

# Institutional Horizontal Shareholdings and Generic Entry in the Pharmaceutical Industry\*

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## Abstract

Brand-name pharmaceutical companies often file lawsuits against generic drug manufacturers that challenge the monopoly status of patent-protected drugs. Institutional horizontal shareholdings, measured by the generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer, are significantly positively associated with the likelihood that the two parties enter into a settlement agreement in which the brand pays the generic manufacturer to stay out of the market. Horizontal shareholdings are also positively associated with the brand's daily abnormal stock returns around the settlement agreement. Generic manufacturers who settle with the brand-name company are more likely to delay the sale of generic substitutes if they have higher horizontal shareholdings with the brand-name firm. These delays preclude other generic firms from entering the market.

**JEL classification:** L41, L12, G23, G30

**Keywords:** Common ownership; Institutional investor; Product market entry; Pharmaceutical industry; Patent infringement lawsuit; Settlement agreement; Antitrust

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# 1. Introduction

We show that institutional horizontal shareholdings (i.e., a group of institutional investors who hold large stakes in competitors) are associated with product-market interactions between competitors.<sup>1</sup> To do so, we analyze patent-litigation lawsuits between brand-name pharmaceutical companies and generic-drug manufacturers over the sample period of 1999–2017. Paragraph IV of the Hatch-Waxman Act of 1984 allows generic manufacturers to challenge the monopoly status of patent-protected drugs. Brand-name manufacturers can respond by filing patent-infringement lawsuits against generic challengers. We find the ownership of the generic firm’s shareholders in the brand-name manufacturer relative to their ownership in the generic manufacturer is positively associated with the likelihood that the two parties enter into a settlement agreement in which the brand manufacturer pays the generic manufacturer to stay out of the market.

Growing literature documents evidence consistent with common institutional owners of natural competitors pushing product markets toward monopolistic outcomes.<sup>2</sup> Azar et al. (2018a) develop a modified Herfindahl-Hirschman index (MHHI) that takes into account common institutional ownership in the U.S. airline industry. They show that ticket prices are 3–12% higher on the average airline route than would be the case under separate ownership. Azar et al. (2016) find similar results in the banking industry. Azar (2012), He and Huang (2017), Bindal (2019), and Aslan (2019) show an increase in a within-industry common-ownership density predicts industry margins. These findings have sparked debate on whether the Department of Justice and the Federal Trade Commission (FTC) should enforce the antitrust policy against institutional investors (Elhauge, 2015, 2019; Posner et al., 2017; Hemphill and Kahan, 2019; Rock and Rubinfeld, 2018).

Yet, the emerging literature is silent on how common ownership influences firms’ strategy to compete. What existing studies document is industrial equilibrium outcomes arising from firm managers acting in the interest of common owners. In the spirit of

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<sup>1</sup>Elhauge (2015) uses the term “horizontal shareholdings” to describe the situation in which a common set of investors own significant shares in corporations that are already horizontal competitors in a product market. We use the term “horizontal shareholdings” to describe the extent to which institutional shareholders of the entrant also hold shares in the incumbent.

<sup>2</sup>A long theoretical literature in industrial organization shows that well-diversified shareholders maximize aggregate portfolio profits, because the benefits to one firm from competing aggressively can be at the expense of other portfolio firms (e.g., Rotemberg, 1984; Reynolds and Snapp, 1986; Farrell and Shapiro, 1990; Gordon, 1990; Admati et al., 1994; Hansen and Lott, 1996; O’Brien and Salop, 2000; Gilo et al., 2006; Azar, 2012, 2017; López and Vives, 2018).

Azar et al. (2018a), airline companies’ strategy is to refrain from increasing capacity in markets where powerful shareholders hold stakes in competitors.<sup>3</sup> Because individual airlines’ capacity precommitment is not observable, the authors regress route-level average price on common ownership to indirectly test their story. This approach might invalidate the study’s policy implication because the rise in common ownership could coincide with the consolidation of an industry increasing prices or margins (Gilje et al., 2017; Lewellen and Lowry, 2018).<sup>4</sup>

We analyze patent-infringement lawsuits filed by brand-name drug manufacturers against generic manufacturers who filed Paragraph IV applications with the Food and Drug Administration (FDA). Our empirical design is appealing for two reasons. First, we observe practices that are plausibly anticompetitive. The wide use of pay-for-delay settlements in which a brand-name pharmaceutical company (incumbent) and generic-drug manufacturers (would-be entrants) settle a Paragraph IV patent challenge has been considered as anticompetitive, because such settlements delay generic entry, increase drug prices, and decrease quantity (Branstetter et al., 2011; Helland and Seabury, 2016). An FTC staff study shows that agreements with compensation from the brand manufacturer to the generic manufacturer, on average, prohibit generic entry for 17 months longer than agreements without payments.<sup>5</sup>

Second, our pre-entry setting allows us to establish a link between institutional ownership and product-market outcomes without the confounding effects of product-market shares. For example, Kennedy et al. (2017) argue that MHHI depends on both institutional ownership and product-market shares, both of which may be endogenous. We rely on the incumbent-entrant relationship and regress institutional horizontal shareholdings

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<sup>3</sup>Gutiérrez and Philippon (2017) document a strong negative correlation between fixed investment and MHHI in the U.S. over the past 30 years.

<sup>4</sup>As conveyed by a FTC public hearing dated on December 8, 2018, enforcers stressed the need for more rigorous studies before any policy shift is undertaken and called for studies on the effects of common ownership across a broad range of industries. The hearing is accessible via the following website: <https://www.ftc.gov/news-events/events-calendar/ftc-hearing-8-competition-consumer-protection-21st-century>.

<sup>5</sup>The study is based on patent-settlement agreements filed with the FTC between January 1, 2004, and September 30, 2009. See also “Cash is not always king in pharma pay-to-delay deals: appeals court” (June 26, 2015, Wall Street Journal).

on a variety of outcomes between brand-name and generic firms.<sup>6</sup> In this regard, our study shares a similar spirit with Matvos and Ostrovsky (2008) who recognizes the conflict of interest between cross-owners and other shareholders.

Our main sample consists of 666 distinct Paragraph IV lawsuits filed by publicly listed brand-name plaintiffs against publicly listed generic defendants. The sample period starts with cases pending as of November 1, 2003, and ends with cases closed as of August 2017. We document several stylized facts for this sample. First, only 31.2% of the disputes end in a trial. Second, the mean settlement rate at the patent level is 36.8%, and it varies substantially across federal district courts. Third, 29.4% of lawsuits were dismissed by either the judge or the plaintiff (brand). Fourth, common institutional ownership exists in 73% of Paragraph IV challenges. Conditional on common ownership, the top 10 generic shareholders hold 13.2% of the brand’s shares and 23.6% of the generic’s shares.

In Table 1, we use the litigation between Mylan (generic) and Bristol-Myers Squibb (brand) in the second quarter of 2013 as an illustration. We list the top 10 institutional shareholders on Mylan, based on their ownership, and the ownership of these same institutional shareholders on Bristol-Myers Squibb. The table suggests that at the individual-shareholder level, common ownership is common and varies across institutions.

Fund families typically vote their voting shares together, regardless of the investment strategies of their individual funds (Bioy et al., 2017; He et al., 2018). For example, mutual fund families, even they are passive, often have family-level governance teams that cast votes on behalf of their affiliated funds.<sup>7</sup> We aggregate holdings at the institution level.<sup>8</sup>

We rely on the brand-generic pair to calculate generic shareholders’ economic interests in the branded product relative to their economic interests in the would-be generic substitute. Using generic voting rights as weights, we treat generic shareholders’ economic incentives on the brand incumbent differentially. This measure allows us to rule out the possibility that influential investors with large generic stakes might have small stakes in

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<sup>6</sup>When making investment decisions surrounding patent litigation, major funds frequently retain industry experts or counsel to watch dockets, attend key hearings, and advise on the status and potential outcome of individual cases (“Litigation trading: an introduction to Wall Street’s interest in patent cases,” Matthew P. Larson, published in *Landslide*, Volume 8, Number 1, 2015 by the American Bar Association).

<sup>7</sup>Appel et al. (2016) find that passive mutual funds influence firms’ governance choices, resulting in more independent directors, removal of takeover defenses, and more equal voting rights.

<sup>8</sup>Brav et al. (2018) find a low level of disagreement within fund families at contested shareholder meetings. As a robustness test, we do not aggregate holdings that are reported separately in 13F filings, and find similar results.

the brand and, thus, care little about the sales of the branded drug (e.g., Harford et al., 2011).

One important concern is that a positive correlation between ownership and settlement, if observed, could be driven by unobservables determining both the selection of entrants and the type of generic manufacturers in which institutional shareholders choose to invest. To address this concern, we analyze the selection of potential entrants. We document evidence consistent with horizontal shareholdings *not* affecting the selection of generic entrants.

In our baseline specification, we identify a challenge outcome as settled if the two litigants settle at least one patent dispute.<sup>9</sup> Our panel regression results show that the likelihood that the two parties enter into a settlement agreement increases in the extent that institutional investors in the generic defendant(s) hold shares in the brand-name firm. The economic magnitude is such that a one standard deviation increase in horizontal shareholdings increases the probability of settlement by 5.8 percentage points, which is 16% of the sample mean. In our main specifications, we control for drug sales and fixed effects at the generic defendant, the brand plaintiff, federal district court, and time levels. We find similar results if we use variation within active ingredients (identified by trade name). Most important, we find the strongest effects of horizontal shareholdings on settlement are attributable to the three largest generic shareholders.

Our main results survive under a battery of robust checks. First, we further correct the potential omitted variable bias by controlling for the S&P 1500 status of both brand and generic, as well as the generic's market capitalization. Second, we find the effect of horizontal shareholdings on settlement rates is not driven by the litigants filed during the Great Recession.<sup>10</sup> Third, we show our results are neither driven by the nonlinear nature of horizontal shareholdings nor by Paragraph IV challenges with high profiles. Fourth, we use the averaged settlement rate across patents involved in the same litigation as our main dependent variable. Fifth, we run the panel-regression specification on the 2,023 lawsuits by including litigants with zero possibility of being held by institutional investors. Sixth, we include shared votes into firms' control rights.

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<sup>9</sup>A brand drug is covered by multiple patents. However, a generic entry will be deterred if at least one patent is settled.

<sup>10</sup>One major critic on Azar et al. (2018a) comes from the fact that, during the Great Recession, five of the seven airlines went through bankruptcy (Dennis et al., 2018; BlackRock, 2019).

Our findings could be driven by portfolio-allocation choices of active institutional investors in anticipation of litigations. We address this concern in two ways. First, we show top generic shareholders do not adjust the relative weight of brand ownership versus generic during quarters preceding litigations. Second, in a spirit similar to Azar et al. (2018a), we instrument for horizontal shareholdings based on BlackRock’s acquisition of Barclays Global Investors (BGI) in 2009. We use variation in horizontal shareholdings within generic defendants but across brand-name plaintiffs. The hypothetical combination of the two parties’ portfolios induces such variation. Because drug stocks constituted only a small percentage of the merging parties’ portfolios, this variation is unlikely to be caused by anticipated changes in anticompetitive behavior incentives.

Because our measure of horizontal shareholdings is not a function of market concentration, BlackRock’s acquisition of BGI constitutes a shock only to generic defendants’ relative weight on the branded drug. We find results that are similar to those in panel regressions: Higher horizontal shareholdings predict higher settlement rates and lower dismissal rates. The estimated economic magnitude increases under the IV estimations. A one standard deviation increase in generic shareholders’ weight on the brand-plaintiff increases the settlement rate by 14 percentage points.

Next, we propose three tests to examine whether settlements accepted by generic manufacturers with shareholders holding more shares in the brand are anticompetitive. Anecdotes suggest that brand-name incumbents can prevent all generic entries by paying the first generic entrant — the earliest filer of the Paragraph IV application — to substantially delay the entry (e.g., Bulow, 2004; Hemphill and Lemley, 2011).<sup>11</sup> This delay can occur because the FDA grants a 180 day period of marketing exclusivity to reward the first generic, allowing it to be the only seller of the generic substitutes for the branded drug within the first 180 days. However, we do not find a more pronounced effect of institutional horizontal shareholdings on the likelihood of settlement between the brand and the first generic. We discuss several possible reasons for this result, including the FTC’s escalated monitoring of settlement agreements after 2003, as well as the uncertainty for the first filer to secure its exclusivity.

The above reasons do not, however, indicate that the brand and the first generic do not leverage the 180-day exclusivity through “pay-for-delay” settlements. Unfortunately,

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<sup>11</sup>See also “Justices to take up generic drug case” (New York Times, December 7, 2012) and “How big pharma sandbags generic competition?” (Wall Street Journal, November 14, 2017).

settlement agreements are typically confidential. In the second test, we infer the nature of the settlements by examining stock returns around the event. If a settlement is anticompetitive, it will extend the brand's monopoly status beyond the expected date of generic entry had the two parties gone to trial. If horizontal shareholdings have anticompetitive effects, the brand's stock price around the date on which the two parties settle should increase with generic shareholders' weight on the brand.<sup>12</sup>

Our results suggest settlement agreements signed by generic firms whose shareholders hold more brand shares are more anticompetitive. The brand's daily returns around the event window  $(-3, +3)$  are positively associated with horizontal shareholdings. More importantly, the brand's settlement with the first generic is associated with more positive returns around the event. The economic magnitude is such that a one standard deviation increase in the first generic shareholders' weight on the brand is associated with an abnormal return of 120 basis points. We also document a positive relation between horizontal shareholdings and the first generic's daily returns around settlement. Our event study findings suggest that, first, settlement extends the monopolistic status of a brand drug and, second, a reduction in litigation fees does not explain the positive brand returns, and third, generic shareholders also benefit from pay-for-delay settlements.

In the third test, we exploit the differential timings of generic firms marketing generic drugs to evaluate the anti-competitiveness of a settlement agreement. We find horizontal shareholdings by the first generic settling with the brand strongly reduces the likelihood that the generic substitute of branded drug will be marketed by *all* ANDA filers challenging the same branded drug irrespective of challenge outcomes. By contrast, we do not find horizontal shareholdings of the first generic delay the marketing of generic drugs in other litigation outcomes. We conclude that managers of the first generic whose top shareholders hold more brand shares are likely to accept legal requirements defined by a settlement agreement. These requirements delay the entry of the first generic so that all the other potential entrants are precluded.

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<sup>12</sup>Drake et al. (2015) document evidence indicating anticompetitive settlements for those with an indication of reverse payment. They find a brand's stock prices rise, on average, 6% at the announcement of these settlements.

## 2. Background

In 1984, Congress adopted the Hatch-Waxman Act, which reduced regulatory barriers to the entry of generic drugs. Prior to 1984, generic drug manufacturers had to repeat the same expensive, lengthy clinical trials that brand-name companies had already conducted. Furthermore, the investigation and testing of a branded drug covered by patents could subject generic manufacturers to patent-infringement lawsuits.

Hatch-Waxman offers four paths (or Paragraphs) for a generic manufacturer to produce a branded drug product. The entry process begins with the generic manufacturer filing an abbreviated new drug application (ANDA) with the FDA under one of the four Paragraph certifications. A Paragraph I certification is issued when the drug innovator (i.e., brand company) has not filed patents to cover its branded product. Paragraph II certification involves a branded drug's patents having expired (i.e., the end of market exclusivity), and Paragraph III certification relates to the generic manufacturer acknowledging that patents covering the branded product will expire on a certain date and that it will enter only after that date.

Under Paragraph IV certification, the generic manufacturer argues the generic drug does not infringe on patents covering a branded product or that the patents at issue are simply invalid. Under this provision, generic manufacturers file ANDAs to challenge the validity of patents so that generic drugs can be marketed before patents expire. The first generic to submit a Paragraph IV certification is entitled to 180-day exclusivity if it successfully defends a patent-infringement suit.<sup>13</sup> Once this exclusivity right is granted, the FDA may not approve another Paragraph IV application for the same product until six months after the first generic markets its product.

Figure 1 illustrates that the introduction of generics leads to sharp declines in drug prices. Throughout the 1990s, brand incumbents often used two methods to delay generic entry. The first was to list additional patents after the initial Paragraph IV filing, triggering non-concurrent 30-month stays for each patent at issue. However, on June 12, 2003, President Bush, HHS Secretary Thompson, and FDA Commissioner McClellan an-

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<sup>13</sup>The successful defense requirement was established to eliminate “an incentive for frivolous claims of patent invalidity or non-infringement because it would give ANDA applicants exclusivity even if the applicant was unsuccessful in defending against the patent owner’s lawsuit.”

nounced a new regulation limiting an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge.<sup>14</sup>

The second practice, which is the focus of our study, is for brand-name pharmaceutical companies to pay the generic manufacturer filing Paragraph IV to hold the generic product off the market for a certain period of time. In recent years, these pay-for-delay agreements have arisen as part of patent-litigation settlement agreements. The Federal Trade Commission's (FTC) investigations and enforcement actions against pay-for-delay agreements deterred their use from April 1999 through 2004. In 2003, an appellate court held that such agreements were illegal. Since 2005, however, several appellate courts have upheld these agreements. Those court decisions have been followed by a reemergence of patent settlements that combine restrictions on generic entry with compensation from the brand to the generic.

According to an FTC staff study released in January 2010, agreements with compensation from the brand to the generic prohibit generic entry for nearly 17 months longer than agreements without payments. The FTC estimates that pay-for-delay agreements cost American consumers \$3.5 billion per year.<sup>15</sup> Since 2001, the FTC has filed several lawsuits to stop these deals, and it supports legislation to end such settlements. In Appendix A, we provide three examples of complaints that the FTC filed against brand and generic manufacturers involved in pay-for-delay settlements.

The brand and generic can, however, settle litigation in ways that do not involve monetary payments. For example, brand-name pharmaceutical companies sometimes agree to not compete through an authorized generic (Berndt et al., 2007). Authorized generics are brand-name pharmaceutical products marketed as generics and can substantially reduce the revenues a first generic earns. Under the Hatch-Waxman Act, although the first generic can market its drugs with no competition from other generics for 180 days, the rule does not protect the first-filer generic from competition from an authorized generic during those 180 days. According to the same FTC staff study, 25% of patent-settlement agreements from 2004–2008 that were with a first generic involved an explicit agreement

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<sup>14</sup>Due to court rulings favoring generics and the Medicare Act of 2003, ANDA applications with Paragraph IV certifications increased from 10% to 20% in the early 1990s to more than 40% by the end of the 2000s (Higgins and Graham, 2009; Berndt et al., 2007).

<sup>15</sup>See "Pay for delay: How Drug Company Pay-Offs Cost Consumers Billions," An FTC Staff Study, January 2010.

by the brand to not launch an authorized generic, combined with an agreement by the first generic to defer entry past the date of the agreement.

### 3. Data

#### 3.1. *Paragraph IV lawsuit documents*

Our data come from The Paragraph Four Report®, which is an electronic publication of Parry Ashford Inc. The company tracks and analyzes Paragraph IV activities. The database starts with Paragraph IV cases that were active as of November 1, 2003. Active branded products are those that had a Paragraph IV challenge, had a pending lawsuit, and were not available as a generic as of November 1, 2003. The company followed each case through completion (i.e., settlement or court of appeals). Once a generic product enters the market after final termination of litigation, the product is removed from the list and sent to the Old Cases section. The Old Cases section includes products and cases closed after November 1, 2003.

From the online Paragraph Four Report®, we manually extract the relevant data fields. For each challenge, we collect (1) the name of the brand and generic manufacturers involved in the litigation, (2) the timeline of the litigation (e.g., the date on which a brand company files a patent-infringement suit), (3) the trade name and formulation of the challenged product, (4) patents at issue, (5) the district court, (6) the names of the lead attorneys/law firms and judge, and (7) a brief summary on the progress of the case with critical scheduled dates.

For each case closed, we read the progress summary and documents attached to each case to discern the final outcome. We classify challenge outcomes into five categories: the brand does not file suit, the brand wins, the brand loses, the parties settle, the parties dismiss the case, and unknown.<sup>16</sup>

Our sample starts with active Paragraph IV cases as of November 1, 2003, and ends with Paragraph IV cases closed before December 31, 2017. Our unit of observation is a

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<sup>16</sup>Figure 2 provides a snapshot of the online publication. The brand and generic either enter into a settlement agreement or request that the case be dismissed. A consent judgment is issued when two parties agree to a settlement. The parties write up an agreement for the judge to sign. A dismissal, in theory, allows the brand to re-open the case. When the two parties settle and agree to dismiss the suit, the brand manufacturer usually states that the case is dismissed without giving a reason. In these cases, Parry Ashford Inc. labels the challenge as dismissed.

distinct Paragraph IV application filed by a generic firm to challenge a branded drug. We treat different formulations (e.g., tablets, capsule, and injection) under the same trade name (i.e., the name of the branded drug) as different products. In other words, we define a challenge at the level of the date on which a brand manufacturer files patent-infringement lawsuits against an ANDA filer challenging the formulation of a trade name. If multiple generic firms file the same ANDA under Paragraph IV certification with the FDA, we record distinct challenges based on the number of ANDA filers. We collect a total of 2,415 distinct Paragraph IV challenges. We further exclude cases (1) in which the brand-name company does not sue the generic ANDA filer for patent infringement and (2) for which the start date of litigation is not available. Our sampling procedure yields 2,023 challenges.

Table 2 presents descriptive statistics for our sample. It consists of 2,023 unique challenges to 1,578 unique patents covering 521 unique trade names. The 2,023 challenges are launched by 202 distinct generic manufacturers. The 521 trade names are held by 157 distinct brand-name companies. One Paragraph IV challenge often triggers litigation for multiple patents covering a brand drug.

Sometimes, litigation outcomes vary across patents covering the same drug. At the level of Paragraph IV challenge, we code litigation outcomes based on whether a certain outcome applies to at least one patent when two litigants end the dispute. For example, we regard a case as “settled” if the two litigants settle the dispute for at least one patent.<sup>17</sup>

Table A.1 presents the sample distributions of the Paragraph IV litigation outcomes across U.S. Federal District Courts following the filing of an ANDA under Paragraph IV certification with the FDA. Figure 3 plots the distributions of the number of challenges and the settlement rates over calendar years in which lawsuits are filed.

### *3.2. First generic challenger*

The Paragraph Four Report® provides the dates on which the brand sues the generic ANDA filer for patent infringement. Unfortunately, the company does not provide the date/month in which generic firms file ANDA applications under Paragraph IV. We are not aware of any public sources (e.g., FDA websites) providing such timings. The lack of

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<sup>17</sup>To sell a generic drug under the Paragraph IV certification, the ANDA filer has to prove in the court that all patents covering the drug are not valid.

these dates can introduce measurement error if we determine the first ANDA filer based on when the brand incumbent sues the generic firm.

To address measurement error, we conduct a fuzzy search for the first ANDA filer. We define a pseudo entry date as the earliest of (1) the date an ANDA was filed (if data are available),<sup>18</sup> (2) the date the brand incumbent was noticed by the ANDA filer(s), and (3) the date the brand sued the ANDA filer. The Paragraph Four Report  $\text{\textcircled{R}}$  includes original documents for summons, complaints, and answers related to each lawsuit. From these documents, we search for (1) and (2) as mentioned above. Among all generics challenging the same drug, the first-filer is defined as the one with the earliest pseudo entry date. Under this method, 686 out of 2,023 lawsuits are triggered by the first generic.

### *3.3. Institutional shareholdings*

We gather institutional holdings from the Thomson-Reuters Spectrum dataset of 13F filings. The dataset covers investment in all U.S. publicly traded stocks by institutional investors managing more than \$100 million. Thomson-Reuters assigns a manager number to each institutional investor. The dataset includes the percentage of shares and percentage of shares with voting rights. We measure institutional shareholding as the percentage of ownership, including voting and non-voting shares.

In our main analysis, we only include sole voting shares to measure control rights.<sup>19</sup> We also combine holdings from separate filings by the same asset manager. Following Azar et al. (2018a), we add missing filings that we obtain from the SEC’s website for BlackRock in 2010 and 2013 to 2015, Barclays in 2003Q4, Northern Trust in 2014Q1, BNY Mellon in 2013Q3, and JPMorgan in 2003Q4, 2008Q3, and 2013Q3 to Q4.<sup>20</sup>

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<sup>18</sup>FDA only records information about ANDA applications that are eventually approved. However, few ANDA applications under the Paragraph IV certification were approved during our sample period; most such applications were withdrawn by the generics after the cases were either settled or dismissed.

<sup>19</sup>We combine sole and shared voting shares, and find similar results.

<sup>20</sup>We thank Martin Schmalz for making the following two datasets publicly available: (1) missing filings by several asset-management funds and (2) the updated aggregation of manager IDs for the Thomson Reuters 13F data.

## 4. Generic shareholders' horizontal shareholdings

In this section, we first describe a firm's objective function under common ownership. We then discuss our empirical measure of generic shareholders' horizontal shareholdings in the entry game.

### 4.1. Firm objective under common ownership

We propose a measure of horizontal shareholdings based on the statement of a firm's profit function proposed by O'Brien and Salop (2000), in which shareholders of a firm (generic entrant) acquire shares in a competing firm (brand incumbent). Such an acquisition is equivalent to a partial horizontal merger.<sup>21</sup> This framework has been modified by Azar et al. (2018a) in various post-entry games. Our measure differs from Azar et al. (2018a)'s in that it is only a function of ownership and control—not a function of product-market shares.

O'Brien and Salop (2000) assume that firm  $j$  maximizes a weighted average of its  $M$  shareholders' (indexed by  $i$ ) portfolio profits that arise from cash-flow rights  $\beta_{i,k}$  in  $N$  different firms ( $k$ ) that make profits  $\pi_k$ , whereas  $\gamma_{i,j}$ s are the respective shareholders' voting shares:

$$\max \Pi_j = \sum_{i=1}^M \gamma_{i,j} \sum_{k=1}^N \beta_{i,k} \pi_k = \pi_j + \sum_{k \neq j} \underbrace{\frac{\sum_i \gamma_{i,j} \beta_{i,k}}{\sum_i \gamma_{i,j} \beta_{i,j}}}_{\lambda_{j,k}} \pi_k. \quad (1)$$

Schmalz (2018) summarizes a full set of properties underlying the above objective function. Here, we restate properties that are relevant to our implementation of equation 1. First, firm  $j$  (the generic entrant) internalizes externalities on other firms  $k$  (brand-name incumbents). However, it only does so to the extent  $\lambda_{j,k}$  that owners with economic interests in firm  $k$  ( $\beta_{i,k}$ ) have control rights over firm  $j$  ( $\gamma_{i,j}$ ), relative to the control and cash-flow rights it has in firm  $j$ . Second, cross-ownership and control are reflected in a continuous fashion, and the measure imposes no artificial ownership cutoffs. Third, the measure reflects that large generic shareholders have more influence on generic managers' behavior than a collection of small shareholders with diverging economic in-

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<sup>21</sup>A firm's profit function is similarly defined in Gilo et al. (2006).

terests that is equally large in aggregate. The second and third properties address the concern with alternative measures that treat generic shareholders equally.<sup>22</sup>

#### 4.2. Empirical measurement

Because generic entrant  $j$  and brand-name incumbent  $k$  are the only two players in the pre-entry game, we modify firm  $j$ 's objective function as follows:

$$\max \Pi_j = \mathbb{E}\pi_j + \frac{\sum_i \gamma_{i,j} \beta_{i,k}}{\sum_i \gamma_{i,j} \beta_{i,j}} \mathbb{E}\pi_k. \quad (2)$$

$\mathbb{E}\pi_j$  is the present value of future profits, net of entry costs, if a generic substitute is allowed to be sold before patents expire.  $\mathbb{E}\pi_k$  is the present value of the future (monopolistic) profits from selling the brand drug during the remaining life of patents. We consider only one generic entrant in the above framework. Newham et al. (2018) show that an increase in the level of horizontal shareholdings by entrant A reduces its incentives to enter, holding the probability that entrant B will enter constant.<sup>23</sup>

Following Azar et al. (2018a), we calculate the control share of shareholder  $i$  in generic firm  $j$ ,  $\gamma_{i,j}$ , as the percentage of the sole and shared voting shares of firm  $j$  held by shareholder  $i$ . Analogously, we calculate the ownership share of investor  $i$  in firm  $j$ ,  $\beta_{i,j}$ , as the percentage of all shares (voting and non-voting) of firm  $j$  held by shareholder  $i$ . If we set  $w_{j,k} = \frac{\sum_i \gamma_{i,j} \beta_{i,k}}{\sum_i \gamma_{i,j} \beta_{i,j}}$ , firm  $j$ 's objective function in equation 2 can be expressed as:

$$\max \Pi_j = (1 + w_{j,k}) \left( \frac{1}{1 + w_{j,k}} \mathbb{E}\pi_j + \frac{w_{j,k}}{1 + w_{j,k}} \mathbb{E}\pi_k \right). \quad (3)$$

Our empirical measure of horizontal shareholdings, the weight the manager of generic firm  $j$  puts on the brand-incumbent  $k$ , is expressed as follows:

$$Horizontal\% = \frac{w_{j,k}}{1 + w_{j,k}}. \quad (4)$$

In this paper, we implement equation 4 by assuming control by only the largest 3,

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<sup>22</sup>Harford et al. (2011) point that influential investors with large stakes in firm  $j$  tend to have only small stakes in firm  $k$  and care little about  $k$ 's profits. Our measure addresses their concern.

<sup>23</sup>Hansen and Lott (1995) study a setting in which the entrant can profit from trading stocks of the incumbent. The authors find that cross-trading by the entrant produces a smoothing effect on the likelihood of entry: when entry is otherwise unlikely, cross-trading increases its likelihood, and vice versa.

5, and 10 shareholders. In other words, we assign zero cashflow rights and control to all shareholders outside the top 10 coalition. By doing so, we exclude the possibility that our results are driven by an increase in horizontal shareholdings in general. Figure 4 illustrates the time series variation of horizontal shareholders by top 3, 5, and 10 generic shareholders over the sample period of 2001Q1-2017Q4.

### 4.3. Identification strategy

Our findings could be driven by either portfolio-reallocation choices of institutional investors in anticipation of settlements, or by omitted variables determining both institutional ownership and settlements. We develop an identification strategy based on BlackRock’s acquisition of Barclays Global Investors (BGI) in 2009. On June 11, 2009, BlackRock announced its bid to acquire Barclays Global Investors (BGI), iShares’ parent division, for \$13.5 billion. The bid was successful and the acquisition was formally completed in December 2009. Similarly to Azar et al. (2018a), we exploit the variation in ownership generated by BlackRock’s acquisition of Barclays BGI.

Azar et al. (2018a) extensively discuss the institutional background. Even before June 11, 2009, Barclays intended to sell iShares to investors other than BlackRock, suggesting product-market considerations did not drive the acquisition. Similar to U.S. airline stocks, pharmaceutical stocks constituted only a small share of BGI’s portfolio, and thus drug makers are unlikely to have been central to BlackRock’s decision to acquire BGI.

We start by calculating the horizontal shareholdings for each brand-generic pair as of 2009Q1 ( $Horizontal\%^{09Q1}$ ), the quarter before the acquisition was announced. We then calculate the counterfactual, horizontal shareholdings ( $\widehat{Horizontal\%^{09Q1}}$ ) for the same pair in the same quarter with the only difference being that we treat the holdings of BlackRock and Barclays as if they had been held by a single entity already. Similar to Azar et al. (2018a), we call the difference between the latter and the former the implied change in horizontal shareholdings ( $\Delta Horizontal\%^{09Q1}$ ), expressed as follows:

$$\Delta Horizontal\%^{09Q1} = \widehat{Horizontal\%^{09Q1}} - Horizontal\%^{09Q1}. \quad (5)$$

The exclusion restriction is that the cross-sectional distribution across Paragraph IV litigation lawsuits in the implied change in horizontal shareholdings from a hypothetical,

pre-merger combination of BlackRock and BGI’s equity portfolios is uncorrelated with errors in the settlement-rate regression (see equation 8 for detailed descriptions).

We run the first-stage regression on the post-acquisition period:

$$Horizontal\%_{j,k,s-1} = \alpha + \beta \times High \Delta_{j,k}^{09Q1} + X' \times \gamma_1 + \phi_j + \phi_l + \phi_s + \epsilon_{i,j,k}, \quad (6)$$

where  $High \Delta_{j,k}^{09Q1}$  is an indicator variable coded as one if  $\Delta Horizontal\%_{j,k}^{09Q1}$  is greater than the mean (40%) of its sample distribution, and zero otherwise.<sup>24</sup> In equation 6, we exploit variation within generic defendant(s)  $j$ , district court  $l$ , and year-quarter  $s$ . Our instruments vary across generic-brand pairs because the same generic shareholders in  $j$  have different brand shares across brand plaintiffs ( $k$ ). The BlackRock’s acquisition of Barclays BGI generates these differences. We therefore do not exploit variation either within brand plaintiffs.

## 5. Horizontal shareholdings and settlement

In this section, we present our main findings. Section 5.1 presents a shareholder-by-shareholder analysis. Section 5.2 shows horizontal shareholdings do not correlate with the probability that generic firms challenge a branded drug. Section 5.3 reports panel regression results. Section 5.5 shows our baseline results are robust to a broad array of checks. Section 5.4 shows institutional investors do not adjust their holdings prior to Paragraph IV litigations. Section 5.6 shows our baseline results survive under an instrumental variable (IV) approach.

### 5.1. Shareholder-by-shareholder analysis

We restrict our sample on brand-generic firm pairs in which both parties are publicly listed firms. This is because we consider the fact that pairs with a zero possibility of having horizontal shareholdings (private-public or private-private pairings) might differ systematically from public-public pairs with a positive probability of having horizontal shareholdings.

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<sup>24</sup>The relative benefits of the discrete-treatment specification are that it may mitigate concerns related to measurement error and it is easier to understand and depict graphically. Our results, however, are not materially altered if we use the continuous-treatment specification.

Table 3 reports ownership stakes, voting shares, and horizontal shareholdings of the 10 largest shareholders. We form ranks based on shareholders' generic ownership. We require both the brand-name plaintiff and the generic defendant to be publicly listed firms. We only include brand-generic pairs that have had Paragraph IV disputes in our sample. For each of the 10 largest institutional shareholders, we calculate horizontal shareholdings based on equation 4. On average, the generic's largest institutional shareholder owns 5.6% of generic shares, 3.4% of voting shares, and 1.6% of brand shares, and puts a weight of 19.6% on the brand incumbent. The weights assigned to the brand range from 25.0% to 33.8% among other top shareholders. The standard deviation of horizontal shareholdings is 22.4% among the largest investors, and increases to 30.2% among the 10th largest investors.

The pattern revealed by Table 3 seems to echo the concern raised by Harford et al. (2011). That is, influential generic shareholders might have small stakes in the brand and, as a result, care little about the brand's sales. In our empirical setting, two factors, mitigate this concern. First, because profits generated by a branded drug strictly dominate the profits generated by the generic substitute, horizontal owners gain more from selling the patent-protected drug than from selling its generic substitutes. The following statistics support our conjecture. From 2006–2016, U.S. sales of generics, on average, only account for 18% of brand prescription medication sales.<sup>25</sup> In addition, an average generic price is only 3.6% of the pre-expiry price of their brand version,<sup>26</sup> and generic drugs suffered a price reduction of 51% within 12 months after their loss of exclusivity.<sup>27</sup> These statistics imply generic horizontal-owners gain much from selling the brand drug than from selling the generic.<sup>28</sup>

Second, unlike the M&A case, where bidders' losses are exactly targets' gains, generic shareholders may not lose that much if they allow the entrant to collude with the brand incumbent, because settlement fees can (at least partially) compensate their loss for delay-

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<sup>25</sup>Medicines Use and Spending in the U.S. - A Review of 2016 and Outlook to 2021, page 43. May 2017. Published by IQVIA.

<sup>26</sup>Drug Store News, November 2016, page 50

<sup>27</sup>Drug Store News - Generic Drug Report, February, 2016, page 4

<sup>28</sup>Untabulated results show that, if we calculate cross-holdings from the brand-name incumbent to generic entrant(s), cross-holdings are not associated with the settlement rate. These results are consistent with our conjecture that the gains from encouraging generic entry, despite how large a stake is held by an incumbent on the entrant side, are not attractive enough for institutional investors to give up the brand drug.

ing an entry. According to an FTC study released on July 2010, brand-name companies typically pay generic manufacturers between \$1.75 million and \$132.5 million for a delay period of between four months and 10 years.

## 5.2. *Determinants of Paragraph IV challenge*

In equilibrium, the outcome of patent-infringement lawsuits and the selection of generic ANDA filer (under the Paragraph IV certification) are jointly determined. One concern is that unobservables match the brand incumbent and generic ANDA filer and simultaneously lead institutional investors to hold both firms.<sup>29</sup>

To address this concern, we check whether generic manufacturers with higher horizontal shareholdings with a brand-name firm are more or less likely to challenge the monopoly status of a drug owned by that brand-name firm. We are particularly interested in whether the level of horizontal shareholdings, measured one quarter prior to the litigation, has a tangible effect on the selection of Paragraph IV challengers.

To do so, we estimate the following linear probability model:

$$Challenge_{j,k,s} = \alpha + \beta \times Horizontal\%_{j,k,s-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_s + \epsilon_{j,k,s}, \quad (7)$$

where  $Challenge_{j,k,s}$  is a dummy variable equal to 1 if a brand-name company  $k$  files a patent-infringement lawsuit against generic firm  $j$  in year-quarter  $s$ , and zero otherwise.

$Horizontal\%_{j,k,s-1}$  is top N (N=3, 5, 10) generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer (as described by equation 4) one quarter prior to the brand's initiation of lawsuit. We lag  $Horizontal\%$  by one quarter because once the brand company has received the notice that an ANDA application is filed under the Paragraph IV certification, it has 45 days to sue generics for patent infringement. Our results are not materially altered if we measure generic horizontal shareholdings several quarters prior to the brand's initiation of lawsuit.

To address potential omitted variables, we use  $\phi_j$ ,  $\phi_k$ ,  $\phi_l$ , and  $\phi_s$  to capture fixed effects from the generic defendant  $j$ , the brand plaintiff  $k$ , federal district court  $l$ , and the

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<sup>29</sup>Harford et al. (2011) find cross-holdings do not lead to wealth transfer from bidders to targets, but strongly affect the selection of targets of acquisition.

year-quarter  $s$  in which the brand sues. In alternative specifications, we exploit variation within trade names ( $\phi_m$ ) to control for unobservables.

To select “potential challengers”, we require public generic manufacturers to have submitted at least 20 distinct applications to the FDA under *any* form of Paragraph certification over the most recent three years. Our estimates are similar if we vary the above cutoff between 15 and 30. The vector of  $X'$  includes the following variables: (1) a set of dummy variables indicating a drug’s ranking status regarding sales (if observable), (2) a dummy indicating whether a generic  $j$  has experience in the brand drug form/route (*Route*), (3) a dummy indicating whether a generic  $j$  has experience in the brand drug’s therapy class (*Therapy*), and (4) the number patents covering a drug. The inclusion of these variables is motivated by prior studies on the determination of generic entry in the pharmaceutical industry (Scott Morton, 1999, 2000; Kyle, 2006; Ellison and Ellison, 2011; Hemphill and Sampat, 2011).<sup>30</sup>

Table 5 presents linear probability estimates of the effect of institutional horizontal shareholdings on the likelihood of a generic manufacturer filing Paragraph IV challenges. The results in all columns indicate that horizontal shareholdings do not predict Paragraph IV challenges. In addition, almost all the other variables also do not have predictive power of Paragraph IV challenges. One exception is that generics with prior experience in the drug form/route are more likely to file ANDA applications under the Paragraph IV certification.

One concern is that horizontal shareholdings might be correlated with unobservables determining the Paragraph IV challenge, which in turn bias our estimation of equation 7. To address this endogeneity concern, we exploit the variation in the implied change in horizontal holdings caused by the BlackRock’s acquisition of Barclays Global Investors (BGI).

Figure 5 plots histograms of the distribution of implied percentage changes in horizontal shareholdings by the ten largest generic shareholders across sample units at the brand-generic-year-quarter level. Table A.2 presents the instrument variable (IV) estimates. Panel A presents the first-stage regression and Panel B presents the second-stage. Although  $High \Delta_{j,k}^{09Q1}$  is a strong instrument, the effect of horizontal shareholdings on the selection of Paragraph IV challenger into sample is literally zero.

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<sup>30</sup>Hemphill and Sampat (2011) document that The likelihood of Paragraph IV challenge varies with brand-name sales and the nature of patent portfolio.

### 5.3. Baseline results

Our regression sample includes the 666 Paragraph IV challenges in which both litigants are publicly listed firms. Table 4 presents descriptive statistics for our regression sample of 666 challenges in which both the brand-name plaintiff and generic defendant are publicly listed. Several patterns emerge. First, the parties typically did not go to trial: 36.8% of cases were settled and 29.4% were dismissed and 31.2% end up going to trial. Second, more than one generic manufacturer was involved with the same Paragraph IV challenge in 25.5% cases. Third, forty percent of challenges were launched by first generics. Fourth, generic manufacturers challenged an average of two patents in each case. Fifth, thirty one percent of challenges were launched by generic manufacturers with previous experience in drug dosage form/route in the most recent three years. Sixth, sixty eight percent of challenges were launched by generic manufacturers with previous experience in therapy class in the most recent three years. Seventh, about forty percent challenges were targeted at top 200 best-selling drugs ranked in the year in which lawsuits were filed.

In Figure 6, we graphically illustrate our key findings. Panel A of Figure 6 compares the fraction of settled lawsuits for generic defendants with high and low horizontal shareholdings. We classify high and low based on whether horizontal shareholdings are greater than the sample mean. The fraction of settled lawsuits is about nine percentage points higher for generic firms with high horizontal shareholdings (0.43 vs. 0.34). Our untabulated statistics show the difference is statistically significant. In Panel B, the parties in the high group are six percentage points less likely to go to trial than those in the low group. Our untabulated statistics show the difference in the fraction of dismissed lawsuits for low and high groups is not distinguishable from zero.

To formally test our story, we lay out the following linear probability regression model:

$$Settlement_{i,j,k} = \alpha + \beta \times Horizontal\%_{j,k,s-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{i,j,k}, \quad (8)$$

where  $Settlement_{i,j,k}$  is an indicator variable set equal to 1 if the two parties entered into a settlement agreement with respect to *at least* one patent dispute triggered by litigation lawsuit  $i$  filed by brand-name plaintiff  $k$  against generic defendant  $j$ , and zero otherwise.

The lawsuit is filed in year-quarter  $s$ . *Horizontal%* is our empirical measure of horizontal shareholdings as in equation 4.  $X'$  is the same set of control variables as in equation 7.

To address potential omitted variables, we use  $\phi_j$ ,  $\phi_k$ ,  $\phi_l$ , and  $\phi_s$  to capture fixed effects from the generic defendant  $j$ , the brand plaintiff  $k$ , federal district court  $l$ , and the year-quarter  $s$  in which the brand sues. In alternative specifications, we exploit variation within trade names ( $\phi_m$ ) to control for unobservables. Each trade name identifies a unique active ingredient and thus captures unobservables such as expected revenue of the brand before patent expiration, elasticity of demand, customer mix, switching costs, FDA regulations, and advertising intensity (Scott Morton, 1999, 2000). We cluster standard errors at the U.S. Federal District Court level.<sup>31</sup>

Table 6 presents linear probability estimates of the effect of institutional horizontal shareholdings on the likelihood of settlement. *Horizontal%* is significantly associated with the likelihood of settlement. In columns (1)-(3), *Horizontal%* is measured as the top 3 generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant. In column (1), we do not control for any fixed effects. A one standard deviation increase in *Horizontal%* is associated with a 4 percentage point increase the settlement rate ( $0.235 \times 0.174$ ). This estimate is 11.1% of the sample mean. In column (2), we include full sets of year-quarter, district court, brand plaintiff, and generic defendant fixed effects. The economic magnitude of our estimates increases by 30%. In column (3), we use variation within trade names. The estimated effect of horizontal shareholdings on settlement increases by 45% relative to that in column (1). A one standard deviation increase in *Horizontal%* is associated with a 5.8 percentage point increase in the settlement rate by ( $0.34 \times 0.172$ ).

In columns (4)-(6) and (7)-(9), we perform same panel-regression specifications to estimate the impact of horizontal shareholdings by the top 5 and 10 largest generic shareholders on the likelihood of settlement. The economic magnitudes of our estimates are similar. This is not surprising because we assign smaller weight on shareholders with less voting rights to construct institutional horizontal shareholdings.

Beyond the independent variable of our interest, other challenge-level characteristics also correlate with the likelihood of settlement. Settlement occurs more frequently in

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<sup>31</sup>For robustness checks, we also cluster standard errors at the following levels: generic entrants, brand plaintiffs, and trade names. Finally, we also cluster standard errors at both court and year levels. Our estimation results are not sensitive to the choice of clusters.

heavily-patented drugs, is less frequent when the generic is experienced in either dosage form/route or therapy class, and is less observed in blockbuster drugs.

#### 5.4. *Do institutional investors adjust holdings prior to litigations?*

Correlations between common ownership and settlement rates across brand-generic pairs do not necessarily have a causal interpretation, as potentially omitted control variables or reverse causality may play a role. To address the omitted-variable problem, we control for a full set of fixed effects in equation 8. Our baseline estimates, however, could still be plagued by reverse causality in which horizontal shareholdings might be correlated with investors' anticipation of litigations.

To assess the extent to which holdings are adjusted prior to litigations, we estimate the following ordinary linear square (OLS) equation:

$$Horizontal\%_{j,k,s} = \alpha + \sum_{t=-8}^{t=0} \beta_t \times Lawsuit_{j,k,t} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{i,j,k}, \quad (9)$$

where  $Lawsuit_{j,k,t}$  is a dummy variable indicating the  $t^{th}$  ( $-8 \leq t \leq 0$ ) quarter prior to a litigation initiated by brand-name company  $k$  against generic manufacturer  $j$ , and zero otherwise. In addition to the same set of control variables as in equation 8, we also include three variables determining the level of horizontal shareholdings: two dummies indicating whether the brand and generic are constituents of the S&P 1500 index, respectively, and one continuous variable measuring the market capitalization of the generic defendant.

Table 7 presents the estimation results, and Figure 7 plots  $\hat{\beta}_t$  and the 95% confidence intervals over the window of  $[-8, 0]$  months relative to the quarter in which a brand sues the generic. In all columns, the coefficients of  $\hat{\beta}_t$  ( $-3 \leq t \leq 0$ ) are not statistically different from zero, suggesting top generic shareholders do not adjust their portfolio holdings in response to the impending litigations. There are some evidence suggesting that, between quarters -8 and -4, the five largest generic shareholders slightly adjust downward their holdings with the brand but the economic magnitude is negligible.

## 5.5. Robustness

In Table 8, we show that our results are robust to several alternative measures of horizontal shareholdings.

First, we further expand the scope for omitted variables by identifying potential determinants of horizontal shareholdings (Gilje et al., 2017). Based on results in Table 7, we expand the list of control variables by adding two dummies indicating whether the brand and generics are constituents of S&P 1500 index and one continuous variable measuring the market capitalization of generic dependent. In Panel A, we show our main results are robust to the inclusion of these determinants.

Second, Dennis et al. (2018) point out that when a firm files for bankruptcy protection, shareholders do not retain ownership and control rights in the bankrupt firm. Azar et al. (2018b) conclude the anticompetitive effect is weaker in markets affected by bankruptcies. To address this concern, we follow two steps. First, we search our sample for firms that filed bankruptcy during the period from the start of litigation until the resolution of litigation. On the generic side, KV Pharmaceutical filed for bankruptcy in August 2012 and emerged in 2014; on the brand side, Savient pharmaceuticals filed for bankruptcy in October 2013 and sold its assets to Crealta Pharmaceuticals on January 10, 2014. None of the above periods coincide with the infringement lawsuits.

Second, we exclude lawsuits filed during the Great Recession. In Panel B, we show our estimates of the impact of horizontal shareholdings on settlement turn out to be more statistically and economically significant. In column (8), for example, a one standard deviation increase in *Horizontal%* by the top 10 largest generic shareholders is associated with a 7.4 percentage point increase the settlement rate ( $0.45 \times 0.165$ ). This estimate is about 20% of the sample mean.

Third, our results might be driven by the nonlinear nature of the measure of horizontal shareholdings. We therefore create an indicator variable for whether *Horizontal%* is greater than its sample mean.<sup>32</sup> In Panel C, we document a strongly positive correlation between this indicator variable and the settlement rate. In column (1), for example, the litigants involved with generic shareholders putting more than 30% weight on the brand plaintiff are 26 percentage points more likely to settle.

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<sup>32</sup>Our estimation results are not sensitive to the choice of cutoffs to define the discrete version of horizontal shareholdings.

Fourth, we estimate our baseline specification by weighted least squares (WLS). To assess whether high-profile Paragraph IV challenges drive our results, we weight observations based on the total number of patents covering a drug in Panel D. Results become more statistically significant and the size of the estimated effects is similar to the baseline analysis of Table 6. In Panel E, we also weight observations based on the number of generic manufacturers filing the same ANDA with the FDA under the Paragraph IV certification. Our point estimates across specifications are similar to the baseline. We conclude the high-profile challenges do not fully drive our results.

Fifth, a branded drug is covered by several patents. The brand-name incumbent typically files infringement lawsuits with respect to all patents at issue. In our baseline specification, we code a challenge-level litigation outcome as settled if the two parties settle at least one patent dispute. In Panel F, we construct the settlement rate for each challenge by taking the mean of the settlement indicator across patents at issue. We regress these continuous variables on horizontal shareholdings, and we arrive at the same conclusion.

Sixth, in our main specification, we focus on the subsample in which both litigants are publicly listed firms. In Panel G, we perform panel regressions on the 2,023 challenges which include patent disputes in which at least one private firm is involved. To mitigate the concern that the variation of horizontal shareholdings might be driven by the zeros due to litigants' listing status, we regress settlement rates on a dummy variable indicating whether horizontal shareholdings is above the mean estimated based on the both-public sample. Our estimates remain statistically significant in most columns but the size of the coefficients is much smaller compared with the baseline estimates.

Seventh, we previously measure an institution's control by only using sole voting rights. In Panel H, we show our results are robust to the inclusion of shared votes into the calculation of control rights. In fact, the magnitude of our estimated coefficients in the most restrictive specification increases (columns (3), (6) and (9)) compared with the same columns in Table 6.

## 5.6. BlackRock's acquisition of Barclays Global Investors

In the following first stage, we run the first-stage regression on the post-period:

$$\begin{aligned} Horizontal\%_{j,k,s-1} = \alpha + \beta \times High \Delta_{j,k}^{09Q1} + X' \times \gamma_1 + \\ \phi_j + \phi_l + \phi_s + \epsilon_{i,j,k}, \end{aligned} \tag{10}$$

where  $High \Delta_{j,k}^{09Q1}$  is an indicator variable coded as one if  $\Delta Horizontal\%_{j,k}^{09Q1}$  is greater than the mean of its sample distribution, and zero otherwise. In equation 10, we exploit variation within generic defendant(s)  $j$ , district court  $l$ , and year-quarter  $s$ . Our instruments vary across generic-brand pairs because the same generic shareholders in  $j$  have different brand shares across brand plaintiffs ( $k$ ). The BlackRock's acquisition of Barclays BGI generates these differences. We therefore do not exploit variation either within brand plaintiffs.

Figure 8 plots histograms of the distribution of implied percentage changes in horizontal shareholdings by top 10 generic shareholders across 424 Paragraph IV lawsuits. These lawsuits were filed after the first quarter of 2009. The implied percentage change in horizontal shareholdings, as of the first quarter of 2009, vary substantially across these lawsuits, ranging from 0% to 99%. The standard deviation is 28.7%.

Panel A of Table 9 presents the first-stage regression according to equation 10. The dummy variable indicating a high level of the implied change in horizontal shareholdings ( $High \Delta_{j,k}^{09Q1}$ ) appears to be strong instruments. Following the recommendation of Jiang (2017), we also report the partial  $R^2$  of the excluded instrumental variables in explaining the variation in the endogenous variable. We show that the excluded instrumental variable well explains the variation in the endogenous variable.

Panel B of Table 9 reports the second stage of the IV estimation. Compared to the baseline findings, the economic magnitude of the IV estimates increases. In column (4), for example, a one standard deviation increase in  $Horizontal\%$  is associated with a 14.0 percentage point increase in the settlement rate, which is 39.4% of the sample mean.

## 6. Are settlements anticompetitive?

In this section, we examine whether settlements are more anticompetitive when top institutional shareholders of generic defendant hold more brand shares. We pay particular attention to settlements with the first generic. Subsection 6.1 examines the role of the first generic on the impact of generic horizontal shareholdings on settlement. Subsection 6.2 examines the impact of generic horizontal shareholdings on firm value around settlement. Subsection 6.3 examines how horizontal shareholdings affect the timing for a settled generic firm to market generic drugs.

### 6.1. First generic

Under the Hatch-Waxman Act, the FDA sets a requirement that the first ANDA filer submitting a paragraph IV certification successfully defend a patent infringement suit to be entitled the 180 day of marketing exclusivity. Settlements with the first-filer can prevent all generic entries. This is because every subsequent generic entrant has to wait until the first generic has been marketed for 180 days. In appendix A, we present several high-profile cases in which the brand company paid the first generic to substantially delay the entry.

We specify the following linear probability regression model to assess the impact of the first generic on the likelihood of settlement through the channel of common institutional owners.

$$\begin{aligned} \text{Settlement}_{i,j,k,s} = & \alpha + \beta_1 \times \text{Horizontal}\%_{j,k,s-1} + \beta_2 \times \text{Horizontal}\%_{j,k,s-1} \times \text{First} + \\ & \beta_3 \times \text{First} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_t + \epsilon_{i,j,k,s}. \end{aligned} \tag{11}$$

Table 10 reports the regression results. Surprisingly, despite all regression specifications, we fail to find strong evidence suggesting that common ownership increases the likelihood of the brand settling with the first generic.<sup>33</sup>

We next evaluate two possible explanations the findings presented in Table 10. The first is the escalated monitoring of settlement agreements by FTC. In recent years, FTC

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<sup>33</sup>As we show in section 6, however, the results presented in Table 10 do not suggest that, when the two parties are negotiating for the settlement agreement, the brand incumbent will not exploit the 180 day exclusivity to preclude other generic entrants.

has been actively monitoring those anti-competitive settlement agreements. Following its 2002 study, which concluded that settlements substantially delayed generic entries, FTC recommended that Congress pass legislation to require pharmaceutical companies to file agreements with the FTC. After passing in Congress by a close margin, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA Act) was signed by President George W. Bush on December 8, 2003. Pursuant to the MMA Act, pharmaceutical companies must file settlement agreements with the FTC and the Department of Justice within ten days of their execution. On June 17, 2013, the Supreme Court ruled that the FTC can pursue antitrust challenges of drug patent settlements. However, the court did not completely reject these so-called “pay for delay” deals between brand-name and generic drug makers, suggesting that drug makers will have some room to keep making them as long as they meet federal antitrust rules.

After 2003, pharmaceutical companies thus were not able to sidestep competition by only settling with the first generic. They can, however, settle with multiple generics to prevent all generics from entering at the same time. The brand need to settle with all generics but to allow them to enter at different time points. By doing so, the incumbent’s profits will decline more slowly.

The second explanation for the results in Table 10 is that settlement agreement may not resolve the patent dispute. In this case, the generic firm receives no assurance of being entitled with the exclusivity period. According to the 1984 Hatch-Waxman Act, the first generic submitting a Paragraph IV certification is entitled to 180 day exclusivity if it successfully defends in the court. The “successful defense” requirement was established to eliminate “an incentive for frivolous claims of patent invalidity or non-infringement because it would give ANDA applicants exclusivity even if the applicant was unsuccessful in defending against the patent owner’s lawsuit”.

In many cases, however, the two parties settle before hearing court rulings. By reaching an agreement on entry dates, the first generic firm retains its eligibility for the 180 day exclusivity. On one hand, because the patent is never adjudicated, the first-filer does not risk the possibility that it might lose the patent suit. On the other hand, however, the generic is not absolutely certain of owning exclusivity because, for example, a later-filing generic might win the suit, triggering the exclusivity period prior to the first

filer’s FDA approval. Hence, the brand has an equal incentive to settle with later ANDA filers.<sup>34</sup>

## 6.2. *Horizontal shareholdings, settlements, and the brand’s and generics’ returns around settlement*

### 6.2.1. *Brand returns*

If horizontal shareholdings have anticompetitive effects, the brand’s stock price around the settlement date is expected to increase with the weight of generic shareholders’ ownership in the brand relative to their ownership in the generic. By contrast, if the payment to a generic manufacturer simply reflects a risk premium that a risk-averse brand-name manager would pay to resolve uncertainty, the stock price should decrease upon settlement.<sup>35</sup> Under the risk-premium story, we expect the brand’s stock price to decline in proportion to the level of institutional horizontal shareholdings.

The regression specification of the event study is as follows:

$$AR_{i,j,k}^b = \alpha + \beta \times \text{Horizontal}\%_{j,k,s-1} + X' \times \gamma + \phi_k + \phi_l + \phi_s + \epsilon_{i,j,k}. \quad (12)$$

where  $AR_{i,j,k}^b$  is the cumulative market adjusted return for the brand manufacturer over the window around the event in which the generic defendant(s)  $j$  and the brand plaintiff  $k$  enter into a settlement agreement with respect to lawsuit  $i$ . The lawsuit is initiated in year-quarter  $s$ . We use  $(-3, +3)$  to specify the length of the window. Abnormal returns are winsorized at the 1% and 99% levels.

To conduct the event study, we require the litigants to have stocks publicly traded in a stock exchange around settlement. Under this requirement, we have very few observations based on the sample which only includes challenges in which both litigants are publicly listed. To expand the sample, we thus include all publicly listed brand-name plaintiffs

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<sup>34</sup>For details about the eligibility of the 180 day exclusivity, please see “Guidance for industry 180-Day exclusivity: Questions and answers”. The article is accessible via the following website: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536725.pdf>.

<sup>35</sup>The risk-premium hypothesis relies on the assumption that the brand manager holds an undiversified portfolio. See Drake et al. (2015) for a similar discussion. The authors use the LexisNexis, Factiva databases, and Google internet searches to identify 68 settlements as a resolution of Paragraph IV lawsuits from 1993 to 2013. The authors document a 6% increase in brand stock prices for settlements with an indication of pay-for-delay.

settling with generic defendants with any listing status. Our sample consists of 363 distinct lawsuits associated with publicly-traded brand-name companies settling with 96 distinct generic entrants on 152 distinct trade names. We also create an indicator variable (*Generic Private*) equal to 1 if the brand plaintiff is publicly listed and the generic defendant is not, and zero otherwise. The indicator variable helps prevent zero horizontal shareholdings from influencing the estimates.

An assumption that underlies equation 12 is that all Paragraph IV litigations are conducted in the form of public hearings, in which interested parties are well aware of the resolution of the patent disputes. Unfortunately, our data do not distinguish between public and private hearings in recording the disputes. We therefore likely have measurement error in our dependent variable, which would increase standard errors.

Panel A of Table 11 reports the estimation results. We perform OLS regressions. In odd-number columns, we find a significantly positive correlation between horizontal shareholdings, as of the commencement of Paragraph IV litigation, and brands' market adjusted abnormal returns over the  $(-3, +3)$  -day window around the settlement. The estimates have sizable economic magnitude and are robust to the inclusion of brand-plaintiff fixed effects. In column (1), for example, a one standard deviation increase in horizontal shareholdings by the top 3 largest shareholders increases the brand's market capitalization over the  $(-3, +3)$  -day window by 0.7% ( $0.042 \times 0.17$ ).<sup>36</sup>

In even-number columns, we interact a dummy indicating whether a defendant is the first generic and allow  $\beta$  to vary across the first generic and other generics. Interestingly, the interaction term  $Horizontal\% \times First$  turns out to be strongly positive in all columns. A one standard deviation increase in horizontal shareholdings further creates 0.6 — 0.8% value for the brand if it settles with the first generic.

### 6.2.2. *Generic returns*

We next investigate the value implication of horizontal shareholdings for generic manufacturers (Paragraph IV filers) entering into a settlement agreement. We specify the following regression equation:

$$AR_{i,j,k}^g = \alpha + \beta \times Horizontal\%_{j,k,s-1} + X' \times \gamma + \phi_j + \epsilon_{i,j,k}, \quad (13)$$

---

<sup>36</sup>Our untabulated statistics show that the standard deviation of horizontal shareholdings by all generic shareholders is 0.17 in the subsample in which stock prices of brand firms are available.

where  $AR_{i,j,k}^g$  is the cumulative market adjusted return for the generic firm over the short window around the settlement. Our untabulated statistics show that less than 15% of 2,023 lawsuits are associated with public generic manufacturers challenging 157 distinct trade names, which only account for less than 30% of the total number of drugs.

*Horizontal%* helps to identify differential incentives across shareholders in the generic during the litigation. A generic shareholder with more ownership in the brand has incentives to seal a deal that makes other shareholders of the same generic manufacturer worse off. The conflicts of interest among institutional shareholders is similar in spirit to the argument by Matvos and Ostrovsky (2008). We thus expect a negative relation between horizontal shareholdings and generic returns around the settlement date. Alternatively, top generic shareholders could force the two litigants to coordinate by quickly entering into a settlement without sacrificing the interests of generic investors, especially when they are risk averse. If this alternative hypothesis is true, we expect a positive relation between horizontal shareholders and generic returns.

Panel B of Table 11 presents estimates of the effect of horizontal shareholdings on the generic's cumulative market adjusted returns over the  $(-3, +3)$ -day window centered on the settlement event. In odd-number columns, we report zero impact of horizontal shareholdings on generic value without conditioning on whether the defendant is the first generic. In even-number columns, however, we document a (weakly) positive correlation between horizontal shareholders and even returns when the first generic enters into a settlement agreement with the brand plaintiff.

### 6.2.3. *Additional Tests*

We perform three additional tests to further verify the notion that settlement agreements are anticompetitive. In our first additional test, we re-estimate the impact of horizontal shareholdings on returns around settlement by requiring both the plaintiff and defendant to be publicly listed. As Panel A of Table A.4 shows, compared to what we find in Table 11, the estimates show a remarkable difference between brand returns settlements with the first and other generics. In column (4), for example, one standard deviation increase in horizontal shareholdings creates 1.7% if the settled generic is the first one. By contrast, horizontal shareholdings bear a zero correlation with returns if the brand settles with the other generics. In Panel B, we also document a strongly positive correlation

between horizontal shareholdings and generic returns around the event date only when the brand enters into a settlement agreement with the first ANDA filer.

Our analysis so far does not include the reaction of stock markets prior to the settlement date. One potential concern is that the net wealth effects are overall negative for the incumbent irrespective of the positive abnormal returns around the settlement date. In our second additional test, we estimate the wealth implication around the date in which the brand-name plaintiff filed lawsuits against the generic. We present our estimates in Table A.5. In general, we conclude that horizontal shareholdings do not have a material impact of generic and brand values around the commencement of the lawsuit.

Viewed as a whole, positive brand returns around settlement indicate an extension of brands' monopoly status rather than a reduction in litigation fees. The brand's monopoly is mainly extended by its settlement with the first generic which is entitled to claim the 180-day exclusivity. Our results also suggest settlements benefit large shareholders of the first generic if they have more ownership with the brand. Thus, these "pay-for-delay" deals are a win-win for the generics as much as they are for the brand incumbent. The incumbents' drug prices stay high and the profits of the incumbents' monopoly are shared with the first generic.

### *6.3. Horizontal shareholdings and the timing to market generic drugs*

In this subsection, we examine whether the observed stock market reactions are consistent with the marketing of drugs by settled generic manufacturers. We pay particular attention to the impact of settlements by the *first* generic on the timing to market the same drug at issue by all ANDA filers under the Paragraph IV certification. The FDA does not approve another Paragraph IV application for the same product until 180 days after the first ANDA filer markets the generic substitute of the branded product. By entering into a "pay-for-delay" agreement, the brand-name incumbent pays the first generic in exchange for the forfeit of the exclusivity or for the delay of marketing, which precludes all other generic firms from entering the market.

We download the product file, which is publicly available from the FDA's official website. The product file provides detailed information about the exact date on which a drug product is marketed and by which company. The company can be either an NDA filer (brand manufacturer) or an ANDA filer (generic manufacturer). We extract

marketing dates associated with ANDA filers. We match these marketing dates to our Paragraph IV lawsuit documents based on active ingredient, drug formulation, and the name of the generic manufacturer. Among the 2,023 patent-infringement lawsuits, in 25% of the cases, Paragraph IV filers marketed the generic version of branded product by the end of our observation period (August 8, 2019).

We specify the following linear probability model to estimate the effect of horizontal shareholdings of the first generic with the brand plaintiff on the timing of all ANDA filers to market the challenged drug following the settlement by the first generic with the brand. In this regression, we include only lawsuits against generic manufacturers challenging a branded drug. We impose two criteria on this sample. First, both the first generic and the brand-name plaintiff are publicly listed firms. Second, the first generic settles with the brand.

$$Market_{i,j,k} = \alpha + \beta_1 \times Horizontal\%_{j',k,s-1} + X' \times \gamma + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{i,j,k}, \quad (14)$$

where  $Market_{i,j,k}$  is an indicator variable coded as one if a generic version of the branded drug is marketed by generic  $j$  sued by brand  $k$  for challenge  $i$ , and zero otherwise.  $Horizontal\%_{j',k,s-1}$  is the weight of top  $N$  ( $N=3, 5, 10$ ) shareholders of the first generic  $j'$  in the brand plaintiff  $k$  relative to their ownership in the first generic  $j'$ . The lawsuit is filed against the first generic  $j'$  in year-quarter  $s$ .

One potential concern is that many ADNA applications with an attempt to sell the generic substitutes have not yet been approved. To avoid the truncation problem, we only include lawsuits that are resolved prior to 2015, despite litigation outcomes.

Panel A of Table 12 reports OLS estimates of the effect of horizontal shareholdings by the settled first generic on the probability of all generic manufacturers marketing drugs by the end of our observation period. Our estimates suggest generic manufacturers are less likely to market generic substitute by August 8, 2019, if shareholders of the settled first generic hold more brand shares. In column (4), for example, a one standard deviation increase in horizontal shareholdings by the settled first generic is associated with a 25.3 percentage points ( $-1.540 \times 0.164$ ) reduction in the probability that a settled generic manufacturer will sell a generic drug. These magnitudes are about 75% of our sample mean (33%).

In Panel B of Table 12, we exclude lawsuits associated with the settled first generic itself to address the concern that horizontal shareholdings in equation 14 might be correlated with unobservables determining its marketing behavior, which in turn drives the results in Panel A. Our estimates, however, suggest the first generic’s horizontal shareholdings are strongly negatively correlated with the probability that non-first generics will market drugs. The improvement in economic magnitudes is huge. We again use column (4) as an example: a one standard deviation increase in horizontal shareholdings now is associated with a 72.4 percentage points ( $-4.47 \times 0.162$ ) reduction in the probability that a settled generic manufacturer will sell a generic drug. These magnitudes are about 230% of the sample mean!

To further address the right-truncation problem, we only consider lawsuits that are resolved three years before August 8, 2019. We set the dependent variable as an indicator variable coded as one if a generic version of the branded drug is marketed by generic  $j$  within three years after the dispute is resolved, and zero otherwise. Our results are similar. Eighteen percent lawsuits end up with generics marketing drugs within three years after the resolution. Panel C of Table 12 suggests our estimates are not affected by the truncation problem.

In unreported tables, we examine whether the marketing of generic drugs is delayed if the first generic does not settle with the brand incumbent. The estimated coefficients are not statistically significant. This is because the unsettled, first generic manufacturers probably neither forfeit the entitlement of the 180-day exclusivity nor delay the start of the it. As a result, other generics are flexible to market drugs.

## 7. Conclusion

We examine how common institutional owners of natural competitors affect the product-market outcome in the pharmaceutical industry. Such a pre-entry setting allows us to directly regress anticompetitive product-market outcomes on institutional ownership. We analyze a sample of patent-infringement lawsuits filed by brand drug manufacturers against generic manufacturers that filed Paragraph IV applications to the FDA. Paragraph IV allows generic manufacturers to produce bioequivalent drugs before the expiration of patents covering the branded product at issue. We find institutional horizontal sharehold-

ings, measured by the weight of top generic shareholders' ownership in the brand-name manufacturer relative to their ownership in the generic entrant, increases the likelihood of the two litigants entering into a settlement agreement in which the brand manufacturer often pays the generic manufacturer for the purpose of delaying entry. By investigating the brand's daily stock returns around settlement and the timing to sell the drugs by generic manufacturers who accepted a settlement offer, we conclude that institutional horizontal shareholdings facilitates anticompetitive behavior between incumbents and entrants in the U.S. pharmaceutical industry.

Coordination in the pharmaceutical industry is not uncommon. For example, Ellison and Wolfram (2006) find drug manufacturers coordinate on a specific percentage price increase in response to the health care reform in the early 1990s. Another example, generic-drug makers often coordinate on price-fixing ("Generic-Drug Companies to Face First Charges in U.S. Probe", David McLaughlin and Drew Armstrong, Bloomberg News, April 25, 2018).

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Fig. 1. Generic competition and drug prices

This figure plots the relation between the number of generic entries and drug prices. The horizontal axis represents the number of generic manufacturers marketing a branded drug. The vertical axis represents the average relative drug price per dose. Data Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999–2004, extracted February 2005.

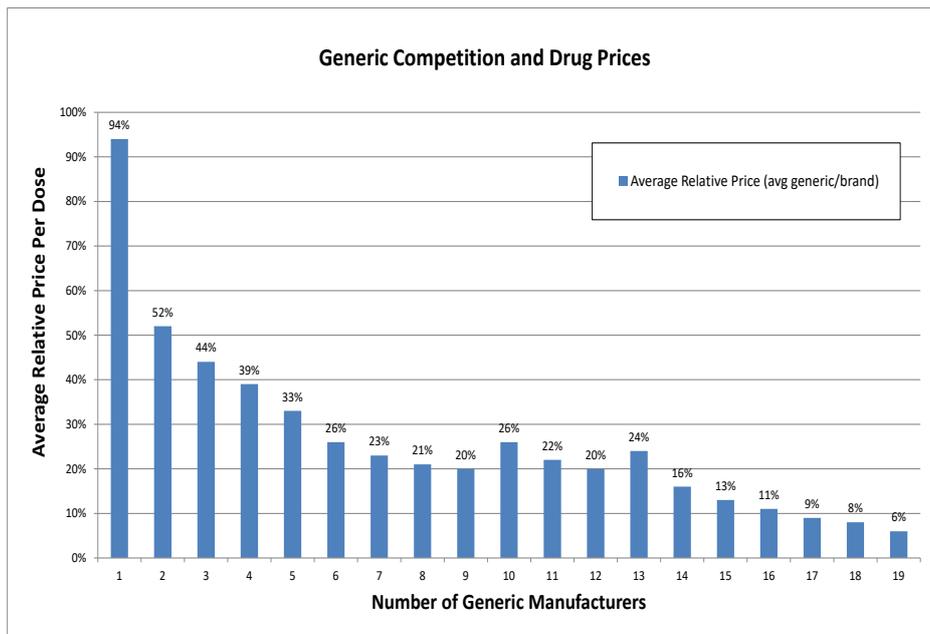


Fig. 2. Paragraph IV report from Parry Ashford Inc.

This figure provides an example of an observation in our data (i.e., a challenge by a generic manufacturer of a brand's patents). In this example, the generic manufacturer and the brand manufacturer enter into a settlement agreement.

**Arthrotec® (diclofenac and misoprostol) Delayed-release Tablets**  
**Company** PFIZER  
**Date of First Filing** November 28, 2008 (75mg/0.2mg) and June 29, 2009 (50mg/0.2mg)

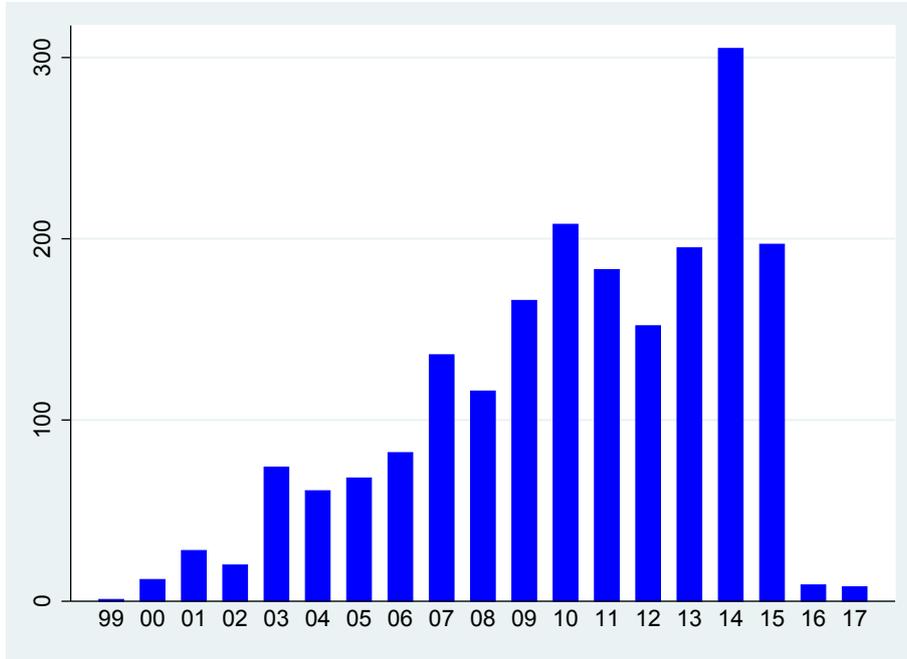
**Paragraph IV Applicant:** Teva Pharamceuticals (Barr)  
**Case Name:** PFIZER v. TEVA PHARMACEUTICALS  
**Court/Case #:** New York Southern District Court (nysdc) 1:2009cv03965  
**Date Filed:** 4/21/2009  
**Judge:** Sullivan  
**Product Strength:** 75 mg/0.2 mg and 50mg/0.2mg  
**Litigated Patents (expiration):** 5,601,843 (2/11/2014)  
**Non-Litigated Patents (expiration):** 5,698,225 (5/3/2010)  
**Plaintiff Lawyer/Firm:** Thom Beck/Sidley Austin  
**Defendant Lawyer/Firm:** David Hashmall/Goodwin Procter  
**Related Case:** None. Amended Complaint adds 50mg/0.2mg strength  
**Status:** The parties entered settlement agreement and consent judgment entered 1/22/10.  
[Complaint](#) [Amended Complaint](#) [Answer](#)  
[Consent Judgment](#)

**Product Links from FDA and USPTO**  
[Orange Book Patent & Exclusivity Data](#)  
['843 Patent](#)  
['225 Patent](#)

Fig. 3. Time trend of Paragraph IV challenges and settlement rates

Panel A plots the number of Paragraph IV litigations over years. Panel B plots the mean of settlement rates over years.

Panel A: Number of Paragraph IV challenges



Panel B: Settlement Rate

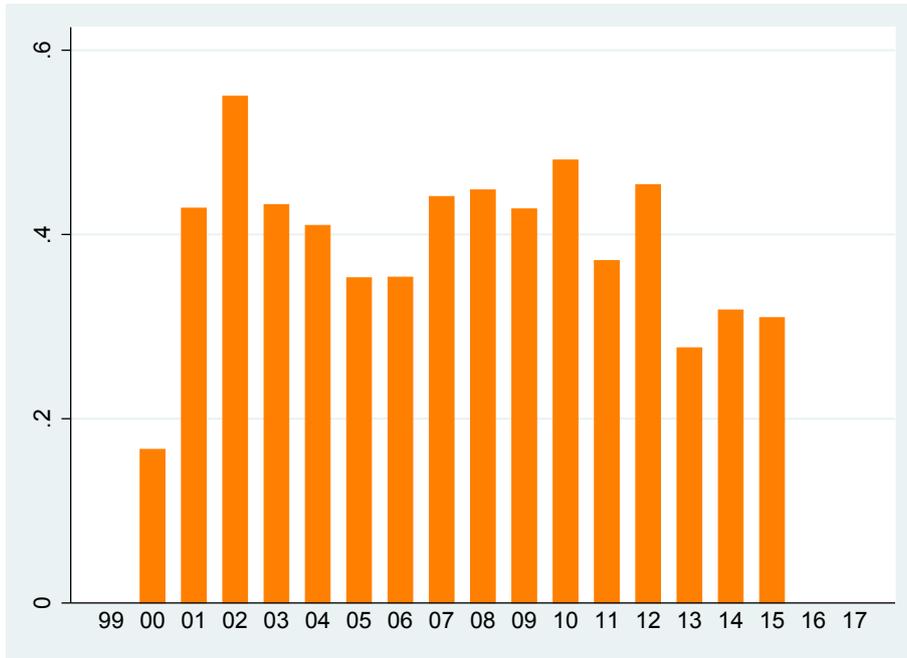


Fig. 4. Time-series variation of generic horizontal shareholdings

This figure plots the mean of horizontal shareholdings held by top 3, 5, and 10 generic shareholders from the first quarter of 2001 through the fourth quarter of 2017. We require both the generic manufacturers and the brand-name pharmaceutical companies are publicly listed firms. Horizontal shareholdings (*Horizontal%*) are measured as the weight of generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer. Generic and brand ownerships are weighted by generic shareholders' voting rights in the generic manufacturer (see equation 4 for a detailed description).

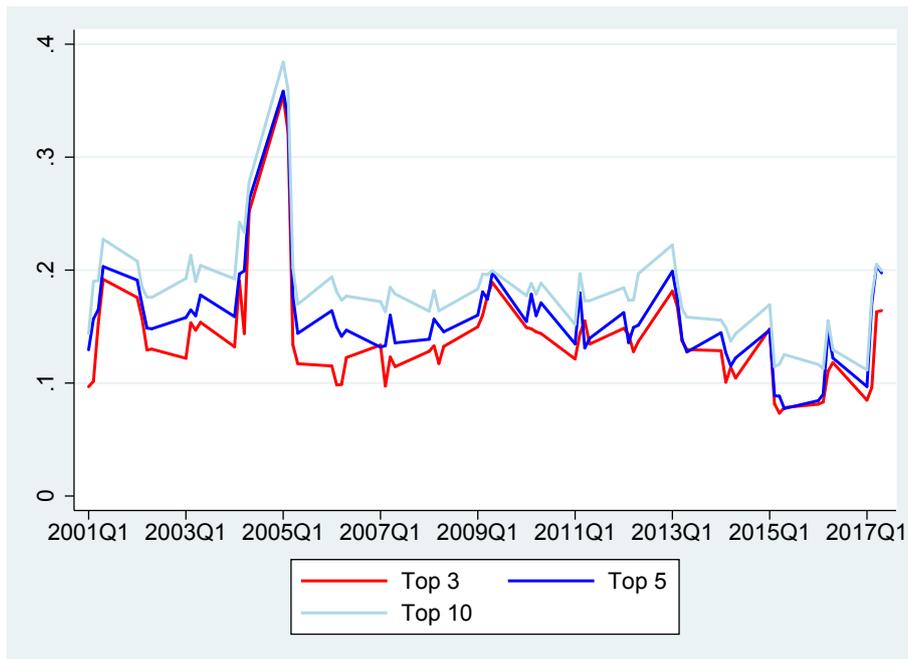


Fig. 5. Cross-sectional distribution of implied change of horizontal shareholdings (BlackRock-BGI DiD): entry selection

The figure plots the distribution of implied changes in horizontal shareholdings by top 10 generic shareholders ( $\Delta Horizontal\%^{09Q1}$ ) across observations in which both the generic defendant and the brand-name plaintiff are publicly listed firms.  $\Delta Horizontal\%^{09Q1}$  is constructed as follows: (1) We calculate the actual horizontal shareholdings in the first quarter of 2009; (2) we calculate counterfactual horizontal shareholdings in the first quarter of 2009 combining the holdings of Barclays and BlackRock; and (3) we calculate the difference between the counterfactual and the actual for each brand-generic pair. Horizontal shareholdings ( $Horizontal\%$ ) are measured as the weight of generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer. Generic and brand ownership (cash-flow rights) are weighted by generic shareholders' voting rights in the generic (see equation 4 for a detailed description).

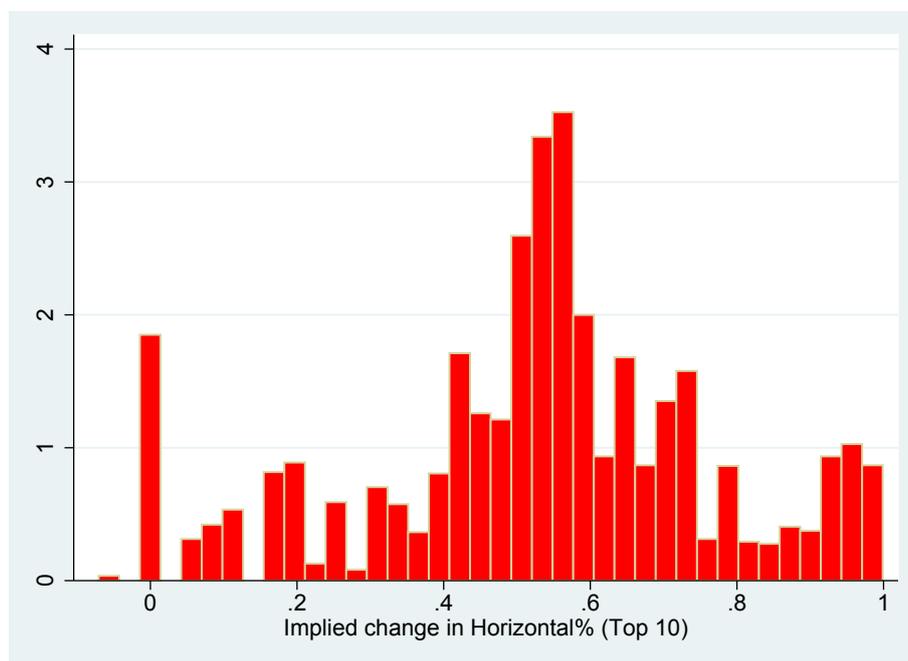
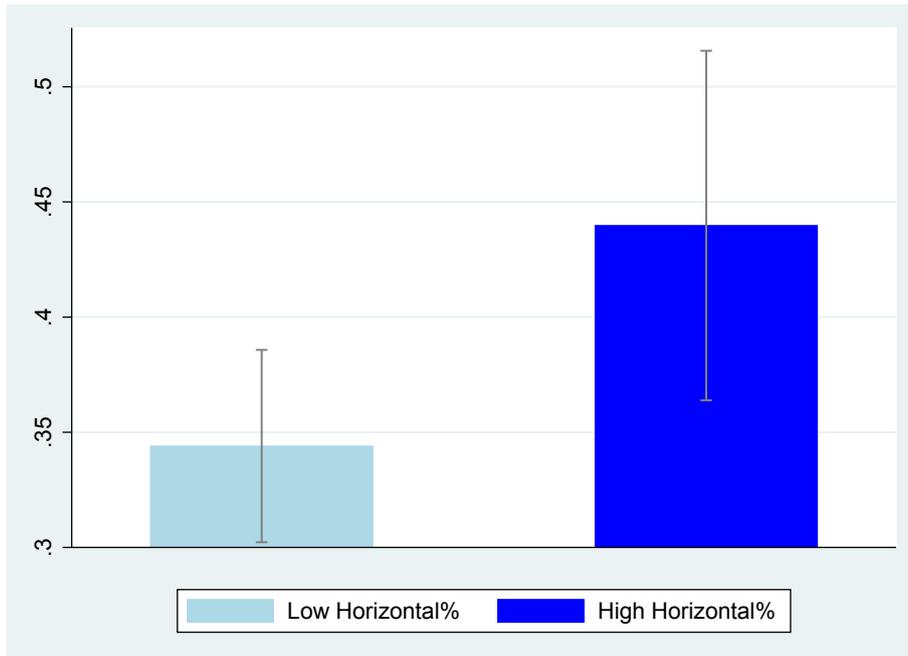


Fig. 6. Challenge outcomes: High vs. low horizontal shareholdings

This figure compares challenge outcomes for which generic defendants have high and low horizontal shareholdings. We classify a generic defendant's horizontal shareholdings as high if it exceeds 30%, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top 10 generic shareholders' ownership in the brand-name plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownerships are weighted by generic shareholders' voting rights in the generic manufacturer (see equations 4 for a detailed description). *Horizontal%* is measured as of the beginning of the quarter in which a brand files an infringement lawsuit.

Panel A: Settlement Rate



Panel B: Trail Rate

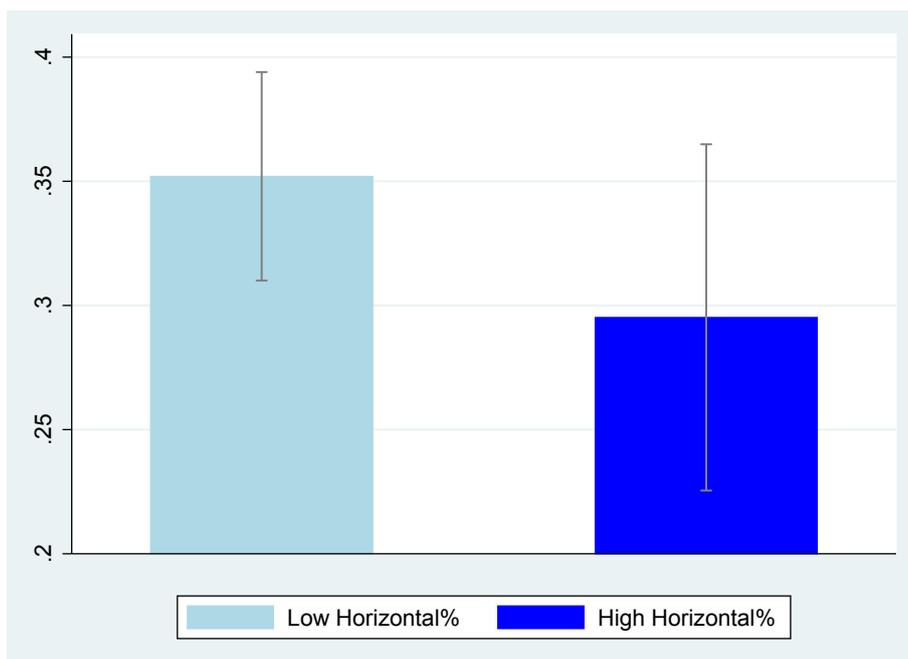


Fig. 7. Horizontal shareholdings preceding the Paragraph IV litigation

This figure plots the estimated coefficients  $\hat{\beta}_t$  and the 95% confidence intervals from equation 9.

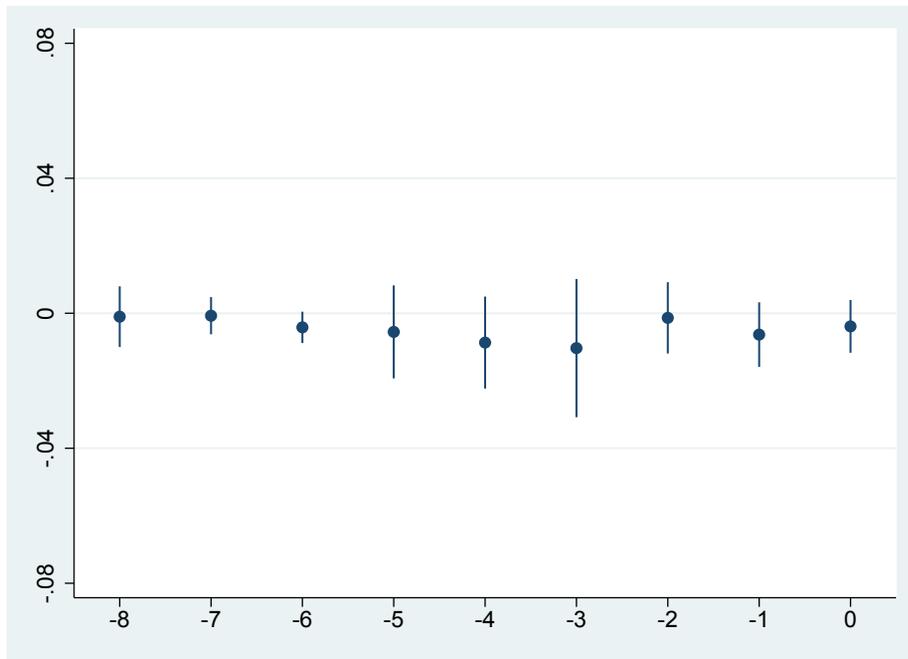


Fig. 8. Cross-sectional distribution of implied change of horizontal shareholdings (BlackRock-BGI DiD)

The figure plots the distribution of implied changes in horizontal shareholdings by top 10 generic shareholders ( $\Delta Horizontal\%^{09Q1}$ ) across patent-infringement lawsuits in which both the generic defendant and the brand-name plaintiff are publicly listed firms.  $\Delta Horizontal\%^{09Q1}$  is constructed as follows: (1) We calculate the actual horizontal shareholdings in the first quarter of 2009; (2) we calculate counterfactual horizontal shareholdings in the first quarter of 2009 combining the holdings of Barclays and BlackRock; and (3) we calculate the difference between the counterfactual and the actual for each brand-generic pair. Horizontal shareholdings ( $Horizontal\%$ ) are measured as the weight of generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer. Generic and brand ownership (cash-flow rights) are weighted by generic shareholders' voting rights in the generic (see equation 4 for a detailed description).

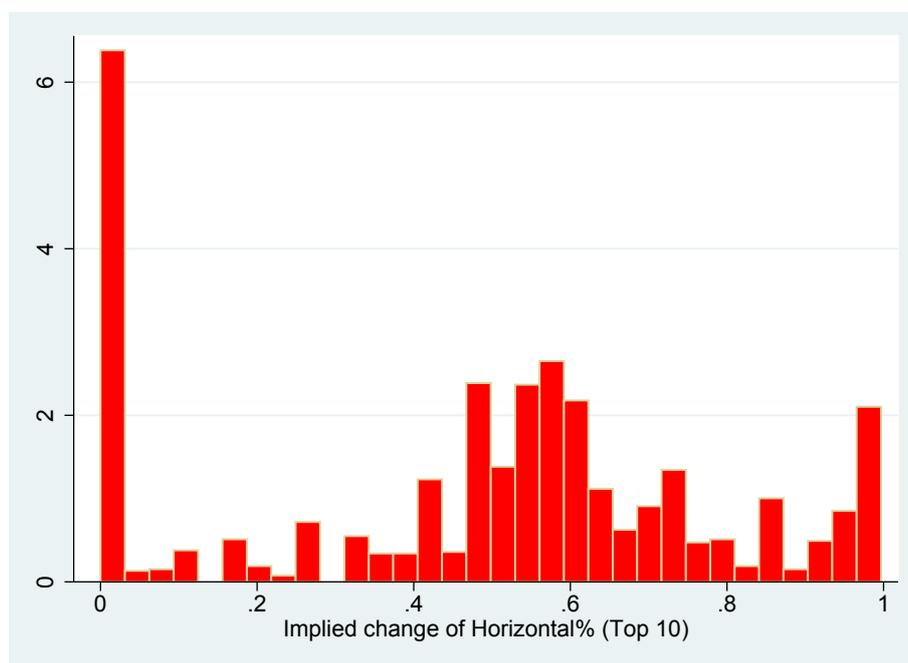


Table 1: **An example**

This table presents a disaggregation of horizontal shareholdings by institutional investors. In the second quarter of 2013, Bristol-Myers Squibb filed a patent-infringement lawsuit against Mylan, which challenged Bristol-Myers Squibb's patents covering a branded drug. Institutional shareholders of Mylan are ranked according to their percentage ownership invested in Mylan. *Generic shares* refers the percentage ownership of Mylan's top 10 institutional shareholders invested in Mylan. *Brand shares* refers to the percentage ownership of Mylan's top 10 institutional shareholders invested in Bristol-Myers Squibb. Institutional ownership is measured as of the end of the first quarter of 2013.

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*First quarter of 2013*

Generic firm: Mylan

Brand firm: Bristol-Myers Squibb

	Generic shares	Brand shares
Vanguard	7.04%	4.61%
BlackRock	5.03%	4.50%
Paulson & Co. Inc.	4.72%	0.00%
State Street	4.35%	4.06%
Bank of America	3.91%	1.09%
Wellington Management	3.67%	2.46%
Goldman Sachs	2.72%	0.46%
Janus Capital Management	2.40%	0.19%
Mellon Bank	1.79%	1.55%
Nordea Investment Management	1.65%	0.02%

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Table 2: **Sample**

This table presents descriptive statistics for our sample of patent challenges by generic-drug manufacturers. The sample consists of 1,399 challenges to 1,170 distinct patents covering 377 trade names (i.e., the name of the branded drug). A challenge occurs when a generic-drug manufacturer files an ANDA under Paragraph IV certification with the FDA. In a Paragraph IV certification, the generic manufacturer argues its generic drug does not infringe on patents covering a branded product or that the patents at issue are simply invalid. Under this provision, generic manufacturers can challenge the validity of patents so that the effective patent life of a branded drug can be reduced. We start from active cases as of November 1, 2003, and end our sample with cases in which challenge outcomes were known by July 23, 2016. Active cases refer to those that had a pending lawsuit. We define a challenge at the level of the date that a brand files a patent-infringement lawsuit against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a brand-name drug. Panel A presents the data structure of the sample and the frequency with which drugs and patents in the sample are challenged. Panel B presents the distribution of private and public firms at the challenge level.

Panel A: Data structure

Patents at issue	1578
Brand-name drugs	521
Brand incumbents	157
Generic challengers	202
Formulations of brand-name drugs	587
Challenges	2023

Panel B: Distribution by listing status

Generic public & brand public	666	32.9%
Generic public & brand private	302	14.9%
Generic private & brand public	651	32.2%
Generic private & brand private	404	20.0%
Total	2023	100.0%

Table 3: **Horizontal shareholdings by the largest generic institutional shareholders**

This table reports ownership stake, voting shares, and horizontal shareholdings of the 10 largest institutional shareholders of each generic manufacturer that files the ANDA under Paragraph IV certification with the FDA. The sample period is from the first quarter of 2001 through the fourth quarter of 2017. We require both the brand-name plaintiff and the generic defendant to be publicly listed firms. We only include brand-generic pairs that appear in the sample of 666 challenges as described in Table 4. For each of the 10 largest generic institutional shareholders, horizontal shareholdings (*Horizontal%*) are measured as the weight of generic shareholders' ownership in the brand-name company relative to their ownership in the generic manufacturer. Generic and brand ownership (cash flow rights) are weighted by generic shareholders' voting rights in the generic (see equation 4 for a detailed description).

Rank	N	Generic ownership			Generic voting shares			Brand ownership			Horizontal%		
		Mean	Median	Std	Mean	Median	Std	Mean	Median	Std	Mean	Median	Std
1	7107	5.6%	5.1%	3.6%	3.4%	2.6%	3.3%	1.6%	0.5%	2.6%	19.6%	10.2%	22.4%
2	6420	3.7%	3.5%	2.4%	2.3%	1.8%	2.2%	1.7%	0.5%	2.5%	25.0%	16.2%	25.1%
3	7859	2.8%	2.7%	1.9%	1.7%	1.4%	1.7%	1.7%	0.5%	2.5%	27.1%	19.2%	26.3%
4	7669	2.3%	2.2%	1.6%	1.6%	1.3%	1.5%	1.6%	0.5%	2.4%	29.1%	21.8%	27.6%
5	7873	2.1%	2.1%	1.4%	1.5%	1.2%	1.3%	1.3%	0.4%	2.1%	29.1%	22.1%	27.2%
6	7539	1.8%	1.7%	1.3%	1.3%	1.0%	1.2%	1.2%	0.4%	2.0%	31.0%	24.7%	27.9%
7	7665	1.6%	1.5%	1.1%	1.2%	1.0%	1.1%	1.2%	0.4%	1.8%	32.0%	26.7%	28.2%
8	7793	1.4%	1.3%	1.0%	1.1%	1.0%	0.9%	1.0%	0.3%	1.8%	31.2%	25.6%	27.9%
9	7548	1.2%	1.2%	0.9%	0.9%	0.8%	0.8%	1.0%	0.3%	1.8%	31.6%	24.5%	29.3%
10	7538	1.1%	1.0%	0.8%	0.8%	0.6%	0.7%	0.9%	0.3%	1.7%	33.8%	27.2%	30.2%

Table 4: **Descriptive statistics**

This table presents descriptive statistics for our horizontal-shareholdings measure and other variables on 666 Paragraph IV litigations in which both the brand-name plaintiff and generic defendant are publicly listed firms. The sample unit is at the level of the date that brand sues a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of branded drug). Horizontal shareholdings are measured as the weight of generic shareholders' ownership in the brand-name plaintiff relative to their ownership in the generic defendant(s) as of the beginning of the quarter in which a patent-infringement lawsuit is filed by a brand-name plaintiff. Generic and brand ownership are weighted by generic shareholders' voting rights in the generic (see equation 4 for a detailed description). *Top 3*, *Top 5*, and *Top 10* refer to the 3, 5, and 10 largest generic shareholders' horizontal shareholdings with the brand-name plaintiff. *Settlement*, *Dismiss*, and *Trail* are indicator variables indicating different challenge outcomes. *Settlement* is defined as one if the two litigants settle the dispute for at least one patent. *Dismiss* is defined as one if the two litigants dismiss the dispute for all patents. *Trail* is defined as one if the two litigants go to trail to resolve the dispute for all patents. *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was noticed by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. *Group* is an indicator variable coded as one if more than two generic manufacturers challenge the same drug in the same date, and zero otherwise. *# Patents* is the number of litigated patents triggered by patent-infringement lawsuits in response to a Paragraph IV challenge. *Route* is an indicator variable coded as one if the generic defendant has previous experience in drug dosage form/route within the last three years. *Therapy* is an indicator variable coded as one if the generic defendant has previous experience in therapy class, measured by the two-digit Anatomical Therapeutic Chemical (ATC) Classification System, within the last three years. *Rank N* is an indicator variable coded as one if the branded drug at issue is ranked between  $N-24$  and  $N$  among the top 200 pharmaceutical drugs by retail sales in the year in which the lawsuit is filed.

	Mean	Std	Min	p10	p25	p50	p75	p90	Max	N
Horizontal% (Top 3)	0.121	0.174	0	0	0	0.018	0.202	0.402	0.987	666
Horizontal% (Top 5)	0.130	0.164	0	0	0	0.051	0.220	0.380	0.987	666
Horizontal% (Top 10)	0.145	0.165	0	0	0	0.090	0.241	0.382	0.987	666
Settle	0.368	0.483	0	0	0	0	1	1	1	666
Dismiss	0.294	0.456	0	0	0	0	1	1	1	666
Trail	0.312	0.464	0	0	0	0	1	1	1	666
First	0.407	0.492	0	0	0	0	1	1	1	666
Group	0.255	0.436	0	0	0	0	1	1	1	666
#Patents	1.883	1.596	1	1	1	1	2	4	12	666
Route	0.318	0.466	0	0	0	0	1	1	1	666
Therapy	0.676	0.468	0	0	0	1	1	1	1	666
Rank25	0.134	0.341	0	0	0	0	0	1	1	666
Rank50	0.033	0.179	0	0	0	0	0	0	1	666
Rank75	0.054	0.226	0	0	0	0	0	0	1	666
Rank100	0.053	0.223	0	0	0	0	0	0	1	666
Rank125	0.032	0.175	0	0	0	0	0	0	1	666
Rank150	0.033	0.179	0	0	0	0	0	0	1	666
Rank175	0.023	0.148	0	0	0	0	0	0	1	666
Rank200	0.023	0.148	0	0	0	0	0	0	1	666

Table 5: **Determinants of Paragraph IV challenges**

This table presents linear probability-model estimates of the effect of institutional horizontal shareholdings on the probability that a generic-drug manufacturer will file a Paragraph IV challenge against patents covering a branded drug. The dependent variable is an indicator variable coded as one if a generic-drug manufacturer files an ANDA under Paragraph IV certification with the FDA. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. Standard errors are clustered at the level of generic manufacturers.

	Top 3			Top 5			Top 10		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Horizontal%	0.033 (0.032)	0.059 (0.037)	0.043 (0.037)	0.027 (0.035)	0.057 (0.041)	0.037 (0.043)	0.018 (0.030)	0.005 (0.052)	0.017 (0.041)
Ln(# Patents)	0.004 (0.006)	0.007 (0.005)	0.003 (0.006)	0.003 (0.006)	0.007 (0.005)	0.003 (0.006)	0.003 (0.006)	0.007 (0.005)	0.003 (0.006)
Route	0.038** (0.016)	0.019* (0.011)	0.062*** (0.019)	0.038** (0.016)	0.019* (0.011)	0.062*** (0.019)	0.038** (0.016)	0.019* (0.011)	0.062*** (0.019)
Therapy	-0.016 (0.014)	0.007 (0.008)	-0.032 (0.031)	-0.015 (0.014)	0.007 (0.008)	-0.032 (0.031)	-0.015 (0.014)	0.007 (0.008)	-0.032 (0.031)
Group	0.068*** (0.019)	0.032 (0.063)	0.301 (0.245)	0.068*** (0.019)	0.034 (0.063)	0.301 (0.245)	0.069*** (0.020)	0.035 (0.062)	0.300 (0.244)
Rank25	0.052 (0.036)	0.030 (0.024)	0.048 (0.034)	0.052 (0.036)	0.030 (0.024)	0.048 (0.034)	0.052 (0.036)	0.030 (0.024)	0.049 (0.035)
Rank50	0.075 (0.054)	0.036 (0.029)	0.028 (0.049)	0.076 (0.054)	0.037 (0.029)	0.029 (0.049)	0.076 (0.054)	0.038 (0.029)	0.029 (0.049)
Rank75	0.038 (0.042)	0.020 (0.031)	0.043 (0.041)	0.038 (0.042)	0.020 (0.031)	0.043 (0.041)	0.038 (0.041)	0.020 (0.031)	0.043 (0.041)
Rank100	0.049** (0.024)	0.007 (0.029)	0.012 (0.037)	0.049** (0.024)	0.007 (0.029)	0.012 (0.037)	0.050* (0.025)	0.009 (0.029)	0.013 (0.038)
Rank125	0.029 (0.041)	0.025 (0.034)	0.021 (0.064)	0.030 (0.041)	0.025 (0.034)	0.021 (0.064)	0.030 (0.041)	0.026 (0.034)	0.021 (0.064)
Rank150	0.017 (0.036)	0.010 (0.030)	0.046 (0.041)	0.018 (0.036)	0.010 (0.030)	0.046 (0.042)	0.018 (0.036)	0.011 (0.030)	0.047 (0.042)
Rank175	-0.000 (0.014)	0.004 (0.015)	0.029 (0.036)	-0.000 (0.014)	0.004 (0.015)	0.029 (0.036)	-0.001 (0.014)	0.005 (0.015)	0.029 (0.035)
Rank200	0.025 (0.028)	-0.013 (0.024)	0.002 (0.035)	0.025 (0.028)	-0.012 (0.024)	0.002 (0.034)	0.026 (0.028)	-0.011 (0.024)	0.003 (0.034)
Constant	0.000 (0.018)	-0.001 (0.020)	-0.015 (0.029)	0.000 (0.018)	-0.001 (0.020)	-0.015 (0.029)	0.001 (0.018)	-0.001 (0.020)	-0.015 (0.029)
Year-Quarter FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Generic FE	No	Yes	No	No	Yes	No	No	Yes	No
Brand FE	No	Yes	No	No	Yes	No	No	Yes	No
Tradename FE	No	No	Yes	No	No	Yes	No	No	Yes
N	8089	8089	8089	8089	8089	8089	8089	8089	8089
<i>adj.R</i> <sup>2</sup>	0.01	0.17	0.00	0.01	0.17	0.00	0.01	0.17	0.00

Standard errors in parentheses

\* $p < 0.10$ , \*\* $p < 0.05$ , \*\*\* $p < 0.01$

Table 6: **Effect of horizontal shareholdings on the likelihood of settlement**

This table presents linear probability-model estimates of the effect of institutional horizontal shareholdings on challenge outcomes. The sample unit is at the level of the date that a brand files patent-infringement lawsuit(s) against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). The dependent variable is an indicator variable coded as one if the two parties settle a litigation for at least one disputed patent, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. See Table 4 for descriptions of other independent variables. Standard errors are in parentheses clustered at the U.S. Federal District Court level.

	Top 3			Top 5			Top 10		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Horizontal%	0.235*** (0.073)	0.308*** (0.112)	0.340*** (0.109)	0.262** (0.120)	0.270* (0.134)	0.303* (0.154)	0.213** (0.097)	0.334** (0.162)	0.337* (0.172)
Ln(# Patents)	0.047* (0.026)	0.060* (0.033)	-0.017 (0.094)	0.050* (0.029)	0.060* (0.034)	-0.011 (0.093)	0.049* (0.027)	0.065* (0.032)	-0.011 (0.093)
Route	-0.084* (0.042)	-0.039 (0.060)	0.005 (0.066)	-0.077* (0.038)	-0.033 (0.060)	0.004 (0.066)	-0.083* (0.043)	-0.035 (0.058)	0.006 (0.065)
Therapy	-0.117*** (0.030)	0.157** (0.060)	-0.055 (0.045)	-0.106*** (0.033)	0.171*** (0.059)	0.051 (0.046)	-0.113*** (0.031)	0.161** (0.061)	-0.050 (0.047)
Group	0.049 (0.050)	0.020 (0.046)	0.074 (0.052)	0.057 (0.048)	0.031 (0.051)	0.073 (0.052)	0.052 (0.050)	0.024 (0.048)	0.072 (0.053)
Rank25	-0.162*** (0.057)	0.209 (0.125)	-0.680*** (0.164)	-0.173*** (0.054)	0.217* (0.115)	-0.681*** (0.168)	-0.166*** (0.054)	0.206* (0.120)	-0.690*** (0.174)
Rank50	-0.299*** (0.032)	0.418*** (0.066)	0.607* (0.349)	-0.300*** (0.035)	0.390*** (0.071)	0.608* (0.342)	-0.298*** (0.035)	0.420*** (0.071)	0.619* (0.347)
Rank75	-0.024 (0.146)	-0.214 (0.145)	-0.586*** (0.106)	-0.023 (0.160)	-0.216 (0.146)	-0.602*** (0.109)	-0.028 (0.140)	-0.222 (0.139)	-0.596*** (0.108)
Rank100	-0.121 (0.108)	-0.311*** (0.111)	0.226 (0.174)	-0.134 (0.104)	-0.322*** (0.105)	0.245 (0.183)	-0.127 (0.106)	-0.321*** (0.110)	0.245 (0.173)
Rank125	0.302** (0.137)	0.121 (0.117)	0.026 (0.358)	0.286** (0.137)	0.098 (0.121)	0.008 (0.362)	0.296** (0.138)	0.112 (0.118)	0.022 (0.352)
Rank150	0.217** (0.083)	0.022 (0.042)	-0.054 (0.510)	0.213** (0.097)	0.010 (0.032)	-0.046 (0.514)	0.217** (0.083)	0.022 (0.043)	-0.059 (0.509)
Rank175	-0.010 (0.122)	-0.189 (0.140)	-0.377** (0.180)	-0.022 (0.103)	-0.218 (0.145)	-0.381* (0.190)	-0.013 (0.122)	-0.194 (0.140)	-0.393** (0.187)
Rank200	0.257** (0.117)	0.055 (0.148)	0.007 (0.224)	0.266** (0.101)	0.050 (0.135)	0.012 (0.227)	0.256** (0.117)	0.065 (0.147)	-0.002 (0.222)
Constant	0.430*** (0.048)	0.146 (0.436)	-0.810** (0.337)	0.727*** (0.180)	0.630 (0.566)	-0.800** (0.340)	0.425*** (0.051)	0.100 (0.464)	-0.815** (0.347)
Year-Quarter	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Court	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Generic	No	Yes	No	No	Yes	No	No	Yes	No
Brand	No	Yes	No	No	Yes	No	No	Yes	No
Tradename	No	No	Yes	No	No	Yes	No	No	Yes
N	666	666	666	666	666	666	666	666	666
adj.R <sup>2</sup>	0.05	0.21	0.45	0.06	0.21	0.44	0.05	0.21	0.44

Standard errors in parentheses

\* $p < 0.10$ , \*\* $p < 0.05$ , \*\*\* $p < 0.01$

Table 7: Horizontal shareholdings preceding the Paragraph IV lawsuits

This table presents the ordinary least squares (OLS) estimates of the effect of Paragraph IV lawsuits on the level of institutional horizontal shareholdings. The sample unit is at the firm-year-quarter level. The dependent variable horizontal shareholdings (*Horizontal%*) that are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. *Lawsuit<sub>-t</sub>* is an indicator variable coded as one if it is *t* quarter prior to the quarter in which a generic-drug manufacturer files an ANDA under Paragraph IV certification with the FDA, and zero otherwise. *Generic S&P 1500* is an indicator variable coded as one if a generic defendant is in the S&P 1500 index, and zero otherwise. *Brand S&P 1500* is defined analogously. *Ln(Generic Cap)* is the logarithm of market capitalization of the generic defendant. Standard errors are in parentheses clustered at the level of generic manufacturers.

	Top 3		Top 5		Top 10	
	(1)	(2)	(3)	(4)	(5)	(6)
<i>Lawsuit<sub>-8</sub></i>	-0.000 (0.007)	-0.000 (0.008)	-0.000 (0.005)	0.003 (0.006)	-0.008 (0.007)	-0.001 (0.005)
<i>Lawsuit<sub>-7</sub></i>	-0.004 (0.004)	-0.008** (0.003)	-0.007 (0.007)	-0.006 (0.004)	-0.005 (0.008)	-0.001 (0.003)
<i>Lawsuit<sub>-6</sub></i>	-0.008 (0.007)	-0.008* (0.004)	-0.013** (0.006)	-0.011** (0.004)	-0.009 (0.006)	-0.004 (0.003)
<i>Lawsuit<sub>-5</sub></i>	-0.008 (0.009)	-0.009 (0.008)	-0.012 (0.009)	-0.010 (0.007)	-0.010 (0.010)	-0.006 (0.008)
<i>Lawsuit<sub>-4</sub></i>	-0.006 (0.010)	-0.006 (0.009)	-0.017* (0.008)	-0.015** (0.007)	-0.013 (0.010)	-0.009 (0.008)
<i>Lawsuit<sub>-3</sub></i>	-0.008 (0.008)	-0.011 (0.009)	-0.016 (0.011)	-0.016 (0.012)	-0.013 (0.013)	-0.010 (0.012)
<i>Lawsuit<sub>-2</sub></i>	0.002 (0.005)	-0.001 (0.006)	-0.001 (0.008)	-0.002 (0.008)	-0.002 (0.008)	-0.002 (0.006)
<i>Lawsuit<sub>-1</sub></i>	-0.004 (0.008)	-0.006 (0.007)	-0.007 (0.007)	-0.006 (0.007)	-0.008 (0.008)	-0.006 (0.006)
<i>Lawsuit<sub>0</sub></i>	0.004 (0.005)	0.003 (0.005)	-0.004 (0.005)	-0.004 (0.005)	-0.006 (0.006)	-0.004 (0.005)
Generic S&P1500	0.031** (0.012)	-0.018 (0.019)	0.028** (0.010)	-0.005 (0.025)	0.020 (0.013)	-0.001 (0.027)
Brand S&P1500	0.103*** (0.007)	0.060*** (0.012)	0.115*** (0.007)	0.061*** (0.012)	0.131*** (0.008)	0.062*** (0.012)
Ln(Generic Cap)	0.023*** (0.003)	0.045*** (0.013)	0.024*** (0.003)	0.039*** (0.010)	0.026*** (0.003)	0.042*** (0.011)
Constant	-0.449*** (0.077)	-0.945*** (0.294)	-0.454*** (0.065)	-0.739*** (0.253)	-0.471*** (0.065)	-0.740** (0.268)
Year-quarter	No	Yes	No	Yes	No	Yes
Generic	No	Yes	No	Yes	No	Yes
Brand	No	Yes	No	Yes	No	Yes
N	12317	12317	12317	12317	12317	12317
<i>adj. R<sup>2</sup></i>	0.13	0.32	0.16	0.37	0.20	0.46

**Table 8: Effect of horizontal shareholdings on the likelihood of settlement: Robustness**

This table presents linear probability-model estimates of the effect of institutional horizontal shareholdings on challenge outcomes. The sample unit is at the level of the date that a brand files patent-infringement lawsuit(s) against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). The dependent variable is an indicator variable coded as one if the two parties settle a litigation for at least one disputed patent, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. In Panel A, we control for determinants of horizontal shareholdings, including *Generic S&P 1500*, *Brand S&P 1500*, and *Ln(Generic Gap)*. In Panel B, we exclude lawsuits filed during the Great Recession. In Panel C, horizontal shareholdings are measured as an indicator variable coded as one if *Horizontal%* is above the 75 percentile of its sample distribution, and zero otherwise. In Panel D, regressions are weighted by the total number patents involved in a lawsuit. In Panel E, regressions are weighted by the total number of generic manufacturers filing the same ANDA under Paragraph IV certification with the FDA. In Panel F, the dependent variable is calculated as the mean of settlement rates across disputed patents covering a brand drug. In Panel G, we perform regressions on the entire sample by including Paragraph IV litigations between parties at least one of which is not publicly listed. In Panel H, we include both sole and shared votes to measure voting rights. See Table 4 for descriptions of other independent variables. Standard errors are in parentheses clustered at the U.S. Federal District Court level.

	Top 3			Top 5			Top 10		
Panel A: Control for Horizontal% determinants									
Horizontal%	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	0.258**	0.278**	0.337**	0.248**	0.255*	0.298	0.238	0.290*	0.331
	(0.110)	(0.110)	(0.135)	(0.119)	(0.138)	(0.194)	(0.182)	(0.165)	(0.221)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.05	0.21	0.44	0.05	0.20	0.44	0.05	0.20	0.44
Panel B: Exclude the Great Recession									
Horizontal%	0.239**	0.363***	0.266**	0.242**	0.398***	0.329**	0.227***	0.450***	0.428**
	(0.087)	(0.091)	(0.113)	(0.098)	(0.107)	(0.139)	(0.076)	(0.136)	(0.214)
N	577	577	577	577	577	577	577	577	577
adj. R <sup>2</sup>	0.04	0.19	0.47	0.04	0.19	0.47	0.03	0.19	0.47
Panel C: Dummy Horizontal%									
Horizontal%	0.110*	0.168**	0.174***	0.129***	0.112*	0.090	0.109**	0.111*	0.126
	(0.056)	(0.063)	(0.055)	(0.038)	(0.058)	(0.085)	(0.040)	(0.062)	(0.077)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.06	0.22	0.45	0.06	0.21	0.44	0.06	0.21	0.44
Panel D: WSL, W=# patents									
Horizontal%	0.338***	0.365***	0.338***	0.263***	0.388***	0.299**	0.353*	0.372***	0.318**
	(0.108)	(0.084)	(0.088)	(0.080)	(0.092)	(0.117)	(0.184)	(0.115)	(0.133)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.07	0.32	0.54	0.06	0.30	0.54	0.07	0.32	0.54
Panel E: WSL, W=# Challengers									
Horizontal%	0.199***	0.277**	0.283*	0.229***	0.282*	0.293	0.249**	0.302*	0.321
	(0.068)	(0.123)	(0.157)	(0.077)	(0.151)	(0.193)	(0.112)	(0.164)	(0.201)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.08	0.25	0.50	0.08	0.25	0.50	0.08	0.25	0.50
Panel F: Mean settlement rate									
Horizontal%	0.224***	0.292***	0.314***	0.203***	0.274*	0.263*	0.195**	0.319*	0.294*
	(0.069)	(0.104)	(0.091)	(0.071)	(0.142)	(0.136)	(0.093)	(0.164)	(0.156)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.05	0.22	0.46	0.05	0.22	0.45	0.05	0.22	0.45
Panel G: Entire sample, Dummy Horizontal%									
Horizontal%	0.084**	0.146***	0.091**	0.100***	0.132***	0.070**	0.082***	0.122***	0.058
	(0.041)	(0.037)	(0.041)	(0.020)	(0.033)	(0.028)	(0.026)	(0.035)	(0.039)
N	2023	2023	2023	2023	2023	2023	2023	2023	2023
adj. R <sup>2</sup>	0.02	0.25	0.49	0.02	0.25	0.49	0.02	0.25	0.49
Panel H: Include shared votes									
Horizontal%	0.187**	0.258**	0.366***	0.198***	0.298***	0.375***	0.194**	0.338**	0.412***
	(0.069)	(0.096)	(0.098)	(0.070)	(0.103)	(0.112)	(0.076)	(0.127)	(0.131)
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.05	0.21	0.45	0.05	0.21	0.45	0.05	0.21	0.45
Year-Quarter	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Court	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Generic	No	Yes	No	No	Yes	No	No	Yes	No
Brand	No	Yes	No	No	Yes	No	No	Yes	No
Tradename	No	No	Yes	No	No	Yes	No	No	Yes

Standard errors in parentheses

\* $p < 0.10$ , \*\* $p < 0.05$ , \*\*\* $p < 0.01$

Table 9: **Effect of horizontal shareholdings on the likelihood of settlement: IV estimations**

This table presents the instrumental variable (IV) estimates of the effect of institutional horizontal shareholdings on the likelihood of litigation outcomes. Panel A presents the first stage estimates. Panel B presents the second stage estimates. The sample unit is at the level of the date that a brand files patent-infringement lawsuit(s) against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). The sample period starts from the second quarter of 2009. The dependent variable is an indicator variable coded as one if the two parties settle a litigation for at least one disputed patent, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N = 3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant. Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. *Horizontal%* is instrumented by  $\Delta^+$ , which is coded as one if  $\Delta Horizontal\%^{09Q1}$  is greater than 45%, and zero otherwise.  $\Delta Horizontal\%^{09Q1}$  is constructed as follows: (1) We calculate the actual horizontal shareholdings in the first quarter of 2009; (2) we calculate a counterfactual horizontal shareholdings in the first quarter of 2009 combining the holdings of Barclays and BlackRock; (3) we calculate the difference between the counterfactual and the actual for each brand-generic pair. See Table 4 for descriptions of other independent variables. Standard errors are in parentheses clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A: First stage						
<i>Horizontal%</i>	(1) 0.069*** (0.012)	(2) 0.055*** (0.012)	(3) 0.099*** (0.012)	(4) 0.085*** (0.009)	(5) 0.105*** (0.014)	(6) 0.093*** (0.008)
N	424	424	424	424	424	424
<i>adj. R</i> <sup>2</sup>	0.08	0.16	0.15	0.22	0.17	0.24
F-stat	34.05	22.67	68.43	87.69	59.97	138.68
Partial <i>R</i> <sup>2</sup>	0.056		0.116		0.138	
Panel B: Second stage						
<i>Horizontal%</i>	0.657** (0.278)	0.394 (0.670)	0.716** (0.297)	0.825* (0.476)	0.647** (0.257)	0.678* (0.389)
N	424	424	424	424	424	424
<i>adj. R</i> <sup>2</sup>	0.03	0.09	0.04	0.07	0.05	0.09
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter	No	Yes	No	Yes	No	Yes
Court	No	Yes	No	Yes	No	Yes
Generic	No	Yes	No	Yes	No	Yes

Table 10: **Effect of horizontal shareholdings on the likelihood of settlement: first vs. other generics**

This table presents linear probability-model estimates of the effect of institutional horizontal shareholdings on challenge outcomes. The sample unit is at the level of the date that a brand files patent-infringement lawsuit(s) against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). The dependent variable is an indicator variable coded as one if the two parties settle a litigation for at least one disputed patent, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. See Table 4 for descriptions of other independent variables. In Panel A, lawsuits are between the brand-name plaintiff and the first generic (*First*). *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was notified by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. In Panel B, lawsuits are between the brand-name plaintiff and other generics. Standard errors are in parentheses clustered at the U.S. Federal District Court level.

	Top 3			Top 5			Top 10		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Horizontal%	0.104 (0.090)	0.288** (0.119)	0.209** (0.082)	0.057 (0.096)	0.244* (0.130)	0.114 (0.123)	0.087 (0.094)	0.300* (0.160)	0.178 (0.127)
Horizontal% × First	0.238* (0.118)	0.022 (0.164)	0.471 (0.681)	0.313* (0.164)	0.098 (0.195)	0.673 (0.816)	0.218 (0.137)	0.052 (0.157)	0.610 (0.740)
First	0.079** (0.035)	0.171*** (0.034)	0.093 (0.104)	0.068* (0.037)	0.160*** (0.036)	0.066 (0.121)	0.077** (0.035)	0.166*** (0.034)	0.067 (0.124)
Year-quarter FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Court FE	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Generic FE	No	Yes	No	No	Yes	No	No	Yes	No
Brand FE	No	Yes	No	No	Yes	No	No	Yes	No
Tradename FE	No	No	Yes	No	No	Yes	No	No	Yes
N	666	666	666	666	666	666	666	666	666
adj. R <sup>2</sup>	0.07	0.23	0.46	0.06	0.23	0.46	0.06	0.23	0.46

Table 11: **Effect of horizontal shareholdings on brand's and generic's abnormal returns around settlement**

This table presents estimates of the effect of horizontal shareholdings on the abnormal returns around the date on which the generic filer of Paragraph IV and the brand either enter into a settlement agreement. In Panel A, the dependent variable is the cumulative market adjusted returns for publicly listed brand plaintiffs over the window  $(-3, +3)$ . In Panel B, the dependent variable is the cumulative market adjusted returns for publicly traded generic defendant(s) over the window  $(-3, +3)$ . Dependent variables are winsorized at 1% and 99%. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was noticed by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. The specific group of top generic shareholders appears at top of each column. *Generic Private* is an indicator variable coded as one if the brand plaintiff is publicly listed but the generic defendant is not, and zero otherwise. *Brand Private* is an indicator variable coded as one if the generic defendant publicly listed but the brand plaintiff is not, and zero otherwise. See Table 4 for definitions of control variables. Standard errors are in parentheses and are clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A: Brand returns						
	(1)	(2)	(3)	(4)	(5)	(6)
Horizontal%	0.053*** (0.008)	0.033* (0.018)	0.049*** (0.007)	0.027 (0.017)	0.046*** (0.009)	0.024* (0.014)
Horizontal% $\times$ First		0.038** (0.018)		0.044* (0.022)		0.048** (0.020)
First		0.007 (0.005)		0.007 (0.006)		0.006 (0.006)
Generic Private	Yes	Yes	Yes	Yes	Yes	Yes
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Brand FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	363	363	363	363	363	363
<i>adj. R</i> <sup>2</sup>	0.25	0.27	0.24	0.26	0.24	0.26
Panel B: Generic returns						
Horizontal%	0.012 (0.019)	-0.013 (0.017)	0.018 (0.016)	-0.005 (0.020)	0.016 (0.015)	-0.002 (0.017)
Horizontal% $\times$ First		0.052* (0.025)		0.044 (0.031)		0.037 (0.030)
First		-0.006 (0.012)		-0.006 (0.011)		-0.005 (0.011)
Brand Private	Yes	Yes	Yes	Yes	Yes	Yes
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Generic FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	265	265	265	265	265	265
<i>adj. R</i> <sup>2</sup>	0.07	0.07	0.08	0.07	0.07	0.07

**Table 12: Effect of horizontal shareholdings on the timing of generic manufacturers marketing drugs conditioning on the first generic settling**

This table presents the estimates of the effect of horizontal shareholdings by the settled first generic with the brand-name plaintiff on the timing of generic manufacturers to market drugs. In Panel A and B, the dependent variable is an indicator variable coded as one if a generic manufacturer markets a generic version of branded drugs by the end of the observation period (August 8, 2019), and zero otherwise. In Panel C, the dependent variable is an indicator variable coded as one if a generic manufacturer markets a generic version of branded drugs within three years after the resolution of dispute, and zero otherwise. We only include Paragraph IV lawsuits in which (1) the first generic (among all generics challenging the same drug) settles with the brand-name plaintiff and (2) both the settled first generic and brand are publicly listed firms. In Panel A and C, all lawsuits satisfying (1) and (2) are included. In Panel B, lawsuits between non-first generics and brand satisfying (1) and (2) are included. In Panel A and B, we require all disputes resolve before 2015, despite outcomes. In Panel C, we require the resolution of a dispute to be at least three years before the end of our observation period (August 8, 2019). Horizontal shareholdings ( $Horizontal\%^{1st}$ ) are measured as the weight of top  $N$  ( $N=3, 5, 10$ ) shareholders of the settled first generic in the brand-name plaintiff relative to their ownership in the generic defendant. Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant (see equation 4 for a detailed description). See Table 4 for descriptions of other independent variables. Standard errors are in parentheses and are clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A. All generics						
	(1)	(2)	(3)	(4)	(5)	(6)
$Horizontal\%^{1st}$	-0.252 (0.155)	-1.758** (0.708)	-0.337* (0.187)	-1.540*** (0.529)	-0.380** (0.169)	-1.543** (0.600)
N	327	327	327	327	327	327
$adj. R^2$	0.06	0.21	0.06	0.21	0.06	0.21
Panel B. Exclude first generics						
	(1)	(2)	(3)	(4)	(5)	(6)
$Horizontal\%^{1st}$	-0.438** (0.181)	-7.075*** (2.083)	-0.595** (0.217)	-4.472*** (1.122)	-0.641*** (0.201)	-4.021*** (1.076)
N	221	221	221	221	221	221
$adj. R^2$	0.06	0.15	0.07	0.16	0.08	0.16
Panel C. Market within 3 years						
	(1)	(2)	(3)	(4)	(5)	(6)
$Horizontal\%^{1st}$	-0.190** (0.075)	-1.269** (0.506)	-0.207 (0.123)	-1.196*** (0.274)	-0.270** (0.125)	-1.325*** (0.181)
N	349	349	349	349	349	349
$adj. R^2$	0.07	0.31	0.07	0.31	0.07	0.31
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	No	Yes	No	Yes	No	Yes
Court FE	No	Yes	No	Yes	No	Yes
Generic FE	No	Yes	No	Yes	No	Yes
Brand FE	No	Yes	No	Yes	No	Yes

# Online Appendix: Institutional Horizontal Shareholdings and Generic Entry in the Pharmaceutical Industry

Joseph Gerakos and Jin Xie

*Not for Publication*

## *Appendix A. Examples of pay-for-delay settlements*

Since 2001, the Federal Trade Commission (FTC) has filed a number of lawsuits to stop the so called pay-for-delay settlement agreements signed between brand and generic manufacturers.

### *Example 1. Endo Pharmaceuticals vs. other generics*

On March 30, 2016, FTC filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania alleging that Endo Pharmaceuticals Inc. and several other drug companies violated antitrust laws by using pay-for-delay settlements to block consumers' access to lower-cost generic versions of Opana ER and Lidoderm.

The complaint is summarized as follows. In 2010, Endo and Impax illegally agreed that until January 2013, Endo would not compete by marketing an authorized generic version of Endo's Opana ER.<sup>1</sup> In exchange, Endo paid Impax more than \$112 million, including \$10 million under a development and co-promotion agreement signed during the same time period. Endo used this period of delay to transition patients to a new formulation of Opana ER, thereby maintaining its monopoly power even after Impax's generic entry. In 2010, Opana ER sales in the United States exceeded \$250 million.

In May 2012, Endo and its partners, Teikoku Seiyaku Co. Ltd. and Teikoku Pharma USA, Inc., illegally agreed with Watson Laboratories, Inc. that until September 2013, Watson would not compete with Endo and Teikoku by marketing a generic version of Endo's Lidoderm patch. In exchange, Endo paid Watson hundreds of millions of dollars, including \$96 million of free branded Lidoderm product that Endo and Teikoku gave to Watson. As a result, Endo illegally maintained its monopoly over Lidoderm. In 2012, Lidoderm sales in the United States approached \$1 billion.

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<sup>1</sup>Authorized generics are prescription drugs produced by brand pharmaceutical companies and marketed under a private label, at generic prices. The courts have ruled that 180 day exclusivity does not preclude a brand-name company from entering with its own generic because it already has approval for its product; therefore, it can sell an authorized generic during that exclusivity period.

Endo and Watson illegally agreed that, for 7.5 months after September 2013 (including the 180 day first-filer exclusivity period for which Watson was eligible), Endo would not compete by marketing an authorized generic version of Lidoderm. This agreement left Watson as the only generic version of Lidoderm on the market, substantially reducing competition and increasing prices for generic lidocaine patches. As a result, Watson made hundreds of millions of dollars more in generic Lidoderm sales. Brand manufacturers have been able to sidestep competition by offering patent settlements that pay generic companies not to bring lower-cost alternatives to market. According to an FTC study, these anticompetitive deals cost consumers and taxpayers \$3.5 billion in higher drug costs every year.

*Example 2. Solvay Pharmaceuticals vs. Watson & Par*

On January 28, 2009, FTC filed a complaint in the U.S. District Court for the Central District of California challenging agreements in which Solvay Pharmaceuticals, Inc. paid generic drug makers Watson Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. to delay generic competition to Solvay's branded testosterone-replacement drug AndroGel. The annual sales of AndroGel was more than \$400 million. The complaint was filed jointly with the Office of the Attorney General of California.

The complaint is summarized as follows. The court action seeks to promote competition between Solvay and generic drug makers that had sought to introduce generic versions of the branded prescription drug AndroGel. AndroGel, Solvay's second highest selling pharmaceutical product, is a pharmaceutical gel containing synthetic testosterone. It is approved for testosterone replacement therapy in men with low testosterone levels, which often are associated with advancing age, certain cancers, and HIV/AIDS, among other conditions.

In May 2003, Watson and Paddock, which partnered with Par, each filed applications

for FDA approval to market generic versions of AndroGel. Solvay's patent on AndroGel had been issued in January 2003, with an expiration date of August 2020. By early 2006, Watson had received final approval to market its generic product. According to the complaint, it was well-known that if Watson or Par were to enter with cheaper generic versions of AndroGel, Solvay's AndroGel sales would plummet and consumers would benefit from the lower prices.

The complaint alleges that Solvay, realizing the devastating effect generic entry would have on its AndroGel franchise, acted unlawfully to eliminate this threat: Solvay paid Watson and Par a share of its AndroGel profits to abandon their patent challenges and agree to delay generic entry until 2015. As a result, the complaint states that the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing.

Table A.1: Paragraph IV litigation outcomes across U.S. Federal District Courts

This table presents the distributions of the challenge outcomes at the patent-level across the U.S. Federal District Courts following the filing of an ANDA under Paragraph IV certification with the FDA. We start with cases active as of November 1, 2003, and end our sample with cases for which the challenge outcomes were known by July 23, 2016. Active cases refer to those that had a pending lawsuit. We define a challenge at the level of the date that a brand files a patent-infringement lawsuit against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug).

	Entire Sample				Both Public			
	#Suits	Settle	Dismiss	Trail	#Suits	Settle	Dismiss	Trail
California Central District	17	35.3%	47.1%	23.5%	8	25.0%	50.0%	25.0%
California Northern District Court	16	56.3%	12.5%	31.3%	6	16.7%	16.7%	66.7%
California Southern District Court	2	0.0%	100.0%	0.0%	1	0.0%	100.0%	0.0%
Colorado District Court	3	66.7%	33.3%	0.0%	3	66.7%	33.3%	0.0%
Delaware District Court	727	36.5%	39.2%	24.9%	225	36.9%	33.3%	30.2%
District of Columbia Court	4	25.0%	75.0%	0.0%				
Florida District Court	1	0.0%	0.0%	100.0%	1	0.0%	0.0%	100.0%
Florida Middle District Court	4	50.0%	0.0%	25.0%	1	0.0%	0.0%	0.0%
Florida Southern District Court	12	41.7%	16.7%	41.7%	2	0.0%	50.0%	50.0%
Georgia Northern District Court	9	66.7%	0.0%	44.4%	1	100.0%	0.0%	0.0%
Illinois Northern District Court	63	36.5%	36.5%	27.0%	16	37.5%	25.0%	37.5%
Indiana Southern District Court	60	20.0%	35.0%	45.0%	27	18.5%	37.0%	44.4%
Maryland District Court	34	47.1%	47.1%	5.9%	14	71.4%	28.6%	0.0%
Massachusetts District Court	18	16.7%	66.7%	5.6%	2	50.0%	50.0%	0.0%
Michigan Eastern District Court	9	44.4%	11.1%	44.4%	5	40.0%	20.0%	40.0%
Michigan Western District Court	2	100.0%	0.0%	0.0%				
Minnesota District Court	4	50.0%	0.0%	50.0%				
Nevada District Court	14	7.1%	21.4%	57.1%	7	0.0%	28.6%	57.1%
New Jersey District Court	713	43.5%	32.0%	27.5%	229	40.6%	28.8%	34.1%

	Entire Sample				Both Public			
	#Suits	Settle	Dismiss	Trail	#Suits	Settle	Dismiss	Trail
New York Eastern District Court	7	28.6%	28.6%	42.9%	3	33.3%	0.0%	66.7%
New York Southern District Court	172	47.7%	34.9%	20.9%	57	42.1%	33.3%	28.1%
North Carolina Eastern District Court	14	7.1%	35.7%	57.1%	1	0.0%	0.0%	100.0%
North Carolina Middle District Court	10	10.0%	60.0%	40.0%	3	0.0%	100.0%	33.3%
North Carolina Western District Court	1	0.0%	0.0%	100.0%				
Ohio Southern District Court	2	100.0%	0.0%	0.0%				
Pennsylvania Eastern District Court	25	12.0%	64.0%	20.0%	7	0.0%	71.4%	14.3%
Pennsylvania Western District Court	1	0.0%	0.0%	100.0%	1	0.0%	0.0%	100.0%
Pennsylvania Middle District Court	1	0.0%	100.0%	0.0%	1	0.0%	100.0%	0.0%
Puerto Rico District Court	1	100.0%	0.0%	0.0%				
Texas Eastern District Court	20	20.0%	20.0%	70.0%	15	26.7%	6.7%	80.0%
Texas Northern District Court	12	75.0%	25.0%	0.0%	7	71.4%	28.6%	0.0%
Vermont District Court	1	0.0%	0.0%	100.0%	1	0.0%	0.0%	100.0%
Virginia Eastern District Court	14	7.1%	35.7%	57.1%	5	20.0%	20.0%	60.0%
West Virginia District Court	3	0.0%	0.0%	100.0%	3	0.0%	0.0%	100.0%
West Virginia North District Court	15	33.3%	60.0%	20.0%	11	36.4%	45.5%	27.3%
Unknown	12	0.0%	16.7%	83.3%	3	0.0%	0.0%	100.0%
Total	2023	38.6%	35.6%	27.4%	666	36.8%	31.2%	33.8%

Table A.2: **Determinants of Paragraph IV challenges: IV estimations**

This table presents the instrumental variable (IV) of the effect of institutional horizontal shareholdings on the probability that a generic-drug manufacturer will file a Paragraph IV challenge against patents covering a branded drug. The sample period starts from the second quarter of 2009. The dependent variable is an indicator variable coded as one if a generic-drug manufacturer files an ANDA under Paragraph IV certification with the FDA. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. *Horizontal%* is instrumented by  $\Delta^+$ , which is coded as one if  $\Delta Horizontal\%^{09Q1}$  is greater than 40%, and zero otherwise.  $\Delta Horizontal\%^{09Q1}$  is constructed as follows: (1) We calculate the actual horizontal shareholdings in the first quarter of 2009; (2) we calculate a counterfactual horizontal shareholdings in the first quarter of 2009 combining the holdings of Barclays and BlackRock; (3) we calculate the difference between the counterfactual and the actual for each brand-generic pair. Standard errors are clustered at the level of generic manufacturers.

	Top 3		Top 5		Top 10	
Panel A. First stage						
	(1)	(2)	(3)	(4)	(5)	(6)
High $\Delta^+$	0.059***	0.059***	0.071***	0.073***	0.100***	0.097***
	(0.015)	(0.014)	(0.019)	(0.018)	(0.011)	(0.012)
Year-quarter FE	No	Yes	No	Yes	No	Yes
Court FE	No	Yes	No	Yes	No	Yes
Generic FE	No	Yes	No	Yes	No	Yes
N	5977	5977	5977	5977	5977	5977
<i>adj. R</i> <sup>2</sup>	0.12	0.25	0.15	0.27	0.20	0.30
F-stat	236.98	250.78	339.91	370.84	721.01	700.99
Partial <i>R</i> <sup>2</sup>	0.06		0.07		0.13	
Panel B. Second stage						
Horizontal%	-0.197	-0.028	-0.110	-0.008	-0.102	-0.060
	(0.255)	(0.217)	(0.141)	(0.119)	(0.117)	(0.098)
Year-quarter FE	No	Yes	No	Yes	No	Yes
Court FE	No	Yes	No	Yes	No	Yes
Generic FE	No	Yes	No	Yes	No	Yes
N	5977	5977	5977	5977	5977	5977
<i>adj. R</i> <sup>2</sup>	-0.01	0.12	0.00	0.12	0.00	0.12

Table A.3: **Effect of horizontal shareholdings on the likelihood of settlement: Post BlackRock's Acquisition of BGI**

This table presents linear probability-model estimates of the effect of institutional horizontal shareholdings on challenge outcomes. The sample unit is at the level of the date that a brand files patent-infringement lawsuit(s) against a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). The sample period starts from the second quarter of 2009. The dependent variable is an indicator variable coded as one if the two parties settle a litigation for at least one disputed patent, and zero otherwise. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). The specific group of top generic shareholders appears at top of each column. See Table 4 for descriptions of other independent variables. Standard errors are in parentheses clustered at the U.S. Federal District Court level.

	Top 3			Top 5			Top 10		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Horizontal%	0.321**	0.310**	0.411	0.407**	0.473***	0.549	0.456***	0.534***	0.667
	(0.132)	(0.114)	(0.349)	(0.151)	(0.133)	(0.445)	(0.155)	(0.125)	(0.543)
Ln(# Patents)	-0.031	0.029	-0.046	-0.031	0.031	-0.038	-0.029	0.033	-0.035
	(0.034)	(0.051)	(0.127)	(0.034)	(0.050)	(0.132)	(0.034)	(0.052)	(0.132)
Route	-0.055	-0.068	0.007	-0.053	-0.057	0.009	-0.052	-0.051	0.016
	(0.067)	(0.100)	(0.138)	(0.069)	(0.101)	(0.131)	(0.071)	(0.101)	(0.128)
Therapy	-0.103	-0.134	-0.071	-0.098	-0.124	-0.062	-0.093	-0.128	-0.054
	(0.071)	(0.119)	(0.096)	(0.071)	(0.118)	(0.100)	(0.071)	(0.119)	(0.105)
Group	0.105*	0.127	0.175	0.101	0.123	0.175	0.101	0.122	0.177
	(0.061)	(0.109)	(0.150)	(0.062)	(0.108)	(0.144)	(0.061)	(0.106)	(0.146)
Rank25	0.174	0.330**	-0.388	0.177	0.344**	-0.336	0.176	0.344**	-0.369
	(0.164)	(0.122)	(0.475)	(0.165)	(0.128)	(0.523)	(0.168)	(0.132)	(0.491)
Rank50	-0.151**	-0.350	-0.871	-0.157**	-0.346	-0.830	-0.171**	-0.345	-0.843
	(0.067)	(0.232)	(0.828)	(0.063)	(0.234)	(0.848)	(0.064)	(0.232)	(0.844)
Rank75	-0.311**	-0.378**	-1.038**	-0.319**	-0.389**	-1.010**	-0.325**	-0.392**	-0.999**
	(0.147)	(0.179)	(0.383)	(0.144)	(0.179)	(0.401)	(0.143)	(0.180)	(0.400)
Rank100	-0.004	-0.416***	0.121	-0.027	-0.446***	0.195	-0.025	-0.442***	0.201
	(0.093)	(0.146)	(0.331)	(0.093)	(0.145)	(0.395)	(0.093)	(0.146)	(0.390)
Rank125	0.054	-0.218	-0.289	0.032	-0.245	-0.309	0.028	-0.231	-0.255
	(0.201)	(0.254)	(0.838)	(0.195)	(0.244)	(0.817)	(0.190)	(0.238)	(0.828)
Rank150	0.320***	0.258*	0.481	0.318***	0.260*	0.463	0.321***	0.258*	0.437
	(0.085)	(0.136)	(0.374)	(0.087)	(0.140)	(0.368)	(0.085)	(0.139)	(0.338)
Rank175	-0.039	-0.244	-0.481**	-0.049	-0.246	-0.493**	-0.064	-0.263	-0.524***
	(0.096)	(0.197)	(0.195)	(0.092)	(0.192)	(0.185)	(0.087)	(0.200)	(0.181)
Rank200	0.097	0.017	0.166	0.097	0.021	0.133	0.100	0.019	0.099
	(0.090)	(0.162)	(0.316)	(0.094)	(0.162)	(0.332)	(0.097)	(0.166)	(0.339)
Constant	0.395***	1.401***	0.789***	0.382***	1.381***	0.769***	0.368***	1.378***	0.693***
	(0.081)	(0.279)	(0.200)	(0.078)	(0.278)	(0.217)	(0.076)	(0.277)	(0.226)
Year-Quarter	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Court	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Generic	No	Yes	No	No	Yes	No	No	Yes	No
Brand	No	Yes	No	No	Yes	No	No	Yes	No
Tradename	No	No	Yes	No	No	Yes	No	No	Yes
N	424	424	424	424	424	424	424	424	424
<i>adj.R</i> <sup>2</sup>	0.05	0.21	0.45	0.06	0.21	0.44	0.05	0.21	0.44

Standard errors in parentheses

\* $p < 0.10$ , \*\* $p < 0.05$ , \*\*\* $p < 0.01$

Table A.4: **Effect of horizontal shareholdings on brand's and generic's abnormal returns around settlement: both public**

This table presents estimates of the effect of horizontal shareholdings on the abnormal returns around the date on which the generic filer of Paragraph IV and the brand either enter into a settlement agreement. We require that both parties are publicly listed firms. In Panel A, the dependent variable is the cumulative market adjusted returns for publicly listed brand plaintiffs over the window  $(-3, +3)$ . In Panel B, the dependent variable is the cumulative market adjusted returns for publicly traded generic defendant(s) over the window  $(-3, +3)$ . Dependent variables are winsorized at 1% and 99%. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders' ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders' voting rights in the generic defendant(s) (see equation 4 for a detailed description). *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was noticed by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. The specific group of top generic shareholders appears at top of each column. See Table 4 for definitions of control variables. Standard errors are in parentheses and are clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A: Brand returns						
	(1)	(2)	(3)	(4)	(5)	(6)
Horizontal%	0.042*	0.005	0.039*	-0.002	0.031	-0.006
	(0.021)	(0.022)	(0.019)	(0.023)	(0.020)	(0.023)
Horizontal% $\times$ First		0.091**		0.098**		0.104**
		(0.036)		(0.041)		(0.047)
First		0.002		0.002		-0.002
		(0.019)		(0.019)		(0.022)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Brand FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	172	172	172	172	172	172
<i>adj. R</i> <sup>2</sup>	0.35	0.38	0.34	0.39	0.33	0.39
Panel B: Generic returns						
	(1)	(2)	(3)	(4)	(5)	(6)
Horizontal%	0.020	-0.012	0.021	-0.013	0.021	-0.011
	(0.022)	(0.025)	(0.018)	(0.023)	(0.018)	(0.023)
Horizontal% $\times$ First		0.083***		0.085***		0.079***
		(0.018)		(0.023)		(0.025)
First		-0.017		-0.018		-0.018
		(0.013)		(0.013)		(0.014)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Generic FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	178	178	178	178	178	178
<i>adj. R</i> <sup>2</sup>	0.23	0.24	0.23	0.24	0.23	0.24

Table A.5: **Effect of horizontal shareholdings on brand’s and generic’s abnormal returns around the commencement of lawsuit**

This table presents estimates of the effect of horizontal shareholdings on the abnormal returns around the date on which a patent-infringement lawsuit is filed by a brand-name plaintiff. In Panel A, the dependent variable is the cumulative market adjusted returns for publicly listed brand plaintiffs over the window  $(-3, +3)$ . In Panel B, the dependent variable is the cumulative market adjusted returns for publicly traded generic defendant(s) over the window  $(-3, +3)$ . Dependent variables are winsorized at 1% and 99%. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders’ ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders’ voting rights in the generic defendant(s) (see equation 4 for a detailed description). *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was noticed by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. The specific group of top generic shareholders appears at top of each column. See Table 4 for definitions of control variables. Standard errors are in parentheses and are clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A: Brand returns						
	(1)	(2)	(3)	(4)	(5)	(6)
Horizontal%	-0.024 (0.015)	-0.000 (0.033)	-0.020 (0.014)	0.002 (0.034)	-0.028** (0.012)	-0.003 (0.030)
Horizontal% * First		-0.055 (0.068)		-0.054 (0.073)		-0.062 (0.071)
First		-0.002 (0.011)		-0.002 (0.012)		0.000 (0.013)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Brand FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	571	571	571	571	571	571
<i>adj. R</i> <sup>2</sup>	0.25	0.27	0.24	0.26	0.24	0.26
Panel B: Generic returns						
Horizontal%	0.006 (0.011)	0.015 (0.010)	-0.003 (0.013)	0.004 (0.012)	0.000 (0.014)	0.004 (0.012)
Horizontal% × First		-0.021 (0.035)		-0.014 (0.039)		-0.007 (0.048)
First		0.001 (0.009)		-0.000 (0.010)		-0.001 (0.012)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Generic FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	539	539	539	539	539	539
<i>adj. R</i> <sup>2</sup>	0.14	0.14	0.14	0.14	0.14	0.14

Table A.6: **Effect of horizontal shareholdings on brand’s and generic’s abnormal returns around dismiss**

This table presents estimates of the effect of horizontal shareholdings on the abnormal returns around the date on which the patent-infringement litigation is dismissed. In Panel A, the dependent variable is the cumulative market adjusted returns for publicly listed brand plaintiffs over the window  $(-3, +3)$ . In Panel B, the dependent variable is the cumulative market adjusted returns for publicly traded generic defendant(s) over the window  $(-3, +3)$ . Dependent variables are winsorized at 1% and 99%. Horizontal shareholdings (*Horizontal%*) are measured as the weight of top N (N=3, 5, 10) generic shareholders’ ownership in the brand plaintiff relative to their ownership in the generic defendant(s). Generic and brand ownership are weighted by generic shareholders’ voting rights in the generic defendant(s) (see equation 4 for a detailed description). *First* is an indicator variable coded as one if the settled generic defendant is the first challenger based on a pseudo entry date, which is the earliest of: (1) the date an ANDA was filed, (2) the date the brand plaintiff was noticed by the ANDA filer(s), and (3) the date the brand plaintiff sues the ANDA filer. The specific group of top generic shareholders appears at top of each column. *Generic Private* is an indicator variable coded as one if the brand plaintiff is publicly listed but the generic defendant is not, and zero otherwise. *Brand Private* is an indicator variable coded as one if the generic defendant publicly listed but the brand plaintiff is not, and zero otherwise. See Table 4 for definitions of control variables. Standard errors are in parentheses and are clustered at the U.S. Federal District Court level.

	Top 3		Top 5		Top 10	
Panel A: Brand returns						
	(1)	(2)	(3)	(4)	(5)	(6)
Horizontal%	0.019 (0.030)	0.034 (0.026)	0.038* (0.021)	0.050** (0.018)	0.028** (0.013)	0.043*** (0.009)
Horizontal% $\times$ First		-0.050 (0.030)		-0.042 (0.033)		-0.056 (0.038)
First		-0.005 (0.009)		-0.006 (0.009)		-0.004 (0.008)
Generic Private	Yes	Yes	Yes	Yes	Yes	Yes
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Brand FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	297	297	297	297	297	297
<i>adj. R</i> <sup>2</sup>	0.43	0.44	0.44	0.44	0.44	0.44
Panel B: Generic returns						
Horizontal%	-0.024 (0.058)	0.006 (0.086)	-0.015 (0.059)	0.010 (0.083)	0.014 (0.036)	0.042 (0.042)
Horizontal% $\times$ First		-0.083 (0.079)		-0.062 (0.050)		-0.082*** (0.016)
First		0.011* (0.006)		0.011 (0.006)		0.012 (0.008)
Brand Private	Yes	Yes	Yes	Yes	Yes	Yes
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Year-quarter FE	Yes	Yes	Yes	Yes	Yes	Yes
Generic FE	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes
N	208	208	208	208	208	208
<i>adj. R</i> <sup>2</sup>	0.36	0.36	0.35	0.35	0.35	0.36