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

Ruben Jacobo-Rubio∗  John L. Turner†  Jonathan W. Williams‡

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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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∗Department of Economics, University of Georgia, ruben1@uga.edu.
†Department of Economics, University of Georgia, jltturner@uga.edu.
‡Department of Economics, University of Georgia, jonwms@uga.edu.
1. Introduction

The Drug Price Competition and Patent Term Restoration Act, passed by the US Congress in 1984 and commonly referred to as the 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). One of its key provisions, the Paragraph (iv) Abbreviated New Drug Application (ANDA) certification process, creates a very specific role for patent litigation in striking this balance. Specifically, the US Food and Drug Administration (in implementing the Paragraph (iv) ANDA process) 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 successful generic challenger 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 weaker patents that do not hold up in court and later against stronger patents that do hold up in court (Hemphill 2006). In recent years, however, brand and generic firms have settled Paragraph (iv) litigation out of court with increasing frequency (FTC 2010). Such settlements often involve delayed generic entry and payments from the brand firm to the generic, characteristics that economic theory suggests are anti-competitive (Shapiro 2003; Bulow 2004). This suggests that incentives in the US pharmaceutical industry may have drifted from the balance sought by the Hatch-Waxman Act.

We develop a novel framework, using the probabilistic nature of Paragraph (iv) litigation decisions, to shed light on the distribution of surplus in the US pharmaceutical industry during the Hatch-Waxman era. Specifically, we use an event study of 93 Paragraph (iv) patent infringement suits during 1988-2012 to produce statistics on changes in publicly-traded brand and generic firm values following district court decisions. Separately, we estimate ex ante
probabilities of district court wins and losses and appellate reversals. Combining these estimates with a simple theoretical model of litigation, we estimate the size of the stakes in Paragraph (iv) disputes for brand and generic firms.

With these estimates, 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). Hence, the value of entry is only about five percent of the value of deterrence. This gap between the value of entry and deterrence suggests that, by settling their disputes efficiently (for themselves) rather than litigating, firms would realize sizable additional surpluses. Assuming that, under settlement, firms would bargain prior to litigation and would 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. 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.¹ Hence, this number indexes what the Paragraph (iv) ANDA process gains, in allocative efficiency, by using patent litigation to strike its balance.

Second, we estimate intertemporal changes in average dispute values and implied bargaining surpluses, to study the effect of a more permissive environment for so-called “pay-for-delay” settlements. On June 27, 2002, an Administrative Law Judge ruled in favor of such a settlement in the closely-watched case Schering-Plough vs. FTC (40 LEXIS 244 [FTC 2002]). This decision, eventually upheld by the 11th Circuit Court of Appeals (402 F.3d 1056 [11th Cir. 2005]), led to a surge in this type of settlement (FTC 2010). With an increased incidence of settlements, it is important to determine whether the remaining cases that do not settle maintain the same characteristics of cases proceeding to trial before the surge in settlements. In our model, the bargaining surplus (net of transactions costs) is the product of the probability the brand firm ultimately loses the litigation and the difference in the

¹For 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.
values of entry and deterrence. Hence, in an environment that permits greater scope in the terms of potential settlements, we should expect the cases that do go to trial to have a higher probability of brand victory, a smaller gap between the value of deterrence and entry, and a lower overall bargaining surplus.

When we divide our sample into cases before and after the 2002 *Schering-Plough* decision, 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 cases decided prior to *Schering-Plough*. 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, settlements strongly reduce the (per-case) average allocative-efficiency surplus delivered by Paragraph (iv) litigation.

These results are important primarily because the courts have yet to clearly delineate the antitrust implications of reverse payments. Having declined to hear *Schering-Plough*, the Supreme Court took on a later case involving a pay-for-delay settlement over AndroGel. In a 5-to-3 decision on June 17, 2013 in *FTC vs. Actavis et al.* (133 US 2223 [2013]), the Court remanded the case and instituted a “rule of reason” for courts to apply to such cases (Hovenkamp forthcoming). They instructed the 11th Circuit Court of Appeals to hear Federal Trade Commission (FTC) antitrust arguments for the AndroGel case in particular, and paved the way for the FTC to make such arguments in other cases.

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, Chatterjee and Higgins (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.

While a number of scholars have debated the anti-competitive nature of pay-for-delay settlements, there has been little empirical work. In one recent exception, Drake, Starr and McGuire (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. These results, which strongly suggest that pay-for-delay settlements secure large bargaining surpluses, are consistent with our finding of decreased bargaining surpluses, after the Schering-Plough decision, in cases that instead proceed to trial.

We also contribute to the broader 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, Roberts and Sweeting 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 to the US pharmaceutical industry demonstrates how a simple event study framework, along with a limited set of assumptions, can be used to exploit patent litigation as a source of randomness in the entry process to infer the value of entry and deterrence and provide insights into firms’ incentives.

2For arguments that pay-for-delay settlements are both harmful and are unanticipated by the Hatch-Waxman Act, see Hovenkamp, Janis and Lemley (2003), Hemphill (2006, 2009), Elhauge and Krueger (2012) and Edlin, Hemphill, Hovenkamp and Shapiro (2013). For arguments that pay-for-delay settlements are not anti-competitive, see Willig and Bigelow (2004), Yu and Chatterji (2011) and Harris, Murphy, Willig and Wright (2014).
to settle disputes.

2. Innovation and Entry in the US Pharmaceutical Industry

For a brand firm, drug development is long and costly. It begins when a researcher identifies a new molecule. After testing to determine if the molecule is biologically active and to identify what it does (typically in animals), the 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.\(^3\) 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, formulations, methods of use, devices and processes as they develop these innovations. Outside of pharmaceuticals, patents do not generally block entry. Rather, they grant their owners the right to sue for damages, after entry, from firms that infringe. Unless a patent is ironclad, a potential entrant may decide it is worth risking damages in an infringement suit. Within the US pharmaceutical industry, however, the FDA explicitly uses patents to block entry as part of its regulation under the Hatch-Waxman Act of 1984 (Korn, Lietzan and Shaw 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 produce its version of the drug without infringing any valid brand-firm patent. Hence, for a generic firm to compete in the brand firm’s market for a particular drug, either the generic applicant must wait for expiration of the patents or challenge them before they expire. 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.

\(^3\)Trials follow a strict, costly three-phase process. See Bradford et al. (2013, section 2.1) for further details.
In the most common scenario, the FDA grants a five-year new chemical entity (NCE) exclusivity to a pioneer drug (whose active ingredient has never been marketed before). During the NCE exclusivity period, the firm does not even need patent protection because the FDA will not approve any other firm to sell the drug. Once this exclusivity expires, however, the status quo is a monopoly but other firms may seek to enter. The Hatch-Waxman Act encourages Paragraph (iv) challenges by granting a 180-day marketing exclusivity to the first generic applicant to successfully obtain ANDA approval.\(^4\) To earn this exclusivity, a successful entrant must provide in its ANDA to the FDA:\(^5\)

(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

\(^{4}\)Sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the FDCA regulate the 180 DE. There are other types of exclusivities, including the three-year new indication (NI), the three-year new drug formulation (NDF), the seven-year orphan drug (ODE) and the six-month pediatric exclusivity (PED). During these time periods warranted by the respective exclusivity, the FDA will not approve another firm to sell the covered product. However, for the NI and NDF exclusivities, there is a significant difference in terms of the scope of monopoly a brand firm enjoys, and the PED exclusivity lasts just six months. See Voet (2008).

\(^{5}\)Federal Food, Drug, and Cosmetic Act (21 USC. 355); Section 505; Subsection (j)(2)(A)(vii)(IV).
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. As long as the generic is not simultaneously seeking Paragraph (iv) certification with respect to another patent, Paragraph (i)-(iii) certifications do not lead to patent litigation and the FDA typically approves generic entry. When a firm pursues entry under Paragraph (iv), however, the FDA temporarily blocks entry as soon as the brand firm initiates a patent infringement lawsuit in response to the certification.

The FDA Orange Book lists three basic types of patents: active ingredient, formulation and method of use.\(^6\) Under Section (B) above, the generic 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. This does not prevent the brand firm from suing the generic for patent infringement, but it does mean that the FDA will not base its decision to grant an ANDA, and entry, upon the outcome of litigation over this patent.

For each of the other types of patents, the FDA uses the outcome of litigation under Paragraph (iv) to determine whether to grant an ANDA and entry. Active ingredients in pharmaceutical patents are typically claimed by their chemical structure. To receive an ANDA, 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. 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 submitting the ANDA letter to the FDA, the generic serves notice to the brand firm, typically within 20 days.\(^7\) The brand firm has 45 days, from the date it receives notice of the ANDA filing, to initiate a lawsuit. If the brand firm sues within this window, the


\(^7\)Not later than 20 days after the date of the postmark or if the certification is in an amendment at the time at which the applicant submits the amendment or regardless of whether the applicant has already given notice with respect to another such certification. Subsection (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 USC. 355).
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). The FTC reports that the FDA usually takes over 25 months to approve the ANDA even when no litigation occurs. By filing the first Paragraph (iv) ANDA, a generic firm can prevent 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).

To prove invalidity, the generic firm must show that the patent does not satisfy the statutory requirements of novelty, utility, and non-obviousness. Patents can also be invalidated if the brand firm deceived the Patent Office during the application process (inequitable conduct). To prove non-infringement, a challenger must show that its product’s specifications fall outside the scope of the patents’ claims. Because decisions on validity and infringement are made by humans—typically a judge in a Paragraph (iv) case—they are random.

Brand and generic firms sometimes settle their dispute rather than go through a Paragraph (iv) litigation. Typically, such settlements specify a negotiated generic entry date and royalties or other payments made between the firms. Because settlements often maintain the status quo monopoly beyond when it would end if the generic were to win the Paragraph (iv) case, and because the settlements may involve some form of payment from the brand to the generic (often called a “reverse” payment), they raise antitrust concerns (Shapiro 2003; Bulow 2004). Although such pay-for-delay settlements date to at least 1993 (Drake et al. 2014; Hemphill 2009), the first major FTC challenge to one came in Schering-Plough vs. 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.

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).

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.

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.

Patent infringement suits are heard in federal district courts throughout the United States. Once a decision is reached, a written opinion is published in the Federal Register. If a party to litigation appeals the district court decision, the appeal is heard by the Court of Appeals for the Federal Circuit, which has handled appeals of US patent cases since its establishment in 1982.
FTC (40 LEXIS 244 [FTC 2002]). On June 27, 2002, an Administrative Law Judge upheld a pay-for-delay settlement over the drug K-Dur. Although the decision was appealed and reversed by the full Commission, the 11th Circuit Court of Appeals eventually upheld the settlement [Schering-Plough vs. FTC, 402 F.3d 1056 (11th Cir. 2005)].

The Supreme Court declined to hear the Schering-Plough case. Since then, there has been a surge in pay-for-delay settlements (FTC 2010). Still, the FTC has stated continuing opposition to such settlements and has selectively challenged them in court.12 In a recent key decision involving a reverse settlement over the drug Androgel [FTC vs. Actavis, Inc. (133 US 2223 [2013]), the Supreme Court remanded the case back to the 11th Circuit Court of Appeals, and instituted a type of “rule of reason” for courts to apply to such cases. Essentially, this rule instructs courts to apply antitrust scrutiny, but not a per se violation rule, whenever a settlement includes a “large, unexplained” payment from the brand to the generic (Hovenkamp forthcoming). This paves the way for the FTC to make antitrust arguments in other cases.13

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

Figure 1 shows a game tree mapping the outcomes of litigation. In the pre-litigation

12In addition to the FTC, other groups representing payers (e.g., consumer groups, insurance companies and state-funded payers) have also challenged these settlements.

13Note that some cases put on hold until the Supreme Court’s ruling have been revisited and their settlements have been upheld. Some of these revisited cases include Re: Lipitor Antitrust, in September 2013 (2013-2 Trade Cas. (CCH) P78,512); and Re: Lamictal Antitrust, in January 2014 (2014-1 Trade Cas. (CCH) P78,656).
Figure 1: A Model of Paragraph (iv) Patent Litigation

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

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 district court level. Let $\alpha$ 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 $\beta_B$ be the probability a brand win is upheld and let $\beta_G$ be the probability that a generic win is upheld.

To conserve on notation, we do not explicitly model a decision to appeal. Implicitly, $\beta_B$
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. Moreover, we do not model the timing settlements which can occur either before or after a district court decision.

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

- **Brand Wins:** $\pi_B = V_{B,\text{Win}}$  $\pi_G = V_{G,\text{Loss}}$
- **Generic Wins:** $\pi_B = V_{B,\text{Loss}}$  $\pi_G = V_{G,\text{Win}}$.

We assume joint profits are higher when the brand wins and the monopoly is preserved, $V_{B,\text{Win}} + V_{G,\text{Lose}} \geq V_{B,\text{Lose}} + V_{G,\text{Win}}$.

These payoffs are realized only at the conclusion of the dispute. The *dispute values*, $V_{i,\text{Win}} - V_{i,\text{Loss}}$, or stakes in the case, are not necessarily symmetric to the brand and generic. Denote $V_{B,\text{Win}} - V_{B,\text{Loss}}$ as the *value of deterrence* and $V_{G,\text{Win}} - V_{G,\text{Loss}}$ as the *value of entry*.

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 just upon hearing the district court decision as:

- **Brand Wins District Court Stage:** $E_1\{\pi_B\} = V_{B,\text{Win}}^*$  $E_1\{\pi_G\} = V_{G,\text{Loss}}^*$
- **Generic Wins District Court Stage:** $E_1\{\pi_B\} = V_{B,\text{Loss}}^*$  $E_1\{\pi_G\} = V_{G,\text{Win}}^*$.

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

$V_{B,\text{Win}}^* = \beta_B V_{B,\text{Win}} + (1 - \beta_B) V_{\text{Loss}}$  
$V_{B,\text{Loss}}^* = \beta_G V_{\text{Lose}} + (1 - \beta_G) V_{B,\text{Win}}$.

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

$E_0\{\pi_B\} = \alpha V_{B,\text{Win}}^* + (1 - \alpha) V_{B,\text{Loss}}^*$.
Rearranging terms, we can write

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

Denote \( V_{i}^{*,\text{Win}} - E_0\{\pi_i}\) and \( V_{i}^{*,\text{Loss}} - E_0\{\pi_i\}\) as the decision impact of a win and a loss, respectively, for a firm of type \( i \). 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. The decision impacts relate to the dispute values in the following ways:

**Brand Win:**

Effect on B: \( V_{B}^{*,\text{Win}} - E_0\{\pi_B\} = (1 - \alpha) (\beta_B + \beta_G - 1) \left( V_{B}^{\text{Win}} - V_{B}^{\text{Lose}} \right) \)

Effect on G: \( V_{G}^{*,\text{Loss}} - E_0\{\pi_G\} = - (1 - \alpha) (\beta_B + \beta_G - 1) \left( V_{G}^{\text{Win}} - V_{G}^{\text{Lose}} \right) \)

**Brand Loss:**

Effect on B: \( V_{B}^{*,\text{Loss}} - E_0\{\pi_B\} = -\alpha (\beta_B + \beta_G - 1) \left( V_{B}^{\text{Win}} - V_{B}^{\text{Lose}} \right) \)

Effect on G: \( V_{G}^{*,\text{Win}} - E_0\{\pi_G\} = \alpha (\beta_B + \beta_G - 1) \left( V_{G}^{\text{Win}} - V_{G}^{\text{Lose}} \right) \)

These equations form the basis of our methodology for estimating the value of deterrence and the value of entry. With consistent estimates of \( V_{B}^{*,\text{Win}} - E_0\{\pi_B\} \), \( \alpha \), \( \beta_B \), and \( \beta_G \), we can use (2) to calculate consistent estimates of \( V_{B}^{\text{Win}} - V_{B}^{\text{Lose}} \).

The structure of the model can also be used to calculate the joint surplus at stake in a case.\(^{14}\) Assume that, prior to the start of litigation, brand and generic firms engage in Nash Bargaining to settle the dispute. Conditional on a settlement, the firms maximize the joint surplus by maintaining the brand monopoly and achieving joint profit \( V_{B}^{\text{Win}} + V_{G}^{\text{Lose}} \). If they settle, the firms increase total profit by the difference between this and the expected joint surplus under litigation. Thus, the bargaining surplus, net of litigation costs, is

\[ S_{\text{Bargain}} = [\alpha (1 - \beta_B) + (1 - \alpha)\beta_G] \left[ (V_{B}^{\text{Win}} - V_{B}^{\text{Lose}}) - (V_{G}^{\text{Win}} - V_{G}^{\text{Lose}}) \right] \tag{3} \]

\(^{14}\)We are not necessarily interested in how the surplus is divided between the firms, nor do we have data to infer this division, so we do not model it.
Let the net transaction cost of an efficient bargain, $C_{\text{Bargain}}$, incorporate any litigation costs. Then, firms settle if and only if $S_{\text{Bargain}} \geq C_{\text{Bargain}}$.\textsuperscript{15} We see that $S_{\text{Bargain}}$ 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 value of entry.

Risk-reduction is a prominent explanation for settlement of Paragraph (iv) cases (e.g., Willig and Bigelow 2004). If the firms in our model are risk-averse, then $S_{\text{Bargain}}$ would also include a positive risk premium because settlement removes all risk linked to litigation outcomes. Our model would then predict that firms would be more inclined to settle, the more risk-averse they are. We do not have data to test this prediction, but we do discuss the implications of risk aversion for our main results in the conclusion.

Now consider the welfare implications of settlement. To fix ideas, assume the only differences between a brand win and loss stem from competition in the drug market itself—namely, prices fall, quantity demanded rises and total profits fall with entry. Define welfare as follows:

\[
W(V^\text{Win}_B, V^\text{Loss}_G) = V^\text{Win}_B + V^\text{Loss}_G + CS(V^\text{Win}_B, V^\text{Loss}_G)
\]

\[
W(V^\text{Loss}_B, V^\text{Win}_G) = V^\text{Loss}_B + V^\text{Win}_G + CS(V^\text{Loss}_B, V^\text{Win}_G).
\]

Then, net of transaction and litigation costs, we have $W(\text{Settlement}) = W(V^\text{Win}_B, V^\text{Loss}_G)$ and, defining

\[
\gamma = [\alpha \beta_B + (1 - \alpha)(1 - \beta_G)]
\]

(4)

to be the probability the brand ultimately wins, we can write $W(\text{Litigation}) = \gamma W(V^\text{Win}_B, V^\text{Loss}_G) + (1 - \gamma)W(V^\text{Loss}_B, V^\text{Win}_G)$. Doing a bit of algebra, we have

\[
W(\text{Litigation}) - W(\text{Settlement}) = (1 - \gamma) \left\{ CS(V^\text{Loss}_B, V^\text{Win}_G) - CS(V^\text{Win}_B, V^\text{Loss}_G) \right\}
\]

\[
- \left\{ (V^\text{Win}_B - V^\text{Loss}_B) - (V^\text{Win}_G - V^\text{Loss}_G) \right\}
\]

If demand is perfectly inelastic, then $W(\text{Litigation}) = W(\text{Settlement})$ because lower prices under generic entry would merely transfer surplus from the firms to the consumers. If demand

\textsuperscript{15}If explicitly modeled, litigation costs from Paragraph (iv) litigation would enter negatively on the right-hand side of this expression, while expected costs from possible antitrust scrutiny of the settlement would enter positively on the right-hand side.
is downward-sloping but not perfectly inelastic, then generic entry would also yield higher sales volume, so that \( W(Litigation) > W(Settlement) \) and

\[
CS(V_B^{\text{Loss}}, V_G^{\text{Win}}) - CS(V_B^{\text{Win}}, V_G^{\text{Loss}}) > (V_B^{\text{Win}} - V_B^{\text{Lose}}) - (V_G^{\text{Win}} - V_G^{\text{Lose}}).
\]

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

### 4. Data

The centerpiece of our study is a novel, comprehensive collection of data on Paragraph (iv) patent litigation decisions from the establishment of the Hatch-Waxman Act until 2012. We first describe how we use multiple data sources to build this comprehensive set of decisions. Next, we describe the construction of our final sample used in the analysis and provide descriptive statistics.

#### 4.1. Paragraph (iv) Patent Filings and Litigation Decisions

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.\(^\text{16}\) 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.

\(^{16}\)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.
We match the Orange Book information to filed cases in the Derwent Litalert data. Available through WESTLAW, these data include firm names, litigated patents and filing dates for lawsuits during 1975-present. Federal courts report all patent lawsuits to the US Patent and Trademark Office, and the Derwent data are captured from these filings. It is appropriate to think of Derwent data as a random sample with a rate of sampling that varies across time, in most years covering 50-70% of all filed cases (Bessen, Neuhäusler, Turner and Williams 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 for written opinions in LexisNexis. This archive includes all opinions in district court cases recorded by the Federal Reporter. Opinions always include decisions, decision dates and courts, 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. LexisNexis records also reveal whether there is an appellate decision in the case. 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.\(^{17}\) The sample spans May 05, 1987-July 24, 2009, and includes 373 letters representing 200 brand drugs.\(^{18}\) 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 information on the outcomes of litigation. Comparing these letters to our Derwent and LexisNexis records, 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

\(^{17}\)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.

\(^{18}\)We combine different formulations and dosages under one drug name.
as an active-ingredient patent if it has at least one active-ingredient claim.\footnote{This is similar to Hemphill and Sampat (2011; 2013).} We check our patent classification accuracy by comparing, for all patents classified in the ANDA letters, our claims-based classifications versus the letter-based classifications. We misclassify just three out of 953 patents in the ANDA letters (0.3%).\footnote{They 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.}

Figure 2: \textit{Trends in Patents (OB) and Drug Sales (IMS) 1985-2010.}

![Graph showing trends in patents and drug sales](image)

\textbf{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 number of listed patents has increased substantially.

Patenting has increased overall, however, and the number of patents listed in the Orange Book closely tracks growth in sales from 1985 to 2010. Figure 2(b) shows annual sales (in 2010 US billions) for the top one thousand drugs according to IMS sales data over this period.
The rapid increase in sales during this period keeps the ratio of patents to sales fairly steady. The low of 4.8 patents per billion dollars of sales occurs in 1995, while the high of 8.7 occurs in 1985. Only in recent years has the ratio of patents to sales neared the highs observed in the 1980s.

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. “Year” is the year lawsuits are filed. The trend of “Cases Litigated, Not Decided” is mostly cases that settled rather than cases that are still pending.

Figure 3 shows the number of Paragraph (iv) litigations across time, based on when the lawsuit is initiated, along with the number of cases continuing to a decision.\(^{21}\) 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).

For the entire period (1985-2010), 301 generic Paragraph (iv) certifications are challenged in court by the incumbent brand firm. Of these challenges, 159 are litigated to a decision,\(^{21}\) 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. However, over 90% of cases whose litigations started before 2009 and were not decided represent settlements. For instance, FTC (2010, 2013) lists the number of reported annual settlements, and the numbers in that report very closely match the trend of “Cases Litigated, Not Decided.”
and these decisions take place between 1988 and 2012.\textsuperscript{22} Both the number of challenged cases and the number of decided cases count only the first Paragraph (iv) challenge per drug. We compare our data capture to FTC (2002), which includes a comprehensive list of drug and firm names for 104 Paragraph (iv) ANDAs during 1992-2000. Of these ANDAs, 75 are litigated to a district court decision. Our data construction misses just one of the 75 cases (we add this case).\textsuperscript{23} This gives us confidence that our complete data set includes the disproportionate majority of litigations initiated during 2000-2010 as well.

4.2. 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.\textsuperscript{24} We also drop six Paragraph (iv) cases where the decision did not pertain to the validity and/or infringement of the patents.\textsuperscript{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.\textsuperscript{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

\textsuperscript{22}For comparison purposes, in Figure 3 we use the year these decided cases are filed instead of when they are decided.

\textsuperscript{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.

\textsuperscript{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. A launch at risk arises when the generic firm could face infringement damages to the brand firm because the case has not been resolved. Only one case is eliminated due to a generic launching at risk (Neurontin).

\textsuperscript{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.

\textsuperscript{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.
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. This data source allows to also keep track of parent firms in the US and their foreign subsidiaries. We use SDC Platinum by Thomson Financial Securities Data to track mergers and acquisitions (M&A).\textsuperscript{27} COMPUSTAT and SDC also allow us to eliminate a small number of ambiguities between the name of the firm that appears in the litigation documents and the stock security that ultimately reflects the litigation outcome.

4.3. 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.

At each decision stage, we classify the decision 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 all district-court decisions, an appellate decision is also reached about 72% of the time. Generics win 5 out of 36 appeals of brand wins (about 14%), and achieve reversals in 5 of 53 district-court brand wins (about 9%). Brands win 6 out of 31 appeals of generic wins (about 19%), and achieve reversals in 6 of 40 district-court brand losses (about 15%).\textsuperscript{28}

In Table 2, we also summarize the time of patent expiration relative to when the district court issues its verdict. The last patent to expire (youngest patent) typically expires 6.2 years after the verdict is issued. The first patent (oldest patent) expires on average 5.0 years after the verdict.

\textsuperscript{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.

\textsuperscript{28}For reversal calculations, which are pertinent for estimating $\beta_B$ and $\beta_G$, we count cases not appealed as maintaining the district court decision.
after the verdict. Also, the verdict is reached 5.3 years after the expiration of the NCE exclusivity, or about ten years after first approval of the drug.

The 93 drug-cases in our sample yield 82 public-firm brand events and 68 public-firm generic events, where an event is a firm-decision pair (e.g., “Pfizer Win”). The reason the number of brand-events is not the same as the number of generic-events is because in a few cases only one of the two types of firms has either public information or information with no other overlapping events. In addition, Table 3 highlights characteristics of brand and generic events. Brand firms are three times as large as generic firms on average (by employees and by revenue). 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).

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

![Graph](image-url)

(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.

For the event-study approach to identify the value of generic entry and brand deterrence, we need an unpredictable component to district court decisions. That is, the district court’s decision must represent a sudden, exogenous release of information to investors regarding
Figure 5: Mean Return for Generic Firms Around District Court Decision

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.

generic entry. If the stock market aggregates this information efficiently (Fama 1970), then changes in firms’ stock prices will reflect the impact of the court’s decision on the firms’ valuations.

When a district court decides in favor of a brand firm, i.e., generic entry is deterred, the brand firm’s stock price should increase. Conversely, when generic entry is successful, the brand firm’s stock price should decrease. Figures 4(a) and 4(b) confirm this basic intuition for brand wins and losses, respectively. They show the average return and a 95% confidence interval, for the ten weeks prior to the day of the decision, the event window, and the subsequent ten weeks after these days. For both types of events, there is statistically significant variation in returns on the day following the event, but not otherwise. On the day following the decision, brand firms’ market value increases by an average of 1% when generic entry is deterred and decreases by an average of more than 1.5% when generic entry is successful.

The results for generic returns follow a nearly identical pattern, and are presented in
Figures 5(a)-(b). On average, on the day following the decision, generic firms’ market value increases by about 2.3% when the challenge is successful, and decreases by about 1.6% when the challenge fails. Collectively, the results in Figures 4(a)-(b) and 5(a)-(b) suggest an event-study approach is appropriate for measuring the decision impact on firm value, and that a three-day event window is sufficient for capturing the effects of litigation decisions.

5. Econometric Model

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

\[ V_{B,\text{Win}}^* - E_0\{\pi_B\} = (1 - \alpha) (\beta_B + \beta_G - 1) (V_{B,\text{Win}}^* - V_{B,\text{Lose}}) \]

We first use our event study to estimate \( V_{B,j,\text{Win}}^* - E_0\{\pi_{B,j}\} \) for each event \( j \). We then use other parts of our data to estimate, for each event, values of the parameters \( \hat{\alpha}_j, \hat{\beta}_{B,j} \) and \( \hat{\beta}_{G,j} \). Once we have consistent estimates of each component, we can recover an estimate of the dispute value for the brand firm,

\[ V_{B,j,\text{Win}} - V_{B,j,\text{Lose}} = \frac{V_{B,j,\text{Win}}^* - E_0\{\pi_{B,j}\}}{(1 - \hat{\alpha}_j) (\hat{\beta}_{B,j} + \hat{\beta}_{G,j} - 1)}. \]

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

Assuming that the efficient-market hypothesis holds, investors respond to an event by changing their expectations regarding future earnings of the firm in the event (Fama 1970). In our setting, the efficient-market hypothesis implies that the effect of the decision will reflect one of the formulas in (2), depending upon the type of firm (B or G) and on who wins the case. Following Salinger (1992), consider the following model of stock-market returns:

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

where \( \rho_{jt} \) is stock \( j \)'s return on day \( t \), \( \rho_{jt}^m \) is the return on the market index, and \( \epsilon_{jt} \) 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:

\[ \rho_{jt} = \kappa_1 + \kappa_2 \rho_{jt}^m + \psi I_{jt} + \epsilon_{jt}, \]

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 window of 271 trading days which covers the day before the event and back, \( t = [-271, -1] \). We consider a three-day event window, \( t = [0, 2] \), to capture the stock market’s reaction the day of the event and two days after.\(^{31}\)

\(^{29}\)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.
We repeat this estimation procedure for each event involving a generic or brand firm that is publicly traded. This yields an estimate, $\hat{\psi}$, of the change in market value due to the district court outcome for each firm ($V^{\pi_{\text{Win}}}_{0} - E_0\{\pi_B\}$, in the case of a brand win). We refer to $\hat{\psi}$ as the estimated cumulative abnormal return (CAR).

5.2. Estimating Decision Probabilities

If investors have information about the probability the brand will win the case at the district court level, $\alpha$, they will incorporate this into their expectations. Decision impacts then follow according to (1). Hence, we must get consistent estimates of $\alpha, \beta_B$ and $\beta_G$ for each case. For estimating the reversal rates $\beta_B$ and $\beta_G$, we count cases not appealed as maintaining the district court decision.

We consider three primary variables as part of 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 Schering-Plough decision and the surge in settlements that followed. 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 this into their expectations. We include sales because firms may commit different levels of resources to litigation, depending upon how important the drug is. Finally, past work suggests that possessing an active-ingredient patent substantially increases a brand firm’s probability of prevailing in litigation (Hemphill and Sampat 2011; Hemphill and Sampat 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 $\alpha$, we permit both $\beta_B$ and $\beta_G$ to vary by the same three factors during estimation.

To flexibly estimate $\alpha_j, \beta_{Bj}$, and $\beta_{Gj}$ for each event, $j$, we employ a multidimensional nearest-neighbor estimator similar to that of Nevo, Turner and Williams (2013). There are two primary reasons for using the nearest-neighbor observations. First, the distribution of events across the time-sales plane, which is plotted 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 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 understand this approach, consider estimation of \( \alpha_j \). 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

\[
d_{ij} = \frac{\phi(\tilde{Y}ear_{ij}, \tilde{S}ales_{ij})}{\sum_j \phi(\tilde{Y}ear_{ij}, \tilde{S}ales_{ij})}.
\]

The arguments of the standard multivariate normal density, \( \phi \), are the difference in two of the predictors of a brand win, \( Y_ear_{ij} \) 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.\footnote{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 $\alpha_j$ as

$$\alpha_j = \frac{\sum_j 1 \left[ d_{ij} \geq d_j^N, AI_j = 1 \right] 1 \left[ BrandWin_j = 1 \right]}{\sum_j 1 \left[ d_{ij} \geq d_j^N, AI_j = 1 \right]}.$$ \hspace{1cm} (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 $\alpha_j$ 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 $\beta_{Bj}$ and $\beta_{Gj}$ for each $j$ similarly.

\section*{6. Results}

Table 5 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 5.\footnote{Standard errors are calculated using jackknife resampling.} The average values of $\alpha$, $\beta_B$, and $\beta_G$ 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 $\alpha$. Though the surfaces are not strictly monotonic, there are clear trends whereby the probability of a brand win in the district court case, $\alpha$, 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, depending upon the drug’s sales and the timing of the case. Our estimates of $\beta_B$ and $\beta_G$ (not shown) indicate that none of the three predictors induce substantial variation in the probability of a given outcome.

Figure 7: Probability Brand Win, Sales and Year.

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

For each event $j$, we 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, $V_{ij}^{Win} - V_{ij}^{Lose}$. Averaging across all brand events, we estimate the mean value of deterrence is about $4.6$ billion. Averaging across all generic events, we estimate the mean value of entry is about $236.8$ million. Hence, the value of entry is about 5.1% of the value of deterrence. The distribution of estimated dispute values is highly skewed for both brands and generics, as shown by the lower median values of deterrence and entry ($\$355.9$ million and $\$79.4$ million, respectively). Using the formula in (3), average dispute values and average decision probabilities, we estimate an average bargaining surplus of just under $\$2$ billion.

We interpret the 2002 Schering-Plough decision as likely shifting the distribution of
$C_{Bargain}$ to the left, increasing the frequency with which cases settle. 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 estimate for generic wins is marginally insignificant at the 10% level). 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 win at the district court level about 34% of the time, and just 40% of the time overall [calculating $\gamma$ using (4)]. Applying our technique to estimate event-specific estimates of the dispute values, 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 $S_{Bargain}$ 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 $\gamma$) 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 $S_{Bargain}$ is about $1.3$ billion for the post-SP period, nearly 73% lower than
in the pre-SP period. If we recall that $S_{\text{Bargain}}$ 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, on average, at about $4.6$ billion. In contrast, generic firms value the right to enter at about $236.8$ million. Hence, the value of entry is only about five percent of the value of deterrence, suggesting 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.

Second, we study the effect of a more permissive environment for so-called “pay-for-delay” settlements. In Paragraph (iv) litigation decisions after the closely-watched Schering-Plough decision in 2002, the ex ante probability of an ultimate brand victory is far higher than for cases decided prior to Schering-Plough, and the estimated stakes in the cases are far lower. The average bargaining surplus falls by about 73% across time due removal of cases and their surplus for potential redistribution to consumers. Hence, settlements strongly reduce the average allocative-efficiency surpluses delivered by Paragraph (iv) litigation.

Our results bolster the FTC’s conclusions that pay-for-delay settlements will cost consumers significant surplus over the next decade (FTC 2013), and also reinforce the Supreme Court’s guidelines for lower courts to use in deciding antitrust disputes. The key challenge is identifying settlements that occur because the patents are weak, as these are the cases where a disproportionate share of potential consumer surplus is lost under a pay-for-delay settlement. Our model is clearly useful for quantifying the effect of patent weakness on
bargaining surpluses. Moreover, our framework could also be modified to estimate potential bargaining surpluses even without the decision impact of a court decision and in situations where firms agree to licensing and non-competitive agreements involving Authorized Generics (Berndt et al. 2007; FTC 2011). For example, we could estimate the relationship between a drug’s sales, patent characteristics, and the implied bargaining surplus. This would help courts generalize their application of the “large, unexplained payment” rule in identifying anti-competitive settlements.

We do not have data permitting us to identify the risk-premium component of bargaining surpluses. If firms are risk-averse, then our estimates of $S_{\text{Bargain}}$ 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. We are also unable to test for the effects of risk premia on settlement. If the Schering-Plough decision slackens the constraints on settling litigation, we should expect to see a lower overall level of risk aversion for the firms in cases after this key decision. Unless changes in risk premia swamp the changes in decision probabilities and dispute values, however, this omission does not alter the qualitative implications of our findings.

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 (IMS 2013, Levy 1999). Due to higher generic prescriptions, savings in 2012 were estimated to be over $217 billion (GPhA 2013).

Finally, our methodology does not allow us to 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 efficiency. However, given the time required to develop new drugs and have them approved by the FDA, such a surge has yet to materialize. This is a fruitful area for future research and we look forward to further progress.
References


Harris, Barry; Murphy, Kevin; Willig, Robert; Wright, Matthew. 2014. “Activating Actavis: A More Complete Story,” *Antitrust Magazine* 28, 83-89.


Table 1: *Pharmaceutical Patent Litigation Data Sources*

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

**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*

<table>
<thead>
<tr>
<th>Lawsuits Litigated to a Decision</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>Brand Win</td>
<td>53</td>
<td>56.99</td>
</tr>
<tr>
<td><strong>Brand Win DC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appealed</td>
<td>36</td>
<td>67.92</td>
</tr>
<tr>
<td>District Decision Reversed</td>
<td>5</td>
<td>9.43</td>
</tr>
<tr>
<td><strong>Brand Loss DC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appealed</td>
<td>31</td>
<td>77.50</td>
</tr>
<tr>
<td>District Decision Reversed</td>
<td>6</td>
<td>15.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Statistics</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Sales (millions)</td>
<td>1,020.69</td>
<td>1,277.42</td>
</tr>
<tr>
<td>Number of Patents</td>
<td>1.87</td>
<td>1.34</td>
</tr>
<tr>
<td>At Least One Active-Ingredient Patent</td>
<td>0.54</td>
<td>0.50</td>
</tr>
<tr>
<td>Drug Had NCE Status Prior to Litigation</td>
<td>0.82</td>
<td>0.39</td>
</tr>
<tr>
<td>Two Public Firms</td>
<td>0.61</td>
<td>0.49</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time Relative to district court Decision</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Youngest Patent-Life Left (years)</td>
<td>6.18</td>
<td>3.76</td>
</tr>
<tr>
<td>Oldest Patent-Life Left (years)</td>
<td>4.95</td>
<td>4.19</td>
</tr>
<tr>
<td>Since NCE Expired (years)</td>
<td>5.28</td>
<td>2.83</td>
</tr>
</tbody>
</table>

**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)*

<table>
<thead>
<tr>
<th>Brand Firm Events</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Sales suit yr (millions)</td>
<td>985.97</td>
<td>1,297.38</td>
</tr>
<tr>
<td>Firm Employees (thousands)*</td>
<td>63.94</td>
<td>37.62</td>
</tr>
<tr>
<td>Firm Revenue (billions)*</td>
<td>29.25</td>
<td>19.51</td>
</tr>
<tr>
<td>Number of Patents</td>
<td>1.85</td>
<td>1.35</td>
</tr>
<tr>
<td>At Least One Active-Ingredient Patent</td>
<td>0.51</td>
<td>0.50</td>
</tr>
<tr>
<td>Brand Wins</td>
<td>0.55</td>
<td>0.50</td>
</tr>
<tr>
<td>Appeal</td>
<td>0.71</td>
<td>0.46</td>
</tr>
<tr>
<td>Affirmed if Appealed</td>
<td>0.60</td>
<td>0.49</td>
</tr>
<tr>
<td>Number of Events</td>
<td>82</td>
<td></td>
</tr>
<tr>
<td>Number of Unique Firms</td>
<td>26</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generic Firm Events</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Sales suit yr (millions)</td>
<td>1,100.46</td>
<td>1,164.47</td>
</tr>
<tr>
<td>Firm Employees (thousands)*</td>
<td>22.59</td>
<td>27.62</td>
</tr>
<tr>
<td>Firm Revenue (billions)*</td>
<td>8.44</td>
<td>11.84</td>
</tr>
<tr>
<td>Number of Patents</td>
<td>2.02</td>
<td>1.49</td>
</tr>
<tr>
<td>At Least One Active-Ingredient Patent</td>
<td>0.54</td>
<td>0.50</td>
</tr>
<tr>
<td>Generic Wins</td>
<td>0.41</td>
<td>0.50</td>
</tr>
<tr>
<td>Appeal</td>
<td>0.75</td>
<td>0.44</td>
</tr>
<tr>
<td>Affirmed if Appealed</td>
<td>0.63</td>
<td>0.49</td>
</tr>
<tr>
<td>Number of Events</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>Number of Unique Firms</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th></th>
<th>Brand Firms ($i=B$)</th>
<th>Generic Firms ($i=G$)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Study</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean CAR (Brand Wins)</td>
<td>2.08%***</td>
<td>-1.63%**</td>
</tr>
<tr>
<td></td>
<td>(0.62%)</td>
<td>(0.69%)</td>
</tr>
<tr>
<td>Mean CAR (Brand Losses)</td>
<td>-2.43%**</td>
<td>3.13%***</td>
</tr>
<tr>
<td></td>
<td>(1.00%)</td>
<td>(1.00%)</td>
</tr>
<tr>
<td><strong>Decision Probability Estimation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean $\alpha$</td>
<td>0.551</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.059)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_B$</td>
<td>0.894</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.049)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_G$</td>
<td>0.855</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.063)</td>
<td></td>
</tr>
<tr>
<td><strong>Final Estimates</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Dispute Value ($V_{i}^{Win} - V_{i}^{Lose}$)</td>
<td>$4,616.8$</td>
<td>$236.8$</td>
</tr>
<tr>
<td>Median Dispute Value ($V_{i}^{Win} - V_{i}^{Lose}$)</td>
<td>$355.9$</td>
<td>$79.4$</td>
</tr>
<tr>
<td>Mean Bargaining Surplus</td>
<td>$1,960.5$</td>
<td></td>
</tr>
</tbody>
</table>

**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 $\beta_B$ and $\beta_G$. 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), $S_{Bargain} = [\alpha (1 - \beta_B) + (1 - \alpha)\beta_G] \left[ (V_{B}^{Win} - V_{B}^{Lose}) - (V_{G}^{Win} - V_{G}^{Lose}) \right]$, using averages reported in this table.
Table 5: Estimation Results: Pre- and Post-Schering-Plough

<table>
<thead>
<tr>
<th></th>
<th>Brand Firms (i=B)</th>
<th>Generic Firms (i=G)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Schering-Plough vs. FTC (2002)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Study</td>
<td>N=17</td>
<td>N=12</td>
</tr>
<tr>
<td>Mean CAR (Brand Wins)</td>
<td>2.98%*</td>
<td>-6.93%**</td>
</tr>
<tr>
<td></td>
<td>(1.42%)</td>
<td>(2.55%)</td>
</tr>
<tr>
<td>Mean CAR (Brand Losses)</td>
<td>-2.59%**</td>
<td>3.79%</td>
</tr>
<tr>
<td></td>
<td>(0.96%)</td>
<td>(2.24%)</td>
</tr>
<tr>
<td>Decision Probability Estimation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean $\alpha$</td>
<td>0.345</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.098)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_B$</td>
<td>0.830</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.101)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_G$</td>
<td>0.823</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.113)</td>
<td></td>
</tr>
<tr>
<td>Final Estimates</td>
<td>N=17</td>
<td>N=12</td>
</tr>
<tr>
<td>Mean Dispute Value ($V_{iWin}^{\text{Win}} - V_{iLose}^{\text{Lose}}$)</td>
<td>$8,759.8$</td>
<td>$532.0$</td>
</tr>
<tr>
<td>Median Dispute Value ($V_{iWin}^{\text{Win}} - V_{iLose}^{\text{Lose}}$)</td>
<td>$2,207.5$</td>
<td>$440.2$</td>
</tr>
<tr>
<td>Mean Bargaining Surplus</td>
<td>$4,928.5$</td>
<td>$4,928.5$</td>
</tr>
<tr>
<td><strong>Post-Schering-Plough vs. FTC (2002)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Study</td>
<td>N=65</td>
<td>N=56</td>
</tr>
<tr>
<td>Mean CAR (Brand Wins)</td>
<td>1.91%***</td>
<td>-0.70%</td>
</tr>
<tr>
<td></td>
<td>(0.69%)</td>
<td>(0.56%)</td>
</tr>
<tr>
<td>Mean CAR (Brand Losses)</td>
<td>-2.37%*</td>
<td>2.95%**</td>
</tr>
<tr>
<td></td>
<td>(1.33%)</td>
<td>(1.14%)</td>
</tr>
<tr>
<td>Decision Probability Estimation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean $\alpha$</td>
<td>0.600</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.064)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_B$</td>
<td>0.909</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.043)</td>
<td></td>
</tr>
<tr>
<td>Mean $\beta_G$</td>
<td>0.863</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.064)</td>
<td></td>
</tr>
<tr>
<td>Final Estimates</td>
<td>N=65</td>
<td>N=56</td>
</tr>
<tr>
<td>Mean Dispute Value ($V_{iWin}^{\text{Win}} - V_{iLose}^{\text{Lose}}$)</td>
<td>$3,533.3$</td>
<td>$173.5$</td>
</tr>
<tr>
<td>Median Dispute Value ($V_{iWin}^{\text{Win}} - V_{iLose}^{\text{Lose}}$)</td>
<td>$201.9$</td>
<td>$47.1$</td>
</tr>
<tr>
<td>Mean Bargaining Surplus</td>
<td>$1,337.2$</td>
<td>$1,337.2$</td>
</tr>
</tbody>
</table>

**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.