Generic Entry, Pay-for-Delay Settlements, and the Distribution of Surplus in the US Pharmaceutical Industry

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Abstract

Using an event study approach, and unique data on Paragraph (iv) pharmaceutical patent litigation decisions, we estimate that brand firms value deterrence at $4.6 billion on average while generic entrants value the right to enter, on average, at $236.8 million. These estimates account for probabilistic district court decisions and an appellate process. In 2002, the *Schering-Plough vs. FTC* decision led to a surge in "pay-for-delay" settlements. We estimate that surpluses at stake in decided cases are 73% lower after this decision, reducing the direct (per-case) consumer surplus gains anticipated by the 1984 Hatch-Waxman Act's procedures for early generic entry.

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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, the Paragraph (iv) Abbreviated New Drug Application (ANDA) certification process, uses patent litigation to help strike this balance. Specifically, the US Food and Drug Administration 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 entry unless and until the generic firm successfully challenges all brand-firm patents covering the active ingredient and formulations of the drug in question. As a reward, or "bounty," the first generic firm to file for an ANDA and win a successful patent challenge receives a 180-day marketing exclusivity upon receiving its ANDA.

Effectively, the Paragraph (iv) ANDA process seeks an average level of competition, where entry occurs sooner against weak patents that do not hold up in court and later against strong patents that do hold up in court. In recent years, however, brand and generic firms have increasingly settled Paragraph (iv) litigation out of court (FTC 2010). In some settlements, brand firms pay generic firms to delay generic entry. Such settlements are potentially anti-competitive (Shapiro 2003; Bulow 2004), suggesting that incentives may have drifted from the balance sought by the Hatch-Waxman Act.

We develop a novel framework to estimate the size of the stakes in Paragraph (iv) disputes for brand and generic firms. Specifically, we use an event study of 93 patent infringement suits during 1988-2012 to produce statistics on changes in publicly-traded brand and generic firms' values following district court decisions. Separately, we estimate ex ante probabilities of district court wins and losses and appellate reversals. We then adjust the estimates from the event study with multipliers based on the ex ante probabilities, to recover values of deterrence (for brands) and values of entry (for generics).

With these estimates, and a theoretical model of litigation, we illuminate several policy-relevant phenomena. First, we find that brand firms value deterring entry, on average, at about $4.6 billion. In contrast, generic firms value the right to enter at about $236.8 million dollars (all values in 2010 dollars). The strongly asymmetric stakes in Paragraph (iv) cases highlight the massive relative payoff to being a monopolist in drug markets, and the potential gains that firms may reap by restricting competition.

The value of entry represents the minimum payment that a generic firm, certain to win its Paragraph (iv) case, would accept to delay entry until the brand firm's patents expire. It is also an upper bound for the value of the 180-day exclusivity.[1] In a settlement stipulating that the generic firm enters prior to patent expiry and retains the exclusivity, the generic would gain (roughly) the value of entry times the probability that it would lose the case, about $132 million on average for the cases in our data.

Second, if firms bargain to a settlement prior to litigation and agree to terms delaying entry for as long as possible, we estimate the average bargaining surplus to be just under $2 billion per Paragraph (iv) case in our data. Given ordinary assumptions about demand for drugs, this is a lower bound for the additional consumer surplus realized by permitting patent challenges under the Paragraph (iv) ANDA process, versus blocking entry for the life of the brand firm's patents.[2] Hence, this number indexes what the Paragraph (iv) ANDA process gains, in allocative efficiency, by using patent litigation to strike its balance.

Third, to contextualize our estimates and provide a check on their reasonableness, we regress the size of the (estimated) stakes on recent (pre-litigation) sales of the relevant brand drug. We find that one dollar of additional yearly brand sales increases the value of deterrence by about $7.19 and increases the value of entry by about $0.19. The projected value of deterrence equals slightly more than recent sales times remaining patent life. The

[1] The opinion in the 2013 *FTC v. Actavis* case noted that in 2006 the Generic Pharmaceutical Association said that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." [*FTC v. Actavis* 570 US at 4].

[2] For perfectly inelastic demand, it is exactly the additional consumer surplus earned. For such demand, quantity sold does not change when price falls, so the lower prices after a successful challenge would yield a transfer of surplus from firms to consumers, but would not create any additional surplus.

projected value of entry—roughly 40% of 180 days' sales—closely resembles an 180-day Cournot duopoly payoff.

Finally, we offer evidence that pay-for-delay settlements reduce the allocative efficiency provided by the Paragraph (iv) process. After the closely-watched 2002 decision in *Schering-Plough v. FTC*,[3] which upheld a pay-for-delay settlement, there was a surge in such settlements (FTC 2010). From a welfare standpoint, these settlements are of concern because firms stand to gain the most from settling precisely when the brand firm is most likely to lose the Paragraph (iv) case. If the post-*Schering-Plough* environment led to strong selection of such cases out of litigation and into settlements, then we expect Paragraph (iv) cases that *do* proceed to trial to have more frequent brand victories and lower stakes.

Our estimates confirm this intuition. In Paragraph (iv) litigation decisions after *Schering-Plough*, the ex ante probability of an ultimate brand victory is 60%, versus just 40% for prior cases. The average value of deterrence falls 60% after *Schering-Plough*, from about $8.8 billion to about $3.5 billion, while the average value of entry falls nearly 67%, from $532.0 million to $173.5 million. The average bargaining surplus falls from about $4.9 billion to about $1.3 billion, a 73% decrease. Hence, pay-for-delay settlements appear to lower the average allocative-efficiency surplus delivered by Paragraph (iv) litigation.

Our results may have implications for how courts apply antitrust analysis to settlements. In addressing a 2013 split among Circuit Courts over whether pay-for-delay settlements are anticompetitive, the Supreme Court found in *FTC vs. Actavis et al.* (133 US 2223 [2013]) that courts should apply a "rule of reason" when a settlement includes a "large and otherwise unexplained" payment from the brand to the generic. Our estimates of the value of entry show that settlements where the generic firm retains the 180-day exclusivity will often confer value to the generic that is "large," relative to typical litigation costs. And unlike cash payments, the value of retained exclusivity depends upon the strength of the patents. This suggests that proper antitrust analysis under the *Actavis* rule may need to

[3]The Administrative Law Judge's decision (40 LEXIS 244 [FTC 2002]) upheld the settlement, and the 11th Circuit Court of Appeals eventually upheld it as well (402 F.3d 1056 [11th Cir. 2005]).

consider outcomes of hypothetical patent litigation.

While a number of scholars have debated the anti-competitive nature of pay-for-delay settlements,[4] there has been little empirical work. In one recent exception, Drake et al. (2014) study announcements of settlement of Paragraph (iv) patent litigation, and capture variables indicating whether the settlement was of the pay-for-delay variety. They find brand firm value rises an average of 6% upon executing a settlement involving a payment from the brand to the generic, but no increase at all for settlements without such a payment. Similarly, McGuire et al. (forthcoming) argue that event studies are potentially useful in showing that pay-for-delay settlements are anticompetitive.

Our results also complement related studies of Paragraph (iv) patent 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 firm value. However, she does not estimate the value of deterrence or the effects on generic firms, which permit important insights into the implications of pay-to-delay settlements. Branstetter et al. (2011) use a nested logit model that relies upon aggregate sales data and focus on 17 Paragraph (iv) cases in the hypertension market (1997-2008). In counterfactual analysis, where generic products are excluded, they claim a static loss to consumers of $92 billion and a gain to brand firms of $14 billion. These results imply that entry by these 17 drugs yields a net static gain to society of $78 billion.

This paper also contributes to the literature estimating patent values. For the drugs in our data, our estimates imply that ironclad versions of the relevant patents would be worth an average of $2.5 billion at the time of the Paragraph (iv) decision. This estimate is important because it is a rare window on the characteristics of perhaps the most-valuable class of patents in the world. It is well known that the distribution of patent values overall is strongly right-skewed and has a fat right-hand tail (Harhoff, Scherer and Vopel 2003).

[4]For arguments that pay-for-delay settlements are both harmful and are unanticipated by the Hatch-Waxman Act, see Hovenkamp et al. (2003), Hemphill (2006, 2009), Elhauge and Krueger (2012) and Edlin et al. (2013). For arguments that pay-for-delay settlements are not necessarily anti-competitive, see Willig and Bigelow (2004), Yu and Chatterji (2011) and Harris et al. (2014).

Moreover, traditional methods for estimating patent values, such as the market-value method (Bessen 2009) or the renewal method (Schankerman and Pakes 1986; Pakes 1986), have a difficult time pinning down estimates for the most-valuable patents.

Finally, our work contributes to the literature on market entry. Generally, the lack of exogenous reasons for the end of status quo monopolies makes it difficult to directly estimate the value of entry and deterrence. To circumvent this, researchers often make difficult-to-test behavioral and parametric modeling assumptions, which rely on temporal or cross-sectional variation in market structure. These models typically take the form of either a complete-information binary game (Bresnahan and Reiss 1990, 1991; Berry 1992; Ciliberto and Tamer 2009) or a dynamic Markov-perfect equilibrium framework (Ericson and Pakes 1995; Gedge et al. 2013). However, in some industries, specific features of the regulatory environment generate plausibly-exogenous variation that permits more direct inference (Snider and Williams 2014). In this spirit, our application demonstrates how a simple event study framework, along with a limited set of assumptions, can be used to exploit the randomness of patent litigation to infer the value of entry and deterrence and provide insights into US pharmaceutical firms' incentives to settle disputes.

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 biological activity (typically in animals), a researcher (often financed by a pharmaceutical manufacturing firm) files an investigational new drug application (IND) to start trials in humans. In these clinical trials, the applicant must prove safety and efficacy.[5] If successful, the applicant files a New Drug Application (NDA) with the FDA; if the FDA approves the NDA, the applicant may sell the drug in the US.

Firms pioneering new drugs typically seek patents to cover active ingredients, formula-

[5]Trials follow a strict, costly three-phase process. See Bradford et al. (2015, section 2.1) for further details.

tions, methods of use, devices and processes as they develop these innovations. To approve a generic version of an NDA, the FDA requests that the generic applicant certify whether or not active-ingredient and formulation patents could prevent such approval under the Hatch-Waxman Act (Korn et al. 2009). Specifically, the Hatch-Waxman Act permits generic manufacturers to bypass clinical trials by filing an Abbreviated New Drug Application (ANDA). But the FDA grants approval of such generic drugs only if the generic can prove in court that it can produce its version of the drug without infringing any valid brand-firm patent. Indeed, FDA regulations lead frequently to scenarios where the outcome of patent litigation determines whether a brand firm maintains a status quo monopoly or a generic firm is able to enter.

In the most common scenario, the FDA grants a five-year new chemical entity (NCE) exclusivity to a pioneer drug. Once this exclusivity expires, other firms may seek to enter. The Hatch-Waxman Act encourages entry by granting a 180-day marketing exclusivity to the first generic applicant to both file for and successfully obtain ANDA approval.[6] To earn this exclusivity, a successful entrant must provide in its ANDA to the FDA:[7]

> **(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

[6]Sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the FDCA regulate the 180 DE.

[7]Federal Food, Drug, and Cosmetic Act (21 USC. 355); Section 505; Subsection (j)(2)(A)(vii)(IV).

> **(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 different types of certifications (A)(i)-(iv) are known, respectively as "Paragraph (i)-Paragraph (iv)" certifications. Paragraph (i)-(iii) certifications lead to entry, but no patent litigation. When a firm pursues entry under Paragraph (iv), however, the FDA may only review, and perhaps tentatively approve, an ANDA if the brand firm initiates a patent infringement lawsuit in response to the certification. However, FDA would not grant final marketing approval to such ANDA until the infringement lawsuit is resolved or the respective patents expire.

The FDA Orange Book lists three basic types of patents: active ingredient, formulation and method of use.[8] Under Section (B) above, 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 would nearly always be found 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 may win by proving either invalidity or non-infringement.

After receiving notice that a generic is pursuing an ANDA (iv), 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: (1) the patents expire; (2) the court decision is issued; (3) the 30-month stay expires (FTC 2002). Note that the 30-month stay is important because it gives incumbent firms incentives to initiate litigation even in cases

[8] See §314.53 of FDA regulations, and FDA proposed rules at 67 Fed. Reg. 65448-65.

where they have a low probability of winning. [9] The FTC reports that the FDA usually takes over 25 months to approve the ANDA even when no litigation occurs.[10] 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 generic has (Korn et al. 2009).[11]

Brand and generic firms sometimes settle their disputes rather than go through Paragraph (iv) litigation. Through 2000, there were at least nine settlements where the brand made a payment to the generic, suggesting anticompetitive motives (FTC 2002; Shapiro 2003; Bulow 2004). Beginning in 2000, the FTC initiated prosecutorial actions against pharmaceutical firms over four settlements: Hoechst-Andrx (Cardizem), Abbott-Geneva (Hytrin), Bristol-Shein (BuSpar) and Schering-Upsher-Smith (K-Dur). The first three of these settlements included maximal entry dates, as well as anticompetitive stipulations that were clearly outside the scope of the patents: e.g., 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 these three cases entered into consent decrees. 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 the case. The FTC's actions sharply reduced reverse settlement activity during 2000-04 (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-Upsher-Smith settlement. Although the decision was appealed and reversed by the full Commission, the 11^{th} Circuit Court of

[9] Prior to 2003, different ANDA filings for different patents of the same drug caused multiple 30-month stays when litigated. Furthermore, after 1998, a court decision of dismissal, a certified settlement, or non-infringement/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 et al. 2009).

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

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

Appeals eventually upheld the settlement [*Schering-Plough vs. FTC*, 402 F.3d 1056 (11^{th} Cir. 2005)]. In this and two subsequent cases in other Circuits,[12] 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 these cases. A 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 size of the reverse payment.

In 2012, the 3rd 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.[13] This created a Circuit Court split, prompting the Supreme Court to engage the reverse-settlement question. In a June 2013 decision over a reverse settlement for the drug Androgel [*FTC vs. Actavis, Inc.* (133 US 2223 [2013]), the Supreme Court remanded the case back to the 11^{th} 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 forthcoming). Numerous cases subject to the *Actavis* rules remain in litigation.

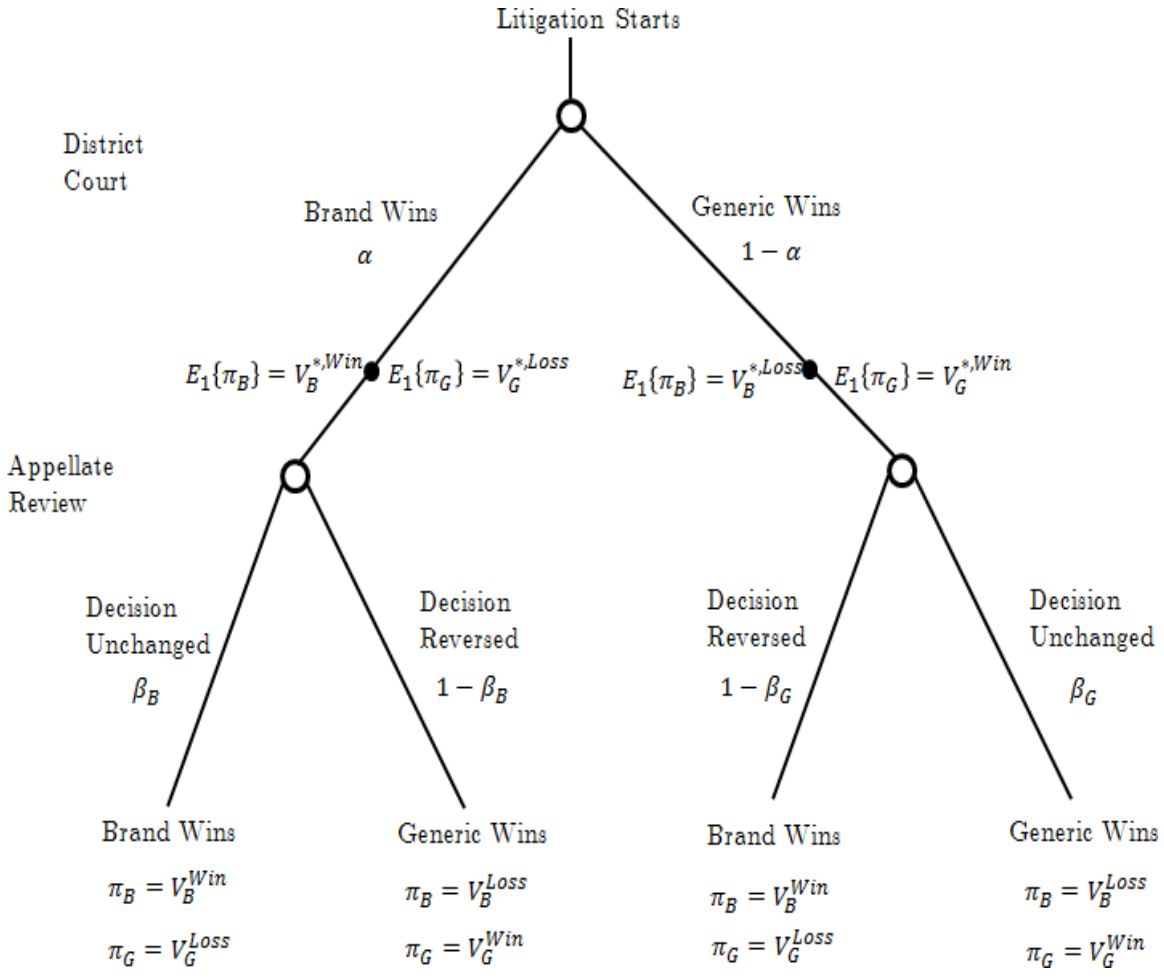
3. Theoretical Model

As a foundation for our empirical analysis, we introduce the following model of the Paragraph (iv) litigation process. Consider a market where a risk-neutral *brand firm* (B) operates as a monopolist and a risk-neutral *generic firm* (G) seeks entry. If the brand firm wishes to deter entry, it initiates litigation. If the brand firm is ultimately successful, the generic firm cannot enter and the brand firm's monopoly continues. If the brand firm is

[12] See *In re Tamoxifen Citrate Antitrust Litigation (466 F.3d 187 [2d Cir. 2006])* and *In re Ciprofloxacin Hydrochloride Antitrust Litigation (544 F.3d 1323 [Fed Cir. 2008])*. See also Elhauge and Krueger (2012, pp. 285-87) for a more complete discussion of the reasoning of the Circuit Courts of Appeal.

[13] *In Re: K-Dur Antitrust Litigation, 686 F.3d 197 (3rd Cir. 2012)*

Figure 1: *A Model of Paragraph (iv) Patent Litigation*



Note: This figure shows the Paragraph (iv) resolution process.

unsuccessful, the generic firm can enter and the brand firm's monopoly ends.

Figure 1 shows a game tree mapping the outcomes of litigation.[14] In the pre-litigation period, at the top of the tree, firms and investors form expectations of future payoffs prior to any decisions. Then, nature decides whether the brand or generic wins the case at the

[14]We do not model the selection process into litigation. We find little evidence that there is any substantial selection into litigation based on observable case-specific covariates, particularly those like sales that would be reflective of welfare. In fact, the annual sales in our sample of drugs involved in litigation averages just over $1 billion, which is slightly larger than the average annual sales reported by Drake et al. (2014) for drugs involved in cases that settled ($751 million). Thus, we expect our results to have some degree of external validity. However, even without this assumption of external validity, our results provide valuable insight for an important and substantial portion of pharmaceutical sales.

district court level. Let α be the probability the brand firm wins. Just after the district court decision, firms and investors update their expectations of future payoffs. Then, in subsequent ("appellate") review, nature determines whether the district court decision stands or is reversed. Let β_B be the probability a brand win is upheld and let β_G be the probability that a generic win is upheld.

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

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

$$\begin{aligned} &\text{Brand Wins (No Entry Occurs):} \quad \pi_B = V_B^{Win} \quad \pi_G = V_G^{Loss} \\ &\text{Generic Wins (Entry Occurs):} \quad \pi_B = V_B^{Loss} \quad \pi_G = V_G^{Win}. \end{aligned}$$

We assume joint profits are higher when the brand wins and the monopoly is preserved, $V_B^{Win} + V_G^{Loss} \geq V_B^{Loss} + V_G^{Win}$. These payoffs are realized only at the conclusion of the dispute. The *dispute value*, $V_i^{Win} - V_i^{Loss}$, gives the stakes in the case for firm i. Denote $V_B^{Win} - V_B^{Loss}$ as the *value of deterrence* for the brand firm and $V_G^{Win} - V_G^{Loss}$ as the *value of entry* for the generic firm.

These values are not directly observed, but can be inferred using the impact of the district court decision on firm value along with the market's expectations regarding the outcome of the district court decision and the subsequent appellate process. Denote the expected payoffs after the district court decision, but before any appeal, as:

$$\begin{aligned} &\text{Brand Wins District Court Stage:} \quad E_1\{\pi_B\} = V_B^{*,Win} \quad E_1\{\pi_G\} = V_G^{*,Loss} \\ &\text{Generic Wins District Court Stage:} \quad E_1\{\pi_B\} = V_B^{*,Loss} \quad E_1\{\pi_G\} = V_G^{*,Win}. \end{aligned}$$

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

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

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

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

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

Rearranging terms, we can write

$$0 = \alpha \left[V_B^{*,Win} - E_0\{\pi_B\} \right] + (1-\alpha) \left[V_B^{*,Loss} - E_0\{\pi_B\} \right]. \tag{1}$$

Denote $V_i^{*,Win} - E_0\{\pi_i\}$ ($V_i^{*,Loss} - E_0\{\pi_i\}$) as the *decision impact* of a win (loss), respectively, for firm i. Then, the first term in (1) is the decision impact when a brand firm wins a Paragraph (iv) lawsuit, weighted by the probability of a brand win. Correspondingly, the second term reflects the decision impact when a brand firm loses the case. Doing a bit of algebra, we find the following relationship between the decision impact and the dispute value for $i \in \{B, G\}$, conditional on the district court decision:

Brand Win:

$$\begin{aligned}
&\text{Effect on B:} \quad \overbrace{V_B^{*,Win} - E_0\{\pi_B\}}^{event\ study} &&= \overbrace{(1-\alpha)(\beta_B + \beta_G - 1)}^{nearest-neighbor} \overbrace{\left(V_B^{Win} - V_B^{Loss}\right)}^{deterrence/entry\ value} \\
&\text{Effect on G:} \quad V_G^{*,Loss} - E_0\{\pi_G\} &&= -(1-\alpha)(\beta_B + \beta_G - 1)\left(V_G^{Win} - V_G^{Loss}\right)
\end{aligned} \tag{2}$$

Brand Loss:

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

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 (e.g., "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 subsection 5.1. Then, we estimate the decision probabilities, α, β_B, and β_G, using a nearest-neighbor technique described in subsection 5.2. Then, we use the event-study and the nearest-neighbor results to solve for the disput value of deterrence, $V_i^{Win} - V_i^{Loss}$.

3.1. Settlement

In civil litigation generally, a sizable majority of cases settle instead of going to trial. This is not true with Paragraph (iv) litigation, where more cases litigate than settle. It would nonetheless be ideal to estimate values of deterrence and entry for settlements as well. But while settlements are in some cases observable and may alter stock market values, they do not include the discrete win/loss characteristic of trial outcomes and it is often difficult to ascertain the terms of a settlement. So we cannot identify values of entry or deterrence for these cases.

We do recognize that the possibility of settlement affects selection into litigation. Indeed, we will see that our data indicate significant intertemporal changes in selection into litigation. To help us interpret our results, we discuss the following stylized model, which fits the characteristics of Paragraph (iv) litigation.

Bargaining Surplus

Prior to the start of litigation, let brand and generic firms engage in Nash Bargaining to settle the case. In a completely unconstrained settlement, the firms would maximize the joint surplus by maintaining the brand monopoly and achieving joint profit $V_B^{Win} + V_G^{Loss}$. In such a settlement, the firms increase total profit by the difference between this joint profit and the expected joint surplus under litigation. Thus, the bargaining surplus, S_{Barg}, net of litigation costs, is

$$S_B = \left[\alpha\left(1-\beta_B\right) + (1-\alpha)\beta_G\right]\left[\left(V_B^{Win} - V_B^{Loss}\right) - \left(V_G^{Win} - V_G^{Loss}\right)\right] \tag{3}$$

Such a settlement is highly anticompetitive, however, and firms will typically face antitrust constraints. To capture this idea in the simplest possible way, let parameter $\theta \in [0,1]$ index the level of antitrust scrutiny. Suppose further that if the brand and generic firm

capture share ω of S_B, then the cost of a bargain is

$$C_{Barg}(\omega, S_{Barg}, \theta, \epsilon_{Barg}) = C^0_{Barg} + \phi(\omega, \theta) S_{Barg} + \epsilon_{Barg}.$$

Let $\phi(\omega, \theta)$ be continuously differentiable, increasing in both arguments and strictly convex in ω whenever $\theta > 0$. Further, let ϵ_{Barg} be a standard normal error term and let $\phi(0, \theta) = \phi(\omega, 0) = 0$. Let litigation costs be

$$C_{Lit}(\epsilon_{Lit}) = C^0_{Lit} + \epsilon_{Lit},$$

where ϵ_{Lit} is a standard normal error term, uncorrelated with ϵ_{Barg}.

Then, the optimal settlement solves the following problem

$$\max_{\omega} \quad E\left[\omega S_{Barg} - C_{Barg}(\omega, S_{Barg}, \theta, \epsilon_{Barg})\right].$$

Denoting ω^* as the optimizer, firms then settle if and only if

$$S_{Barg} \geq \frac{C^0_{Barg} - C^0_{Lit} + (\epsilon_{Barg} - \epsilon_{Lit})}{\omega^* - \phi(\omega^*, \theta)}.$$

Straightforward comparative statics analysis shows that lower antitrust scrutiny leads to a higher probability of settlement. If in addition $C^0_{Barg} - C^0_{Lit} > 0$, then without anticompetitive settlements ($\omega^* = 0$), litigation is more likely than settlement and lower antitrust scrutiny leads to a lower average S_{Barg} among cases that proceed to litigation.[15] Intuitively, firms in high-S_B cases have a stronger incentive to enter into a settlement that secures a higher value of ω^*, and this raises the gains to settling relative to litigation.

Note that S_{Barg} is increasing in both the probability the brand firm ultimately loses the case [the first bracketed term in (3)] and the difference of the value of deterrence and the

[15] In civil litigation generally, it is more natural to imagine that $C^0_{Barg} - C^0_{Lit} < 0$, 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 for some period of time, even if they intend to settle later on. Moreover, most cases are appealed, and generics rarely enter until after the resolution of an appeal. This may stretch the brand'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.

value of entry. Hence, lessened antitrust scrutiny could lead to more frequent settlement for cases with weak patents or high-sales drugs.[16]

Welfare

Let demand for the drug be downward-sloping and assume competition is such that prices are lower under generic entry. Then the relative values of consumer surplus, conditional on firm profits, follow $CS(V_B^{Loss}, V_G^{Win}) > CS(V_B^{Win}, V_G^{Loss})$. Define welfare $W(.)$ as follows:

$$W(V_B^{Win}, V_G^{Loss}) = V_B^{Win} + V_G^{Loss} + CS(V_B^{Win}, V_G^{Loss})$$
$$W(V_B^{Loss}, V_G^{Win}) = V_B^{Loss} + V_G^{Win} + CS(V_B^{Loss}, V_G^{Win}),$$

Net of transaction and litigation costs, we have $W(Settlement) = W(V_B^{Win}, V_G^{Loss})$. Defining $\gamma = [\alpha\beta_B + (1-\alpha)(1-\beta_G)]$ to be the probability the brand ultimately wins, we can write $W(Litigation) = \gamma W(V_B^{Win}, V_G^{Loss}) + (1-\gamma)W(V_B^{Loss}, V_G^{Win})$. Doing a bit of algebra, we have

$$\begin{aligned} W(Litigation) - W(Settlement) = \quad & (1-\gamma)\left\{CS(V_B^{Loss}, V_G^{Win}) - CS(V_B^{Win}, V_G^{Loss})\right. \\ & \left. - \left[\left(V_B^{Win} - V_B^{Loss}\right) - \left(V_G^{Win} - V_G^{Loss}\right)\right]\right\} \end{aligned}$$

If demand is perfectly inelastic, then $W(Litigation) = W(Settlement)$ because lower prices under generic entry would merely transfer surplus from the firms to the consumers. If demand is downward-sloping but not perfectly inelastic, then generic entry would also yield higher sales volume, so that $W(Litigation) > W(Settlement)$ and

$$CS(V_B^{Loss}, V_G^{Win}) - CS(V_B^{Win}, V_G^{Loss}) > \left(V_B^{Win} - V_B^{Loss}\right) - \left(V_G^{Win} - V_G^{Loss}\right).$$

An important implication of this is that $S_{Barg} = (1-\gamma)\left[\left(V_B^{Win} - V_B^{Loss}\right) - \left(V_G^{Win} - V_G^{Loss}\right)\right]$ is a lower bound for the extra consumer surplus, $(1-\gamma)\left[CS(V_B^{Loss}, V_G^{Win}) - CS(V_B^{Win}, V_G^{Loss})\right]$, gained by the Paragraph (iv) ANDA process, versus the alternative where generic entry is blocked until the pivotal patent expires.

[16] 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 more-risk-averse firms settle, but we do discuss the implications of risk aversion for our main results in the conclusion.

4. Data

Table 1 lists the various sources for our litigation data. We capture all drug patents listed in annual issues of the Patent and Exclusivity Addendum to the FDA Orange Book from 1985 to 2010, including those that have expired or been delisted.[17] This yields 3,219 distinct patents. On average, a brand drug, which corresponds to a unique New Drug Application (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 filed cases in the Derwent Litalert data. Federal courts report all patent lawsuits to the US Patent and Trademark Office, and the Derwent data are captured from these filings. During 1985-2010, Derwent data cover 50-70% of all filed cases (Bessen et al. 2013). Derwent data do not include drug names or, more importantly, decisions.

To find decisions, we use our Orange Book and Derwent information to search LexisNexis for written opinions recorded by the Federal Reporter. Opinions always include decisions, decision dates, courts, related appellate decisions, and nearly always include correct patent numbers and firm names. In pharmaceutical cases, they typically include drug names and information on whether the case pertains to a Paragraph (iv) ANDA filing. Opinions do not typically include filing dates. We match Derwent filings to LexisNexis opinions so that filing dates may be matched to other variables.

We supplement this sample of lawsuits with information from a sample of letters from the FDA to generic firms discussing their Paragraph (iv) ANDAs.[18] The sample spans May 05, 1987-July 24, 2009, and includes 373 letters representing 200 brand drugs.[19] These letters record the first generic to file, the listed patents for a particular drug and which ones face Paragraph (iv) certifications. Also, 198 of the letters include litigation outcomes. In the

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

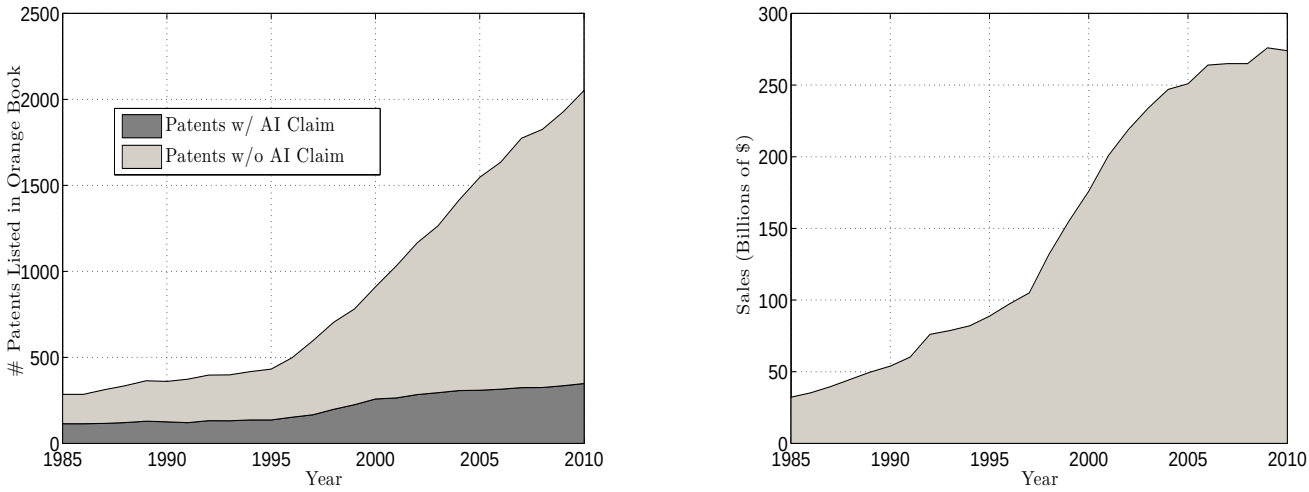
[18]These letters are archived in the FDA Biosciences Library in Silver Spring, MD. We thank Lee Hu, who made scanned .pdf files of these letters, for providing them to us.

[19]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.

letters, we discover 28 additional Paragraph (iv) cases, 5 of which are litigated to a decision.

Where possible, we also use the ANDA letters to classify patents. When information on 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.[20] We compare our classification versus the letter-based classifications, and misclassify just three out of 953 patents in the ANDA letters (0.3%).[21]

Figure 2: *Trends in Patents (OB) and Drug Sales (IMS) 1985-2010.*



(a) *Patents in Orange Book.*

(b) *Annual Drug Sales*

Note: The patent trends reflect cumulative patents showing in a given year according to every annual edition of the OB. Sales are for the top 1000 drugs listed by IMS a given year. All dollar figures are standardized to 2010 US dollars.

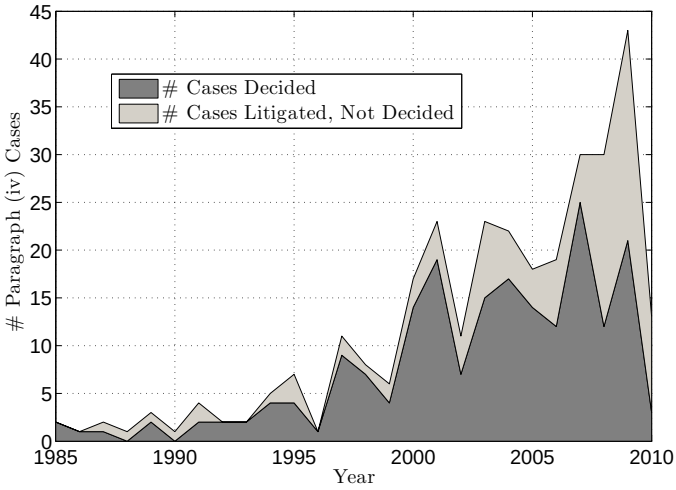
Figure 2(a) presents the total number of patents listed in each edition of the Orange Book, as well as the number of those patents that have at least one active-ingredient claim. The proportion of patents claiming an active ingredient has steadily declined as the total

[20]This is similar to Hemphill and Sampat (2011, 2013).

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

number of listed patents has increased substantially. Patenting has increased overall, and—see Figure 2(b)—closely tracks growth in sales from 1985 to 2010. The low of 4.8 patents per billion dollars of sales occurs in 1995, while the high of 8.7 occurs in 1985.

Figure 3: *Trends in Paragraph (iv) Litigations and Decisions from 1985-2010.*



Note: These Paragraph (iv) challenges count only the first challenge per drug, where different dosages and formulations of the same drug-name are treated as one. The trend of "Cases Litigated, Not Decided" is only the gap between the top-most trend (representing all filed cases) and cases decided, and it is comprised mostly of cases that settled rather than cases that are still pending. "Year" is the year lawsuits are filed.

Figure 3 shows the number of Paragraph (iv) litigations across time, based on when the lawsuit is initiated, along with the number of decisions. Note that the number of these litigations, which represent generic entry attempts, closely tracks the trends in sales and patenting. Moreover, the widening gap between total litigations and decisions suggests firms have more frequently settled cases in recent years (Greene and Steadman, 2010).[22]

For the entire period (1985-2010), 301 generic Paragraph (iv) certifications are challenged in court by the incumbent brand firm. Of these, 159 are litigated to a decision, all between 1988-2012. These data include only the first Paragraph (iv) challenge per drug. We compare our data to FTC (2002), which includes a comprehensive list of drug and firm names for 104 Paragraph (iv) ANDAs during 1992-2000. Of these ANDAs, the brand sued the generic in

[22]The big drop in decisions for the 2010 year is because many of the cases beginning in this year were not yet resolved during the collection of our data. See also FTC (2010, 2013) for similar trends in settlements.

75. Our data construction misses just one of the 75 cases (we add this case).[23] This gives us confidence that our complete data set includes the disproportionate majority of litigations initiated during 2000-2010 as well.

4.1. Final Sample

Among the 159 Paragraph (iv) decisions, we restrict attention to cases where there was no generic entry into the market of any drug with the same active ingredient prior to the district court decision.[24] We also drop six Paragraph (iv) cases where the decision did not pertain to the validity and/or infringement of the patents.[25] When there are multiple cases involving the same active ingredient, or the same patent(s), we use the first case—this drops nine cases. In applying the event study methodology, we drop seven additional cases.[26]

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 just former NCE drugs. Indeed, our sample includes 20% of drugs approved prior to the establishment of the NCE exclusivity in 1984. We match drugs to sales data from IMS Health. Finally, we match the firms involved in Paragraph (iv) decisions with their stock returns from CRSP and company information from COMPUSTAT. We use SDC Platinum by Thomson Financial Securities Data to track mergers and acquisitions (M&A).[27]

[23]FTC (2002) also states that there were 26 Paragraph (iv) decisions during 1984-91 but does not record drug or firm names. Our matching of Orange Book patents to Derwent and LexisNexis records, plus the ANDA letters, captures 16 decisions during this period.

[24]This eliminates 44 cases. We rely on the FDA Orange Book and its website (Drugs@FDA) to determine when any generic entry occurs. We also check with Factiva and LexisNexis news sources if a generic firm launches at risk during the litigation proceeding and before the district court decision due to the expiration of the 30-month stay. This eliminates just one drug (Neurontin).

[25]Four involve issues about patent extensions, one involves a use code associated with the patent, but not the patent itself. The sixth case (Nolvadex) involves the generic firm (Barr) facing the threat of being shut down by the FDA.

[26]Two involve the same firm and are so closely timed that the event windows overlap. Five cases do not have public information for the firms involved at the time of the district court decision.

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

4.2. Descriptive Statistics

Table 2 shows descriptive statistics at the case level. 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% of the cases, the generic and the brand are both public firms.

We classify each decision—district or appellate—as a brand win if one or more patents are found valid and infringed. The brand wins about 57% of the time in the district-court decision. Among district-court decisions, an appellate decision is also reached about 72% of the time. Generics win 5 of 36 appeals of brand wins (about 14%), and achieve reversals in 5 of 53 district-court brand wins (about 9%). Brands win 6 of 31 appeals of generic wins (about 19%), and achieve reversals in 6 of 40 district-court brand losses (about 15%).[28]

Cases typically occur late in the life of the patents. The last patent to expire (youngest patent) typically has just 6.3 years of life after the district-court decision. The first patent (oldest patent) is about one year older. Also, the district-court decision is reached 5.3 years after the expiration of the NCE exclusivity, about ten years after the drug's approval.

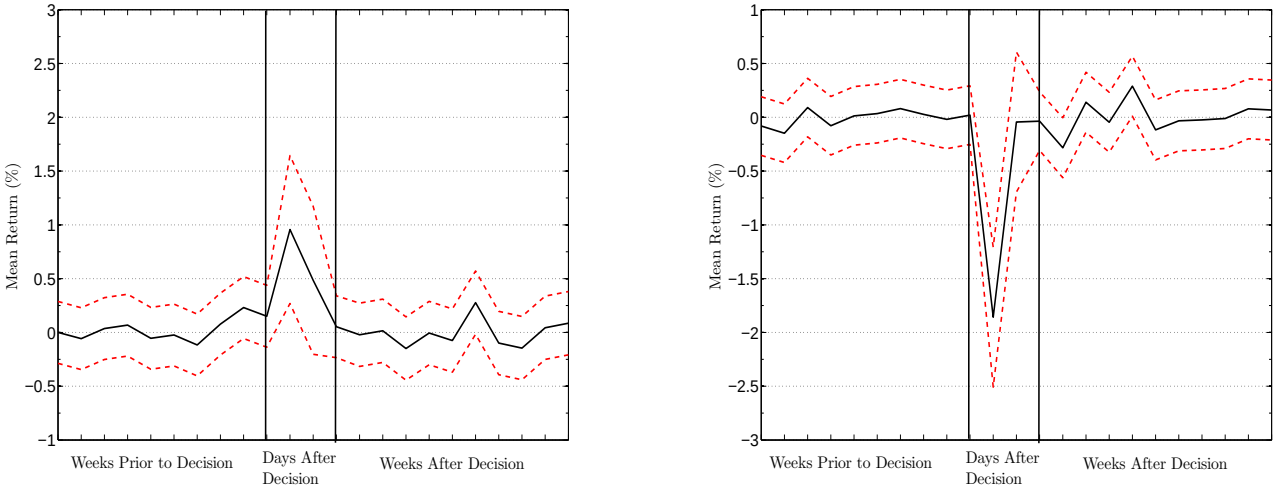
Table 3 highlights characteristics of brand and generic events. The 93 cases in our sample yield 82 public-firm brand events and 68 public-firm generic events, where an event is a firm-decision pair. Brand firms are three times as large as generic firms on average. The total number of brand firms is 26 (approximately 3.2 litigations per firm) and the number of generic firms is 18 (approximately 3.8 litigations per firm).

To identify the value of deterrence and entry using an event study, we need the district court's decision to represent a sudden, exogenous release of information to investors regarding generic 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.

When a brand firm wins the district court decision, the brand firm's stock price should

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

Figure 4: *Mean Return for Brand Firms Around District Court Decision*



(a) *Brand Win* (b) *Brand Loss*

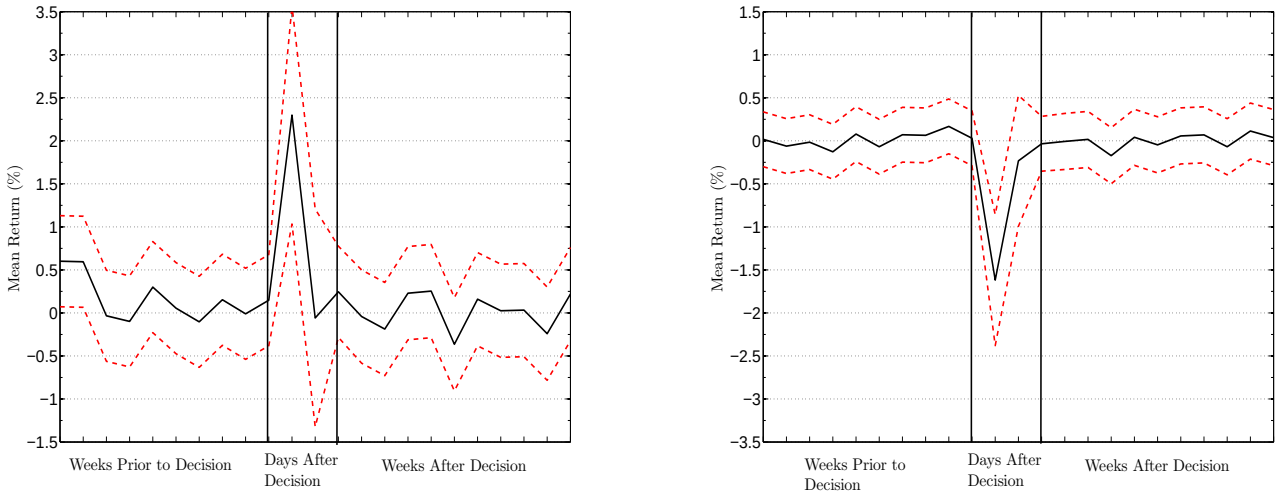
Note: This figure shows the coefficient estimates from a regression of brand firms' returns on dummy variables for both the days immediately after the district court decision and the weeks prior to and following the district court decision. These trends of mean returns do not yet account for the full structure of the event study, rather they motivate the appropriateness of an event study.

increase. Conversely, when the brand firm loses, its stock price should decrease. Figures 4(a) and 4(b), which show the average return and a 95% confidence interval for the 20 weeks surrounding the decision, confirm this basic intuition. On the day following a brand win, brand firms' market value increases by an average of 1%. After a loss, brand firms' value decreases by an average of more than 1.5%. For both types of events, the only statistically significant variation in returns occurs on the day following the event.

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

5. Econometric Model

Figure 5: *Mean Return for Generic Firms Around District Court Decision*



(a) *Generic Win* (b) *Generic Loss*

Note: This figure shows the coefficient estimates from a regression of generic firms' returns on dummy variables for both the days immediately after the district court decision and the weeks prior to and following the district court decision. These trends of mean returns do not yet account for the full structure of the event study, rather they motivate the appropriateness of an event study.

We estimate, for each event, different components of the equations in (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 district court decision is

$$V_B^{*,Win} - E_0\{\pi_B\} = (1-\alpha)\left(\beta_B + \beta_G - 1\right)\left(V_B^{Win} - V_B^{Loss}\right)$$

We first use our event study to estimate $\widehat{V_{B,j}^{*,Win} - E_0\{\pi_{B,j}\}}$ for each event j. We then use other parts of our data to estimate, for each event, values of the parameters $\widehat{\alpha_j}, \widehat{\beta_{B,j}}$ and $\widehat{\beta_{G,j}}$. Once we have consistent estimates of each component, we can recover an estimate of the dispute value for the brand firm,

$$\widehat{V_{B,j}^{Win} - V_{B,j}^{Loss}} = \frac{\widehat{V_{B,j}^{*,Win} - E_0\{\pi_{B,j}\}}}{(1-\widehat{\alpha_j})\left(\widehat{\beta_{B,j}} + \widehat{\beta_{G,j}} - 1\right)}. \tag{4}$$

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

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

5.1. Estimating the Decision Impact: The Event Study Approach

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

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

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.[29]

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

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

where the indicator, I_{jt}, equals one when the market reacts to the event on day T and equals zero otherwise.[30] 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 three-day event window, $t = [0, 2]$, to capture the stock market's reaction the day of the district-court decision and two days after.[31]

We repeat this estimation procedure for each event. This yields an estimate, $\widehat{\psi}$, of the change in market value due to the district court outcome for each firm ($\frac{V_B^{*,Win} - E_0\{\pi_B\}}{E_0\{\pi_B\}}$, in the case of a brand win). We refer to $\widehat{\psi}$ as the estimated cumulative abnormal return (CAR).

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

[30] 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 (e.g., Returns Procedure). However, the dummy variable approach is computationally easier to program and more robust in estimating standard errors (see Salinger 1992).

[31] We also use two-day and four-day windows and find nearly identical results. In addition, we compare the dummy variable results to the returns procedure using EVENTUS (available from Wharton Research Data Services), and the results are robust to both approaches.

5.2. Estimating Decision Probabilities

If investors have information about the probability the brand will win the case at the district and appellate court levels, they will incorporate this into their expectations. Hence, we must get consistent estimates of α, β_B and β_G for each case. For estimating the reversal rates β_B and β_G, we count cases not appealed as maintaining the district court decision.

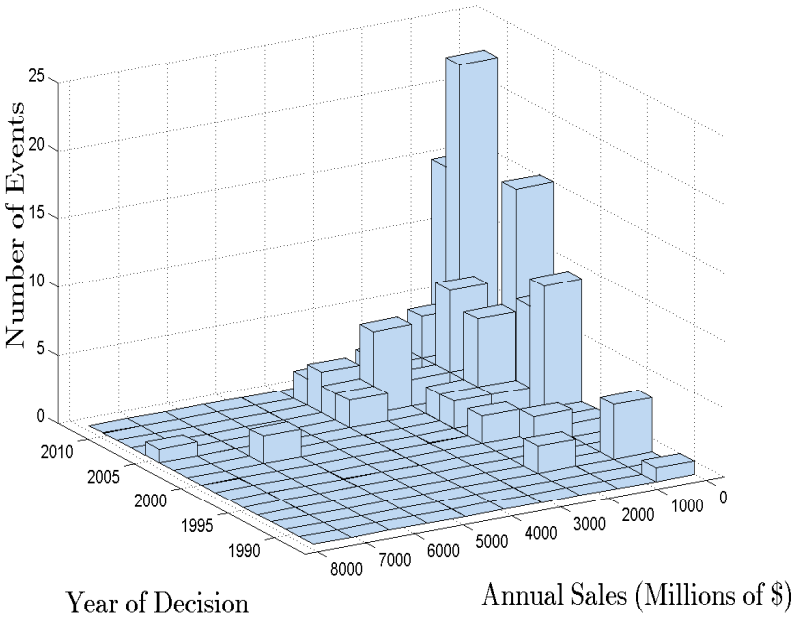
We consider three primary variables in the information set of investors: filing year, drug sales during the filing year, and whether there is an active-ingredient patent. We include year primarily because of the surge in settlements that followed the *Schering-Plough* decision. If cases with a lower probability of brand 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 upon how important the drug is. Finally, active-ingredient patents are virtually always infringed, so brands asserting such a patent tend to prevail in litigation more frequently (Hemphill and Sampat 2011, 2013). While we do not have strong priors regarding how affirmation rates of district court 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 estimator similar to that of Nevo et al. (2013).[32] There are two primary reasons. First, the distribution of events across time and sales, shown in Figure 6, is quite uneven. The low frequency of events early in the sample, and the highly skewed distribution of sales, make a bandwidth-adaptive estimator a good choice to estimate these functions. Second, it is not clear, *a priori*, how the three predictors of outcomes interact (i.e., higher sales drugs may experience a different probability of brand victories over time), which makes

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

the flexibility of a nonparametric approach attractive.

Figure 6: *Distribution of Events by Sales and Decision Year.*



Note: Annual Sales are reported for the litigation filing year, while Year of Decision corresponds to the district court decision year.

To demonstrate this approach, consider estimation of α_j. To define the nearest neighbors for a given decision, j, we first define the *closeness* of this event from every other event in terms of sales and time, d_{ij}, as

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

The arguments of the standard multivariate normal density, ϕ, are the difference 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 and the Cholesky decomposition of the joint variance-covariance matrix.[33]

[33]Since we use the distances only to rank observations rather than calculate weighted averages, a bandwidth normalization leaves our estimates unchanged.

If case j involved an active-ingredient patent ($AI_j = 1$), we then estimate α_j as

$$\alpha_j = \frac{\sum_i 1\left[d_{ij} \geq d_j^N, AI_j = 1\right] 1\left[BrandWin_j = 1\right]}{\sum_i 1\left[d_{ij} \geq d_j^N, AI_j = 1\right]}. \tag{7}$$

The indicator, $1\left[d_{ij} \geq d_j^N, AI_j = 1\right]$, serves to reduce the sample used in estimation to a fixed number of nearest neighbors for cases involving an active-ingredient patent. That is, d_j^N is the N^{th} furthest case from j, or the cutoff value for inclusion in the calculation. We set $N = 15$, but find our estimates to be robust to varying N. 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 now $1\left[d_{ij} \geq d_j^N, AI_j = 0\right]$. We estimate β_{Bj} and β_{Gj} for each j similarly.

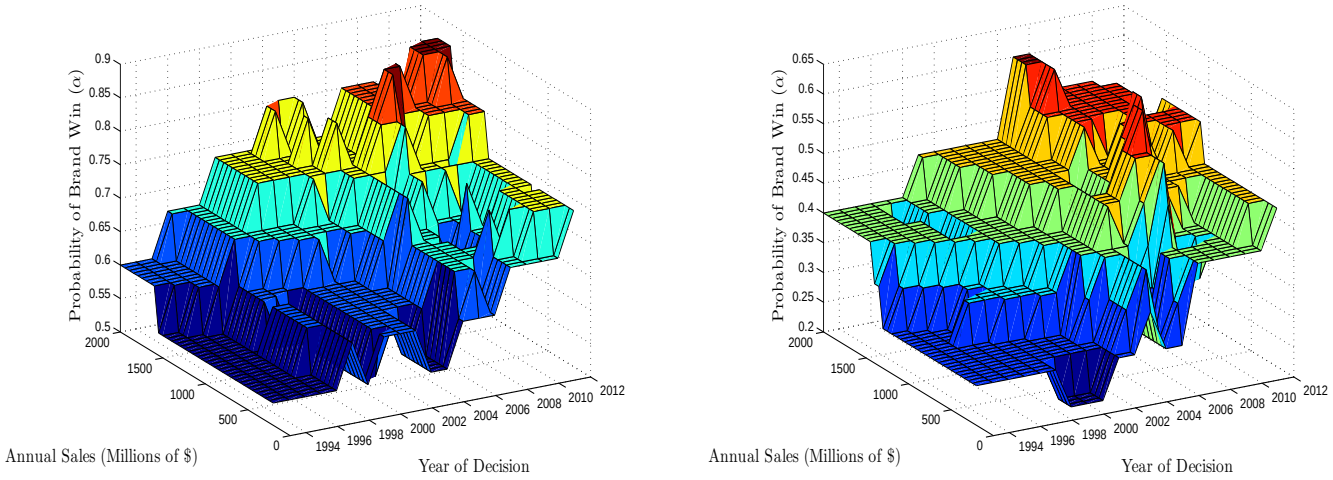
6. Results

Table 4 reports the main results. The event-study results are in the top section. The average CARs are 2.08% for brand wins, -2.43% for brand losses, 3.13% for generic wins and -1.63% for generic losses. All estimates are statistically significant and suggest that firm value varies by about 4.5 percentage points depending upon whether the firm wins or loses.

Estimated means and associated standard errors of the decision probabilities are shown in the middle section of Table 4.[34] The average values of α, β_B, and β_G are similar to averages that can be constructed from Table 2. The surfaces in Figures 7(a)-(b) illustrate more detail of the nearest-neighbor estimation for α. Though the surfaces are not strictly monotonic, there are clear trends whereby the probability of a brand win in the district court case, α, is higher for both higher-sales drugs and during more recent years. In comparing the (a) and (b) panels, we see that the presence of an active-ingredient patent raises the overall probability of a brand win by between 0.20 and 0.35. Analogous surfaces of estimates of β_B and β_G (not shown) indicate that none of the three predictors induce substantial variation in the probability of a given outcome.

[34]Standard errors are calculated using jackknife resampling.

Figure 7: *Probability Brand Win, Sales and Year.*



(a) *Active-Ingredient Patent.*

(b) *No Active-Ingredient Patent*

Note: This figure reflects the estimated probabilities of a brand win, α, for each event using information on whether an active-ingredient patent is involved, sales, and date of the decision.

For each event j, we follow (4) and use CAR_j and the estimates of $\alpha_j, \beta_{B,j}$ and $\beta_{G,j}$ to estimate (for a firm of type $i \in \{B, G\}$) the dispute value, $V_{i,j}^{Win} - V_{i,j}^{Loss}$. For brand events, the mean value of deterrence is about \$4.6 billion. For generic events, the mean value of entry is about \$236.8 million. Hence, the mean value of entry is about 5.1% of the mean value of deterrence, highlighting the strongly asymmetric stakes in Paragraph (iv) cases. The distributions of estimated dispute values are right-skewed, as shown by the lower median vales of deterrence and entry (\$355.9 million and \$79.4 million, respectively).

The value of deterrence is closely linked to the brand's expected flow monopoly profit minus its expected flow oligopoly profit, in the market for the drug in question and for the remaining time that the relevant patents are in force. This exclusion value also gives us a way to estimate the average value of ironclad versions of the patents covering the drugs. For the 82 brand events used to estimate the value of deterrence, the average number of patents is 1.87 per event. Hence, the average patent value for these observations is about \$2.5 billion. This is an important measure of perhaps the most-valuable class of patents in the world.

The value of entry is the generic's 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. Notably, the value of entry is 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, $236.8 million, is similar in size to the total payments in early (1990s) reverse settlements, which typically stipulated that the generic stay out of the market until patent expiry.[35]

In pharmaceutical markets, drug sales are the main determinant of flow profits (Berndt, Kyle and Ling 2003; Reiffen and Ward 2005). Hence, if our model accurately captures changes to firm profits, the values of deterrence and entry should be positively correlated with the relevant drug's sales. To aid interpretation of our results, we regress (estimated) dispute values on recent (pre-litigation) sales of the drug subject to Paragraph (iv) litigation. 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.[36]

The results are shown for brands (columns (1)-(2)) and generics (columns (3)-(4)) in Table 5. Columns (2) and (4) control for timing relative to the *Schering-Plough* decision, which is clearly significant and which we discuss in more detail below.[37] Sales explain a significant amount of the variation in dispute values, and (as seen by comparing the R-squared values) explains more for brand events than for generic events.

A one-dollar increase in a drug's sales is associated with a $7.19 increase in the value of deterrence. Hence, if current sales closely reflect the brand firm's profit as a monopolist, then our model predicts that the value of deterrence is worth just slightly more, on average,

[35]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, footnote 114). These dollar figures are not adjusted for inflation.

[36]Sales are used only as one part of calculating expected decision probabilities. These probabilities enter the estimation routine non-linearly, and adjust the decision impacts of brands and generics in opposite ways to estimate the values of deterrence and entry.

[37]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.

than current profit times remaining patent life. A one-dollar increase in a drug's sales is associated with a $0.19 increase in the value of entry (columns (2) and (4), respectively). Hence, the value of entry is worth just about 40 percent of 180 days worth of sales.[38] 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 4, we use Equation (3), along with average dispute values and average decision probabilities, to estimate an average bargaining surplus of just under $2 billion. This reflects elimination of all legal uncertainty and full exclusion of generic competition.

Under partial exclusion, where entry is delayed but the generic 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, because the settlement increases the probability that the generic will be able to enjoy it (Hemphill 2009). Specifically, this probability rises by the probability that the brand wins the case. Using Equation (3), average dispute values, and average decision probabilities, we find that generic firms may gain as much as $132 million from retained exclusivity.[39]

More interesting is the effect of the *Schering-Plough* decision. Table 6 reports estimates of average CARs, and average and median values of deterrence and entry, in the periods before the first *Schering-Plough* decision (the *pre-SP period*) and after it (the *post-SP period*). Despite the very small number of observations in the pre-SP period, we nonetheless identify large average CARs for all four categories of events and find three of the estimates to be statistically significant. The differences in the average CARs for wins and losses are more than 5.5 percentage points for brands and nearly 11 percentage points for generics. Brands

[38] 40 percent the fraction of a year that the 180 DE represents yields 0.197, or 0.4*(180/365).

[39] Because our analysis uses just cases that reached at least one litigation decision, one might be concerned that this yields cases where the implied value of retained exclusivity is either abnormally low or high. However, cases that tend to complete litigation have low brand drug sales and a high probability of brand victory, while retained exclusivity is most valuable when drug sales are high and there is a high probability of brand victory.

win at the district court level about 34% of the time, and just 40% of the time overall. For these events, we estimate an average value of deterrence of nearly $8.8 billion and an average value of entry of about $532 million. The value of entry is about 6.1% of the value of deterrence. The estimated S_{Barg} is about $4.9 billion.

During the post-SP period, our estimates suggest that average stakes are far lower in Paragraph (iv) cases. Again, three of the four average CAR estimates are statistically significant, with generic 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-SP period. Brands win at the district court level, and overall, about 60% of the time, a much higher probability than in the pre-SP period. This is precisely what would occur if cases with weaker patents (i.e., lower γ) tend to settle more often than cases with stronger patents.

We estimate an average value of deterrence of about $3.5 billion in the post-SP period, which is about 60% lower than the estimated value of deterrence in the pre-SP period. We estimate an average value of entry of $173.5 million, which is about 67% lower than the estimated value of entry in the pre-SP period. The value of entry is about 4.9% of the value of deterrence, similar to but lower than the ratio for the pre-SP period. This is consistent with a more permissive environment for settlements, causing cases with higher stakes to tend to settle more often than cases with lower stakes.

We estimate S_{Barg} is about $1.3 billion for the post-SP period, nearly 73% lower than in the pre-SP period. If we recall that S_{Barg} is a lower bound for the extra consumer surplus gained by the Paragraph (iv) ANDA process, our results suggest that Paragraph (iv) cases during the post-SP period are gaining far less surplus than cases gained in the pre-SP period. Hence, pay-for-delay settlements lead to a lower (per case) level of allocative efficiency in the US pharmaceutical industry.

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 firms in Paragraph (iv) ANDA cases value deterring entry by far more than generic firms value the right to enter. This suggests that firms that settle their disputes rather than litigate would realize sizable additional surpluses. We estimate the average bargaining surplus to be just under $2 billion per Paragraph (iv) case.

We also provide evidence that pay-for-delay settlements reduce allocative efficiency. In Paragraph (iv) litigation decisions after the closely-watched *Schering-Plough* decision in 2002, estimated bargaining surpluses are far smaller than for cases prior to this decision. This suggests that high-bargaining-surplus cases select into settlement, reducing the average allocative-efficiency surpluses delivered by Paragraph (iv) litigation.

We are optimistic that our results will be useful for informing litigation and public policy. Our estimates of the value of entry, 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 interpreted as purchasing *some* delay (e.g., Edlin et al. 2015). We show that the value of retained exclusivity itself may be "large," but it depends on the probability that the generic would win the Paragraph (iv) case. As 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.

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 settlement (Willig and Bigelow 2004; Harris et al. 2014), this represents an important avenue for future research.

Despite our findings, it is clear that the Hatch-Waxman Act has achieved considerable allocative efficiency gains by stimulating generic entry. IMS Health data show that the generic dispensing ratio (percentage of generic to total prescriptions) reached 50% in 1999 and 84% in 2012, compared to 18.6% in 1984 (Levy 1999; IMS 2013). GPhA (2013) estimate savings from generic prescribing in 2012 alone to be over $217 billion.

Finally, we cannot say much about dynamic efficiency. If the increased rents earned by firms due to pay-for-delay settlements lead to a surge in new drugs with significant impact on quality of life, then such settlements could enhance overall efficiency. However, given the time required to develop new drugs, it is too early to expect such a surge to materialize. This is a fruitful area for future research and we look forward to further progress.

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Table 1: *Pharmaceutical Patent Litigation Data Sources*

	Time Frame	**Key Characteristics**
Main Sources		
Drug Patents *FDA Orange Book*	1984-2010	Comprehensive list of patents for FDA-approved drugs.
Lawsuits Filed *Derwent Litalert*	1984-2010	Covers 50-70% of all US patent lawsuits (most years), includes filing dates, settled cases.
Trial Decisions *LexisNexis*	1984-2012	Complete opinions include decisions, decision dates, firms, Paragraph (iv) info, patent numbers.
Additional Sources		
ANDA Filings *FDA*	3/2/2004-present	Comprehensive list of ANDAs, including non Paragraph (iv) cases.
FTC (2002)	1984-2000	Comprehensive list of Paragraph (iv) cases 1992-2000, includes drug and firm names.
P-IV ANDA Approvals *FDA*	5/5/1987-7/24/2009	Sample of letters to generic firms regarding successful Paragraph (iv) ANDAs, includes first filer, patent type and p-III certification.

Note: This table includes all sources for data used in this paper. When possible, we cross check all sources and identify the earliest Paragraph (iv) filing per drug to identify the appropriate generic firm.

Table 2: *Descriptive Statistics at Drug-Observation Level, Paragraph (iv) Cases Main Sample, 1988-2012*

Lawsuits Litigated to a Decision	N	%
Total	93	
Brand Win	53	56.99
Brand Win DC		
Appealed	36	67.92
District Decision Reversed	5	9.43
Brand Loss DC		
Appealed	31	77.50
District Decision Reversed	6	15.00
Additional Statistics	Mean	SD
Drug Sales (millions)	1,020.69	1,277.42
Number of Patents	1.87	1.34
At Least One Active-Ingredient Patent	0.54	0.50
Drug Had NCE Status Prior to Litigation	0.82	0.39
Two Public Firms	0.61	0.49
Time Relative to district court Decision		
Youngest Patent-Life Left (years)	6.30	3.93
Oldest Patent-Life Left (years)	5.50	3.73
Since NCE Expired (years)	5.28	2.83

Note: These statistics reflect a set of Paragraph (iv) litigations constructed from a variety of sources (see Table 1), as well as patent statistics from USPTO data and drug sales statistics from IMS data. Out of the total of 159 Paragraph (iv) lawsuits, 93 reach a decision and survive the selection criteria we apply in constructing our main sample. All "Additional Statistics" are for this main sample of decided cases, except for the Since NCE Expired statistics, which are restricted to NCE drugs (76). The Drug Sales statistics are based upon the year the litigation begins, while the Blockbuster statistics are based upon whether the drug ever achieved top-25 sales.

Table 3: *Descriptive Statistics, Paragraph (iv) Litigation Events Main Sample, Public Firms in Cases Litigated to a Decision (1988-2012)*

	Mean	SD
Brand Firm Events		
Drug Sales suit yr (millions)	985.97	1,297.38
Firm Employees (thousands)*	63.94	37.62
Firm Revenue (billions)*	29.25	19.51
Number of Patents	1.85	1.35
At Least One Active-Ingredient Patent	0.51	0.50
Brand Wins	0.55	0.50
Appeal	0.71	0.46
Affirmed if Appealed	0.60	0.49
Number of Events	**82**	
Number of Unique Firms	**26**	
Generic Firm Events		
Drug Sales suit yr (millions)	1,100.46	1,164.47
Firm Employees (thousands)*	22.59	27.62
Firm Revenue (billions)*	8.44	11.84
Number of Patents	2.02	1.49
At Least One Active-Ingredient Patent	0.54	0.50
Generic Wins	0.41	0.50
Appeal	0.75	0.44
Affirmed if Appealed	0.63	0.49
Number of Events	**68**	
Number of Unique Firms	**18**	

Note: These statistics reflect a set of Paragraph (iv) litigations constructed from a variety of sources (see Table 1), as well as patent statistics from USPTO data, drug sales statistics from IMS data, and firm employment and revenue from COMPUSTAT. All statistics reflect the full set of events, except for those marked with a star (*)—we lack information for 2 of the brand observations 5 of the generic observations. The firm employment and revenue statistics are based upon the year of the district court decision. The Drug Sales statistics are based upon the year the litigation begins, while the Blockbuster statistics are based upon whether the drug ever achieved top-25 sales.

Table 4: *Estimation Results*

	Brand Firms (i=B)		**Generic Firms (i=G)**
Event Study	N=82		N=68
Mean CAR (Brand Wins)	2.08%***		-1.63%**
	(0.62%)		(0.69%)
Mean CAR (Brand Losses)	-2.43%**		3.13%***
	(1.00%)		(1.00%)
Decision Probability Estimation			
Mean α		0.551	
		(0.059)	
Mean β_B		0.894	
		(0.049)	
Mean β_G		0.855	
		(0.063)	
Final Estimates	N=82		N=68
Mean Dispute Value ($V_i^{Win} - V_i^{Loss}$)	\$4,616.8		\$236.8
Median Dispute Value ($V_i^{Win} - V_i^{Loss}$)	\$355.9		\$79.4
Mean Bargaining Surplus		\$1,960.5	

Note: This table shows the results of an event study estimating equation (5) for the main sample, and of estimates of decision probabilities using (7) and analogous formulas for β_B and β_G. All values in parentheses are standard errors. Numbers of observations used in the event study: brand wins N=45; brand losses N=37; generic wins N=28; generic losses N=40. For the average CAR estimates, we report results from a two-sided test of the null hypothesis that the average CAR is zero. Standard errors for the average CAR estimates are calculated assuming independence among events. Asterisks denote significance levels: 1%(***); 5%(**); 10%(*). The total N for the decision probability estimates is smaller than the total number of events because the probability estimates are constructed at the case level. Standard errors for the decision probabilities are calculated using jackknife resampling. The estimate of the mean bargaining surplus applies formula (3), $S_{Barg} = [\alpha(1-\beta_B) + (1-\alpha)\beta_G]\left[\left(V_B^{Win} - V_B^{Loss}\right) - \left(V_G^{Win} - V_G^{Loss}\right)\right]$, using averages reported in this table.

Table 5: *Dispute Values Versus Brand Sales*

	Brands		**Generics**	
	(1)	**(2)**	**(1)**	**(2)**
C	-2071.00	4435.55	56.32	399.32
	(1827.86)	(3157.15)	(140.66)	(246.81)
sales	6.77***	7.19***	0.16*	0.19**
	(1.13)	(1.10)	(0.09)	(0.09)
post-Schering-Plough		-8734.33**		-447.74*
		(3508.33)		(266.45)
N	82	82	68	68
R^2	0.311	0.361	0.050	0.089

Note: The results in column (1) reflect linear regressions of the form $V_i^{Win} - V_i^{Loss} = C + \beta_1 * sales + \beta_2 * post - Schering - Plough + \epsilon$. Sales is for the year the lawsuit commenced, and *post-Schering-Plough* is a dummy variable that takes the value of 1 if the decision occurs after the 2002 *Schering-Plough* decision. All calculations are performed in STATA. Standard errors are unadjusted. The following denote statistical significance: *** 1% level, ** 5% level, * 10% level.

Table 6: *Estimation Results:* **Pre- and Post-*Schering-Plough***

	Brand Firms (i=B)	**Generic Firms (i=G)**
Pre-*Schering-Plough vs. FTC (2002)*		
Event Study	N=17	N=12
Mean CAR (Brand Wins)	2.98%*	-6.93%**
	(1.42%)	(2.55%)
Mean CAR (Brand Losses)	-2.59%**	3.79%
	(0.96%)	(2.24%)
Decision Probability Estimation		
Mean α	0.345	
	(0.098)	
Mean β_B	0.830	
	(0.101)	
Mean β_G	0.823	
	(0.113)	
Final Estimates	N=17	N=12
Mean Dispute Value($V_i^{Win} - V_i^{Loss}$)	\$8,759.8	\$532.0
Median Dispute Value ($V_i^{Win} - V_i^{Loss}$)	\$2,207.5	\$440.2
Mean Bargaining Surplus	\$4,928.5	
Post-*Schering-Plough vs. FTC (2002)*		
Event Study	N=65	N=56
Mean CAR (Brand Wins)	1.91%***	-0.70%
	(0.69%)	(0.56%)
Mean CAR (Brand Losses)	-2.37%*	2.95%**
	(1.33%)	(1.14%)
Decision Probability Estimation		
Mean α	0.600	
	(0.064)	
Mean β_B	0.909	
	(0.043)	
Mean β_G	0.863	
	(0.064)	
Final Estimates	N=65	N=56
Mean Dispute Value($V_i^{Win} - V_i^{Loss}$)	\$3,533.3	\$173.5
Median Dispute Value ($V_i^{Win} - V_i^{Loss}$)	\$201.9	\$47.1
Mean Bargaining Surplus	\$1,337.2	

Note: Estimation and statistical inference in this Table use the same techniques as in the construction of Table 4. Numbers of observations used in the pre-SP event study: brand wins N=7; brand losses N=10; generic wins N=6; generic losses N=6. Numbers of observations used in the post-SP event study: brand wins N=38; brand losses N=27; generic wins N=22; generic losses N=34.