of $\omega^{\star}$, and this raises the gains to settling relative to litigation.

Note that S_{Barg} is increasing in both the overall probability that the brand firm loses the case (the first bracketed term in equation [3]) and the difference of the brand and generic firms' stakes. Hence, lessened antitrust scrutiny could lead to more frequent settlement for cases with weak patents or high-sales drugs.[11] Which margin of substitution is more important is an empirical question, which we address in Sections 5 and 6.[12]

Lowered antitrust scrutiny has two additional implications. First, firms may settle litigation either before or after a district court decision. After a brand-firm win, the status quo joint payoff is $V_{\text{B}}^{\text{Win}} + V_{\text{G}}^{\text{Loss}}$, and reversals are rare. The bargaining surplus is very low, so settlement is unlikely to alter significantly the joint payoffs conditional on a brand-firm win.

After a brand-firm loss, however, generic-firm entry is the status quo, and reversals are rare, so the bargaining surplus is high. If firms execute anticompetitive settlements after brand-firm losses, then settlement may significantly alter the payoffs conditional on a brand-firm loss. Firms that anticipate this prior to the district court decision may then view expected payoffs under a brand-firm loss as higher than the joint payoffs that would occur with immediate generic-firm entry. Hence, if firms anticipate anticompetitive settlements after brand-firm losses, then the stakes in district court decisions will be lower.

Second, the mix of outcomes of the paragraph iv process may change. As shown in Figure 1, the joint payoff to firms under settlement (case C) rises, while the joint payoffs under all other cases are unaffected. Assuming that brand and generic firms compete consistent with subgame-perfect Nash equilibrium strategy up to the point of settling, one implication is that relaxed antitrust scrutiny could lead generic firms to attempt to enter more frequently when they anticipate settlement will occur. This force predicts substitution from case A outcomes to case C outcomes. A second implication is that relaxed antitrust scrutiny could also lead brand firms to contest generic-firm entry more often, again for cases in which they anticipate that settlement will occur. This force predicts substitution from case B outcomes to case C outcomes. Hence, the frequency of settlement rises as a fraction of all possible paragraph iv filings, rises as a fraction of all filed paragraph iv cases (B–D), and rises as a fraction of paragraph iv cases in which the brand firm contests entry (C and D). In addition, the frequencies of uncontested entry and litigation decisions, among all filed paragraph iv cases, fall.

Other factors could also alter the relative incentives to litigate to a decision ver-

[11] See the Online Appendix for a version of the model with divergent expectations à la Priest and Klein (1984). The effect of patent strength is the same, but the effect of sales may be reversed when antitrust scrutiny is relatively high and both firms are overly optimistic about their chance of winning.

[12] If the firms in our model are risk averse, then S_{Barg} would also include a positive risk premium because settlement removes all risk linked to litigation outcomes. We do not have data to test whether firms that are more risk averse settle, but we do discuss the implications of risk aversion for our main results in Section 7.

sus settling. For example, it has been well noted that litigation costs have risen significantly across time. Like relaxed antitrust scrutiny, higher litigation costs should cause the frequency of settlement to rise relative to the frequency of litigation decisions. However, higher litigation costs lower the payoff to contesting entry. This should also cause the frequency of uncontested entry to rise.

4. Data

Our data include a nearly comprehensive set of initial paragraph iv ANDA filings during 1985–2010.[13] By "initial" we mean that at the time the ANDA was filed, there had been no prior entry by any generic drug with the given active ingredient. Table 1 lists the sources for the data. We capture all drug patents listed in annual issues of the FDA's Orange Book from 1985 to 2010, including those that have expired or been delisted.[14] This yields 3,219 distinct patents. On average, a unique NDA number has five patents listed in the Orange Book over its lifespan. We also record all drugs and firms connected to these patents.

We match the Orange Book information to lawsuits in LexisNexis, the Derwent LitAlert data, and Lex Machina.[15] We also match to information about ANDAs in a set of ANDA approval letters, an FDA list of paragraph iv ANDAs, approval letters from the database Drugs@FDA, and the Orange Book blog.[16] These data help us identify ANDAs for which the brand firm did not contest entry, ANDAs for which the brand firm filed a patent-litigation lawsuit but the suit was eventually settled, and ANDAs that led to a patent-litigation decision.

Consider first filed lawsuits. Federal courts report all patent lawsuits to the US Patent and Trademark Office, and the Derwent LitAlert data are captured from these filings. For 1985–2010, Derwent LitAlert data cover 50–70 percent of all filed cases (Bessen et al. 2018). Derwent LitAlert data do not include drug names or, more importantly, decisions. To find decisions, we use our Orange Book and Derwent LitAlert information to search LexisNexis for written opinions recorded by the Federal Reporter. Opinions always include decisions, decision dates, courts, and related appellate decisions and nearly always include correct patent numbers and firm names. In pharmaceutical cases, they typically include drug

[13] We miss a small number filed during 1985–91. We also observe a small number of paragraph iv filings that are withdrawn. These would logically be classified as case A in Figure 1. But it is prohibitively difficult to put together a comprehensive set of potential paragraph iv filings.

[14] The 1986 Orange Book is not available, and the 1984 version did not have the patent and exclusivity addendum. However, patents listed in immediate subsequent years reflect the patents listed in the years missing.

[15] We thank Jacob Malone for designing efficient search algorithms to match patent numbers to litigation queries.

[16] For the FDA's list of paragraph iv ANDAs, see US Food and Drug Administration, Patent Certifications and Suitability Petitions (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm). For the Drugs@FDA database, see US Food and Drug Administration, Drugs@FDA: FDA-Approved Drugs, (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/). See the Orange Book Blog for recent developments on paragraph iv ANDA cases: Aaron F. Barkoff, Orange Book Blog: At the Intersection of Patent and FDA Law (http://www.orangebookblog.com/).

Table 1
Data Sources

	Time Frame	Key Characteristics
Main sources:		
FDA Orange Book	1984–2010	Comprehensive list of patents for FDA-approved drugs
Derwent LitAlert	1984–2010	Covers 50–70 percent of all US patent lawsuits (most years); includes filing dates and settled cases
LexisNexis	1984–2012	Complete opinions from trial decisions; includes decisions, decision dates, firms, paragraph iv info, and patent numbers
Additional sources:		
FDA ANDA filings	March 2, 2004–present	Comprehensive list of ANDAs, including non–paragraph iv cases
Federal Trade Commission (2002)	1984–2000	Comprehensive list of paragraph iv cases 1992–2000; includes drug and firm names
Lex Machina	January 1, 2000–present	Comprehensive information about patent lawsuits, including settlements
Orange Book blog	Mid-2000–present	Case summaries, news, and blogs
FDA paragraph iv ANDA approvals	May 5, 1987–July 24, 2009	Sample of letters to generic firms regarding successful paragraph iv ANDAs; includes first filer, patent type, and paragraph iii certification

Note. When possible, sources were cross checked and use the earliest paragraph iv abbreviated new drug application (ANDA) filing per drug to identify the appropriate generic firm. FDA = US Food and Drug Administration.

names and information about whether the case pertains to a paragraph iv ANDA filing. Opinions do not typically include filing dates. We match Derwent LitAlert filings to LexisNexis opinions and verify with paragraph iv ANDA filing dates so that filing dates may be matched to other variables.

For cases without LexisNexis decisions, we search Lex Machina to identify the nature of a case's conclusion. Lex Machina relies on data from the Public Access to Court Electronic Records database and includes patent lawsuits filed since January 1, 2000. For each filed case, it includes documents detailing facts of the case, such as whether the case reflects a paragraph iv ANDA, the patent numbers, and the name of the brand firm's drug. It also tracks cases through termination and records the nature of the termination. We classify as settled cases in which Lex Machina records "likely settlement" and cases in which a consent judgment terminates the case.

We supplement this sample of lawsuits with information from a sample of letters from the FDA to generic firms discussing their paragraph iv ANDAs.[17] The sample spans May 5, 1987–July 24, 2009, and includes 373 letters representing

[17] These letters are archived in the FDA Biosciences Library in Silver Spring, Maryland. We thank Lee Hu, who made scanned PDF files of these letters, for providing them to us.

200 brand drugs.[18] These letters record the first generic firm to file, the listed patents for a particular drug, and which ones face paragraph iv certifications. In addition, 198 of the letters include litigation outcomes. In the letters, we discover 28 additional paragraph iv cases, five of which were litigated to a decision.

Where possible, we also use the ANDA letters to classify patents. When information about a patent's type is unavailable from the ANDA letters, we classify each patent claim as an active-ingredient claim either if the first noun in the claim is "compound" (or derivatives of this word) or if the claim simply reproduces a chemical formula. We then classify a patent as an active-ingredient patent if it has at least one active-ingredient claim (similar to Hemphill and Sampat 2011, 2013). We compare our classification to the letter-based classifications and misclassify just three of 953 patents in the ANDA letters (.3 percent).[19]

These letters also include ANDAs that were not contested. To this group, we add ANDAs found from the FDA's updated list of ANDAs, from the Orange Book blog, and from some available approval letters in Drugs@FDA. In addition, we meticulously looked for cases not contested in news articles, double-checked Lexis and Lex Machina, and revisited Drugs@FDA for the approval letter if it is posted. The Orange Book files are also helpful in identifying these cases because in the exclusivity data the code PC (patent challenge) helps identify the exact ANDA number and firm.

4.1. Sample of Paragraph iv Abbreviated New Drug Application Filings

For the full paragraph iv filing period (1985–2010), we find 421 trade names that faced paragraph iv ANDA filings.[20] We then apply a filter to consider only cases in which monopoly at the active-ingredient level is the status quo and first-time entry is on the line as of the date of the paragraph iv filing.[21] In applying this filter, we drop multiple drug cases for the same active ingredient.[22] The result is 274 remaining drug cases. The time trends of the number of paragraph iv ANDAs and the filtered group in which monopoly is the status quo are shown in Figure 3*A*. The number of filings tracks the number of patents and total drug sales for drugs associated with these patents.[23]

[18] We combine different formulations and dosages under one drug name. This does not change the interpretation of our results, because a single formulation is often responsible for most of a drug's sales.

[19] The letters sometimes include information about paragraph iii certification filings for a subset of listed patents. Of the 953 patents in these letters, 5 percent face paragraph iii certifications. Most patents facing paragraph iii certifications (79 percent) have an active-ingredient claim.

[20] Of these 421, 72 were approved without a challenge in court (B cases), 159 were litigated but settled (C cases), and 192 were litigated and decided (D cases). There are no pending cases from these filings; thus, our data capture is not censored. We count only paragraph iv ANDAs not withdrawn after filed, and we do not consider extended release, sustained release, or other type of extension to a drug name as different drugs.

[21] We rely on the FDA's Orange Book and its database (Drugs@FDA) to determine when any generic entry occurs.

[22] For example, we count Xanax (alprazolam), which faced a paragraph iv ANDA in 1996, but not Niravam (alprazolam), whose paragraph iv ANDA was filed in 2005.

[23] These statistics are omitted but are available from the authors on request.

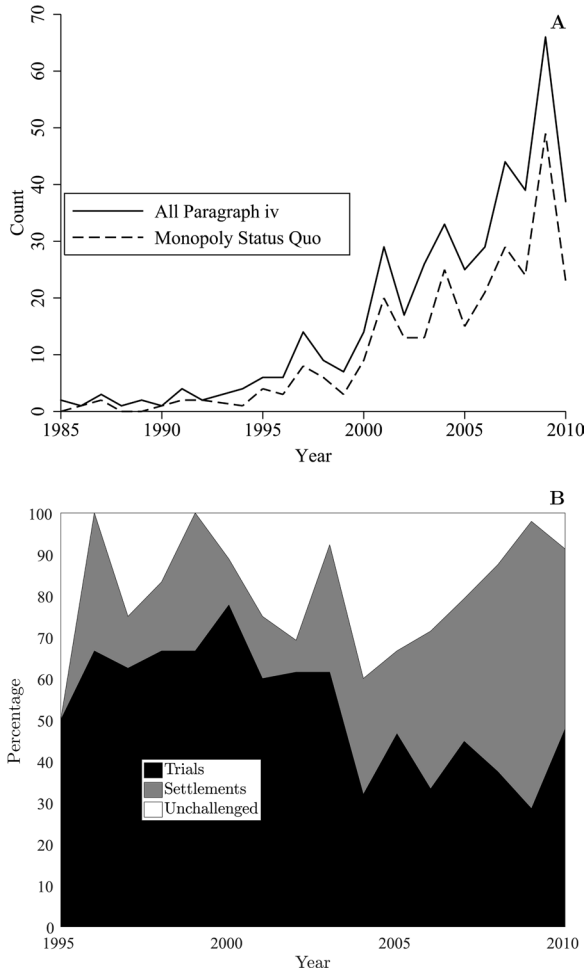

Figure 3. Abbreviated new drug application filings and resolutions, 1985–2010. *A,* All filings**;** *B,* resolutions.

Table 2 show some statistics for the filtered group of 274 paragraph iv ANDAs. The ANDAs approved without a challenge in court include 18 percent of cases, while 36 percent are litigated but settled and 46 percent are litigated and decided. Average annual sales for the drug, in the year prior to the ANDA filing, are about $633 million, and about 45 percent of cases are for a drug covered by at least one active-ingredient patent. Average sales are highest for ANDAs that reach a decision and are lowest for ANDAs for which the brand firm does not contest entry. Similarly, ANDAs that reach a decision are most likely to include a drug covered by an active-ingredient patent, and ANDAs with uncontested entry are least likely to include such a patent.

Table 2
Descriptive Statistics

	N	Mean	SD	Active-Ingredient Patent (%)	Average Annual Sales
Annual sales ($millions)	265	632.7	950.2		
Active-ingredient patent	274	.45	.50		
Unchallenged	274	.18	.39	34.0	359.7
Settlement	274	.36	.48	40.4	485.8
Decision	274	.46	.50	53.6	850.4

Note. The data are for 274 paragraph iv abbreviated new drug applications (ANDAs) filed during 1985–2010 in which the ANDA is the first for the active ingredient. The data are from a variety of sources, including patent statistics from the US Patent and Trademark Office and drug sales statistics from the IMS Institute for Healthcare Informatics. Annual sales are in millions of 2010 dollars for the year the ANDA was filed. In a small number of cases, the drug was not in the top 1,000 in that year, so sales are not observed. Values are rounded to the nearest digit.

Figure 3*B* restricts attention to monopoly status quo ANDAs and shows time trends for the percentage of cases in each of the three categories.[24] Settlements include all cases for which the brand firm filed a patent lawsuit against the generic firm but the case did not reach a district court decision on the validity or infringement of the patents. Trials include all filings for which cases reached at least a district court decision on the validity or infringement of the patents. Years refer to the year the paragraph iv ANDA was filed.

Figure 3 includes multiple noteworthy features. First, the annual fraction of cases reaching a decision is a majority during many of the early years of the data and is always at least 25 percent. Among filed lawsuits, the fraction that reaches a decision (trials) is even higher. This rate of litigation is extremely high when compared with patent litigation generally, where it is common for 90 percent or more of filed lawsuits to settle, and this permits a rich event study of decisions.

Second, the frequency of settlement is higher during the later years, with the five highest yearly settlement rates occurring for paragraph iv ANDAs filed during 2006–10. The fraction of ANDAs with decisions is lower in the later years, with the seven lowest yearly decision rates for paragraph iv ANDAs filed during 2004–10. The fraction of ANDAs with uncontested entry is similar in the later years, with a dip toward the very end. In our theoretical model, these trends are generally consistent with a reduced level of antitrust scrutiny leading to lower competition for entry in the later years of the data. Most of the effect appears to be substitution from decisions into settlements.[25] It is possible that rising litigation costs play some role in these trends, but we do not see a surge in the frequency of uncontested entry predicted by a litigation-costs explanation for the

[24] Note that trends are very similar for the unfiltered count of cases, changing only in the levels.

[25] We observe that after 2003 some cases approved without a challenge for one drug are more likely to settle for a second drug with the same active ingredient. For example, Xanax (alprazolam) faced a paragraph iv ANDA in 1996, but there was no litigation for its approval. However, in 2005, Niravam (alprazolam) faced a paragraph iv ANDA, and the litigation settled.

increase in the frequency of settlements.[26] Although other studies (for example, Greene and Steadman 2010; FTC 2010, 2013) describe trends in settlements, they do not report statistics as a percentage of total paragraph iv ANDAs.

For an additional robustness check, we compare our data with FTC (2002), which includes a comprehensive list of drug and firm names for paragraph iv ANDAs during 1992–2000. The list includes 104 cases, and after eliminating multiple formulations of the same drug, the filtered FTC list sums to 75 unique drug cases; our data construction misses just one (we add it).[27] This gives us confidence that our complete data set includes the disproportionate majority of litigations initiated for 2000–2010 as well.

4.2. Sample of Decisions

Among 124 filtered paragraph iv decisions, we restrict attention to cases in which the decision pertained directly to the validity or infringement of the patents. We also drop a small number of launch-at-risk cases in which the status quo is not a monopoly. In applying the event-study methodology, we restrict attention to publicly traded firms. In all, we lose 31 cases.[28]

Hence, our final sample for empirical estimation includes 93 drug cases, with the first decision occurring in 1988. Note that our inclusion criteria are less strict than restricting attention to former NCE drugs. Indeed, 20 percent of drugs in our sample were approved prior to the establishment of the NCE exclusivity in 1984. We match drugs to sales data from the IMS Institute for Healthcare Informatics. Finally, we match the firms involved in paragraph iv decisions with their stock returns from the Center for Research in Security Prices (CRSP) and company information from the Compustat database. We use SDC Platinum by Thomson Financial Securities Data to track mergers and acquisitions.[29]

[26] Note also that if a general rise in litigation costs were driving the main trends in our data, we would expect to see similar changes in a broader selection of lawsuits. We do not. For patent litigation in general, there is a trend toward less frequent trials from 1945 onward. See Henry and Turner (2016, table A1), which shows that the percentage of patent-infringement suits (all industries) reaching a trial falls steadily from 18.6 percent during 1945–50 to 5.0 percent during 1996–2000. Additional, similar data from the Administrative Office of the US Courts for 2001–7 show a decrease in the trial frequency to slightly below 4 percent (Administrative Office of the US Courts, Statistics and Reports, Caseload Statistics Data Tables [https://www.uscourts.gov/statistics-reports/caseload-statistics-data-tables]). But this is only about a 1-percentage-point reduction in trial frequency from 1996–2000 to 2001–7, whereas Figure 3*B* shows a drop in trial frequency that is significantly higher in both absolute and relative terms.

[27] According to the US Federal Trade Commission (FTC 2002), during 1984–91 there were 26 paragraph iv decisions, which may include different formulations of the same drug, but we are not able to apply our filtering criteria because the FTC does not record drug or firm names. Our matching of Orange Book patents to Derwent LitAlert and LexisNexis records, plus the ANDA letters, captures 14 decisions during this period that meet our filtering criteria of counting only unique drugs without considering different formulations of the same drug or different drugs with the same active ingredient.

[28] After our initial analysis, we discovered a very small number of additional decisions. We did not rerun the analysis, so these are part of the 31 lost cases.

[29] The SDC Platinum database covers all corporate transactions from 1962 to the present. Prior to 1992, it reports cases involving at least 5 percent of the ownership of a company if the transaction was valued at $1 million or more. After 1992, deals of any value are reported.

Tables 3 and 4 show descriptive statistics for the final sample of 93 drugs. Table 4 indicates that the average drug realized just over $1 billion in sales the year the lawsuit commenced. Lawsuits involve an average of about two patents. Moreover, one in every two cases includes an active-ingredient patent. For 61 percent of the cases, the generic firm and the brand firm are both public.

We classify each decision, district or appellate, as a brand-firm win if at least one patent is found valid and infringed. Table 3 indicates that the brand firm wins about 57 percent of the time in the district court's decision. Among district court decisions, an appellate decision is also reached about 72 percent of the time. Generic firms win 5 of 36 appeals of brand-firm wins (about 14 percent) and achieve reversals in 5 of 53 district court brand-firm wins (about 9 percent). Brand firms win 6 of 31 appeals of generic-firm wins (about 19 percent) and achieve reversals in 6 of 40 district court brand-firm losses (about 15 percent).[30]

Cases typically occur late in the life of the patents. The last patent to expire (youngest patent) typically has just over 6 years of life after the district court's decision. The first patent (oldest patent) is about 1 year older. The district court's decision is reached 5.3 years after the expiration of the NCE exclusivity, about 10 years after the drug's approval.

Table 5 highlights characteristics of brand- and generic-firm events. The 93 cases in our sample yield 82 public-brand-firm events and 68 public-generic-firm events, where an event is a firm-decision pair. Because our analysis is at the event level, firms take on a clear role of either brand or generic, and therefore our approach is not affected by whether firms are hybrid (hold both brand and generic products beyond the disputed case). Brand firms are three times as large as generic firms on average. There are 26 brand firms (approximately 3.2 litigations per firm) and 18 generic firms (approximately 3.8 litigations per firm).

To identify the dispute values using an event study, we need the district court's decision to represent a sudden, exogenous release of information to investors regarding generic-firm entry. If the stock market aggregates this information efficiently (Fama 1970), then changes in firms' stock prices reflect the decision's impact on the firms' valuations. The following exercise suggests that these conditions hold in our context.[31]

When a brand firm wins the district court decision, the its stock price should increase. Conversely, when the brand firm loses, its stock price should decrease. Figure 4, which shows the average return (from regressions of brand firms' returns on time dummy variables) and a 95 percent confidence interval for the 20 weeks surrounding the decision, confirm this basic intuition. On the day following a win, brand firms' market value increases by an average of 1 percent. After a loss, brand firms' value decreases by an average of more than 1.5 percent. For

[30] For reversal calculations, which are pertinent for estimating β_B and β_G, we count cases not appealed as maintaining the district court's decision.

[31] We assume that the outcome of the event represents the realization of uncertainty for all market participants. If some participants are privy to inside information regarding the outcome, estimates of abnormal returns may not accurately reflect the change in firm value. Such circumstances seem unlikely in paragraph iv litigation.

Table 3

Decisions at the Drug-Observation Level

	N	%
All decisions	93	
Brand-firm wins	53	56.99
Brand-firm wins in district court:		
Appealed	36	67.92
Reversed	5	9.43
Brand-firm losses in district court:		
Appealed	31	77.50
Reversed	6	15.00

Note. The sample is paragraph iv abbreviated new drug application (ANDA) filings litigated to a district court decision during 1988–2012 in which the ANDA is the first for the active ingredient. The data are from a variety of sources including patent statistics from the US Patent and Trademark Office and drug sales statistics from the IMS Institute for Healthcare Informatics. Percentages for rates of appeal rely on the number of decisions (the appeal rate for brand-firm wins is 36/53). Percentages for rates of reversal also use the number of decisions (the reversal rate for brand-firm wins is 5/53).

Table 4

Descriptive Statistics at the Drug-Observation Level

	Mean	SD
Drug sales	1,026.0	1,283.4
Patents	1.84	1.35
Active-ingredient patent	.54	.50
NCE status	.80	.41
Two public firms	.61	.49
Youngest patent (years)	6.18	3.76
Oldest patent (years)	5.30	3.91
Years since NCE expired	5.30	2.79

Note. The sample is 93 paragraph iv abbreviated new drug application (ANDA) filings litigated to a district court decision during 1988–2012 in which the ANDA is the first for the active ingredient. The data are from a variety of sources including patent statistics from the US Patent and Trademark Office and drug sales statistics from the IMS Institute for Healthcare Informatics. Statistics for new chemical entity (NCE) exclusivity drugs are restricted to that group of 74. Sales are in millions of 2010 dollars for the year the ANDA was filed. Patent life and time since the NCE exclusivity expired are based on the decision date.

Table 5
Descriptive Statistics at the Event Level

	Mean	SD
Brand-firm events:		
Drug sales in suit year ($millions)	985.97	1,297.38
Employees (thousands)[a]	63.94	37.62
Revenue ($billions)[a]	29.25	19.51
Patents	1.85	1.35
At least one active-ingredient patent	.51	.50
Brand-firm wins	.55	.50
Appeals	.71	.46
Affirmed if appealed	.60	.49
Generic-firm events:		
Drug sales in suit year ($millions)	1,100.46	1,164.47
Employees (thousands)[b]	22.59	27.62
Revenue ($billions)[b]	8.44	11.84
Patents	2.02	1.49
At least one active-ingredient patent	.54	.50
Generic-firm wins	.41	.50
Appeals	.75	.44
Affirmed if appealed	.63	.49

Note. The sample is 93 paragraph iv abbreviated new drug application (ANDA) filings litigated to a district court decision during 1988–2012 in which the ANDA is the first for the active ingredient. The data are from a variety of sources including patent statistics from the US Patent and Trademark Office, drug sales statistics from the IMS Institute for Healthcare Informatics, and firm employment and revenue from Compustat. Firm employment and revenue statistics are based on the year of the district court decision. For brand firms, $N = 82$ events and 26 firms; for generic firms, $N = 68$ events and 18 firms.

[a] Two missing observations.

[b] Five missing observations.

both types of events, the only statistically significant variation in returns occurs on the day following the event.

The results for generic-firm returns, highlighted in Figure 5, follow a nearly identical pattern. On average, on the day following the decision, generic firms' market value increases by about 2.3 percent when it wins. In contrast, generic firms' value falls by about 1.6 percent when the challenge fails.

5. Econometric Model

We estimate, for each event, different components of equation set (2) from our theoretical model. Then we calculate an estimate of the dispute value for that event. For example, the decision impact on a brand firm from a favorable decision by the district court is

$$V_{\mathrm{B}}^{*,\mathrm{Win}} - E_0\{\pi_{\mathrm{B}}\} = (1-\alpha)(\beta_{\mathrm{B}} + \beta_{\mathrm{G}} - 1)(V_{\mathrm{B}}^{\mathrm{Win}} - V_{\mathrm{B}}^{\mathrm{Loss}}).$$

We first use our event study to estimate

$$\widehat{V_{\mathrm{B}j}^{*,\mathrm{Win}} - E_0\{\pi_{\mathrm{B}j}\}}$$

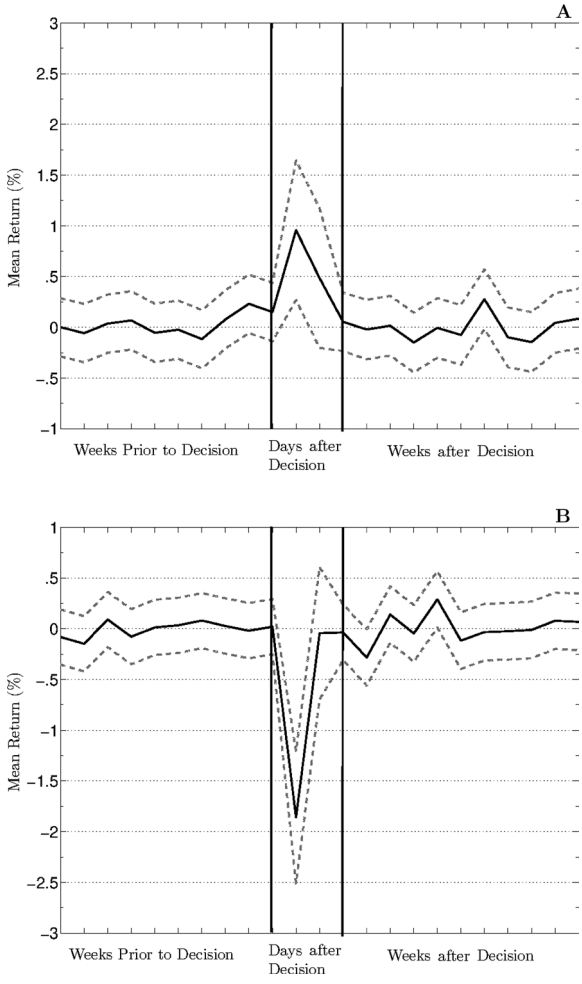

Figure 4. Mean returns for brand firms around district court decision. *A,* Brand-firm win; *B,* brand-firm loss.

for each event *j*. We then use other parts of our data to estimate, for each event, values of the parameters $\hat{a}_j$, $\hat{B}_{\mathrm{B},j}$, and $\hat{\beta}_{\mathrm{G},j}$. Once we have consistent estimates of each component, we can recover an estimate of the dispute value for the brand firm,

$$\widehat{V_{\mathrm{Bj}}^{\mathrm{Win}} - V_{\mathrm{Bj}}^{\mathrm{Loss}}} = \frac{\widehat{V_{\mathrm{Bj}}^{*,\mathrm{Win}} - E_0\{\pi_{\mathrm{Bj}}\}}}{(1-\hat{\alpha}_j)(\hat{\beta}_{\mathrm{Bj}} + \hat{\beta}_{\mathrm{Gj}} - 1)}. \tag{4}$$

Once we have estimates of dispute values for all events, we can look for temporal

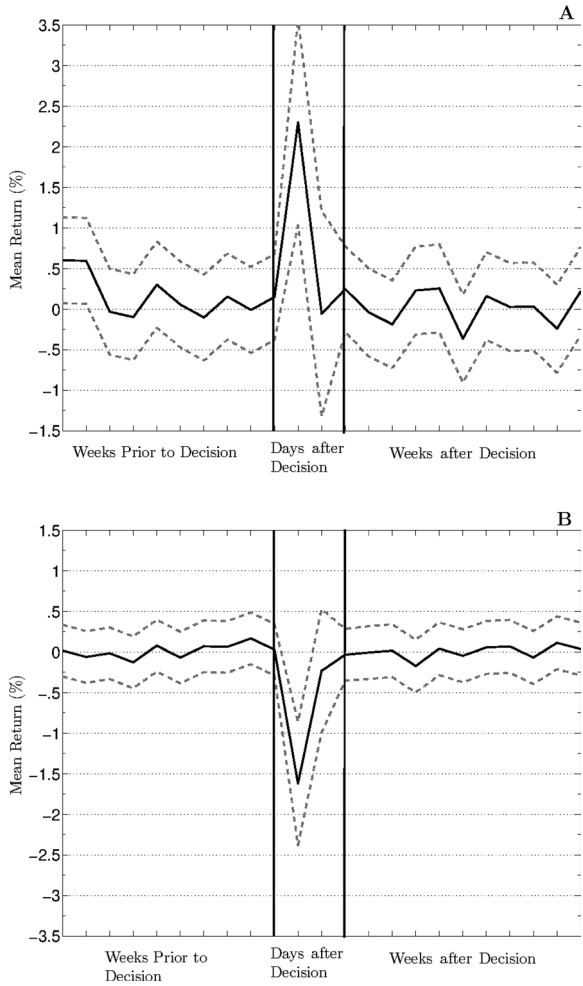

Figure 5. Mean returns for generic firms around district court decision. *A,* Generic-firm win; *B,* generic-firm loss.

variation to assess the impact of the *Schering-Plough* decision. In addition, we can use equation (3) to calculate how bargaining surpluses have changed.

5.1. Estimating the Decision Impact: The Event-Study Approach

Following Salinger (1992), we consider the following model of stock-market returns:

$$\rho_{jt} = \kappa_1 + \kappa_2 \rho_{jt}^{\mathrm{m}} + \varepsilon_{jt},$$

where ρ_{jt} is stock j's return on day t, ρ_{jt}^{m} is the return on the market index, and ε_{jt}

is a zero-mean error. The CRSP value-weighted market index is included to separate the effect of common factors driving market returns from the effect of the litigation decision.[32]

Now consider a day-T event. The following model permits a regression of abnormal returns on that day:

$$\rho_{jt} = \kappa_1 + \kappa_2 \rho_{jt}^{\mathrm{m}} + \psi I_{jt} + \varepsilon_{jt}, \tag{5}$$

where the indicator I_{jt} equals one when the market reacts to the event on day T and equals zero otherwise.[33] We estimate our model for event j by ordinary least squares regression. Following Panattoni (2011), we use a 271-day estimation window, $t = [-271, -1]$. We consider a 3-day event window, $t = [0, 2]$, to capture the stock market's reaction the day of the district court's decision and 2 days after it.[34]

We repeat this estimation procedure for each event. This yields an estimate, $\hat{\psi}$, of the change in market value due to the district court outcome for each firm ($(V_{\mathrm{B}}^{\star,\mathrm{Win}} - E_0\{\pi_{\mathrm{B}}\})/E_0\{\pi_{\mathrm{B}}\}$ in the case of a brand-firm win). We refer to $\hat{\psi}$ as the estimated cumulative abnormal return (CAR) for each event. We calculate standard errors of average CAR estimates assuming independence among events and infer the statistical significance of the estimates using a two-sided test of the null hypothesis that the average CAR is 0.

5.2. *Estimating Decision Probabilities*

Recall from our discussion of equation set (2) that we estimate decision probabilities to capture investors' beliefs and use those estimates to adjust event-study estimates to capture the dispute values. To consistently estimate α, β_{B}, and β_{G} for each case, we must control for factors that influence the decision probabilities conditional on entering litigation, that is, determinants of the unconditional probability of brand-firm victory and the probability of selection into litigation.

We consider three primary variables in the information set of investors: filing year, drug sales during the filing year, and whether there is an active-ingredient patent. We include the year primarily because of the surge in settlements that followed the *Schering-Plough* decision. If cases with a lower probability of brand-firm success tend to settle more often, then investors are likely to be aware of this and incorporate it into their expectations. We include sales because firms may commit different levels of resources to research, development, intellectual property protection, and litigation, depending on how important the drug is. Finally,

[32] We exclude dividends from returns in our analysis, but our results are virtually identical if we include them.

[33] Note that the dummy-variable approach suggested by Salinger (1992) is equivalent to estimating a prediction of returns using only information prior to the event (for example, returns procedure). However, the dummy-variable approach is computationally easier to program and more robust in estimating standard errors (see Salinger 1992).

[34] We also use 2-day and 4-day windows and find nearly identical results. In addition, we compare the dummy variable results with the returns procedure using Eventus (available from Wharton Research Data Services), and the results are robust to both approaches. In the Online Appendix, we provide estimates from three- and five-factor Fama and French models, which are also very similar.

active-ingredient patents are virtually always infringed, so brand firms asserting such a patent tend to prevail in litigation more frequently (Hemphill and Sampat 2011, 2013). While we do not have strong prior beliefs regarding how affirmation rates of district courts' decisions may vary with any of these factors, as we do for α, we permit both β_B and β_G to vary by the same three factors during estimation.

To flexibly estimate α_j, β_{Bj}, and β_{Gj} for each event j, we employ a multidimensional nearest-neighbor approach.[35] This approach uses the three predictors of outcomes to construct weights to apply to other events. The flexibility of a nonparametric approach is attractive for two reasons. First, it is not clear, a priori, how the three predictors of outcomes interact. For example, higher sales drugs could have a different probability of brand-firm victories over time. Second, the distribution of events across time and sales is quite uneven. Sales are highly skewed, and there are relatively few observations during the early years.

To demonstrate this approach, consider estimation of α_j. To measure the weights (applied to other events) for a given event j, we use a kernel density estimator. First define the closeness of this event from every other event in terms of sales and time d_{ij} as

$$d_{ij} = \frac{\phi(\widetilde{\text{Year}}_{ij}, \widetilde{\text{Sales}}_{ij})}{\sum_j \phi(\widetilde{\text{Year}}_{ij}, \widetilde{\text{Sales}}_{ij})}. \tag{6}$$

The arguments of the standard multivariate normal density ϕ are the differences in two of the predictors of a brand win, Year_{ij} and Sales_{ij}, for events i and j. As suggested by Pagan and Ullah (1999), prior to taking these differences, we normalize both variables using their respective means, the Cholesky decomposition of the joint variance-covariance matrix. For choosing a bandwidth parameter, we start with the multidimensional Silverman (1986) rule of thumb and smooth a bit to account for our skewed data.[36]

If case j involved an active-ingredient patent ($\text{AI}_j = 1$), we estimate α_j as

$$\alpha_j = \frac{\sum_i d_{ij} 1[\text{AI}_j = 1] 1[\text{Brand Win}_j = 1]}{\sum_i d_{ij} 1[\text{AI}_j = 1]}. \tag{7}$$

The estimates are also robust to the choice of kernel used to define distances. Estimation of α_j for cases without an active-ingredient patent is identical, except the sample stratification indicator is then $1[\text{AI}_j = 0]$. We estimate β_{Bj} and β_{Gj} for each j similarly.

[35] Estimates from both probit and logit specifications with interactions between covariates are very similar. We also estimated the specifications with indicators for the court and firm and find them to be jointly insignificant.

[36] The bandwidth is $h = kn^{-1/(4+d)}$, where n is the number of cases used in the nearest-neighbor estimation and the dimension of the data $d = 2$ because we use both sales and filing year. We set the smoothing parameter $k = 3.5$ but find that the results are not highly sensitive to k in this range.

Table 6
Estimation Results

	Brand Firms ($N = 82$)	Generic Firms ($N = 68$)
Event-study mean CAR (%):		
Brand-firm wins	2.08**	−1.63*
	(.62)	(.69)
Brand-firm losses	−2.43*	3.13**
	(1.00)	(1.00)
Decision probability means:		
α	.565	
	(.050)	
β_B	.906	
	(.043)	
β_G	.846	
	(.063)	
Final estimate means ($millions):		
Dispute value ($V_i^{Win} - V_i^{Loss}$)	4,313.8**	204.3**
	(1,115.1)	(38.7)
Bargaining surplus	1,728.5**	
	(437.9)	

Note. Results are from an event study estimating equation (5) for the main sample and from estimates of decision probabilities using equation (7) and analogous formulas for β_B and β_G. Standard errors are in parentheses. In the event study, for brand wins $N = 45$; for brand losses $N = 37$; for generic wins $N = 28$; for generic losses $N = 40$. There are fewer observations for the decision probability estimates than number of events because the estimates are constructed at the case level. Individual dispute values are calculated from equation set (2). The estimate of the mean bargaining surplus applies equation (3) to the averages reported here. For estimates of average cumulative abnormal returns (CARs), average and median dispute values, and the bargaining surplus, results are from a two-sided test of a null hypothesis of 0 effect. Standard errors for the average CAR estimates are calculated assuming independence among events. Standard errors for the decision probabilities, mean dispute values, and mean bargaining surplus are calculated using standard jackknife resampling.

* Significant at the 5% level.

** Significant at the 1% level.

6. Results

6.1. General Results

Table 6 reports the main results. The average CARs for the event study are 2.08 percent for brand-firm wins, −2.43 percent for brand-firm losses, 3.13 percent for generic-firm wins, and −1.63 percent for generic-firm losses. All estimates are statistically significant. Larger CARs for brand-firm losses and generic-firm wins reflect larger surprises than when brand firms win. For example, estimated deci-

sion probabilities, also in Table 6, reflect that brand firms have an average probability of .565 of a district court win.[37]

There is substantial variation in $\hat{\alpha}$ across events, however, and the values are higher both for high-sales drugs and during more recent years. In addition, the presence of an active-ingredient patent raises the overall probability of a brand-firm win. There are 50 cases with active-ingredient patents, and the average $\hat{\alpha}$ is .70 with a range of [.54, .89]. By contrast, there are 43 cases without active-ingredient patents, and their average $\hat{\alpha}$ is .41 with a range of [.35, .77].

Some district court outcomes are surprising, conditional on the estimated decision probabilities. For example, we estimate a probability of about 70 percent for a brand win for the January 17, 2006, decision over AstraZeneca's beta-blocker drug Toprol, but the district court found against AstraZeneca (*In re Metoprolol Succinate Patent Litig.*, 2006 U.S. Dist. LEXIS 1328 [E.D. Mo. 2006]). For comparison, the pharmaceutical marketing and commercialization website MM&M reported on January 9 that analysts from Deustche Bank believed that AstraZeneca had a 60 percent chance of winning (MM&M 2006).[38] More surprising outcomes than this are relatively uncommon. The estimate of $\hat{\alpha}_j$ is higher than for the Toprol case in 26 cases, but just 12 percent of the district courts' decisions in these high-$\hat{\alpha}$ cases (three of 26) go against the brand firm.

For each event j, we follow equation (4) and use the percentage impact, CAR_j, multiplied by firms' values to calculate the unadjusted impact of decisions. Then we divide by adjustment factors from estimates of α_j, $\beta_{\text{B},j}$, and $\beta_{\text{G},j}$ to estimate (for a firm of type $i \in \{\text{B, G}\}$) the dispute value $V_{i,j}^{\text{Win}} - V_{i,j}^{\text{Loss}}$ according to equations set (2). For brand-firm events, the mean brand-firm stakes are about \$4.3 billion. For generic-firm events, the mean generic-firm stakes are about \$204.3 million. Both estimates are highly significant.[39] The point estimates indicate that generic-firm stakes are about 4.7 percent of brand-firm stakes, which highlights the strongly asymmetric stakes in paragraph iv cases. The distributions of estimated dispute values are right skewed, as median stakes are lower (\$426.5 million for brand firms and \$59.0 million for generic firms).

[37] Standard errors are calculated using jackknife resampling. Note that the standard errors are for the estimate of the mean probability. Variability among the decision probabilities is substantially higher, as we next illustrate in detail for estimates of α.

[38] Note that our estimator uses cases that occur after the subject case, to which analysts making on-the-spot forecasts would not have access. In essence, we assume that investors form correct beliefs about mean outcomes of a set of (similar) cases, where some have already been decided and others have not. In principle, one could adapt this approach for out-of-sample forecasts. To do so, one would need to drop the observations that occur after the decision in the subject case. With our small sample, this approach would leave many observations with very few close neighbors (especially in earlier years). Hence, we feel that optimizing the in-sample fit is most prudent.

[39] As mentioned above, we use jackknife resampling to calculate standard errors for average dispute values and for average bargaining surpluses. Calculation of standard errors (using resampling procedures) requires some care because the estimated decision probabilities enter into the denominator of the dispute-value estimates. For example, a standard bootstrap procedure is problematic because resample draws may yield estimates of decision probabilities that imply infinite dispute values—for example, if a resample draw includes just brand-firm wins, then we would estimate $\hat{\alpha}_j = 1$, which in brand-win equation (4) implies an infinite dispute value. Jackknife resampling attenuates this problem by limiting the variation in the decision probability estimates produced by resample draws.

Table 7
Dispute Values versus Brand Sales

	Brand Firms ($N = 82$)		Generic Firms ($N = 68$)	
	(1)	(2)	(3)	(4)
C	−2,705.37	4,297.89	95.55	389.64*
	(1,832.23)	(3,145.69)	(113.10)	(197.87)
Sales	7.10**	7.55**	.10	.12+
	(1.13)	(1.10)	(.07)	(.07)
After *Schering-Plough*		−9,401.11*		–383.88+
		(3,495.59)		(213.61)
R^2	.331	.387	.029	.075

Note. Results in column 1 are from linear regressions of the form $V_i^{\text{Win}} - V_i^{\text{Loss}} = C + \beta_1 \times \text{Sales} + \beta_2 \times \text{After Schering-Plough} + \varepsilon$. Sales are for the year the lawsuit commenced; After *Schering-Plough* equals one if the decision occurs after the 2002 *Schering-Plough* decision. All calculations are performed in Stata. Standard errors, in parentheses, are unadjusted.

+ Significant at the 10% level.

* Significant at the 5% level.

** Significant at the 1% level.

The generic firm's stakes are its profit as an oligopolist. It includes the duopoly profit that the firm would earn during its 180-day exclusivity plus additional profit after more generic firms enter. If settlement never occurs after the district court's decision, then the stakes are equivalent to the minimum payment that a generic firm, certain to win its paragraph iv case, would accept to stay out of the market until the brand firm's patents expire. Hence, this is an important benchmark in evaluating the size of observed reverse payments. Our estimated average, $204.3 million, is similar in size to the total payments in early (1990s) reverse settlements, which typically stipulated that the generic firm stay out of the market until patent expiry.[40]

In pharmaceutical markets, drug sales are the main determinant of profit flow (Berndt, Kyle, and Ling 2003; Reiffen and Ward 2005). Hence, if our model accurately captures changes to firms' profits, the dispute values should be positively correlated with the relevant drug's sales. To aid interpretation of our results, we regress estimated dispute values on the sales of the drug during the year the litigation is filed. Note that we do not use this relationship directly in estimating dispute values, so this exercise is a useful test of our model and the event-study methodology.[41]

The results are shown in Table 7. Columns 2 and 4 control for timing relative to the *Schering-Plough* decision, which is clearly significant and motivates the dis-

[40] Reliable cash payments are known for the settlements over Nolvadex (1993, $66.4 million), BuSpar (1995, $72.5 million), Zantac (1995, $132.5 million), and Cipro (1997, $398.1 million). See Hemphill (2009, n. 114). These dollar figures are not adjusted for inflation.

[41] Sales are used only as one part of calculating expected decision probabilities. The probabilities enter the estimation routine nonlinearly and adjust the decision impacts of brand and generic firms in opposite ways to estimate the dispute values.

cussion in Section 6.2.[42] Sales explain a significant amount of the variation in dispute values and (as seen by comparing the R^2 values) explain more for brand-firm events than for generic-firm events.

A $1 increase in a drug's annual sales is associated with a $7.55 increase in brand-firm stakes. Hence, if current sales closely reflect the brand firm's profit as a monopolist, then our model predicts that brand-firm stakes are worth just slightly more, on average, than current profit times remaining patent life. A $1 increase in a drug's sales is associated with a $.12 increase in the generic firm's stakes. Hence, generic-firm stakes are about 25 percent of 180 days' worth of brand sales. Relative to a monopoly payoff, this is similar in size to a Cournot duopoly payoff for the period of the 180-day exclusivity.

Now consider the implications of these results for settlements. Returning to Table 6, we use equation (3), along with average dispute values and average decision probabilities, to estimate an average bargaining surplus of just over $1.7 billion. This reflects elimination of all legal uncertainty and full exclusion of generic-firm competition.

Under partial exclusion, where entry is delayed but the generic firm retains the 180-day exclusivity, we cannot generally calculate how the bargaining surplus changes with the timing of entry. However, we can estimate an upper bound for the value of retaining the 180-day exclusivity. Retained exclusivity has value for the generic firm because the settlement increases the probability that the generic firm will be able to enjoy it (Hemphill 2009). This probability increases by the probability that the brand firm wins the case. Using average decision probabilities to estimate this at .579, we find that generic firms may gain as much as $118.2 million from retained exclusivity.

6.2. Comparison of Results before and after the Schering-Plough Case

More interesting is the effect of the *Schering-Plough* decision in June 2002. To start, Tables 8 and 9 show descriptive statistics for cases decided in the periods before the first *Schering-Plough* decision and after it. There is little difference among these cases in the number of patents, patent type, and NCE status. However, the average sales are nearly twice as high for drugs in the post–*Schering-Plough* period, while the average patent life is somewhat lower.[43] In addition, brand firms win at the district court level, and overall, about 60 percent of the time, a much higher probability than in the pre–*Schering-Plough* period (Table 8). The rate of appeal of brand-firm losses is also lower in the post–*Schering-Plough* period, at 70

[42] We also run versions of the model with patent years left, an interaction between sales and years left, and a dummy for whether there was an active-ingredient patent. None of the coefficient estimates on these variables are significant.

[43] Comparing sales multiplied by patent life across eras, this product is higher in the post–*Schering-Plough* era by at least 32 percent, regardless of whether the oldest or newest patent is used. If the 2005 appellate decision in *Schering-Plough* is used, the difference in sales is not quite as high but is still 44 percent higher, while the difference in patent life is nearly the same as with the 2002 cutoff. Thus, the qualitative conclusions from the comparison of estimates of the dispute values would be similar if this cutoff were used instead.

Table 8
Decisions at the Drug-Observation Level by Time Period

	Before *Schering-Plough*		After *Schering-Plough*	
	N	%	*N*	%
All decisions	17		76	
Brand-firm wins	7	41.12	46	60.53
Brand-firm wins in district court:				
Appealed	5	71.42	31	67.39
Reversed	1	14.29	4	8.70
Brand-firm losses in district court:				
Appealed	10	100.00	21	70.00
Reversed	2	20.00	4	13.33

Note. The sample is 93 paragraph iv abbreviated new drug application (ANDA) filings litigated to a district court decision during 1988–2012 in which the ANDA is the first for the active ingredient. The data are from a variety of sources including patent statistics from the US Patent and Trademark Office and drug sales statistics from the IMS Institute for Healthcare Informatics. Percentages for rates of appeal rely on the number of decisions (the appeal rate for brand wins during the pre–*Schering-Plough* period is 5/7). Percentages for rates of reversal also use the number of decisions (the reversal rate for brand wins during the pre–*Schering Plough* period is 1/7).

Table 9
Descriptive Statistics at the Drug-Observation Level by Time Period

	Before *Schering-Plough*		After *Schering-Plough*	
	Mean	SD	Mean	SD
Drug sales ($millions)	592.65	671.71	1,117.23	1,363.71
Patents	1.59	1.23	1.89	1.37
Active-ingredient patent	.59	.49	.53	.50
NCE status	.76	.44	.80	.40
Two public firms	.71	.47	.59	.49
Youngest patent (years)	7.16	4.63	5.96	3.53
Oldest patent (years)	6.99	4.71	4.92	3.63
Years since NCE expired	4.94	2.95	5.38	2.77

Note. The sample is 93 paragraph iv abbreviated new drug application (ANDA) filings litigated to a district court decision during 1988–2012 in which the ANDA is the first for the active ingredient. The data are from a variety of sources including patent statistics from the US Patent and Trademark Office and drug sales statistics from the IMS Institute for Healthcare Informatics. Annual sales are in millions of 2010 dollars for the year the ANDA was filed. Results for new chemical entity (NCE) exclusivity drugs are restricted to that group of 74. Patent life and time since the NCE exclusivity expired are based on the decision date.

percent versus 100 percent in the pre–*Schering-Plough* period. Rates of appeal of brand-firm wins are similar across eras.

Table 10 reports estimates of average CARs and average and median dispute values for the two time periods. Despite the very small number of observations in the pre–*Schering-Plough* period, we nonetheless identify large average CARs for all four categories of events and find three of the estimates to be statistically

Table 10
Estimation Results by Time

	Before *Schering-Plough*		After *Schering-Plough*	
	Brand Firms ($N = 17$)	Generic Firms ($N = 12$)	Brand Firms ($N = 65$)	Generic Firms ($N = 56$)
Event-study mean CAR (%):				
Brand-firm wins	2.98+	−6.93*	1.91**	−.70
	(1.42)	(2.55)	(.69)	(.56)
Brand-firm losses	−2.59*	3.79	−2.37+	2.95*
	(.96)	(2.24)	(1.33)	(1.14)
Decision probability means:				
α	.534		.573	
	(.055)		(.051)	
β_B	.891		.909	
	(.052)		(.041)	
β_G	.820		.852	
	(.076)		(.061)	
Final estimate means ($millions):				
Dispute value $(V_i^{Win} - V_i^{Loss})$	8,843.3**	473.8**	3,129.2**	146.6**
	(1,692.6)	(80.3)	(1,142.4)	(34.2)
Bargaining surplus	3,679.0**		1,240.9**	
	(756.7)		(442.3)	

Note. Results are from an event study estimating equation (5) for the main sample and estimates of decision probabilities using equation (7) and analogous formulas for β_B and β_G. The estimate of the mean bargaining surplus applies equation (3). For estimates of average cumulative abnormal returns (CARs), average and median dispute values, and the bargaining surplus, results are from a two-sided test of a null hypothesis of 0 effect. In the pre–*Schering-Plough* event study, for brand-firm wins $N = 7$; for brand-firm losses $N = 10$; for generic-firm wins $N = 6$; for generic-firm losses $N = 6$. In the post–*Schering-Plough* event study, for brand-firm wins $N = 38$; for brand-firm losses $N = 27$; for generic-firm wins $N = 22$; for generic-firm losses $N = 34$.

+ Significant at the 10% level.

* Significant at the 5% level.

** Significant at the 1% level.

significant. The differences in the average CARs for wins and losses are more than 5.5 percentage points [−2.59 percent to 2.98 percent] for brand firms and nearly 11 percentage points [−6.93 percent to 3.79 percent] for generic firms. For these events, we estimate an average brand-firm stake of nearly $8.8 billion and an average generic-firm stake of about $473.8 million. The ratio of the dispute values is about 5.4 percent. The estimated S_{Barg} is about $3.7 billion.

Our estimates for the period after *Schering-Plough* suggest that average stakes are far lower in paragraph iv cases. Again, three of the four average CAR estimates are statistically significant, with generic-firm losses (the exception) estimated to have a near-zero effect. The differences in the average CARs, for wins and losses, are smaller than in the pre–*Schering-Plough* period. Recall from Table 8 that brand firms win at the district court with a much higher probability than in

the pre–*Schering-Plough* period.[44] This is precisely what would occur if cases with weaker patents tend to settle more often than cases with stronger patents.

We estimate an average brand-firm stake of about $3.1 billion in the post–*Schering-Plough* period, which is about 65 percent lower than the estimated stake in the pre–*Schering-Plough* period. We estimate an average generic-firm stake of $146.6 million, which is about 69 percent lower than the estimated stake in the pre–*Schering-Plough* period. The ratio of the dispute values is about 4.7 percent, similar to the ratio for the pre–*Schering-Plough* period.[45]

Because our model accounts for decision probabilities, the estimated average stakes reflect average differences in expected brand-firm (and generic-firm) payoffs under winning with certainty and losing with certainty. Hence, it is quite striking that the average dispute values fall by more than 65 percent after *Schering-Plough* while average sales nearly double. This strongly suggests that the stakes are lower in post–*Schering-Plough* cases, apart from any changes in the average strength of patents in the cases. This decline in stakes is consistent with investors expecting settlements after district court decisions to be more favorable to brands (that is, $V_B^{Loss} + V_G^{Win}$ is higher) in the post–*Schering-Plough* era.[46] To summarize, our results indicate that investors expect less within-market competition.

We estimate S_{Barg} to be about $1.2 billion for the post–*Schering-Plough* period, about 66 percent lower than in the pre–*Schering-Plough* period. This calculation accounts for average patent strength, which is higher during the post–*Schering-Plough* era. Hence, bargaining surpluses fall for two reasons. Patents in cases that reach decisions are stronger in the post–*Schering-Plough* era, and the stakes are lower apart from patent strength.

7. Conclusion

We develop a novel framework to shed light on the distribution of surplus in the US pharmaceutical industry and illuminate several policy-relevant phenomena. First, we find that brand-firm stakes in paragraph iv ANDA cases are far higher than generic-firm stakes. This suggests that firms that settle their disputes

[44] Note that the average estimated α parameter for the pre–*Schering-Plough* period (.53, Table 9) is higher than in the raw data (.41, Table 8). Segmenting the data using the AI patent variable (following equation [7]) reduces the influence of the year variable. In principle, higher estimates of α could affect implied average dispute values. But note in the Online Appendix that our conclusions about the intertemporal changes in dispute values are not sensitive to the way in which decision probabilities are estimated.

[45] As with the overall estimates, median dispute values are lower for both brand and generic firms during both periods. For the pre–*Schering-Plough* period, the median brand- and generic-firm dispute values are $1,207.2 million and $339.3 million, respectively. For the post–*Schering-Plough* period, the median brand- and generic-firm dispute values are $259.4 million and $37.7 million, respectively.

[46] In the Online Appendix, we discuss how divergent expectations may affect the pattern of substitution into settlement. In addition, we also show that the finding that average dispute values fall after *Schering-Plough* is not an artifact of our particular estimated decision probabilities. The same pattern emerges for a naive model in which all decisions are specified as complete surprises, so that the dispute value is the same (in absolute value) as the decision impact.

rather than litigate would realize sizable additional surpluses. We estimate the average bargaining surplus to be about $1.7 billion per paragraph iv case. We also provide evidence that pay-for-delay settlements reduce within-market competition. In paragraph iv litigation decisions after the closely watched *Schering-Plough* decision in 2002, estimated bargaining surpluses are far smaller than for cases before the decision.

Our work clearly shows that pay-for-delay settlements significantly altered allocative efficiency, while the Hatch-Waxman Act's provisions for promoting dynamic efficiency (for example, patent-term extensions) remained unchanged. However, our data do not permit us to study the effect of such settlements on dynamic efficiency. In addition to richer within-market data, a broader theoretical frame should also be considered when analyzing this trade-off. For example, competition for the market could be enhanced by lessened competition within the market (Segal and Whinston 2007).

A direct question for understanding the allocative and dynamic trade-off is whether $1 in consumer surplus today can be offset by more future medicines or, as some firms compete in both brand and generic markets, if the $1 promotes future generic competition across other markets. However, the dynamic effect quickly becomes challenging to study and difficult to compare, as it may depend on more than the time dimension. For example, the definition of the market may also expand to include international markets, and there are no current studies of whether brand firms alter future prices abroad as a result of paragraph iv outcomes. Another consideration in comparing the two effects is that the allocative efficiency estimates do not include all benefits to society. For example, our estimated change in S_{Barg} does not include additional externalities such that early generic-firm entry may lead to increased access to medications from new-to-therapy consumers, and it may also lead to greater compliance from existing consumers. The value of these externalities is an open question for further research.

Furthermore, the losses in allocative efficiency from pay-for-delay settlements are also potentially mitigated by reductions in litigation costs. Clearly, pay-for-delay settlements have reduced the average frequency of litigation in paragraph iv cases, which reduces litigation costs. In practice, litigation costs may significantly exceed direct expenses paid to lawyers (Bessen et al. 2018). For example, firms facing uncertain outcomes of litigation may alter their behavior. Tucker (2014) and Cohen, Gurun, and Kominers (2014) show that firms sued for patent litigation by nonpracticing entities significantly reduce innovative activity, and Tucker (2014) further shows that this leads to lost demand for products. Future empirical research on the size of both indirect costs of litigation and dynamic effects of settlements are important for understanding the impact of pay-for-delay settlements.

We are optimistic that our results will be useful for informing litigation and public policy. Our estimates of generic-firm stakes, in particular, help frame the "large and otherwise unexplained" payment inquiry under the *Actavis* rules. Many authors argue that any payment in excess of litigation costs should be in-

terpreted as purchasing some delay (for example, Edlin et al. 2013). We show that the value of retained exclusivity may be large, but it depends on the probability that the generic firm would win the paragraph iv case. As a consequence, in a settlement with retained exclusivity but no other payments, the court would need to inquire into the strength of the patents under hypothetical litigation.

We also hope that our methodology will support extensions that incorporate additional data. Ideally, a more general study of stakes in paragraph iv cases would use data on stock-market reactions to lawsuit filings and settlements. This would increase the amount of data used to estimate stakes for each event and would extend the event-study analysis beyond just district courts' decisions. It would require extending our structure to model investors' beliefs at the time that firms decide to sue and/or settle and a process for how beliefs evolve across time. Estimation would then require disentangling these multiple layers of beliefs (and their evolution) from the true impact of the events. Developing a tractable model and identifying appropriate data are key challenges for future research.[47]

If firms are risk averse, then our estimates of S_{Barg} understate the true size of bargaining surpluses. If firms are strongly risk averse, then these estimates could be higher than the changes in consumer surplus achieved via the paragraph iv process. Unfortunately, we do not have data to study this further. Given the emphasis some commenters have placed on risk aversion as a motivation for pay-for-delay settlements (Willig and Bigelow 2004; Harris et al. 2014), this also represents an important avenue for future research.

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[47] Data may be the biggest of these challenges. While data on stock-market reactions to lawsuit filings and settlements exist, they are noisier than data from district courts' decisions. With regard to lawsuit filings, Bessen et al. (2018) are not able to estimate precise average cumulative abnormal returns separately by industry. Thus, it is not clear that using event-study data from filings in paragraph iv cases would help estimation of beliefs. Regarding settlements, it is often difficult to ascertain the terms of a settlement, which would be key information for disentangling beliefs from true impacts.

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