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Fake Entry

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Abstract

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Keywords: ownership, corporate objective, corporate governance

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November 16, 2024

Abstract

We show the financial interests of a generic-drug manufacturer’s largest shareholders in a branded competitor predict the generic’s likelihood of being the first to challenge a drug patent. Conditional on a challenge, these common-ownership links predict settlements and delayed generic entry in exchange for payments to the generic. The stock price reactions are positive for the brand but negative for the generic, implying wealth transfers from one portfolio firm to another, with net benefits to investors. These facts suggest that in supracompetitive markets, corporate objectives depend on shareholder preferences.

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Because the Fund normally invests at least 80% of its assets in the stocks of companies related to the health care industry, the Fund's performance largely depends – for better or for worse – on the overall condition of this industry. Vanguard Health Care Fund Prospectus (May 25, 2017)

Investors say competition needs to be put aside for the greater good... Institutional investors in 15 major pharmaceutical companies have called on the drugmakers to set aside rivalries and short-term interests and cooperate... Reuters (April 17, 2020)

Pay-for-delay deals are a bad prescription for America; when drug companies agree not to compete, consumers lose. Jon Leibowitz, Chairman of Federal Trade Commission (January 13, 2010)

1 Introduction

What is the objective function of the firm? A convenient and ubiquitous assumption across all subfields of economics is that widely held corporations maximize their own value, irrespective of shareholder's preferences. The Fisher separation theorem proves this assumption is warranted under a number of assumptions, including that the firm is a price taker. The interpretation of empirical findings in the literature, however, tends to rely on the assumption that firms maximize their own value, irrespective of whether the markets in which they operate are competitive.¹

The question thus arises of whether widely held corporations maximize their own value not only in theory but also in practice, and whether own-value maximization depends on the competitiveness of their product markets. The alternative hypothesis that firms maximize the value of their most influential investors' portfolios: if influential shareholders of one firm have

¹Own-firm value and investors' portfolio value can differ when firms strategically interact. [Fisher \(1930\)](#) is often cited as the rationale behind the assumption of own-firm value maximization. Firms are price takers in that theory. [Hart \(1979\)](#) shows the price-taking assumption is *necessary* for shareholders to agree on firm value maximization as the objective of the firm. Theory further predicts that when firms strategically interact in the product market and shareholders are sufficiently diversified, shareholders unanimously prefer firms to maximize industry profits rather than their own value (e.g., [Diamond, 1967](#); [Drèze, 1974](#); [Grossman and Hart, 1979](#); [Rotemberg, 1984](#)). No widely accepted theory for the objective of the firm exists for intermediate cases.

large ownership stakes in other firms, these shareholders could financially benefit from taking value-destroying decisions for the benefit of these other firms. If that were the case, much of extant theory in corporate finance, and by extension in other areas of economics including industrial organization, trade, labor, and macroeconomics, could be enriched by re-examining standard questions while assuming alternative objective functions of the firm. To find out whether such an endeavor is potentially worthwhile, first addressing the *empirical* question of whether such situations do in fact occur seems important. Do widely held corporations take value-destroying decisions for the benefit of the value of their largest shareholders' portfolios?

In this paper, we document in a specific industry that some firms predictably make decisions that systematically destroy firms' own value, while the same decision benefits the value of the portfolio of their largest shareholders. Specifically, we examine the market-entry attempts and settlement decisions of generic-drug companies into the product markets of branded drugs, as well as accompanying stock price reactions. In particular, we study whether ownership predicts *which* generic posts the first (fake) entry threat to the market and whether the entrant settles with the rival offering the branded drug, thus precluding actual entry by other generics and helping the branded drug maintain its monopoly for longer. We then examine how the equity market for the generic's and the brand's shares reacts to both entry and the announcement of settlements.

The pharma industry provides an ideal laboratory for addressing this question, among others, because of a very clearly defined product market, and a unique institutional setting. Pursuant to the Hatch-Waxman Act of 1984, generic manufacturers are allowed to file Paragraph IV certifications with the Food and Drug Administration (FDA) in order to enter into a drug market before patents covering a branded product expire (see [Figure A.1](#)). A brand company typically responds by filing infringement lawsuits against generic entrants. The two parties then either enter into a settlement agreement or go trial with a likelihood that the court might dismiss the case (see [Figure A.2](#)). The FDA does not approve another Paragraph IV application for the same drug until after the first-generic markets the drug for 180 days. By entering into a "pay-for-delay" settlement, the brand incumbent can pay the first generic in exchange for the forfeit of the exclusivity or for the delay of marketing, which precludes other generic firms from entering the market. As such, the first Paragraph IV filer could not only

intensify competition but also foster collusion!²

We first document the extent of common ownership of industry competitors in the sector (see [Table 1](#)). To illustrate, [Table 2](#) reports the stakes the 20 largest generic shareholders hold in the generic manufacturer and the stakes they hold in the brand incumbent whose patents are challenged by that generic manufacturer. On average, the generic’s largest shareholder owns 10.3% of generic shares and 4.3% of brand shares. Due to size differences between brand and generic, the holdings of the largest five generic shareholders are sufficient for them to care more about the typically much larger brand’s profits than the generic’s profits, even if their ownership stakes are smaller in percentage terms. By influencing the generic’s conduct, and in particular by protecting the expensive branded drug’s product market, the generics’ largest shareholders can affect the brand’s profits.³

[Table A.1](#) provides four examples of infringement lawsuits to compare the top five generic shareholders who do and do not hold stakes in the brand plaintiff. The data suggest that, as a coalition, the generic common owners not only have substantial economic incentives on the brand side but also are able to influence the generic’s behavior over the preferences of non-common owners.

Having documented the ownership links, we turn to examining whether they predict firm behavior. We find that the extent to which a generic’s largest shareholders hold financial stakes in the branded drug’s manufacturer predicts both which generic first files a Paragraph IV to challenge the patents protecting the brand’s product market, and, conditional on a Paragraph IV filing, whether a settlement between the generic and the brand is reached. Settlements are accompanied by negative announcement returns for the generic and positive announcement returns for the brand. The largest and most powerful generic shareholders gain more from their holdings in the brand than they lose from the negative returns in the generic. As such, value-destroying product-market decisions by generic manufacturers are explainable by their largest shareholders’ portfolio holdings in their rivals.

One could argue that with common ownership, generic manufacturers should not challenge brand incumbents because the producer surplus is maximized when the generic stays out of

²For related studies, see [FTC \(2002\)](#), [FTC \(2010\)](#), [FTC \(2013\)](#), [Shapiro \(2003\)](#), [Bulow \(2004\)](#), [Hemphill \(2006\)](#), [Panattoni \(2012\)](#), [Hemphill and Lemley \(2011\)](#), [Hemphill and Sampat \(2012\)](#), and [Palikot and Pietola \(2023\)](#). In [Section 3](#), we provide institutional details regarding both Paragraph IV certification and pay-for-delay settlements entered by brand-name plaintiff and generic defendant.

³In a recent study, [Jacobo-Rubio, Turner, and Williams \(2020\)](#) estimate that a \$1 of annual sales of the drug increases the brand’s monetary gain by about \$7.55 and the generic’s monetary gain by about \$.12.

the market. However, one important fact contradicts this intuition: the expected profit for a generic manufacturer that is not the first Paragraph IV filer is literally zero! This is due to the presence of multiple potential entrants without common owners and the rapid decline in profit margin after the 180-day exclusivity period expires.⁴

We establish the above findings first with fixed-effect panel regressions, which difference out a large number of potentially omitted variables. Our panel-regression results suggest the likelihood that, conditional on entry and then lawsuits, the two parties enter into a settlement agreement increases in the extent to which shareholders in the generic defendant hold financial stakes in the brand plaintiff. The economic magnitude is such that a one-standard-deviation increase in common ownership increases the probability of settlement by 4.2 percentage points, which is 12.8% of the sample mean. We control for drug sales and fixed effects at the generic-defendant, the brand-plaintiff, federal-district-court, and time levels. The strongest effects of common ownership on the likelihood of settlement are attributable to the five largest generic shareholders.

One reason to challenge an interpretation of the above correlations as a causal effect of common ownership on product-market behavior is that both ownership and entry (or settlement, or settlement terms) could be determined by the same, unobserved factors that are not differenced out by fixed effects. Alternatively, ownership could depend on product-market behavior — a reverse-causality concern. To examine that possibility, we first test whether common ownership varies either before or around entry or settlement times. We do not find evidence to that effect. We further test whether our main results remain qualitatively similar when we use only variation caused by BlackRock’s acquisition of Barclays Global Investors. We find common ownership changes that are mechanically caused by the event indeed predict post-event settlement probabilities.

We propose that these empirical findings are easiest to understand if one assumes generic

⁴In our sample, each branded drug is typically challenged by four generic manufacturers, the majority of which do not share common owners with the brand incumbent. In about 50% of cases, multiple generics compete to be the first filer. Second, research by IQVIA (formerly Quintiles and IMS Health, Inc.) shows that the average generic drug price is only 3.6% of the pre-expiration price of its brand version, and generic drug prices drop by 51% within 12 months after the 180-day exclusivity period expires. In [Section 4](#), we model a generic’s decision regarding the timing of filing a Paragraph IV by assuming the generic’s expected gain from staying out of the market is zero.

firms maximize not their own value but the portfolio value of their largest investors.⁵ Such investors holding large stakes in the brand can mean sacrificing the own firm’s value for the value of a rival. Thinking about the counterfactual clarifies the intuition behind this strategy: if a generic whose shareholders hold no stakes in the brand would enter the market, that generic would not be as readily willing to settle in ways that transfer wealth to the brand. Instead, a non-commonly owned generic would be less likely to settle and thus more likely to compete away the brand’s margins — perhaps to the benefit of consumers but to the detriment of shareholders as a group. Alternatively, the generic would settle, but only under such terms that make the brand share the additional rents with the generic. Either way, it is more attractive for the brand’s shareholders to maximize the length during which it can charge monopoly prices in the product market. They can achieve that outcome by allowing or inducing a generic to make the sacrifice of being the first Paragraph IV filer and then settling on terms that are attractive to the brand. By doing so, the commonly-owned entrant prevents a more competitive and less cooperative rival from entering.

The portfolio interests of the generic firms’ largest shareholders can explain the above documented facts. To estimate the dollar amount of these shareholders’ portfolio interests, we conduct a shareholder-by-shareholder calculation of wealth changes when the brand settles with generics that are the first challengers. Our calculation suggests that, around the settlement between the first generic and brand, while the top five generic shareholders collectively stand to lose US\$481 million, the top five brand shareholders collectively gain US\$1,760 million.

We also examine whether the minority shareholders implement their preferences by appointing directors, inspired by a recently burgeoning literature on common directors (e.g., [Lemley, Manjunath, Kahrobai, and Kumar, 2022](#); [Barone, Schivardi, and Sette, 2023](#); [Geng, Hau, Michaely, and Nguyen, 2023b](#); [Gopalan, Li, and Žaldokas, 2023](#)) and FTC/DOJ enforcement priorities focusing on Clayton Act Section 8 violations. We manually read proxy statements of parties that entered into a settlement agreement in response to Paragraph IV challenges by the first generic that experienced negative abnormal stock returns around settlement. We do not find evidence that the settlement decisions that destroy generic firm value but benefit its largest shareholders through their holdings in the brand are associated with directors who have

⁵In [Section 4](#), we use a simple model to illustrate that how pay-for-delay settlements, in the presence of 180-day exclusivity, facilitate wealth transfer from the first generic Paragraph IV filer to the brand-name incumbent, which, in turn, affects the decision about the timing of Paragraph IV filing by generic manufacturers whose influential shareholders hold large stakes in the brand incumbent.

a connection to the brand or to the largest shareholders.⁶

Finally, we ask whether generic managers, when entering settlements that destroy their firm’s value, face significant litigation risks. We manually review lawsuits involving first generic manufacturers or their managers who entered into pay-for-delay settlements that destroy generic firms’ own valuation. We find generic firms often receive lawsuits filed either by a class of investors, both individual and institutional, or by the states and the FTC, often on behalf of consumers. Investors sue generic firms for making false and misleading statements or for failing to disclose key information, thus violating shareholder fiduciary duties. The states and the FTC sue generic firms due to the conspiracy among generic competitors to keep product prices inflated. Nevertheless, we find generic managers face negligible and remote litigation risks as a result of pay-for-delay settlements.

2 Related Literature

The main import of the finding that firms whose largest shareholders hold large stakes in rivals not only appear to put weight on rival profits, but do so to an extent that hurts their own value, is in providing systematic empirical evidence to inform a thus-far largely theoretical debate with a long history on the objective of the firm (e.g, [Azar and Vives, 2021](#); [Philippon, 2021](#); [Ederer and Pellegrino, 2024](#)).⁷ The present paper contributes first evidence of situations in which firms not controlled by a majority shareholder make value-destroying decisions for the benefit of commonly owned rivals, with far-reaching implications for the study of corporate finance and all areas of economics in which assumptions are made about firm behavior.

Our findings also contribute to a more applied literature on common ownership and competition. The finding that common ownership of industry rivals likely causes higher product prices in some markets in specific industries has triggered a vigorous policy debate and new literatures in industrial organization and antitrust law. However, whether the findings also have first-order implications for corporate finance depends on whether the findings imply firm objectives depend on shareholder portfolios and preferences, thus rejecting the predictions of the Fisher separation theorem. For example, [Azar et al. \(2018\)](#) speculate whether their evidence

⁶In a similar spirit, [Geng, Hau, Michaely, and Nguyen \(2023a\)](#) find no incremental effect on product-market outcomes after controlling for the effect of common ownership on firm profitability.

⁷Individual data points have been discussed informally, for example, by [Schmalz \(2015\)](#), but no systematic study of wealth transfers across commonly owned firms exists.

suggests a rejection of the Fisher separation theorem, but their evidence does not necessitate that conclusion. [He and Huang \(2017\)](#) find cross-held firms experience higher market share growth, and [He, Huang, and Zhao \(2019\)](#) find institutional cross-ownership internalizes corporate governance externalities, but this evidence also does not distinguish between different firm objective functions. [Antón, Ederer, Giné, and Schmalz \(2022\)](#) show that a model in which firms maximize their own value but their cost structure depends on common ownership can explain a causal link between common ownership and product prices at the market level, as documented in [Azar et al. \(2018\)](#) and later literature.

Our study also relates to [Harford, Jenter, and Li’s \(2011\)](#) study of mergers under common ownership. The authors document that, at the time, in the industries they study, “cross-holdings are too small to matter in most” cases and “do not explain value-reducing acquisitions.” Unlike the M&A case in [Matvos and Ostrovsky \(2008\)](#), where bidders’ losses are targets’ gains, generic shareholders can increase the overall size of the pie shared by shareholders by guaranteeing a longer period during which the brand can charge high prices to consumers due to the absence of generic competition. [Geng, Hau, and Lai \(2021\)](#) show common ownership can alleviate holdup problems.

Our study provides the most direct evidence that shareholder expropriation via “tunneling” extends to the [Berle and Means \(1932\)](#) world of widely held firms. Three takeaways are worth mentioning. First, our documented wealth transfer occurs between legally independent firms through arm’s-length transactions, which is in sharp contrast to wealth transfers between related parties through self-dealing transactions mediated by controlling shareholders (e.g., [Johnson, La Porta, Lopez-de Silanes, and Shleifer, 2000](#); [D’Acunto, Weber, and Xie, 2019](#)). Second, wealth transfer in our setting occurs in the presence of diversified institutional investors holding shares in single-class firms, whereas tunneling in prior literature is typically driven by under-diversified large shareholders with excess control over cash-flow rights, often established through a pyramidal ownership structure (e.g., [Claessens, Djankov, and Lang, 2000](#)). Third, we show wealth transfer from one portfolio firm to another takes place in common-law countries, where legal protection of minority shareholders is strong; by contrast, tunneling by controlling shareholders is more frequent in civil-law countries, where government and family control is pervasive.

Although our main motivation is conceptual, our study is also important given the enor-

mous public-health implications of competition in the market for affordable pharmaceuticals. We thus also contribute to a literature of generic entry under common ownership. [Xie and Gerakos \(2020\)](#) and [Xie \(2021\)](#) show common ownership correlates with settlement. Neither study supports evidence suggesting a causal interpretation, neither studies effects on entry, and neither studies shareholder wealth implications. Moreover, those papers’ measurement of ownership omits insiders and blockholders, which explains much of the variation in common ownership (see [Amel-Zadeh, Kasperk, and Schmalz 2022](#)) and for that reason alone reports likely biased estimates. Ours is the first paper showing common ownership predicts entry by the *first* generic challenger, thus blocking further entry by challengers with less common ownership and leading to potentially welfare-reducing pay-for-delay settlements. Third, and most importantly, our study is the first to complement an analysis of product-market entry with an analysis of accompanying stock-market reactions and wealth transfers among commonly owned firms. A second related paper in this literature is by [Newham, Seldeslachts, and Banal-Estanol \(2019\)](#). The authors examine the empirical relation between common ownership and generic entry in the setting of Paragraph *III* (!) certification, in which generic manufacturers make an entry decision *after* the expiration of all patents protecting the branded drug. In such a scenario, a drug market is opened up by the end of regulatory protection in the US, and no patent disputes, settlements, and thus wealth transfers are involved.

In a third closely related paper in this literature, [Li, Liu, and Taylor \(2022\)](#) study product-market *exit* of commonly owned firms. This paper shows that, once a commonly owned project shows first promise in trials, venture capital investors cut funding to early-stage drug-development projects that are not publicly traded.

3 Institutional Background

This section provides a background review about the Paragraph IV certification and pay-for-delay settlement.

3.1 Paragraph IV certification

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.

The Hatch-Waxman Act 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. 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.⁸

A distinct feature of Paragraph IV is that the FDA rewards 180-day exclusivity to the first generic submitting this certification. 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. Brand-name companies often pay the first-generic manufacturer to hold the generic product off the market for a certain period of time so that all generics cannot enter the market.

Figure A.1 illustrates the time period during which Paragraph IV generic entry is allowed. When a brand-name company submits a New Drug Application (NDA) to the FDA for approval they are required to list all relevant patents in the FDA Orange Book. In addition, the FDA will also grant each newly approved product a regulatory protection called “data exclusivity” lasting for five years (seven years for orphan drugs and five and a half years for pediatric drugs) that runs concurrently with patent protection. During this data-exclusivity period, regardless of whether underlying patent(s) are valid, no generic entry may occur. At the end of data exclusivity, only patents protect branded products. The period running from the end of data exclusivity to the expiration of patents protecting a branded drug is referred to as “marketing exclusivity.” Paragraph IV generic entry is only allowed during the marketing-exclusivity period.

⁸A Paragraph I certification is issued when the drug innovator has not filed patents to cover its branded product. Paragraph II certification involves a branded drug’s patents having expired, 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.

3.2 Pay-for-delay settlement

Despite settlements having various forms, they share one common feature: the brand-name company pays the generic firm in one of several ways (discussed), whereas the generic firm agrees to delay entry, and thus generates value for the brand, which gets to enjoy a delay of the end of its patent-protected monopoly.

More specifically, a generic firm files a Paragraph IV challenge seeking to market a generic version of a branded drug prior to the expiration of patents covering the drug. Rather than take a chance it might lose the patent-infringement lawsuit, the brand-name company agrees to pay the generic firm in exchange for its agreement to abandon its Paragraph IV challenge and to delay entry. The surplus thus created for the shareholders of generic and brand comes from increased consumer rents, compared with a more competitive equilibrium in which the generic does not delay entry.⁹

Relevant to our study, one important issue concerns the timing of settlement. According to [Hemphill \(2007\)](#), in many settlements, the Paragraph IV challenger retains eligibility for the 180-day exclusivity period by agreeing to enter at a particular date that is at least 180 days prior to patent expiration. The economic incentive for the Paragraph IV filer to retain the eligibility for the 180-day exclusivity is as follows. Because the patent at issue is never adjudicated, the generic firm does not risk the possibility that it will lose the infringement lawsuit. If the generic firm lost, it would not only be forced to wait until patent expiration but also lose the 180-day entitlement. By reaching an agreement on entry dates, the generic firm retains the entitlement, turning the mere probability of enjoying it (if it won the patent suit) to a near certainty.

⁹The brand-name company can transfer value to the generic filer in different ways. First, it can pay cash, including over-payment for goods and services provided by the generic firm. The amount of cash paid varies greatly across the settlements. 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 ([FTC, 2010](#)). Second, the generic firm agrees to license the brand company's intellectual property or to develop new products for sale by the innovator. Third, 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. Fourth, the brand-name company either overpays for goods and services provided by the generic firm or sets a very low price for goods and services provided to the generic firm.

4 A simple model

In this section, we present a theoretical framework to illustrate how a pay-for-delay settlement facilitates wealth transfer from the first generic to the brand-name incumbent.

We summarize the model’s idea as follows. A payment from brand to the generic in exchange for delayed entry by generic manufacturers does not generate productive efficiencies. Instead, it causes consumers to face monopolistic prices for a longer time. This effect generates shareholder wealth, but reduces consumer welfare.¹⁰ Moreover, when influential generic shareholders hold more stakes in the brand incumbent, the shareholders benefit on net when a wealth transfer of gains from settlement from one portfolio firm to another occurs. Given the expected gain for a generic to stay out of the market is zero, this eventual payoff gives the ex-ante incentive for generic manufacturers whose shareholders hold large stakes on brand-side to strive to be the first patent challenger under Paragraph IV.

Strictly speaking, the “incentive to be the first Paragraph IV filer” equals the difference between the expected profit from being the first Paragraph IV filer and the expected profit from not being the first filer (or staying out of the market). However, based on extensive discussions in [Section 1](#), we assume in the model that the latter equals zero due to multiple generic manufacturers, including many without common ownership.

4.1 Bertrand competition with capacity constraint

We assume that after the first generic enters the market, the generic entrant plays a Bertrand game with the brand-name incumbent. The rationale for this assumption is that generic and brand drug products are bio-equivalent.

However, consistent with the FDA’s rationale to reward the first generic entrant with positive margins, we assume the two firms are initially capacity constrained and, as a result, the equilibrium price is higher than marginal cost, causing duopoly margins to be positive during the first 180 days. [Figure A.4](#) supports our model assumption — drug prices do not fall significantly immediately after the first generic enters into market; that is, the generic price is 94% of the brand price. The generic-to-brand price ratio, however, drops to 50% after the

¹⁰A settlement can be reached either before or after courts take an action. Similar to [Shapiro \(2003\)](#), we do not distinguish between settlements occurring before and after patent litigation, because both types of settlements take place in the shadow of an ultimate court ruling on patent validity and/or infringement.

second entry and rapidly declines after more generics enter.

Assume the aggregate (inverse) demand curve is

$$D(p) = A - q, \quad (1)$$

where $A > 1$ and marginal cost is a constant c . Prior to any generic entries, the brand incumbent's monopoly price is $p_b^M = \frac{1}{2}(A + c)$ and its monopoly profit is $\pi_b^M = \frac{1}{4}(A - c)^2$.

We assume the brand's capacity is fixed at the level when it monopolizes the market. Specifically, we impose two capacity constraints on brand and generic, namely, $q_b = q^M = \frac{1}{2}(A - c)$ and $q_g = \frac{1}{6}(A - c)$, respectively, and that $q_b + q_g = \frac{2}{3}(A - c)$. We calculate the Bertrand equilibrium price such that firms work on the basis of own capacity and sell all inventory. According to equation (1), the equilibrium price with capacity constraint is greater than marginal cost c but less than the monopoly price p^M :

$$p^* = A - q_b - q_g = c + \frac{1}{3}(A - c). \quad (2)$$

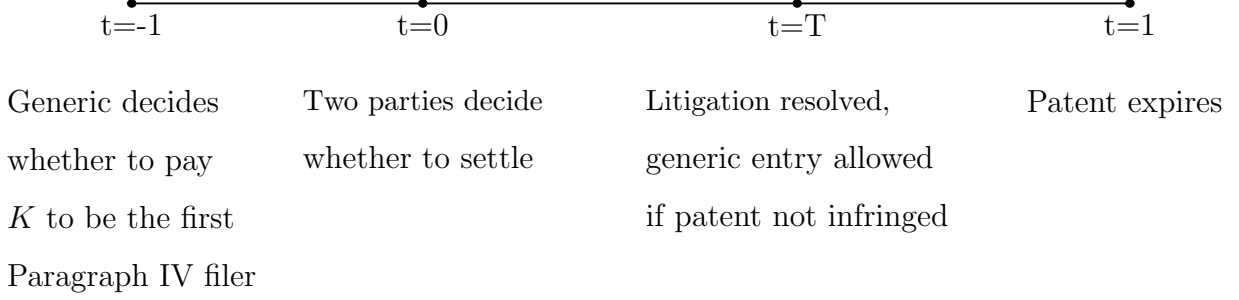
Duopoly brand and generic profits are therefore $\pi_b^D(p^*) = \frac{1}{6}(A - c)^2$ and $\pi_g^D(p^*) = \frac{1}{18}(A - c)^2$, respectively.

4.2 Paragraph IV and settlement without common ownership

Timeline of Events: We assume generic and brand shareholders are risk neutral and ignore discounting. Suppose that there are only two litigation outcomes: the patent either is valid and infringed with probability θ or is invalid with probability $1 - \theta$. The patent's strength is common knowledge and is captured by θ . As illustrated by the following timeline of events, the date at which generics decide whether to pay a cost K to be the first Paragraph IV filer is $t = -1$, the date of settlement is $t = 0$, the date at which the patent expires is $t = 1$, and the date at which patent litigation is resolved is $t = T$ ($0 < T < 1$), in which generic firms could

enter if the court rules the patent is invalid.¹¹

Timeline of events



Settlement at $t=0$: Absent settlement, the expected number of days on which the brand sells as a monopolist is $T+\theta(1-T)$. We first assume the 180-day exclusivity does not exist. All generics can enter at $t=T$ if the patent is invalid, which eliminates the import of capacity constraints. As such, the equilibrium price under pure Bertrand competition is c and all firms earn zero profits. Under the above assumption, the brand's expected profits at $t = 0$ is

$$\mathbb{E}_{t=0}(\pi_b) = T\pi_b^M + \theta(1 - T)\pi_b^M, \quad (3)$$

where, between $t=T$ and $t=1$, the brand incumbent is expected to earn zero profit with probability $1 - \theta$ if the patent is invalid. Without the 180-day exclusivity, because profits are fully dissipated by all generic entrants after the court rules that the patent is invalid, the expected payoff to generics is:

$$\mathbb{E}_{t=0}(\pi_g) = 0. \quad (4)$$

We next introduce the 180-day exclusivity into the game. Assume τ is the length of exclusivity period during which the FDA rewards the first generic. The brand's expected

¹¹The cost a generic manufacturer incurs to be the first Paragraph IV filer includes the managerial efforts the generic firm has made to prove that the patents in question are invalid or will not be infringed by its production, use, or sale of the drug product for which the ANDA is submitted. Entry costs also include litigation and physical expenses related to Paragraph IV. In several cases, generic firms' representatives had sought to be the first to submit a patent challenge by "lining up outside, and literally camping out adjacent to, an FDA building for periods ranging from 1 day to more than 3 weeks." For details, see [Guidance for Industry 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day](#).

profits with and without settling with are

$$\mathbb{E}_{t=0}(\pi_b) = \begin{cases} \pi_b^M - P & \text{Settle} \\ T\pi_b^M + \theta(1-T)\pi_b^M + (1-\theta)\tau\pi_b^D & \text{Trial,} \end{cases} \quad (5)$$

where P is the brand's payment to the first generic, and $(1-\theta)\tau\pi_b^D$ is the brand incumbent's expected profit when competing with the first generic during the exclusivity period. We assume $P \in [(1-\theta)\tau\pi_g^D, \pi_b^M]$, where $(1-\theta)\tau\pi_g^D$ is the expected payoff to generic if two parties go to trial, and π_b^M is the maximum payment that the brand-name incumbent can afford. The first generic's profit with and without entering into the pay-for-delay settlement is expressed as follows:

$$\mathbb{E}_{t=0}(\pi_g) = \begin{cases} P & \text{Settle} \\ (1-\theta)\tau\pi_g^D & \text{Trial.} \end{cases} \quad (6)$$

After a settlement, therefore, the expected total gains accruing to the two litigated parties is the following:

$$\mathbb{E}_{t=0}(\Delta\pi) = \underbrace{(1-\theta)(1-T)\pi_b^M}_{\text{Monopoly Profit}} - \underbrace{(1-\theta)\tau\pi_b^D}_{\text{Duopoly Profit}}. \quad (7)$$

Equation (7) suggests that if the patent becomes invalid during period $1-T$, a settlement allows the brand to pay the first generic P to stay out of the market in exchange for making $1-T$ days monopoly profits rather than making τ days duopoly profits.

Paragraph IV Filing Decision at $t=-1$: At time $t=-1$, the generic manufacturer decides whether to pay a cost K to be the first generic. Suppose the probability of two parties entering into a settlement agreement is $F(P) = F(u \leq P)$, where u is a random variable capturing the generic's (or its key decision-maker's) reservation utility. At $t=0$, bargaining between the two parties might break down with a probability of $1-F(P)$ for some irrelevant factors related to the generic CEO's irrational behavior (e.g., [Harsanyi, 1961](#)). At time $t=-1$, the generic's expected payoff of filing a Paragraph IV can be expressed as follows:

$$\mathbb{E}_{t=-1}(\pi_g) = \underbrace{F(P)P}_{\text{Settlement Fee}} + \underbrace{[1-F(P)](1-\theta)\tau\pi_g^D}_{\text{Duopoly profit}} - K, \quad (8)$$

where, at $t=-1$, the generic manufacturer forms an expectation about the net gain from entry

to decide whether being the first Paragraph IV filer is ex-ante profitable.

4.3 Paragraph IV and settlement with common ownership

Settlement at $t=0$: According to equation (15), if influential generic shareholders hold stakes with the brand, the generic manager puts a profit weight of κ on the profits of the branded drug (see equation (14)). Given the same total gain accruing to the two litigated parties after a settlement (see equation (7)), the expected payoff for common owners of the first generic is the following:

$$\mathbb{E}_{t=0}(\pi_g^{co}) = \kappa(\pi_b^M - P) + P, \quad (9)$$

where co denotes either generic or brand payoffs under common ownership. The probability that the first generic accepts the settlement offer is

$$F[u < \kappa(\pi_b^M - P) + P]. \quad (10)$$

Taking the first-order derivative with respect to κ in equation (10) yields the following result:

$$\frac{d\{F[u < \kappa(\pi_b^M - P) + P]\}}{d\kappa} = f(u)(\pi_b^M - P) > 0, \quad (11)$$

where $f(u)$ is the density function of $F(u)$. This leads to the following result with respect to the relation between common ownership and the likelihood of settlement.

Proposition 1: *Given that the brand-name incumbent offers payment P , the probability that two parties settle is an increasing function of the profit weight that generic shareholders put on the brand-name incumbent (κ).*

Paragraph IV Filing Decision at $t=-1$: At time $t=-1$, the generic manufacturer whose large shareholders put a profit weight of κ on the brand-name incumbent decides whether to pay a cost K to be the first Paragraph IV filer. At time $t = -1$, the generic's expected payoff from challenging patents is:

$$\mathbb{E}_{t=-1}(\pi_g^{co}) = F[u < \mathbb{E}_{t=0}(\pi_g^{co})]\mathbb{E}_{t=0}(\pi_g^{co}) + \{1 - F[u < \mathbb{E}_{t=0}(\pi_g^{co})]\}(1 - \theta)\tau\pi_g^D - K. \quad (12)$$

Because $(1 - \theta)\tau\pi_g^D \leq P \leq \pi_b^M$, taking the first-order derivative with respect to κ in equation (12) yields the following:

$$\begin{aligned} \frac{d\mathbb{E}_{t=-1}(\pi_g^{co})}{d\kappa} &= F[u < \mathbb{E}_{t=0}(\pi_g^{co})](\pi_b^M - P) \\ &+ f(u)(\pi_b^M - P)[\mathbb{E}_{t=0}(\pi_g^{co}) - (1 - \theta)\tau\pi_g^D] > 0. \end{aligned} \quad (13)$$

This leads to the following result with respect to the relation between common ownership and a generic manufacturer's incentive to be the first Paragraph IV filer.

Proposition 2: *Given that the brand-name incumbent offers payment P and generic entry incurs a cost K , the generic manufacturer's expected profit to be the first Paragraph IV filer is an increasing function of the profit weight that generic shareholders put on the brand-name incumbent (κ).*

5 Data

In this section, we introduce several sets of raw data and explain how we construct common ownership.

5.1 Paragraph IV lawsuit documents

Our data on entry 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).

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. Figure 1 provides a snapshot of the online publication.

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 distinct patent-infringement lawsuit triggered by a 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 active ingredient of the branded drug) as different products.¹² In other words, we define a challenge at the level of the date on which a brand manufacturer files a patent-infringement lawsuit against an ANDA filer challenging the formulation of a trade name. We collect 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.¹³

From the online Paragraph Four Report®, we manually extract the relevant data fields. For each Paragraph IV challenge that results in patent infringement litigations, 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.

Table 3 presents descriptive statistics of our sample for empirical analysis. It consists of 2,023 unique patent-infringement lawsuits caused by Paragraph IV challenges to 1,578 unique patents covering 521 unique trade names. These 2,023 challenges are launched by 202 distinct generic manufacturers. The 521 trade names are owned by 157 distinct brand-name companies. Additionally, in about 86% of brand-generic pairs, both litigating parties are publicly listed firms. Common-(institutional) ownership linkage can only exist when both generic and brand

¹²One concern with treating different formulations under the same trade name differently is that if one generic typically challenges all formulations under a branded drug, and if Paragraph IV litigation outcomes do not vary across formulations under the same drug challenged by the same generic, treating different formulations as different products artificially inflates the number of observations. For several reasons, however, we argue the above issue is less a concern. First, only 10% of trade names are associated with more than one formulation (see Panel C of Table 3). Second, out of 187 generic-tradename pairs in which one generic challenges multiple formulations under the same trade name, about 13% pairs have litigation outcomes that differ across formulations. Third, in approximately 6% of cases, the same generic challenges different formulations under the same trade name at different time points, rendering the necessity to separate formulations to consider time-varying common ownership. Fourth, untabulated results confirm that our results are robust to treating different formulations under the same trade name as the same product.

¹³About 6% challenges did not trigger the brand’s lawsuit against generic manufacturers, and 5% of challenges triggered lawsuits but did not provide information on when lawsuits were filed. We exclude these challenges in our analysis.

are widely held corporations. Finally, nearly 90% of trade names have only one formulation challenged, 8.5% have two formulations challenged, and less than 2% have more than two formulations challenged.¹⁴

5.2 First generic challenger

The Paragraph Four Report® provides the dates on which the brand sues the generic ANDA filer for patent infringement. The company does not provide the date/month in which generic manufacturers file ANDA applications under Paragraph IV. We are not aware of any public sources (e.g., FDA websites) providing such dates either. The lack of these dates can introduce measurement error if we determined the first ANDA filer based on when the brand incumbent in turn sues the generic firm. To address this concern, we conduct a fuzzy search for the first ANDA filer. We define an entry date as the earliest of (1) the date an ANDA was filed (if data are available), (2) the date the ANDA filer(s) noticed the brand incumbent, and (3) the date the brand sued the ANDA filer. The Paragraph Four Report® 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 of the above three dates. Under this method, the first generic triggers 686 out of 2,023 lawsuits.

5.3 Data on pharmaceutical firms' ownership

[Amel-Zadeh et al. \(2022\)](#) show measures of common ownership merely based on 13-F filings lead to biased results because they mask the true variation of ownership. For accurate measures, we also need to capture non-institutional insiders and blockholders. To that end, we start with ownership data from Capital IQ under the S&P Global Market Intelligence. The Ownership dataset provides detailed institutional, mutual fund, and insiders/individuals equity share ownership data for public and private companies, along with public float shares and buys and sells of insiders and major shareholders. The ownership data is available starting from the first quarter of 2004.

¹⁴[Figure A.3](#) plots the distributions of the number of these 2,023 challenges and the settlement rates over calendar years in which lawsuits are filed. [Table A.2](#) presents the sample distributions of the Paragraph IV litigation outcomes across US Federal District Courts following the filing of an ANDA under Paragraph IV certification with the FDA. Settlement rates vary substantially across courts.

In [Table 1](#), we shed light on the extent of common ownership in the current U.S. pharmaceutical industry. For a sample of generic manufacturers and brand patent owners included by our sample, we list the top 10 shareholders for the nine most frequent Paragraph IV challengers (generic manufactures) and the nine most challenged patent owners (brand-name companies), as well as their ownership observed in the fourth quarter of 2016. [Table 1](#) shows generic manufacturers are more often smaller and held by blockholders and insiders. Common ownership is more pronounced among bigger pharmaceutical companies.

5.4 Common ownership

Following [Rotemberg \(1984\)](#), [Backus and Sinkinson \(2019\)](#), [Antón et al. \(2022\)](#), and [Boller and Scott Morton \(2021\)](#), we use a measure of common ownership that calculates the extent to which the most influential shareholders in one firm also hold financial stakes in other firms. This measure can be interpreted as an alternative objective of the firm, whereby firm j maximizes a weighted average of its M shareholders' (indexed by i) portfolio profits that arise from cash-flow rights β_{ik} in N different firms (k) that make profits π_k , whereas γ_{ij} s are the respective shareholders' voting shares:

$$\max \Pi_j = \sum_{i=1}^M \gamma_{ij} \sum_{k=1}^N \beta_{ik} \pi_k = \pi_j + \sum_{k \neq j} \underbrace{\frac{\sum_i \gamma_{ij} \beta_{ik}}{\sum_i \gamma_{ij} \beta_{ij}}}_{\kappa_{jk}} \pi_k. \quad (14)$$

In equation (14), firm j (the generic manufacturer) internalizes externalities on other firms k (brand-name incumbents). However, firm j only does so to the extent κ_{jk} that owners with economic interests in firm k (β_{ik}) have control rights over firm j (γ_{ij}), relative to the control and cash-flow rights they have over firm j . The measure reflects that large generic shareholders have more influence on generic managers' behavior than a collection of small shareholders with diverging economic interests that is equally large in aggregate. This property addresses the concern with alternative measures that treat generic shareholders equally ([Harford et al., 2011](#)).

Because generic entrant j and brand-name incumbent k are the only two players in the pre-entry game, and because the payoff of any litigation outcome is forward looking, we modify

firm j 's objective function as follows:

$$\max \Pi_j = \mathbb{E}\pi_j + Kappa_{jk}\mathbb{E}\pi_k, \quad (15)$$

where $\mathbb{E}\pi_j$ is the present value of future profits, net of entry costs, if a generic substitute is allowed to be sold before patents expire. $Kappa_{jk}$ is the profit weight that generic defendant j places on the present value of the monopolistic profits from selling the brand drug during the remaining life of patents by the brand-name plaintiff k . The profit weight of $Kappa_{jk}$ is the principal object of interest in the common-ownership hypothesis [Backus et al. \(2021a,b\)](#).

[Backus et al. \(2021b\)](#) further shows that under proportional control (“one share, one vote”), each profit weight $Kappa_{j,k}$ can be decomposed into the following two terms:

$$Kappa_{jk} = \underbrace{\cos(v_j, v_k)}_{\text{overlapping ownership}} \times \underbrace{\sqrt{\frac{IHHI_j}{IHHI_k}}}_{\text{relative IHHI}}. \quad (16)$$

The first term of “overlapping ownership” is the cosine of the angle between the vector β_j of ownership positions β_{ij} that shareholders (indexed by i) hold in generic firm j and the corresponding vector k for brand firm k . The cosine similarity captures the overlap in ownership and is the origin of the incentive to internalize the profits of another firm. Without large short positions, the similarity metric is restricted to the $[0, 1]$ interval.

The second term is the ratio of the “investor Herfindahl-Hirschman indices” $IHHI_j = \sum_i \beta_{ij}$ and $IHHI_k = \sum_i \beta_{ik}$ for shareholders of firm j and k (also see [Antón et al. \(2022\)](#) and [Boller and Scott Morton \(2021\)](#)). This second term ties the theory of common ownership to the notion that investor concentration drives a wedge between control rights and cash-flow rights, and, all else being equal, firms with concentrated investors will place more weight on their own profits and less weight on competitor profits.

Our main measure of common ownership is the profit weight that the top 20 generic shareholders put in the brand firm as of the beginning of the quarter in which a patent-infringement lawsuit is filed ($Kappa20$ thereafter). Panel A of [Figure 2](#) shows a secular uptrend of average $Kappa20$, cosine similarity, and investor HHI over the sample period of 2004Q1 – 2017Q4. In each quarter, these metrics are averaged across firm-by-firm pairs, where firms are selected as long as they appear at least once in The Paragraph Four Report®, either as a

defendant or as a plaintiff.

[Amel-Zadeh et al. \(2022\)](#) find the average profit weight across pairs of 4-digit SIC competitors that are S&P 500 single-class firms steadily grew from 0.47 in 2004 to 0.75 in 2020, whereas our calculated mean profit weight across all generic-brand pairs grew from 0.05 in 2004Q1 to 0.12 in 2017Q4. The difference in the level of common ownership is due to the difference in samples, whereas a majority of generic entrants in our sample are predominantly owned by under-diversified blockholders and insiders. As for the decomposed components, the mean cosine similarity steadily increased from 0.07 in 2004 to 0.19 in 2017, whereas the mean IHHI increased from 0.13 to 0.23. Panel B of [Figure 2](#) provides histograms of the distribution of *Kappa20* across generic-brand pairs in 2004Q1 and 2017Q4, respectively.

6 Empirical results

In this section, we present baseline regression results using fixed-effect panel regressions and the instrumental variable approach.

6.1 Sample

Our ownership data start in 2004. However, we also exclude patent-infringement lawsuits filed prior to the fourth quarter of 2003 for another important reason. That is, because a lawsuit typically triggers a 30-month stay of the FDA approval of generic drugs, brand incumbents often listed additional patents to trigger multiple, non-concurrent 30-month stays, thereby delaying entries without using pay-for-delay settlements. On December 8, 2003, President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) into law, after it passed in Congress by a close margin. The new regulation limited each patent owner to only *one* 30-month stay of a generic-drug applicant’s entry for resolution of a patent challenge.¹⁵ The FTC began receiving patent settlement agreements in January 2004 pursuant to the MMA of 2003.

[Table 4](#) presents descriptive statistics of our regression sample. “Settle,” “Dismiss,” and “Trial” are dummy variables indicating whether the two litigants settle, dismiss, or go to trial

¹⁵For legal background, see [Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the Committee on the Judiciary, United States Senate, One Hundred Eighth Congress, First Session, June 17, 2003.](#) (U.S. Government Printing Office, 2003).

for at least one disputed patent at issue. We first note substantial variation exists in settlement outcomes. Namely, 37.8% of lawsuits were settled, 36.3% were dismissed, and only 27.4% went to trial. Conditioning on trial, unreported statistics (at patent level) reveal a 53.5% chance that the brand plaintiff will lose an infringement lawsuit. Second, for about 30.9% of cases, at least two generic manufacturers were involved with challenging patents covering the same branded product on the same day.¹⁶ Third, the share of the first generic challenger accounts for 32.8%. Fourth, generic manufacturers on average challenged 1.5 patents in each case. Fifth, about 23.9% and 55.2% of Paragraph IV challenges were initiated by generic manufacturers with previous production experience in dosage form/route and therapy class, respectively.

6.2 Common ownership does not change around Paragraph IV challenges and lawsuits

Before formally estimating the effect of common ownership on generic entry and settlement, we first assess two theoretical possibilities in which the level of common ownership could change prior to the arrival of either a Paragraph IV challenge or a subsequent patent-infringement lawsuit. First, shareholders of a brand-name plaintiff might anticipate the above events in advance, and as a consequence, they actively invest upfront in stakes in all potential generic entrants to “create” more common ownership. With common ownership, the two litigating parties’ commitment to a pay-for-delay settlement becomes more credible and the generic defendant will have to accept a worse deal in settlement to protect its financial positions in the plaintiff. If the above scenario is true, we might find a correlation between common ownership and challenge or settlement whose interpretation would be different than if ownership were pre-determined.

Second, brand plaintiffs can make more credible threats to go to trial by taking a short position in generic defendants’ stock (see [Choi and Spier, 2018](#)).¹⁷ If the above conjecture is true, an observed positive correlation between common ownership and settlement might be driven by a negative effect of brand ownership of the generic on the likelihood of two litigating parties *not* going to a trial.

¹⁶The FDA grants each new approved product a length of “data exclusivity,” which runs concurrently with patent protection. During this data-exclusivity period, regardless of the status of the underlying patent(s), no generic entry is allowed. At the conclusion of data exclusivity, branded products are protected only by their patents, which are subject to generic manufacturers’ challenge. For this reason, we observe several generic manufacturers simultaneously challenging the same branded product on the same date after the data exclusivity expires.

¹⁷See also “New Hedge Fund Strategy: Dispute the Patent, Short the Stock” (Wall Street Journal, April 7, 2015).

To examine whether evidence for these hypotheses exists, we estimate the following ordinary linear squares (OLS) equation on the sample in which at least one shareholder of the generic entrant holds stakes in the brand-name incumbent. Sample units are measured at the generic-brand-year-quarter level:

$$Kappa20_{jks} = \alpha + \sum_{s=-8}^{s=+8} \beta_s \times First\ Filing_{jks} + \phi_j + \phi_k + \phi_s + \varepsilon_{jks}, \quad (17)$$

where $First\ Filing_{jks}$ is a dummy variable indicating the s^{th} ($-8 \leq t \leq 8$) quarter relative to the event quarter in which the first generic j files a Paragraph IV challenge against brand-name firm k , and 0 otherwise. $Kappa20$ is the profit weight that the top 20 shareholders of a generic defendant put on the brand-name defendant as of the beginning of the quarter in which a patent-infringement lawsuit is filed (see equation (15)).

Figure 3 plots $\hat{\beta}_t$ and the 95% confidence intervals estimated from equation (17). The coefficients are not statistically different from zero. In other words, we fail to detect any systematic changes in common ownership around the Paragraph IV application by the first generic.

Figure 4 plots $\hat{\beta}_t$ and its 95% confidence intervals from estimating the following equation:

$$Kappa20_{jks} = \alpha + \sum_{s=-8}^{s=+8} \beta_s \times Lawsuit_{jks} + \phi_j + \phi_k + \phi_s + \varepsilon_{jks}, \quad (18)$$

where $Lawsuit_{jks}$ is a dummy variable indicating the s^{th} ($-8 \leq t \leq 8$) quarter prior to a litigation initiated by brand plaintiff k against generic defendant j , and 0 otherwise. We again do not detect any systematic changes in common ownership around when brand-name incumbents file a lawsuit against generic Paragraph IV filers.

6.3 Determinants of the first generic

In this section, we establish our first main result. We ask whether generic manufacturers that filed a Paragraph IV are more likely to be the first filer if their shareholders hold more brand shares. Given competition among multiple generic firms, private coordination between commonly owned entrant and incumbent — that is, potential entrants with common ownership stay out of the drug market — seems to be an ineffective mechanism to block other potential

entrants from entering the same market. Instead, from the perspective of a common owner, joint-value maximization implies generic manufacturers with common ownership should secure the 180-day exclusivity by challenging the branded drug as early as possible.

We use the following linear probability model to estimate the effect of common ownership on the likelihood that a Paragraph IV filer is the earliest filer:

$$First_{jkms} = \alpha + \beta \times Common\ Ownership_{jks-1} + X' \times \gamma_1 + \phi_k + \phi_j + \phi_l + \phi_s + \varepsilon_{jkms}, \quad (19)$$

where $First_{jkms}$ indicates whether j is the first generic manufacturer among all firms that file Paragraph IVs with the FDA to challenge patents covering the branded drug m owned by brand-name firm k . Common ownership ($Kappa20$) for a generic manufacturer j is measured as of the beginning of quarter s in which the first generic files.¹⁸

The vector of X' includes the following variables: (1) a set of dummy variables indicating a drug's market size regarding sales (if observable),¹⁹ (2) a dummy indicating whether a generic is the first challenger of the formulation of a trade name, (3) a dummy indicating whether several generics simultaneously challenge patents protecting a brand drug, (4) a dummy indicating whether a generic j has production experience in the brand drug's form/route (*Route*) over the past three years, (5) a dummy indicating whether a generic j has production experience in the brand drug's therapy class (*Therapy*) over the past three years, and (6) the logarithm of number of patents covering the branded drug. The inclusion of these variables is motivated by prior studies on the determination of generic entry in the pharmaceutical industry (e.g., Scott Morton, 1999, 2000; Acemoglu and Linn, 2004; Kyle, 2006; Ellison and Ellison, 2011; Hemphill and Sampat, 2011).

To address omitted variables, we use ϕ_j , ϕ_k , ϕ_l , and ϕ_s to capture fixed effects from the generic defendant j , the brand plaintiff k , the federal district court l , and the year-quarter s when the brand sues. We cluster standard errors at the level of U.S. Federal District Court.

Our estimates are quantitatively similar if we cluster standard errors at the level of generic

¹⁸For each drug being challenged, Paragraph Four Report® does not provide us with dates on which individual generic manufacturers file Paragraph IVs with the FDA. In 1,514 cases, however, Paragraph Four Report® provides exact information about when the first generic challenges. Our study of the determinants of the first generic focuses on these 1,514 cases.

¹⁹We create a set of indicator variables coded as 1 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 when the lawsuit was filed. The benchmark group is brand drugs that were ranked below 200 and hence their sales were not publicly available.

defendant or at the level of drug market (identified by the trade name).²⁰

Panel A of Table 5 presents the linear probability estimates of the effect of common ownership on the likelihood of a generic manufacturer acting as the first Paragraph IV filer. For simplicity, we only report the main independent variable of interests in Table 5 but provide a full set of estimated coefficients in Table A.3. Through all regression specifications, common ownership strongly positively predicts that conditioning on eventually filling a Paragraph IV, a generic will be the first filer. A one-standard-deviation increase in common ownership is associated with a 3.7- to 4.6-percentage-point increase in the likelihood of being the first generic. This number is about 10.9%-13.6% of the sample mean.

We now examine the robustness of these results. In Panel B of Table 5, we construct a dummy variable indicating whether the level of *Kappa20* exceeds a certain cutoff (i.e., 10%) to address the concern that the baseline results are driven by the nonlinearities in the way *Kappa20* is calculated. On average, generic defendants putting more than a 10% profit weight (*Kappa20*) on the brand plaintiff are 8-10 percentage points more likely to be the first Paragraph filer.

Following Backus et al. (2021a), we also decompose profit weights into two subcomponents — cosine similarity structure and investor HHI — to evaluate the separate effects of overlapping ownership and shareholder concentration on the determinants of the first generic. Panel C and D present the estimates for cosine similarity and investors HHI. The results show the effect of common ownership on the first filer is driven by the cosine similarity but not investor concentration.

In Panel E, we estimate specifications that assume control only by the largest five generic shareholders in the calculation of common ownership. As Panel E of Table 5 shows, common ownership by the five largest generic shareholders strongly positively increases the settlement rate.

As a complement to the above top-five-shareholder analysis, we also run two placebo tests that do the opposite: we calculate the common ownership as if only shareholders ranked below the top five, or below the top 10, controlled the firm. Estimates from Panels F and G of Table 5 suggest common ownership calculated in these two ways does not predict who will become the first generic challenger. We interpret this result as a successful “placebo” test: a measure

²⁰Each 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).

calculated only with shareholders who do not have much influence or control over the firm does not help predict who will be the first entrant.

6.4 Determinants of settlement

The previous section established that common ownership predicts the likelihood of being the first entrant. In this subsection, we test whether common ownership also predicts the likelihood of settlement conditional on entry.

In the main specification, we regress a dummy variable indicating whether two litigants enter into a settlement agreement on common ownership — the profit weight that the top 20 shareholders of the generic defendant put on the brand plaintiff (*Kappa20*). Many factors affecting litigation outcomes may also be correlated with common ownership. In our baseline analysis, we address various such omitted variable concerns with explicit controls and a full set of defendant, plaintiff, court, and time fixed effects. Specifically, we lay out the following linear probability regression model:

$$Settle_{jkms} = \alpha + \beta_1 \times Kappa20_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \varepsilon_{jkms}, \quad (20)$$

where $Settle_{jkms}$ is an indicator variable equal to 1 if the two litigants entered into a settlement agreement with respect to *at least* one patent dispute triggered by lawsuit i filed by brand plaintiff k as of year-quarter s against generic defendant j challenging the brand drug m , and 0 otherwise.

Table 6 presents results from our baseline panel regressions. Column (1) regresses the dummy variable indicating settlement on our principal measure of common ownership (*Kappa20*) without adding any control variables and fixed effects. Common ownership (*Kappa20*) is significantly positively associated with the likelihood of settlement. A one-standard-deviation increase in *Kappa* is associated with an almost 4-percentage-point increase in the settlement rate. This number is approximately 11% of the sample mean. Column (2) includes a set of drug- and firm-level covariates, and our coefficient estimates for *Kappa20* are almost identical. As columns (3) – (5) suggest, our estimates are robust to the inclusion of district-court, year, defendant, and brand fixed effects. In Table A.4, we provide a full set of coefficients estimated from equation (20). Regarding coefficient estimates for other covariates, the first generic is 11

percentage points more likely to settle, simultaneous Paragraph IV challengers are 6 percentage points more likely to settle, generic defendants with previous experience in dosage form/route are 4 percentage points less likely to settle, generic defendants with previous experience in therapy class are 10 percentage points less likely to settle, and the two litigating parties having disputes over top-ranked drugs are less likely to settle.

All specifications use firm fixed effects to remove firm-invariant characteristics and time fixed effects to account for trends in settlement that are firm specific and may change over time. The inclusion of these fixed effects ensures we avoid spurious inferences from time trends or time-invariant firm entry/entry-deterrence policies. Importantly, because our regressions include firm (and year-quarter) fixed effects, the results should be interpreted as within-firm (and within-time) associations. Not only are the two litigating parties with high common ownership more likely than parties with low common ownership to settle; generic firms also appear to change their attitudes toward settling lawsuits based on whether their shareholders currently place a lot of weight on the profits of patent owners.

Panels B–G of [Table 6](#) provide robustness checks in a spirit similar to [Table 5](#). Specifically, we use various alternative forms of common ownership. We also conduct placebo tests by assuming only shareholders ranked below the top five, or below the top 10, controlled the firm. We reach the same conclusion: common ownership of the several largest generic shareholders is positively correlated with the likelihood of settlements.

In [Table A.5](#), we restrict our sample to brand-generic firm pairs in which both parties are publicly listed firms. We do so because we consider the fact that pairs with a zero possibility of having common ownership (e.g., private-public or private-private pairs) might differ systematically from public-public pairs with a positive probability of having common ownership. Specifically, we identify firms’ listing status by checking whether their stock prices are available on the date a lawsuit is filed. As [Table A.5](#) indicates, the estimates reflect even larger magnitudes for the positive association between common ownership and settlement rate. In column (5), for example, a one-standard-deviation increase in *Kappa20* increases the likelihood of settlement by 6.6 percentage points.

6.5 Variation due to the BlackRock-BGI acquisition

The above discussion illustrates the fixed effects employed in the panel regressions difference out a large number of potentially omitted variables and associated biases in the estimates. However, time-varying omitted variables may persist; also, the results could be due to reverse causality: common ownership could be correlated with shareholders' anticipation of entries, lawsuits and settlements. To examine whether this explanation of our panel results is likely, we focus on variation caused by BlackRock's acquisition of Barclays Global Investors (BGI) in 2009.

6.5.1 Background on BlackRock's acquisition of BGI

Following the financial crisis that began in 2007, Barclays tried to strengthen its balance sheet. On March 16, 2009, Barclays received a \$4 billion bid from CVC Capital Partners for its iShares family of exchange-traded funds, along with an option to solicit competing offers. BlackRock announced a bid to acquire iShares' parent division, BGI, for \$13.5 billion on June 11, 2009 (i.e., in 2009Q2). The history of Barclays' attempt to sell iShares to investors other than BlackRock suggests the divestment decision was not driven by considerations regarding how the iShares portfolio would combine with BlackRock's portfolio to affect Paragraph IV litigation outcomes. Moreover, world-wide pharmaceutical stocks constituted only a very small share of BGI's portfolio, and thus, pharmaceutical companies were unlikely to be pivotal to BlackRock's decision to acquire BGI for the purpose of influencing on Paragraph-IV challenges, which alleviates reverse causality concerns.

More formally, the *exclusion restriction* is that the cross-sectional distribution across generic Paragraph IV patent challengers in the implied increase in common ownership from a hypothetical, pre-merger combination of BlackRock and BGI's equity portfolios is uncorrelated with errors in the entry and settlement regressions. This assumption could fail, for example, if we systematically mismeasured drug-level characteristics causing challenge and settlement at brand-generic pairs in ways that begin to correlate after the acquisition, with the increase in Kappa implied by a hypothetical combination of pre-announcement ownership of BlackRock and BGI. Although we are not aware of a particular reason to expect such a correlation, such a possibility remains a limitation of our analysis.

Although pharmaceutical stocks constituted only a small part of the merging parties'

portfolios, both BlackRock and BGI were among the largest owners of some drugmakers but not others. The variation across portfolio firms in the extent to which the BlackRock-BGI combination changed their ownership structure translates into variation across brand-generic pairs because different combinations of brand incumbent and generic entrant litigate in response to different Paragraph IV challenges.

We illustrate the above point using two examples. In the first example, BlackRock was the largest and BGI was the 11th largest shareholder of Abbott Laboratories (i.e., generic defendant) in 2009Q1. As a result, merging BlackRock and BGIs' equity portfolios had a positive but small effect on Abbott's ownership structure. At the same time, BlackRock was the second largest and Barclays was the third largest shareholder of Medicis Pharmaceutical Corporation (i.e., brand plaintiff) in 2009Q1, and a hypothetically combined BlackRock-BGI entity would have been the first largest shareholder of the brand firm in 2009Q1, and hence much more powerful. In this example, the implied change of common ownership is positive.

In the second example, BlackRock held the largest stake in Amgen (i.e., generic defendant) before the merger and BIG held the 13th largest stake. As a result, merging BlackRock and BGIs' equity portfolios increased BlackRock's power in Amgen's ownership structure. By contrast, although BlackRock was the fifth largest shareholder of Cephalon (i.e., brand plaintiff), BIG did not hold any shares in Cephalon, and hence, a hypothetically combined BlackRock-BGI entity would have not changed Cephalon's ownership structure.

6.5.2 Instrumental variable approach

For each brand-generic pair entering into a patent-infringement litigation, we start by calculating generic shareholders' profit weight on the brand plaintiff as of 2009Q1 ($Kappa20^{09Q1}$), the quarter before the acquisition was announced. We then calculate the counterfactual, common ownership ($\widehat{Kappa20}^{09Q1}$) for the same pair in the same quarter with the only difference being that we treat the holdings of BlackRock and BGI as if they had been held by a single entity already. We label the difference between the latter and the former the "implied change in common ownership ($\Delta Kappa20$)," expressed as follows:

$$\Delta Kappa20_{jk} = \widehat{Kappa20}_{jk}^{09Q1} - Kappa20_{jk}^{09Q1}. \quad (21)$$

The exclusion restriction is that the cross-sectional distribution across sample units in the implied change of $Kappa20$ from a hypothetical, pre-merger combination of BlackRock’s and BGI’s equity portfolios is uncorrelated with errors in the entry regression (see equation (19)) and settlement-rate regression (see equation (20)). Figure 5 plots histograms of the distribution of implied percentage changes in $Kappa20$ across Paragraph IV lawsuits.

One concern regarding our exogeneity assumption is that the composition of portfolios for BGI and BlackRock might have been similar, which motivated BlackRock to acquire BGI. In this case, the implied changes in Kappa ($\Delta Kappa20$) are likely to be highly correlated with the levels of actual Kappa as of 2009Q1 ($Kappa20^{09Q1}$). We examine this concern, and find the correlation between $\Delta Kappa20$ and $Kappa20^{09Q1}$ is zero.

The benefit of a continuous-treatment version of instrument is that it makes use of more variation; the relative cost of using it is to potentially increase measurement error. To mitigate the concern of measurement error while using more variation, we transform the measure in equation (21) into percentile rank forms ($\Delta Rank_{jk}$).²¹ By doing so, we construct our instrumental variable for $Kappa20$ as follows:

$$IV = \Delta Rank_{jk}. \quad (22)$$

Panel A of Table 7 and Table 8 present the first-stage regressions with respect to the determination of first entry and the settlement rate. The percentile-rank-transformed, implied change in common ownership is a strong instrument for the level of common ownership during the post-2009Q2 period. Specifically, the F -statistics from weak identification tests are 208 (column (5) of Table 7) and 36 (column (5) of Table 8) for the two most restrictive specifications. Panel B of Table 7 and Table 8 report the second stage of the IV estimation. We find a positive and economically sizable effect of common ownership on both the likelihood of first entry and the likelihood of settlement. The effect is positive and highly statistically significant, with coefficients ranging from 0.547 to 1.184 in Table 7 and 0.10 to 0.39 in Table 8, which are markedly higher than the effects estimated in panel regressions.²²

²¹Our results are similar when we use the continuous-treatment version of instrument. The results are available upon request.

²²Our research design is not affected by generic criticisms of using institutional mergers as a source of identification. Lewellen and Lowry (2021) argue differential effects of the BlackRock-BGI merger across a broad sample of treatment versus control firms across industries could be contaminated by how firms from different industries responded to the financial crisis differently. Our within-industry analysis does not use across-industry variation for identification. Second, we estimate both the baseline and IV strategy by excluding Paragraph IV lawsuits that occurred during the Great Recession, and we document that the positive correlation between common ownership and the likelihood of settlement remains fairly robust. Our results are available upon request.

6.6 Multiple generics challenging patents on the same day

As a robustness check, we repeat the same analysis in equation (20) but exclude branded drugs whose patents are challenged by more than one first-generic manufacturers on the same day. [Table A.6](#) presents results estimated from both the linear-probability-model and IV approaches. Compared to Panel A of [Table 6](#) (linear-probability estimates) and Panel B of [Table 8](#) (IV estimates), the size of coefficients and statistical significance remain similar.

For background, same-day patent challenges typically occur when the expiration of the exclusivity period allows generic manufacturers to submit ANDAs containing a paragraph IV certification, and multiple ANDA applicants compete to be first generic. In the Hatch-Waxman Act of 1984, the U.S. Congress did not address the specific situation in which multiple ANDA applicants would submit patent challenges on the same day. Similarly, the FDA does not address this specific situation either. The FDA, however, intends to treat all generic manufacturers challenging patents on the same day as first generics, and to allow all first generics to share the 180-day exclusivity.²³

7 Do settlements transfer wealth?

In this section, we show that by using pay-for-delay settlements, common owners transfer wealth within their portfolio from the first generic challenger to the brand.

7.1 Stock returns around settlement

If common ownership blocks generic entry, the life of a branded drug should be extended after a settlement, and hence, the brand plaintiff's stock price surrounding a settlement agreement should increase with the level of common ownership.

We specify the following regression for the event study. Specifically, we compare event stock returns surrounding lawsuit resolutions between settled and dismissed cases, between the first and other generics, and across generic firms with differential profit weights that the top 20

²³Specifically, during the 180-day exclusivity period, FDA may approve any other first ANDA applicants, but no other applicants. Any first applicant whose ANDA is approved after start of the exclusivity period will share the remaining days of exclusivity. For technical details, see [Guidance for Industry 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day](#).

generic shareholders put on the brand plaintiff (*Kappa20*)²⁴:

$$\begin{aligned}
CAR_{jki} = & \alpha + \beta_1 \times Settle_{jki} \times First_{jkm} \times Kappa20_{jks-1} + \beta_2 \times Settle_{jki} \times First_{jkm} \\
& + \beta_3 \times Settle_{jki} \times Kappa20_{jks-1} + \beta_4 \times First_{jkm} \times Kappa20_{jks-1} + \beta_5 \times First_{jkm} \\
& + \beta_6 \times Settle_{jki} + \beta_7 \times Kappa20_{jks-1} + X' \times \gamma + \phi_k + \phi_l + \varepsilon_{jki},
\end{aligned} \tag{23}$$

where CAR_{jki} is the cumulative market-adjusted return for the brand plaintiff over the window of (-3, +3) relative to the event day on which the generic defendant(s) j and the brand plaintiff k enter into a settlement agreement with respect to lawsuit i . s indicates the year-quarter in which a lawsuit is filed.

One assumption that underlies equation (23) 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 possibly biases the analysis against finding a significant relation.

The first four columns of Table 9 estimate the impact of settlement on the value of brand plaintiff. As column (1) suggests, a settlement on average reduces brand value by 0.4%, but a settlement with the first generic increases brand value by 1%, and the estimates are robust to the inclusion of district-court and brand-firm fixed effects (see column (2)). Our results in the first two columns are consistent with the notion that settlements deter generic entries through the delay of marketing under the protection of 180-day exclusivity. In columns (3)-(4), we show the brand-value creation through settling with the first generic is especially pronounced if the generic defendant puts a higher profit weight on the brand plaintiff.

We next investigate the value implication of common ownership for generic Paragraph IV filers entering into a settlement agreement. We find the first generics with higher common ownership experienced more negative returns around a settlement agreement. The second four columns of Table 9 present our estimation results. Columns (5)-(6) suggest that, on average, settled first generics did not earn lower returns than other settled generics. However, columns (7)-(8) suggest settled first generics with higher *Kappa20* earn significantly lower returns around settlement. These results appear consistent with the theory that generics with a shareholder

²⁴We exclude resolutions of lawsuits that ended up with trials, because forming ex ante predictions about the return difference between trialed cases and settled cases is difficult.

base that has significant stakes in the brand sacrifice themselves more often to block entry by other generics who would compete harder or extract a higher settlement from the brand.

In the next section, we calculate the dollar amount of transferred wealth within each individual shareholder’s portfolio from one firm to another.

7.2 Estimating the dollar amount of wealth transfer

We estimate each individual shareholder’s losses and gains around settlement agreements. This empirical exercise serves two purposes. First, our shareholder-level analysis responds to [Harford et al.’s \(2011\)](#) concern with the literature started by [Matvos and Ostrovsky \(2008\)](#). Namely, on the one hand, influential generic shareholders might have smaller stakes in the brand and, therefore, care little about whether branded sales fall off the patent cliff; on the other hand, generic shareholders with large brand stakes might have small stakes in the generic and are unlikely to influence generic-firm behavior. Although our measure of *Kappa20* weights each shareholder’s generic stakes to calculate the profit weight that she assigns to the value of brand firms, by treating all cross-held shares as a consolidated block, we are not able to completely exclude a spurious correlation between the large brand stakes of some shareholders and the large generics stakes of others, which might lead to incorrect conclusions about shareholders’ objectives.

Second, even if the most influential generic shareholders hold large enough stakes in the brand, one needs to ensure the economic gains for them to promote anti-competitive behaviors outweigh the costs. [Lewellen and Lewellen \(2021\)](#) estimate that an average institution’s economic gain from promoting collusion is too small to justify costly engagement and coordination by common owners, presumably because institutional investors overweight in own firms and underweight in rival firms.

We thus calculate dollar amounts that institutional investors gain or lose from potentially anticompetitive settlements in narrowly defined industries (at the drug level) occupied by one incumbent and one potential entrant. Note a lessening of competition implies asymmetric dollar amounts of gains (losses) per 1% increase (decrease) in the value of the incumbent (entrant), because the size of an average incumbent is much larger than that of an average entrant.

Table 10 presents our shareholder-level estimation of the averaged wealth changes experienced by individual common owners surrounding the resolution of lawsuits. We perform this

analysis for two scenarios based on whether the settlement occurs with the first generic challenger. For the purpose of comparison, we also perform this same shareholder-level analysis surrounding dismissals of a lawsuit.

We end up with 765 individual generic shareholders holding stakes in the brand as of when a lawsuit is filed. We assign each individual shareholder into different baskets based on (1) the rank of her corresponding generic ownership and (2) the four event categories (e.g., settlement or dismissal, first vs. other generics). Below, we illustrate how we calculate averaged generic-side wealth changes around settlements:

$$\Delta W^g = \frac{\sum_{i=1}^n CAR(-3, +3)_i^g \times Shares_i^g \times Value_i^g}{N}, \quad (24)$$

where $CAR(-3, +3)_i^g$ is the cumulative market-adjusted returns of the settled generic firm held by shareholder i over the $(-3, +3)$ -day window centered on the settlement event. $Shares_i^g$ is shareholder i 's stake (in percent) in the generic as of when a lawsuit starts. $Value_i^g$ is the generic's stock-market capitalization (millions USD) four trading days prior to the settlement event.

Panel A of Table 10 presents a striking pattern — on average, most shareholders of the settled first generic lose on the generic, but their gains on the brand far more than make up for the losses. For the largest shareholders, their average generic losses are \$264 million, but averaged brand gains are \$318 million. These gains exceed the losses the largest shareholders suffer in the first generic by \$54 million. Note that among top-ranked common owners, the largest shareholders gain by the least dollar amounts, presumably because they heavily hold the first generics (10.7%) that experience negative-event stock returns. Moving toward the second, third, and fourth largest shareholders, we find these common owners' generic losses are negligible compared with their brand gains. For example, the second largest shareholders, as a group, lose an average of \$41.2 million on the generic but gain \$513.7 million from the brand. A similar pattern holds for the third and fourth, and even for the seventh, ninth, and tenth shareholders.

Panel B of Table 10 presents our shareholder-by-shareholder calculation of wealth changes when the brand settles with generics that are not the first challengers. Except for No. 4 shareholders, other top five shareholders have experienced net losses ranging from \$20 million -\$200 million, and the top three shareholders lose on both sides. For example, the largest

shareholders lost an average of \$263 million on the generic and an average of \$198 million on the brand. This finding may help explain why settlements between non-first entrants and the brand are much less economically attractive for shareholders as a group than the settlements with the first, typically commonly owned, generic.

Panels C and D of Table 10 show common owners experience large dollar amounts of brand losses when the court dismisses the case, thus making it impossible to create shareholder wealth, and transfer wealth from generic to brand. When the court decides the brand's claim is not one for which the law offers a legal remedy, Paragraph IV challenges are valid and generic entries could happen upon FDA approvals. The observation that common owners experience net losses is therefore not surprising, although some of them gain on the generic side.

7.3 Stock returns around the time the first generic files Paragraph IV

Our event-study analysis in equation (23) only measures the wealth effects around settlements. The analysis does not include the reaction of stock markets around when the first generic files a Paragraph IV challenge with the FDA. One theoretical possibility is that the net wealth effects are overall negative for the brand-name incumbent despite the positive abnormal returns around settlements. We therefore ask the following questions: How do stock returns react to Paragraph IV challenges filed by the first generic? Do stock markets anticipate that what will eventually happen (i.e., settlement between the first generic and brand) implies wealth effects for the two disputing parties?

The first two columns of Table 11 estimate the impact of common ownership (calculated from the generic to the brand) on the value of brand-name incumbent (-3, +3) days relative to the date on which the first generic files a Paragraph IV challenging the brand.²⁵ We show the profit weight that generic shareholders put on the brand is strongly positively associated with the brand's abnormal daily returns, suggesting the stock market anticipates that, with a higher level of common ownership, a resolution of dispute can be more anticompetitive. As the next two columns of Table 11 show, however, common ownership bears zero correlation between abnormal daily returns associated with the first generic. The non-results of the last

²⁵Unfortunately, Paragraph Four Report® does not provide us with dates in which non-first generic manufacturers file Paragraph IVs with the FDA. As a result, we are not able to benchmark brand returns around the first generic entry with brand returns around other generic entries.

two columns are likely due to the sample for this analysis being unrepresentative. More generic firms than brand incumbents are private firms. As such, no inference can be made from this supplementary analysis on the overall level of wealth gains in the portfolio of the shareholders.

7.4 Discussion

One alternative mechanism through which the first generic, by destroying its own value, settles with the brand is that generic directors “interlock” by also serving on the boards of the brand. Indeed, the Clayton Act of 1914 outlawed board overlap between close competitors. The generic-brand board interlock can be created by generic directors having a connection to either the brand or to common owners. To check whether the wealth transfer is due to board interlock, we focus on the 22 generic-brand pairs in which the settled first generic experienced negative cumulative market-adjusted returns around the event of settlement. We use these firms’ proxy statements to manually check whether, in the year settlement happened, generic directors were connected to either brand or to the largest shareholders holding both the generic and brand. We fail to find any evidence suggesting board interlock is associated with our results.²⁶

A second related issue is that if settlements that destroy their own firm’s value expose the CEOs of generic manufacturers to significant litigation risk, it is not clear whether these CEOs, with their own career concerns, would have enough incentives to go against the interests of their own shareholders. To assess whether this channel might be relevant and explain our results, we collect data from the Federal Judicial Center’s (FJC) Integrated Database on the type of civil lawsuits, their object, and the litigating parties to assess the extent of litigation risks facing generic CEOs who entered into value-destroying settlement agreements.

We notice that the management teams of generic manufacturers are typically subject to two types of litigation risk. First, they have frequently been sued by investors for violating shareholder fiduciary duties as stipulated by the Securities Exchange Act of 1934, either due to false

²⁶We found only three cases suggesting that generic directors had a very remote connection to the brand-name incumbent. When Perrigo and Medtech Products settled in 2008Q1, Gary K. Kunkle, Jr. (then lead independent director of Perrigo) served as president of Vistakon, a division of Johnson & Johnson, which was the parent of Medtech Products. When Teva and Bristol-Myers Squibb settled in 2009Q3, William S. Marth (then President and CEO of Teva North America) held various positions with the Apotthecon division of Bristol-Myers Squibb prior to joining Teva in July 1999. When Teva settled with Merck in 2009Q2 and 2009Q3 concerning different drugs, Abraham E. Cohen (then director of Teva) was a Senior Vice President of Merck & Co. from 1982 to 1992.

and misleading statements or because of their failure to disclose value-relevant information.²⁷

Second, because pay-for-delay settlements hurt customer welfare, generic firms have been sued by the FTC and the states for violating either the Sherman Act or the Clayton Act. However, since these antitrust lawsuits occur very infrequently, take place much later after Paragraph IV litigations are settled, and can take many years to resolve, generic managers face either negligible or remote litigation risks as a result of entering into pay-for-delay settlements with brand incumbents. In fact, we did not observe any lawsuits related to the value-destroying settlements in Table 10.²⁸ In fact, generic managers are more often sued for other antitrust reasons, including collusion among generic firms and opioid distribution.²⁹

8 Conclusion

This paper shows holdings in brands by large shareholders of generic-drug manufacturers predicts which generic enters and whether settlement occurs. Settlement is accompanied by negative stock returns of generics, whereas brands show a positive stock return reaction. These findings suggest entry and settlements are accompanied by wealth transfers from generic shareholders to brand shareholders. Brands' shareholders appear to anticipate settlement and settlement terms to some extent, as evidenced by positive stock returns at the time a commonly-owned generic enters the product market. These findings are a first indication that some widely held corporations (generic manufacturers), some of the time, make value-destroying decisions that are consistent with maximizing the financial interests of their largest and most influential

²⁷In the cases *Highfields Capital I LP v. Perrigo Co.* and *Burlington Loan Management DAC v. Perrigo Co.*, filed on March 10, 2020 and February 12, 2020, respectively, the plaintiffs claimed that most Perrigo shareholders rejected the offer due to false statements made by the defendants while resisting Mylan's hostile takeover bid during the relevant period. In the case *Linus Aruliah v. Impax Laboratories Inc.*; Larry Hsu; G. Frederick Wilkinson, filed on August 13, 2014, the plaintiffs argued that false and misleading statements about quality control issues at Impax's Taiwan production facility kept shareholders uninformed about the new drug Rytary. In the case *Mulligan v. Impax Labs., Inc.*, filed on March 7, 2013, the plaintiffs alleged that the defendants made several false statements and failed to disclose various adverse facts about Impax, thereby misleading the investing public about Impax's prospects and business.

²⁸In the case *Maryland et al. v. Perrigo Company*, filed on August 17, 2004, the FTC and several states claimed that in June 1998, Perrigo paid Alpharma to withdraw its generic version of Children's ibuprofen from the market, creating a pay-for-delay deal. In the case *State of California v. Teva Pharmaceutical Industries, Ltd. et al.*, filed on July 29, 2019, California argued that Teva used four pay-for-delay agreements to postpone the entry of generic competition, thereby illegally maintaining its monopoly over Provigil sales from 2006 to 2012.

²⁹In *Federal Trade Commission v. Perrigo Company; Alpharma Inc.*, filed on August 17, 2004, plaintiffs alleged that defendants conspired to stop competing. In *Mayor and City Council of Baltimore v. Teva Pharmaceuticals Industries Ltd.*, filed on March 11, 2022, the plaintiff alleged that Teva Pharmaceuticals and its associated companies played a role in the opioid crisis in Baltimore.

shareholders; earlier findings in the literature of anticompetitive effects of common ownership do not necessarily imply value destruction for the benefit of rivals.

The conceptual importance of the findings is that taken at face value, they reject the prediction of the Fisher separation theorem, on which much of corporate finance theory is built, and which holds that firms maximize their own value irrespective of shareholder interests. We hypothesize that the failure of the prediction is due to the firm not being a price taker – one of the key assumptions of the theorem.

If the findings were to hold more generally, re-examining standard questions on corporate finance – on capital structure, cash holdings, executive compensation, and so on – while relaxing the assumption of own-firm profit maximization may be worthwhile. Whether the empirical facts documented in the laboratory of generic entry enjoy broader support is an interesting area for future research. Similarly, whether common ownership between incumbents and potential entrants deters entry may be a fruitful area for research on entry deterrence ([Scott Morton, 1999, 2000](#); [Ellison and Ellison, 2011](#); [Goolsbee and Syverson, 2008](#); [Hochberg, Ljungqvist, and Lu, 2010](#); [Cookson, 2017, 2018](#)). In particular, it is interesting to question whether ownership structure and regulation might have jointly caused free entry to fail in certain industries (e.g., [Gutiérrez and Philippon, 2018, 2019](#)).

Whereas our analysis focuses on publicly traded companies, the incidence of common ownership may be even more pronounced in private markets. [Asil, Barrios, and Wollmann \(2023\)](#) show potentially anticompetitive private-equity transactions tend to escape antitrust scrutiny because of the complicated deal structure they tend to employ. Therefore, antitrust authorities interested in strengthening enforcement should not take our paper to indicate public markets are necessarily the most urgent priority. Instead, the public-company setting we employ merely illustrates the point that broadly held corporations should not always be assumed to maximize their own value, irrespective of their shareholders' interests.

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Figure 1: 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](#)

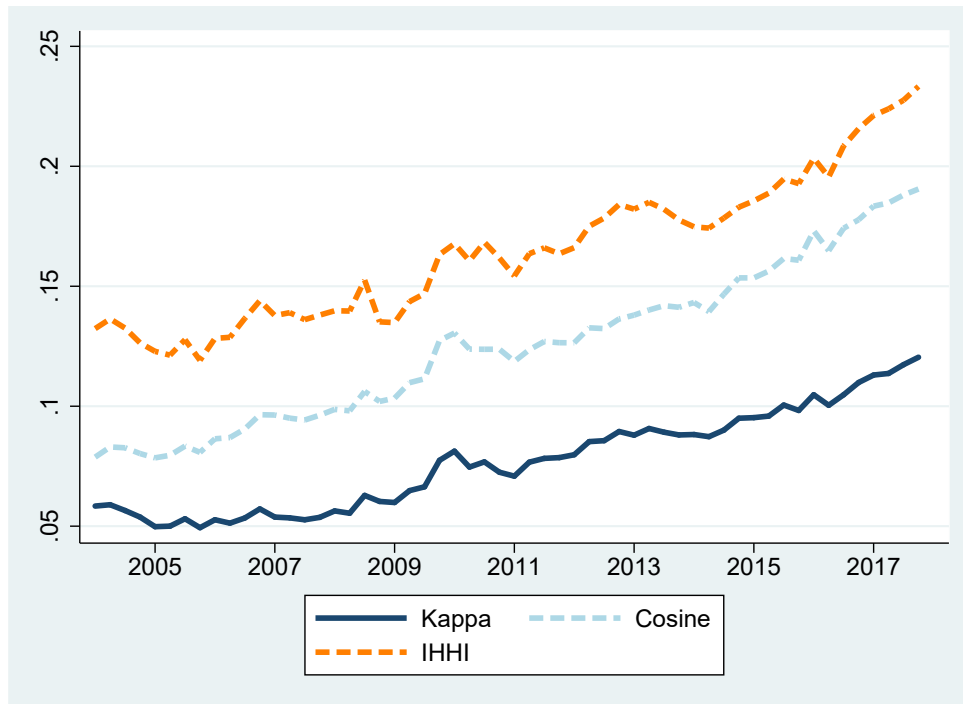
['843 Patent](#)

['225 Patent](#)

Figure 2: **Time-series and cross-sectional variation of common-ownership concentration**

The upper figure plots common ownership (Kappa20) and its two decomposed components (i.e., cosine similarity and IHHI) from 2004Q1 to 2017Q4 (see equations (15) and (16) for detailed descriptions). *Kappa20* is the profit weight of the top 20 generic shareholders put in the brand defendant as of the beginning of the quarter in which a patent-infringement lawsuit is filed (see equation (15) for detailed descriptions). The lower figure plots the distribution of Kappa for 2004Q1 and 2017Q4.

Panel A: Time trends of Kappa and its decomposed components



Panel B: Conditional distribution

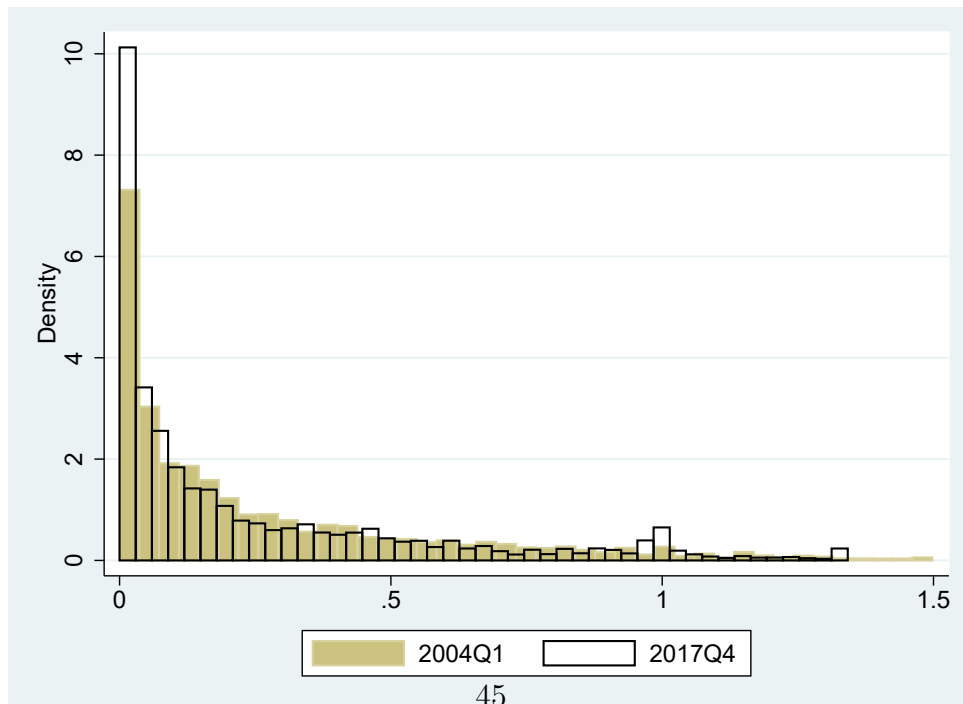


Figure 3: The evolution of common ownership around the time the first generic files a Paragraph IV challenge

This figure plots the estimated coefficients $\hat{\beta}_s$ and the 95% confidence intervals from the following equation:

$$Kappa20_{jks} = \alpha + \sum_{s=-8}^{s=+8} \beta_t \times First\ Filing_{jks} + \phi_j + \phi_k + \phi_s + \epsilon_{jks},$$

where $First\ Filing_{jks}$ is a dummy variable indicating the s^{th} ($-8 \leq t \leq 8$) quarter prior to the Paragraph IV challenge filed by the first generic j , and 0 otherwise. The sample period is from 2004Q1 through 2020Q4. We require that at least one shareholder of the generic defendant holds stakes in the brand plaintiff. The excluded period is the event quarter $s = 0$.

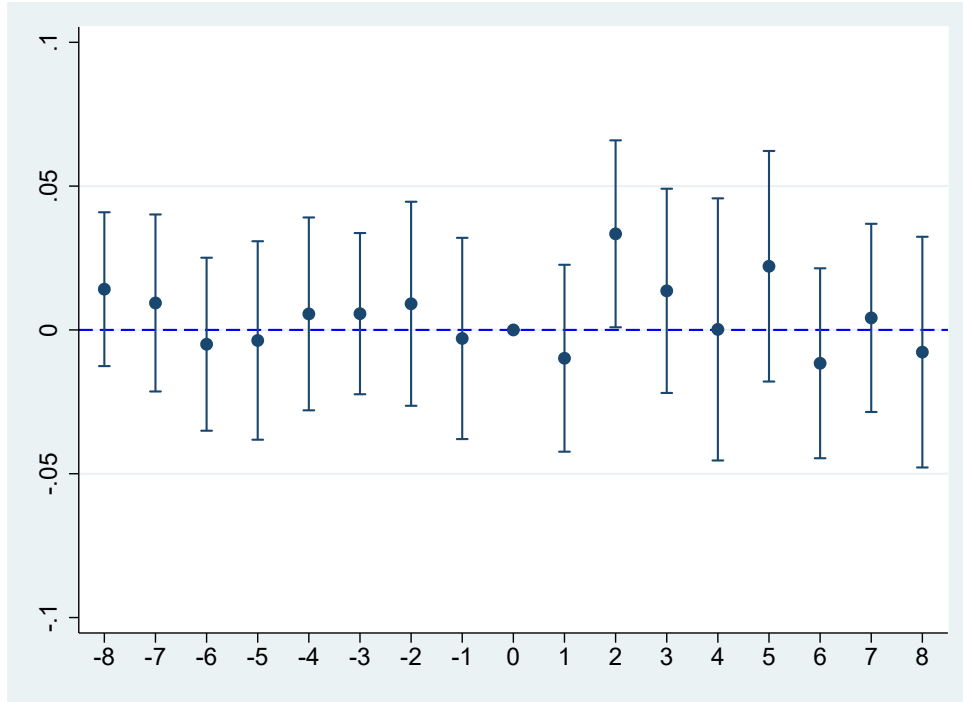


Figure 4: The evolution of common-ownership around the Paragraph IV litigation

This figure plots the estimated coefficients $\hat{\beta}_s$ and the 95% confidence intervals from the following equation:

$$Kappa20_{jks} = \alpha + \sum_{s=-8}^{s=+8} \beta_t \times Lawsuit_{jks} + \phi_j + \phi_k + \phi_s + \epsilon_{jks},$$

where $Lawsuit_{jks}$ is a dummy variable indicating the s^{th} ($-8 \leq t \leq 8$) quarter prior to a litigation initiated by brand plaintiff k against generic defendant j , and 0 otherwise. The sample period is from 2004Q1 through 2020Q4. We require that at least one shareholder of the generic defendant holds stakes in the brand plaintiff. The excluded period is the event quarter $s = 0$.

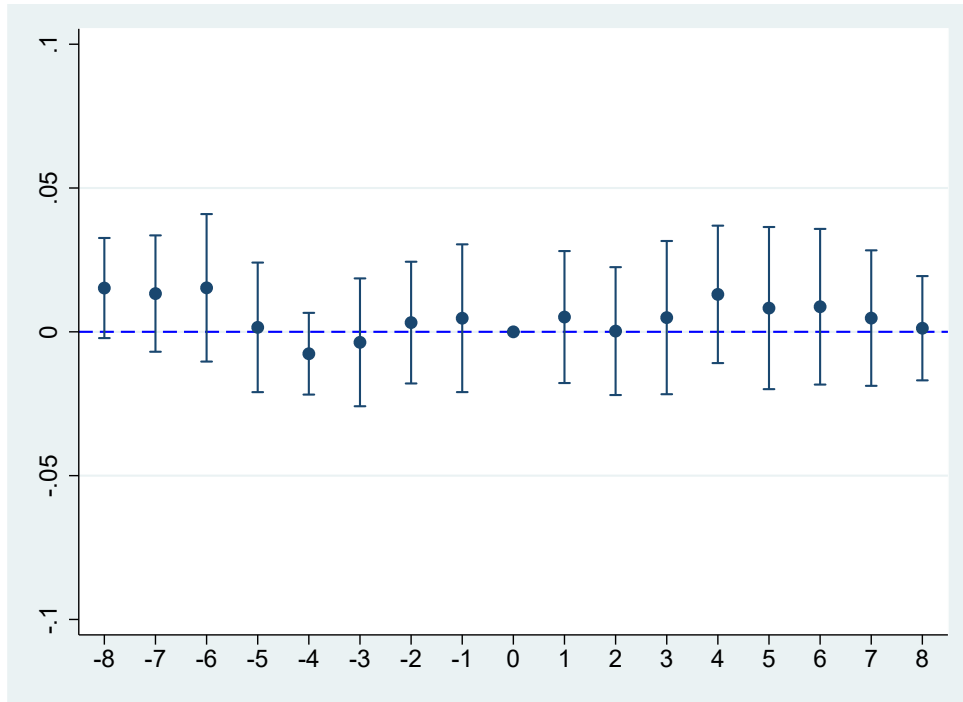


Figure 5: Cross-sectional distribution of implied change of common ownership (BlackRock-BGI DiD)

The graph plots the distribution of implied changes in the profit weight the top 20 generic shareholders put in the brand plaintiff ($\Delta Kappa20$) across 1,543 Paragraph IV lawsuits with zero changes and 214 lawsuits with positive changes, respectively. $\Delta Kappa20$ is calculated as follows:

$$\Delta Kappa20_{jk} = \widehat{Kappa20}_{jk}^{09Q1} - Kappa20_{jk}^{09Q1},$$

where generic defendant and brand plaintiff are indexed by j and k , respectively. $Kappa20^{09Q1}$ is the top 20 generic shareholders' profit weight on the brand plaintiff as of 2009Q1. $\widehat{Kappa20}^{09Q1}$ is the counterfactual, profit weight for the same generic-brand pair in the same quarter with the only difference being that we treat the holdings of BlackRock and BGI as if they had been held by a single entity already.

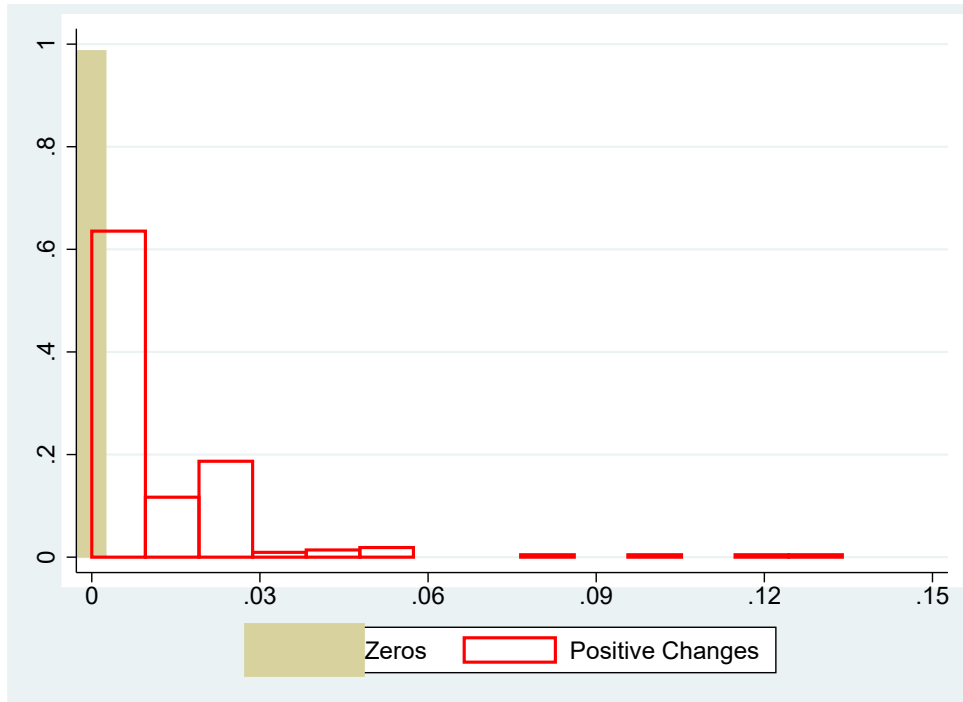


Table 1: Illustrative cases of brand-generic pair common-ownership links

This table shows the largest beneficial owners and corresponding stakes for an illustrative sample of generic manufacturers and brand-name companies as of 2006Q4. The data source is Capital IQ under the S&P Global Market Intelligence.

Panel A. Generic manufacturers					
Teva	%	Viatrix	%	Sandoz	%
Allergan	9.89	Abbott	13.03	JPMorgan Chase	8.74
Capital Rsrch & Mgmt.	9.63	Wellington	8.45	Sandoz Fam Fndn.	3.40
Fidelity	6.14	BlackRock	7.37	Capital Rsrch & Mgmt.	3.22
Franklin Templeton	5.57	Vanguard	5.28	BlackRock	3.04
Barrow Hanley	3.20	Paulson & Co	3.85	Novartis Fndn.	2.60
BlackRock	3.11	State Street	3.73	Dodge & Cox	2.42
Norges Bank Invt. Mgmt.	3.04	GreenLight Cap	1.62	UBS	2.34
BNY Mellon Asset Mgmt.	1.92	UBS	1.30	Vanguard	2.24
Vanguard	1.77	Migdal MF	1.12	Norges Bank Invt Mgmt	2.02
Highfields Cap Mgmt.	1.66	BNY Mellon Asset Mgmt.	1.02	Credit Suisse	1.29
Lupin	%	Dr. Reddy's	%	Sun	%
Lupin Invt.	12.46	Kambam Reddy	25.85	Dilip Shanghvi	9.60
Zyma Lab	12.33	First Sentier Investors	7.30	Viditi Invt.	8.37
Rahas Invt.	10.21	Brown Brothers Harriman & Co.	4.90	Tejaskiran Pharm Ind	8.12
Visionmed Invt.	9.77	First State Invt. Mgmt.	4.35	Virtuous Finance	8.08
First Sentier Investors	2.78	Life Insurance Corp of India	4.04	Family Invt.	7.60
Royal Bank of Scotland	2.43	BlackRock	3.57	Quality Invt.	7.60
JPMorgan Chase	1.95	Fisher Investments	3.44	Life Insurance Corp of India	3.51
Rakesh Jhunjhunwala	1.84	Vontobel Asset Mgmt.	1.94	Virtuous Share Invt.	3.49
BlackRock	1.78	Vanguard	1.87	Sudhir Valia	2.01
Singapore	1.76	Dilip Shanghvi	9.60	Aditya Medisales	1.67
Par Pharmaceutical	%	Impax	%	Aurobindo Pharma	%
Fidelity	15.00	BlackRock	11.39	Kallam Reddy	45.86
TPG Capital	9.94	Vanguard	8.09	HDFC Asset Mgmt.	6.33
Vanguard	8.44	Hound Partners	6.00	Meenakshi Sivakumaran	2.51
BlackRock	7.45	Invesco Specialized Products	5.47	Trident Chemphar Limited	2.08
Capital Rsrch & Mgmt.	7.03	Columbia Mgmt. Invt.	3.23	BlackRock	1.45
State Street	4.33	State Street	3.16	Aditya Birla Sun Life	1.31
Paulson & Co	3.52	Franklin Templeton	2.91	Abu Dhabi Invt. Auth	1.31
Glenview Cap Mgmt.	1.91	Two Sigma Invt.	2.87	Stichting Pensioenfonds ABP	1.09
Camber Cap Mgmt.	1.75	North Tide Capital	2.71	Rakesh Jhunjhunwala	1.09
Miller Value Partners	1.52	Dimensional Fund Advisors	2.43	State Bank of India	0.93

Panel B. Brand firms					
Pfizer	AbbVie	GlaxoSmithKline			
BlackRock	7.38	Capital Rsrch & Mgmt.	11.29	BlackRock	5.99
Vanguard	6.63	Vanguard	6.74	Capital Rsrch & Mgmt.	3.75
State Street	5.29	BlackRock	5.69	Legal & General Invt. Mgmt.	2.79
J.P. Morgan	1.47	State Street	4.39	State Street	2.71
T. Rowe Price Group	1.33	Northern Trust Group	1.32	Vanguard	2.51
Northern Trust	1.32	BNY Mellon Invt. Mgmt.	1.17	Norges Bank Invt. Mgmt.	1.86
BNY Mellon Invt. Mgmt.	1.18	State Farm	0.93	Fidelity	1.74
Wellington	1.13	Federated Hermes	0.93	Aberdeen Asset Mgmt.	1.56
Capital Rsrch & Mgmt.	1.11	Geode Capital Mgmt.	0.86	UBS	1.55
Columbia Mgmt. Invt. Advisers	1.04	UBS	0.82	Columbia Mgmt. Invt. Advisers	1.46
Merck & Co.		Janssen Pharmaceuticals		Allergan	
Vanguard	6.70	Vanguard	7.03	Vanguard	7.19
BlackRock	6.66	BlackRock	6.27	Wellington	6.78
Capital Rsrch & Mgmt.	5.55	State Street	5.64	BlackRock	6.46
State Street	4.54	State Farm	1.39	Goldman Sachs	6.28
Wellington	4.50	Capital Rsrch & Mgmt.	1.33	State Street	5.33
BNY Mellon Asset Mgmt.	1.57	Wellington	1.28	Fidelity	3.92
T. Rowe Price Group	1.37	Northern Trust	1.27	T. Rowe Price Group	2.78
Northern Trust	1.29	BNY Mellon Asset Mgmt.	1.16	ClearBridge Invt.	2.44
Norges Bank Invt. Mgmt.	1.00	Fidelity	1.12	Legg Mason Int. EQ	2.38
Franklin Templeton	0.99	Norges Bank Invt. Mgmt.	1.03	J.P. Morgan	1.72
Shire		Abbott Laboratories		Bristol-Myers Squibb	
BlackRock	8.66	Vanguard	6.94	Wellington	8.87
Jennison Associates LLC	2.57	BlackRock	5.97	Vanguard	6.87
Vanguard	2.49	State Street	4.60	BlackRock	5.97
Paulson & Co	2.44	MFS	2.33	State Street	4.05
Legal & General Invt. Mgmt.	2.15	T. Rowe Price	2.27	Capital Rsrch & Mgmt.	3.16
M&G Invt. Mgmt.	2.08	BNY Mellon	1.96	Fidelity	2.63
Marathon Asset Mgmt.	1.98	Northern Trust	1.56	T. Rowe Price	2.21
State Street	1.95	Macquarie	1.33	Dodge & Cox	1.35
PPM America	1.70	Wellington	1.16	Northern Trust	1.32
Fidelity	1.66	Flossbach von Storch	1.09	Jennison Associates	1.30

Table 2: **Ownership by the 20 largest generic institutional shareholders**

This table reports ownership stakes that the 20 largest generic shareholders hold in the generic manufacturer and brand incumbent whose patents are challenged at least once by the generic manufacturer over our sample period. Regardless of when the generic-brand pair is formed as a result of a patent-infringement lawsuit, we include ownership stakes of the generic-brand pair over the entire sample period. We exclude generic-brand pairs in which no generic shareholders hold financial stakes in the brand incumbent.

Shareholder Rank	N	Generic Ownership %			Brand Ownership %		
		Mean	Median	Std	Mean	Median	Std
1	5,580	10.319	9.842	4.492	4.286	2.909	3.996
2	6,709	6.389	6.399	2.603	4.029	3.035	3.494
3	6,367	4.930	4.586	2.096	3.850	2.780	3.407
4	6,669	3.731	3.398	1.619	4.138	3.254	3.547
5	6,081	3.104	2.957	1.411	3.775	2.686	3.556
6	6,238	2.620	2.498	1.251	3.316	2.125	3.316
7	5,585	2.172	2.073	0.957	2.757	1.584	2.915
8	5,401	1.830	1.786	0.817	2.716	1.582	2.751
9	5,404	1.638	1.660	0.686	2.863	1.682	2.838
10	4,406	1.430	1.428	0.634	2.708	1.544	2.804
11	4,795	1.231	1.184	0.578	2.665	1.536	2.689
12	4,966	1.162	1.103	0.530	2.668	1.567	2.631
13	4,449	1.028	0.973	0.463	2.393	1.375	2.393
14	4,461	0.957	0.966	0.414	2.379	1.338	2.958
15	4,498	0.884	0.873	0.393	2.090	1.235	2.781
16	4,661	0.785	0.789	0.348	2.397	1.392	2.392
17	3,924	0.787	0.775	0.355	2.181	1.311	2.235
18	4,032	0.716	0.717	0.312	2.163	1.268	2.328
19	3,582	0.682	0.669	0.308	2.106	1.286	2.286
20	3,099	0.600	0.577	0.292	1.908	1.276	2.247

Table 3: **Sample**

This table presents descriptive statistics for our sample of patent-infringement lawsuits triggered by patent challenges by generic-drug manufacturers. 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 with Paragraph IV cases that were active as of November 1, 2003. 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 that defines a patent-protected drug. Panel A presents the data structure of the sample and the frequency with which drugs and patents in the sample are challenged by a brand filing lawsuits. Panel B presents the distribution of private and publicly listed firms at the challenge level. A firm's listing status is identified based on whether its stock price data are available on the date the brand files a lawsuit. Panel C presents the distribution of the number of formulations across 521 brand-name drugs (identified by the trade name).

Panel A: Structure of raw data

Patents at issue	1,578
Brand-name drugs	521
Brand incumbents	157
Generic challengers	202
Formulations of brand-name drugs	587
Infringement lawsuits	2,023

Panel B: Distribution by listing status

Generic public & brand public	1,251	61.8%
Generic public & brand private	118	5.8%
Generic private & brand public	428	21.2%
Generic private & brand private	226	11.2%
Total	2,023	100.0%

Panel C: Distribution by the number of formulations

1	467	89.60%
2	44	8.50%
3	9	1.70%
5	1	0.20%

Table 4: **Descriptive statistics**

This table presents descriptive statistics. In Panel A, the sample unit is at the level of the date that the first generic manufacturer files a Paragraph IV to challenge the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). In Panels B and C, the sample unit is at the level of the date that the brand sues a generic manufacturer challenging the formulation (e.g., tablet, capsule, and injection) of a trade name (i.e., the name of the branded drug). In Panel A, common-ownership-related variables are measured as of the beginning of the quarter in which the first patent-infringement lawsuit with respect to a trade-name-formulation combination is filed. In Panel B, common-ownership-related variables are measured as of the beginning of the quarter in which a patent-infringement lawsuit is filed. *Kappa20* is the profit weight the top 20 generic shareholders put in the brand defendant (see equation (15) for detailed descriptions). $Kappa20 \geq 10\%$ is an indicator variable coded as 1 if *Kappa20* is greater than or equal to 10%, and 0 otherwise. *Cosine20* and *IHHI20* are the two components of a decomposition of *Kappa20* (see equation (16) for detailed descriptions). *Settle*, *Dismiss*, and *Trial* are three dummy variables indicating whether the two litigants settle, dismiss, or go to trial for at least one disputed patent at issue. *First* is an indicator variable coded as 1 if the generic defendant is the first generic. *Group* is an indicator variable coded as 1 if more than two generic manufacturers challenge the same drug on the same day, and 0 otherwise. $\ln(\# \text{ Patents})$ is the logarithm of the number of litigated patents. *Route Exp* is an indicator variable coded as 1 if the generic defendant has production experience in drug-dosage form/route within the last three years. *Therapy Exp* is an indicator variable coded as 1 if the generic defendant has production experience in therapy class, measured by the 2-digit Anatomical Therapeutic Chemical (ATC) Classification System, within the last three years. *Rank N* is an indicator variable coded as 1 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 when the lawsuit is filed.

	Mean	Std	Min	p5	p10	p25	p50	p75	p90	p95	Max	N
Panel A. Common ownership (first entry)												
Kappa20	0.045	0.140	0.000	0.000	0.000	0.000	0.000	0.000	0.146	0.319	1.652	1,597
Kappa20 \geq 10%	0.118	0.323	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1,597
Cosine20	0.069	0.172	0.000	0.000	0.000	0.000	0.000	0.000	0.314	0.510	0.935	1,597
IHHI20	0.117	0.308	0.000	0.000	0.000	0.000	0.000	0.000	0.470	0.842	3.183	1,597
Kappa5	0.039	0.138	0.000	0.000	0.000	0.000	0.000	0.000	0.100	0.283	1.856	1,597
Panel B. Common ownership (lawsuit)												
Kappa20	0.047	0.140	0.000	0.000	0.000	0.000	0.000	0.000	0.168	0.354	1.368	1743
Kappa20 \geq 10%	0.126	0.332	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1743
Cosine20	0.076	0.185	0.000	0.000	0.000	0.000	0.000	0.000	0.357	0.530	0.935	1743
IHHI20	0.113	0.280	0.000	0.000	0.000	0.000	0.000	0.000	0.499	0.747	1.998	1743
Kappa5	0.043	0.142	0.000	0.000	0.000	0.000	0.000	0.000	0.141	0.311	1.570	1743
Panel C. Litigation-level characteristics												
Settle	0.378	0.485	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1743
Dismiss	0.363	0.481	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1743
Trial	0.274	0.446	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1743
First	0.328	0.469	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1743
Ln(#Patent)	0.435	0.602	0.000	0.000	0.000	0.000	0.000	0.693	1.386	1.609	3.178	1743
Group	0.309	0.462	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1743
Rank25	0.075	0.263	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1743
Rank50	0.037	0.188	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank75	0.042	0.200	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank100	0.040	0.195	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank125	0.034	0.182	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank150	0.030	0.170	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank175	0.020	0.140	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Rank200	0.021	0.144	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1743
Route Exp	0.239	0.427	0.000	0.000	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1743
Therapy Exp	0.552	0.497	0.000	0.000	0.000	0.000	1.000	1.000	1.000	1.000	1.000	1743

Table 5: **Determinants of the first generic**

This table presents estimates of the effect of common ownership on the probability that a generic-drug manufacturer that files a Paragraph IV with the FDA will be the first Paragraph IV filer:

$$First_{jkm t} = \alpha + \beta \times Common\ Ownership_{jkt-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkm t},$$

where the dependent variable is a dummy variable indicating whether the generic manufacturer is the first generic that files the Paragraph IV with the FDA. *Common ownership* is measured as of the beginning of the quarter in which the first patent-infringement lawsuit with respect to a tradename-formulation combination is filed. In Panel A, *Common Ownership* is measured as *Kappa20* (see equation (15) for detailed descriptions). In Panel B, *Common Ownership* is measured as $Kappa20 \geq 10\%$, which is an indicator variable coded as 1 if *Kappa20* is greater than or equal to 10%, and 0 otherwise. In Panels C and D, we use the two components of a decomposition of *Kappa20* (see equation (16) for a detailed description) to measure *Common Ownership*. In Panel E, *Kappa5* is the profit weight the top five generic shareholders put on the brand plaintiff. In Panels F and G, *Common Ownership* are the profit weights of the top 6-20 (*Kappa620*) and 11-20 (*Kappa1120*) generic shareholders put on the brand plaintiff, respectively. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A: Kappa20					
Kappa20	0.453*** (0.052)	0.456*** (0.042)	0.493*** (0.063)	0.324*** (0.042)	0.276*** (0.066)
Adj R ²	0.01	0.02	0.08	0.20	0.22
Panel B: Kappa20 $\geq 10\%$					
Kappa20 $\geq 10\%$	0.138*** (0.028)	0.140*** (0.030)	0.155*** (0.033)	0.086*** (0.026)	0.078*** (0.028)
Adj R ²	0.01	0.01	0.08	0.20	0.22
Panel C: Cosine Similarity					
Cosine20	0.368*** (0.045)	0.366*** (0.047)	0.382*** (0.060)	0.271*** (0.042)	0.243*** (0.069)
Adj R ²	0.02	0.02	0.08	0.20	0.22
Panel D: IHHI					
IHHI20	0.138*** (0.029)	0.140*** (0.030)	0.156*** (0.039)	0.099*** (0.027)	0.072** (0.034)
Adj R ²	0.01	0.01	0.07	0.20	0.22
Panel E: Kappa top 1-5					
Kappa5	0.465*** (0.066)	0.466*** (0.059)	0.485*** (0.063)	0.314*** (0.051)	0.278*** (0.091)
Adj R ²	0.01	0.02	0.08	0.20	0.22
Panel F: Placebo Tests: Kappa top 6-20					
Kappa620	0.118*** (0.038)	0.119** (0.046)	0.131** (0.049)	0.065 (0.048)	0.006 (0.074)
Adj R ²	0.00	0.01	0.07	0.19	0.22
Panel G: Placebo Tests: Kappa top 11-20					
Kappa1120	0.036** (0.016)	0.035** (0.016)	0.043** (0.019)	0.032* (0.018)	0.023 (0.033)
Adj R ²	0.00	0.01	0.07	0.19	0.22
Controls		✓	✓	✓	✓
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓
N	1,597	1,597	1,597	1,597	1,597

standard errors in parentheses 55

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

Table 6: **Effect of common ownership on the likelihood of settlement**

This table presents linear-probability-model estimates of the effect of common ownership on settlement:

$$Settle_{jkms} = \alpha + \beta_1 \times Common\ Ownership_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. In Panel A, *Common Ownership* is measured as *Kappa20* (see equation (15) for detailed descriptions). In Panel B, *Common Ownership* is measured as *Kappa20* $\geq 10\%$, which is an indicator variable coded as 1 if *Kappa20* is greater than or equal to 10%, and 0 otherwise. In Panels C and D, we use the two components of a decomposition of *Kappa20* (see equation (16) for a detailed description) to measure *Common Ownership*. In Panel E, *Kappa5* is the profit weight the top five generic shareholders put on the brand plaintiff. In Panels F and G, *Common Ownership* are the profit weights the top 6-20 (*Kappa620*) and 11-20 (*Kappa1120*) generic shareholders put on the brand plaintiff, respectively. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A: Kappa20					
Kappa20	0.254*** (0.066)	0.259*** (0.076)	0.274*** (0.083)	0.311*** (0.080)	0.312** (0.141)
Adj R ²	0.00	0.03	0.08	0.10	0.25
Panel B: Kappa20 $\geq 10\%$					
Kappa20 $\geq 10\%$	0.111*** (0.030)	0.116*** (0.030)	0.115*** (0.035)	0.129*** (0.031)	0.116*** (0.039)
Adj R ²	0.01	0.03	0.08	0.09	0.25
Panel C: Cosine Similarity					
Cosine20	0.209*** (0.061)	0.213*** (0.047)	0.217*** (0.053)	0.253*** (0.066)	0.313*** (0.079)
Adj R ²	0.01	0.03	0.08	0.10	0.25
Panel D: IHHI					
IHHI	0.130*** (0.042)	0.138*** (0.034)	0.133*** (0.036)	0.140*** (0.039)	0.113** (0.045)
Adj R ²	0.01	0.03	0.08	0.09	0.25
Panel E: Kappa top 1-5					
Kappa5	0.246*** (0.070)	0.250*** (0.081)	0.274*** (0.085)	0.307*** (0.084)	0.313** (0.138)
Adj R ²	0.00	0.03	0.08	0.10	0.25
Panel F: Placebo Tests: Kappa top 6-20					
Kappa620	0.079** (0.039)	0.076** (0.033)	0.089*** (0.023)	0.067** (0.031)	0.028 (0.020)
Adj R ²	0.00	0.03	0.08	0.09	0.24
Panel G: Placebo Tests: Kappa top 10-20					
Kappa1120	0.030*** (0.009)	0.029*** (0.009)	0.029*** (0.009)	0.021* (0.010)	0.016 (0.012)
Adj R ²	0.00	0.03	0.08	0.09	0.25
Controls		✓	✓	✓	✓
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓
N	1,743	1,743	1,743	1,743	1,743

standard errors in parentheses

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

Table 7: **Determinants of the first generic: IV estimations, post-2009Q2 period**

This table presents the first stage (Panel A) and second stage (Panel B) of instrumental variable (IV) estimates of the effect of common ownership on the likelihood of settlement in the post-2009Q2 period. The first-stage regression is specified as follows:

$$Kappa20_{jks-1} = \alpha + \beta_1 \times \Delta Kappa20_{jk} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where $Kappa20$ (endogenous variable) is the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of the quarter in which the first patent-infringement lawsuit with respect to a tradename-formulation combination is filed. $Kappa20$ is instrumented by the percentile-rank transformed $\Delta Kappa20$ (see equation (21) and equation (22) for detailed descriptions). The second-stage regression is specified as follows:

$$Settle_{jkms} = \alpha + \beta_1 \times Kappa20_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. ϕ_j , ϕ_k , ϕ_l , and ϕ_s represent full sets of generic manufacturer, brand-name-firm, district-court, and time (year-quarter) fixed effects, respectively. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A. First stage					
IV	0.287*** (0.012)	0.284*** (0.014)	0.281*** (0.015)	0.253*** (0.016)	0.197*** (0.014)
N	848	848	848	848	848
F-stat	540.91	408.24	362.60	241.12	208.09
Panel B. Second stage					
Kappa20	0.547** (0.238)	0.538** (0.223)	0.682*** (0.252)	0.687*** (0.249)	1.184*** (0.263)
N	848	848	848	848	848
Controls		✓	✓	✓	✓
Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓

standard errors in parentheses

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

Table 8: **Effect of common ownership on the likelihood of settlement: IV estimations, post-2009Q2 period**

This table presents the first stage (Panel A) and second stage (Panel B) of instrumental variable (IV) estimates of the effect of common ownership on the likelihood of settlement in the post-2009Q2 period. The first-stage regression is specified as follows:

$$Kappa20_{jks-1} = \alpha + \beta_1 \times \Delta Kappa20_{jk} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where $Kappa20$ (endogenous variable) is the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of the quarter a patent-infringement lawsuit is filed (see equation (15) for detailed descriptions). $Kappa20$ is instrumented by the percentile-rank transformed $\Delta Kappa20$ (see equation (21) and equation (22) for detailed descriptions). The second-stage regression is specified as follows:

$$Settle_{jkms} = \alpha + \beta_1 \times Kappa20_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. ϕ_j , ϕ_k , ϕ_l , and ϕ_s represent full sets of generic manufacturer, brand-name-firm, district-court, and time (year-quarter) fixed effects, respectively. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A. First stage					
IV	1.238*** (0.113)	1.252*** (0.106)	1.275*** (0.091)	1.158*** (0.061)	0.603*** (0.100)
N	1,255	1,255	1,255	1,255	1,255
F-stat	120.417	140.188	197.497	357.612	36.181
Panel B. Second stage					
Kappa20	0.107*** (0.027)	0.111*** (0.027)	0.106*** (0.028)	0.170*** (0.048)	0.389*** (0.129)
N	1,255	1,255	1,255	1,255	1,255
Controls		✓	✓	✓	✓
Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓

standard errors in parentheses

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

Table 9: Effect of common ownership on brand's and generic's abnormal returns around settlement

This table presents estimates of the effect of common ownership on the market-adjusted daily stock returns around the date the generic defendant of Paragraph IV lawsuits and the brand-name plaintiff enter into a settlement agreement. We estimate the following linear regression:

$$CAR_{jki} = \alpha + \beta_1 \times Settle_{jki} \times First_{jkm} \times Kappa20_{jks-1} + \beta_2 \times Settle_{jki} \times First_{jkm} + \beta_3 \times Settle_{jki} \times Kappa20_{jks-1} \\ + \beta_4 \times First_{jkm} \times Kappa20_{jks-1} + \beta_5 \times First_{jkm} + \beta_6 \times Settle_{jki} + \beta_7 \times Kappa20_{jks-1} + X' \times \gamma + \phi_k + \phi_l + \epsilon_{jki},$$

where CAR_{jki} is the cumulative market-adjusted return for the brand plaintiff (columns (1)-(4)), or for the generic defendant (columns (5)-(8)), over the window of (-3, +3) relative to the event day on which the generic defendant(s) j and the brand plaintiff k enter into a settlement agreement with respect to lawsuit i . $Kappa20$ is measured as the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of a patent-infringement lawsuit (see equation (15) for detailed descriptions). Cases in which the two parties go to trial are excluded. Dependent variables are winsorized at the 1% and 99% levels. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses and are clustered at the U.S. federal district court level.

	Brand Return			Generic Return				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Settle×First×Kappa20			0.090** (0.034)	0.056** (0.025)			-0.051** (0.020)	-0.063* (0.032)
Settle×First	0.014*** (0.004)	0.014*** (0.003)	0.007* (0.004)	0.009*** (0.002)	0.005 (0.008)	0.010 (0.008)	0.010 (0.009)	0.016 (0.010)
Settle	-0.004*** (0.001)	-0.005*** (0.002)	-0.003* (0.001)	-0.005*** (0.002)	0.002 (0.002)	-0.001 (0.003)	0.001 (0.002)	-0.002 (0.002)
First	-0.007* (0.004)	-0.007 (0.004)	-0.005* (0.003)	-0.005 (0.004)	-0.005* (0.003)	-0.006* (0.003)	-0.007*** (0.002)	-0.007*** (0.002)
Settle×Kappa20			-0.033 (0.032)	0.003 (0.017)			0.012 (0.020)	0.016 (0.027)
First×kappa20			-0.047 (0.031)	-0.031 (0.020)			0.022* (0.011)	0.026* (0.013)
Kappa20			0.023 (0.033)	-0.008 (0.014)			-0.006 (0.013)	-0.001 (0.015)
Constant	0.004*** (0.001)	-0.003 (0.004)	0.004*** (0.001)	-0.003 (0.005)	0.002 (0.002)	-0.024*** (0.007)	0.002 (0.002)	-0.022*** (0.007)
Controls	✓	✓	✓	✓	✓	✓	✓	✓
Court FE	✓	✓	✓	✓	✓	✓	✓	✓
Brand Firm FE	✓	✓	✓	✓	✓	✓	✓	✓
Generic Firm FE								
N	989	989	989	989	631	631	631	631
Adj R ²	0.00	0.23	0.01	0.23	-0.00	-0.01	-0.00	-0.02

standard errors in parentheses

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

Table 10: Shareholder-by-shareholder calculation of dollar amount of wealth transfer

This table presents the shareholder-by-shareholder calculation of dollar amount of wealth transfer from generic defendant to brand plaintiff. *Rank* refers to generic shareholders' rank based on their ownership in the generic. *N* refers to the number of shareholders within each shareholder rank. *Share^g* (*Share^b*) refer to generic (brand) ownership. *Gain%* refers to the percentage of generic shareholders with $\Delta W > 0$, where $\Delta W = \Delta W^g + \Delta W^b$. ΔW^g and ΔW^b (Million USD) are gains/losses on the generic and brand, respectively. We calculate ΔW^g as follows:

$$\Delta W^g = \frac{\sum_{i=1}^n CAR(-3, +3)_i^g \times Shares_i^g \times Market Value_i^g}{N},$$

where $CAR(-3, +3)_i^g$ is the cumulative market-adjusted returns of settled generic defendant held by shareholder *i* over the $(-3, +3)$ -day window centered on the settlement event. $Shares_i^g$ is shareholder *i*'s stake (in percent) in the generic as of when a lawsuit starts. *Market Value_i^g* is the generic's market capitalization (millions USD) as of the beginning of the event window. ΔW^b is calculated analogously.

Rank	N	Share ^g	Share ^b	Gain%	ΔW^g	ΔW^b	N	Share ^g	Share ^b	Gain%	ΔW^g	ΔW^b
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Panel A. Settlement												
with first generic							with other generics					
1	24	10.66	4.59	65.2%	-263.08	318.25	34	10.42	4.19	50.0%	-123.09	-198.20
2	26	5.91	4.54	62.5%	-41.21	513.70	27	7.64	5.61	42.9%	-178.49	-19.15
3	27	4.50	4.03	56.0%	-87.59	507.11	36	5.93	3.82	46.9%	-41.57	-99.94
4	25	3.82	3.46	40.0%	-41.25	381.02	33	5.19	4.57	58.6%	75.92	101.87
5	21	3.77	4.07	36.8%	-48.06	39.93	25	4.05	4.60	45.5%	60.53	-67.70
6	21	3.17	2.52	55.6%	80.42	106.58	35	3.01	3.11	48.1%	-81.34	-64.96
7	14	2.22	1.89	75.0%	-24.86	184.05	15	2.45	3.02	75.0%	11.27	-137.33
8	19	1.96	2.49	52.9%	-21.07	-35.57	25	2.49	2.63	47.4%	45.46	-40.58
9	25	1.99	2.89	40.9%	-26.06	125.38	17	2.43	2.38	69.2%	7.92	87.89
10	19	1.51	2.92	50.0%	-22.78	232.71	16	2.12	1.77	64.3%	59.69	-204.32
Panel B. Dismissal												
with first generic							with other generics					
1	9	8.10	3.86	55.6%	-9.26	-913.28	14	8.75	4.56	33.3%	-95.01	-55.26
2	15	5.98	3.53	35.7%	-32.87	-360.02	23	7.36	4.47	47.1%	-53.11	-604.07
3	8	5.04	1.71	28.6%	33.62	-309.14	23	5.20	4.02	41.2%	12.15	-415.76
4	17	5.12	4.89	29.4%	-53.39	-757.16	20	4.46	3.87	44.4%	-16.75	-314.48
5	11	4.24	2.62	50.0%	0.11	378.72	14	2.67	2.73	50.0%	20.13	10.95
6	11	3.24	2.30	45.5%	-68.91	-145.89	16	3.21	4.23	63.6%	132.80	92.96
7	12	3.65	1.60	66.7%	-33.45	13.95	10	1.40	1.92	40.0%	-18.96	-378.78
8	12	3.28	3.21	33.3%	-16.94	-934.04	19	2.16	2.55	61.5%	21.29	21.53
9	11	2.43	2.38	30.0%	-33.86	-294.86	16	1.59	2.33	41.7%	-45.32	-66.32
10	5	2.27	3.67	0.0%	-47.26	-1,859.62	15	1.54	2.94	45.5%	-25.10	-79.02

Table 11: **Effect of common ownership on brand's and generic's abnormal returns around the first generic challenges**

This table presents estimates of the effect of common ownership on the market-adjusted daily stock returns around the date the first generic files a Paragraph IV with the FDA. We estimate the following linear regression:

$$CAR_{jki} = \alpha + \beta \times Kappa20_{jks-1} + X' \times \gamma + \phi_k + \phi_l + \epsilon_{jki},$$

where CAR_{jki} is the cumulative market-adjusted return for the brand-name company (columns (1)-(2)), or for the first generic filer (columns (3)-(4)), over the window of (-3, +3) relative to the event day in which the first generic manufacturer j files a Paragraph IV with the FDA challenging patents covering drugs owned by brand-name company k . $Kappa20$ is measured as the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of the year-quarter s in which the first generic files a Paragraph IV. Dependent variables are winsorized at the 1% and 99% levels. See [Table 4](#) for descriptions of control variables (the vector of X). Standard errors are in parentheses and are clustered at the U.S. federal district court level.

	Brand Return		Generic Return	
	(1)	(2)	(3)	(4)
Kappa120	0.057*** (0.014)	0.032*** (0.010)	0.009 (0.022)	-0.017 (0.026)
Constant	-0.002 (0.002)	0.015** (0.007)	0.006* (0.003)	-0.033 (0.024)
Controls		✓		✓
Court FE		✓		✓
Brand Firm FE		✓		
Generic Firm FE				✓
N	314	314	136	136
Adj R ²	0.02	0.63	-0.01	0.10

Online Appendix

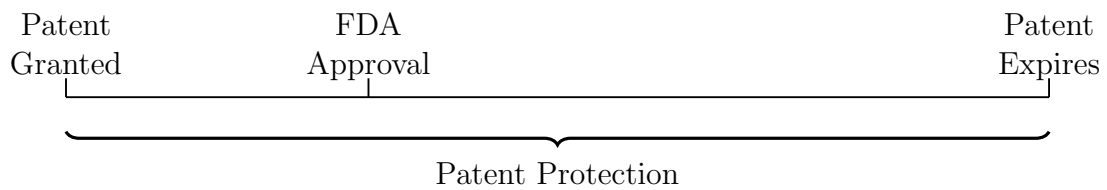
Martin Schmalz and Jin Xie

This Online Appendix provides supplementary material to the manuscript titled “Fake Entry” coauthored by Martin Schmalz (University of Oxford) and Jin Xie (Peking University).

Figure A.1: Marketing exclusivity and Paragraph IV patent challenge

This figure demonstrates the two types of protection conferred on branded drugs. Panel A demonstrates the protection of patents covering a branded drug from the grant of that patent until the expiration of it. Panel B demonstrates that when a new drug is approved by the FDA, a regulatory protection called “data exclusivity,” which runs concurrent with patent protection, protects the underlying clinical data for five-year period (seven years for orphan drugs and five and a half years for pediatric drugs). A period from the conclusion of data exclusivity to the expiration of patents is called “market exclusivity.” During the marketing-exclusivity period, a branded drug is protected only by its patents until they expire, and Paragraph-IV challenges occur only during this period.

Panel A. Patent protection



Panel B. Data exclusivity

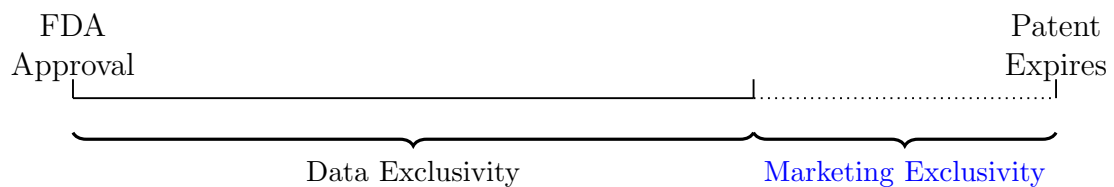


Figure A.2: Paragraph IV decision tree

This figure plots the decision tree for a generic firm to file an abbreviated new drug application (ANDA) with the FDA under a Paragraph IV certification.

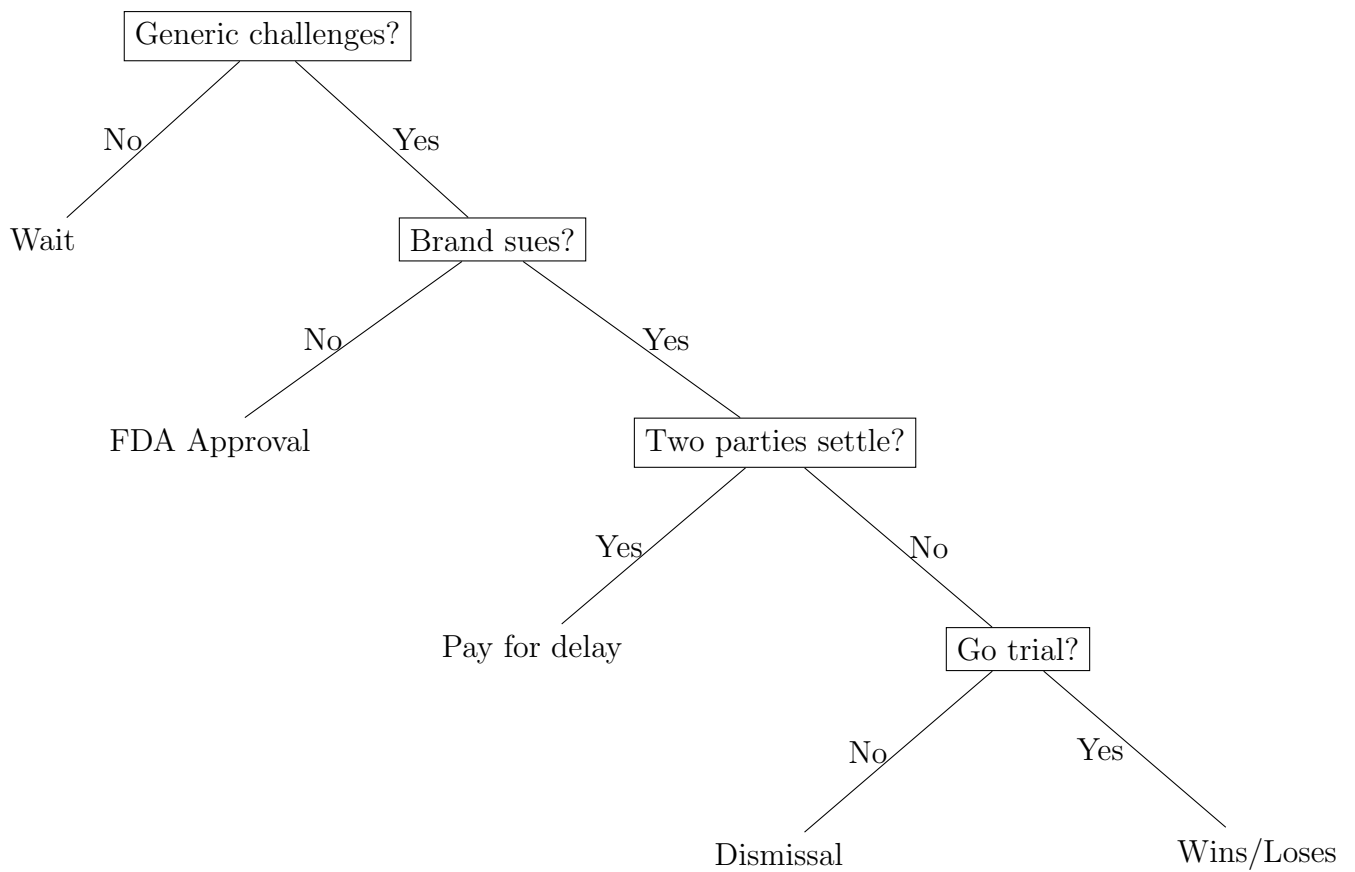
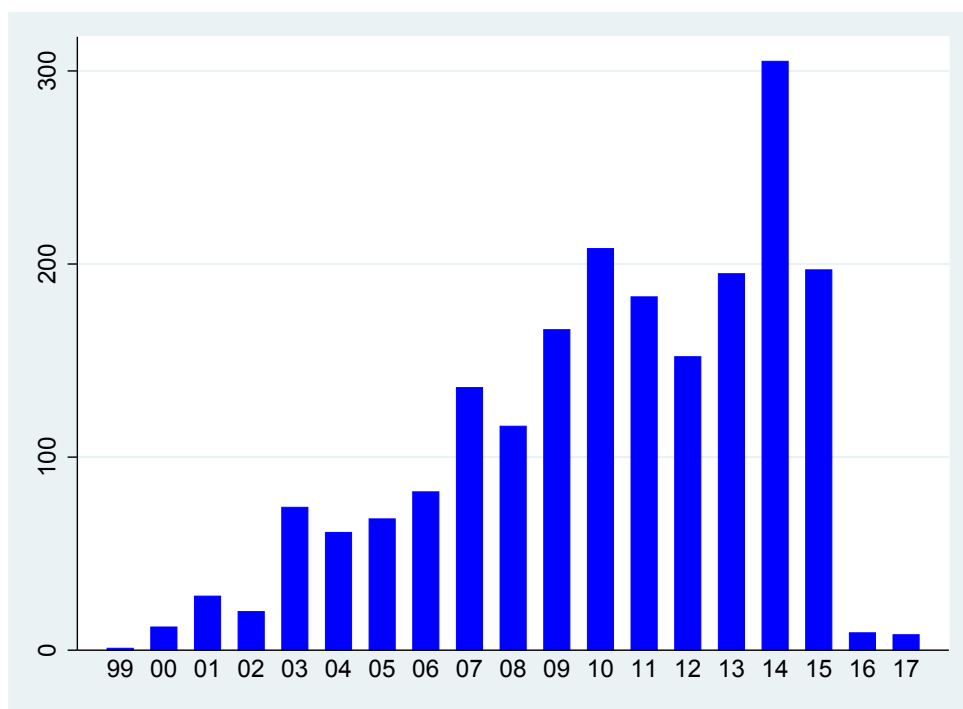


Figure A.3: Time trend of Paragraph IV challenges and settlement rates

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

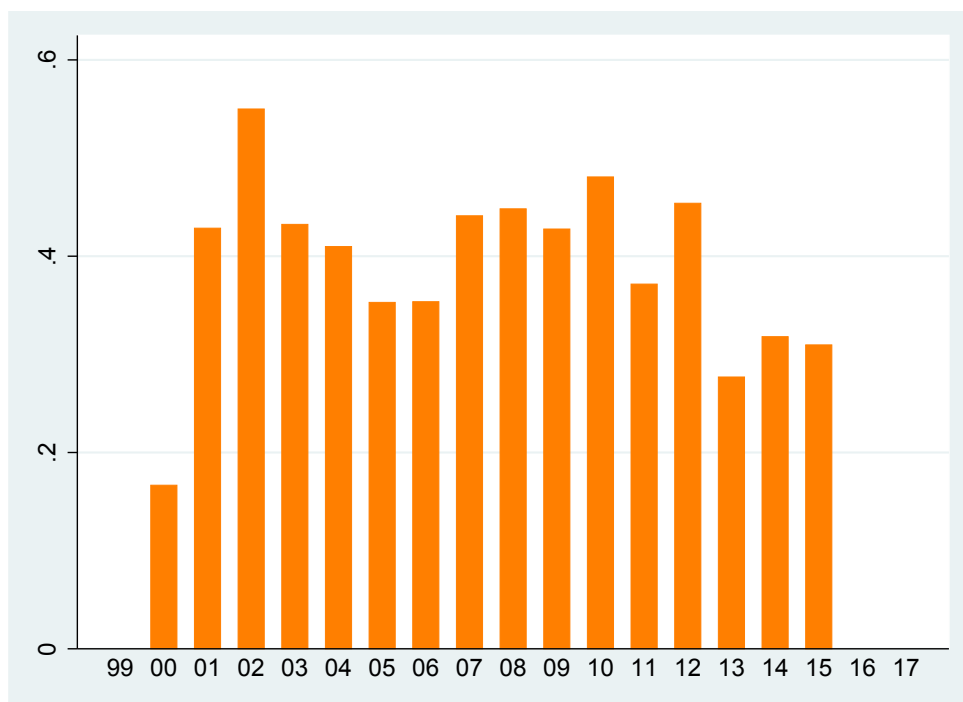


Figure A.4: Generic competition and drug prices

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.

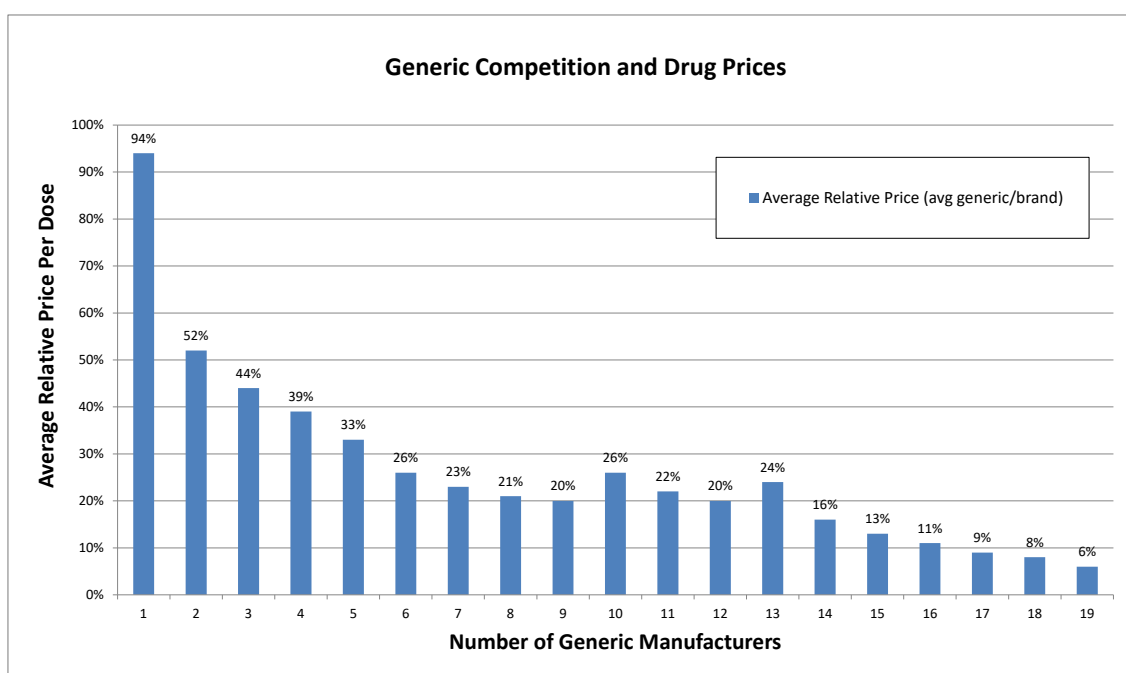


Table A.1: **How influential are generic common owners?**

This table uses four cases with extremely high *Kappa20* to show that, among the top five generic shareholders, common owners dominate over non-common owners in voting rights. *Kappa20* is the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of the quarter when a patent-infringement lawsuit is filed (see equation (15) for detailed descriptions).

Panel A: Teva vs. Merck (2009Q3)		
	Generic Ownership%	Brand Ownership%
Capital Rsrch & Mgmt.	13.7	13.0
Wellington	3.6	4.4
AllianceBernstein	3.1	2.9
FMR	2.8	2.2
Jennison Associates	2.2	0.8
Top 5 generic common owners	25.3	23.2
Top 5 generic non-common owners	0.0	
Kappa20	0.9	
Panel B: Innopharma vs. Spectrum Pharmaceuticals (2015Q2)		
	Generic Ownership%	Brand Ownership%
BlackRock	6.4	14.3
Vanguard	5.8	6.5
State Street	5.1	7.6
Wellington	1.8	3.7
Top 5 generic common owners	19.0	32.1
Top 5 generic non-common owners	2.8	
Kappa20	1.4	
Panel C. Mylan vs. Medicines Co. (2014Q3)		
	Generic Ownership%	Brand Ownership%
BlackRock	7.9	10.3
Vanguard	7.3	6.6
Wellington	5.5	14.0
State Street	4.3	3.5
Top 5 generic common owners	24.9	34.4
Top 5 generic non-common owners	5.9	
Kappa20	1.0	
Panel D. Perrigo vs. Eli Lilly (2016Q2)		
	Generic Ownership%	Brand Ownership%
Vanguard	6.7	6.0
BlackRock	6.1	6.3
Capital Rsrch & Mgmt.	6.0	1.6
State Street	3.9	3.7
Top 5 generic common owners	22.7	17.6
Top 5 generic non-common owners	3.8	
Kappa20	0.6	

Table A.2: **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. We define a Paragraph IV 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). Multiple patents can be involved in a Paragraph IV challenge.

	# Challenges	Settlement	Dismiss	Trial
California Central District	17	35.3%	47.1%	23.5%
California Northern District	16	56.3%	12.5%	31.3%
California Southern District	2	0.0%	100.0%	0.0%
Colorado District	3	66.7%	33.3%	0.0%
Delaware District	727	36.5%	39.2%	24.9%
District of Columbia	4	25.0%	75.0%	0.0%
Florida District	1	0.0%	0.0%	100.0%
Florida Middle District	4	50.0%	0.0%	25.0%
Florida Southern District	12	41.7%	16.7%	41.7%
Georgia Northern District	9	66.7%	0.0%	44.4%
Illinois Northern District	63	36.5%	36.5%	27.0%
Indiana Southern District	60	20.0%	35.0%	45.0%
Maryland District	34	47.1%	47.1%	5.9%
Massachusetts District	18	16.7%	66.7%	5.6%
Michigan Eastern District	9	44.4%	11.1%	44.4%
Michigan Western District	2	100.0%	0.0%	0.0%
Minnesota District	4	50.0%	0.0%	50.0%
Nevada District	14	7.1%	21.4%	57.1%
New Jersey District	713	43.5%	32.0%	27.5%
New York Eastern District	7	28.6%	28.6%	42.9%
New York Southern District	172	47.7%	34.9%	20.9%
North Carolina Eastern District	14	7.1%	35.7%	57.1%
North Carolina Middle District	10	10.0%	60.0%	40.0%
North Carolina Western District	1	0.0%	0.0%	100.0%
Ohio Southern District	2	100.0%	0.0%	0.0%
Pennsylvania Eastern District	25	12.0%	64.0%	20.0%
Pennsylvania Western District	1	0.0%	0.0%	100.0%
Pennsylvania Middle District	1	0.0%	100.0%	0.0%
Puerto Rico District	1	100.0%	0.0%	0.0%
Texas Eastern District	20	20.0%	20.0%	70.0%
Texas Northern District	12	75.0%	25.0%	0.0%
Vermont District	1	0.0%	0.0%	100.0%
Virginia Eastern District	14	7.1%	35.7%	57.1%
West Virginia District	3	0.0%	0.0%	100.0%
West Virginia North District	15	33.3%	60.0%	20.0%
Unknown	12	0.0%	16.7%	83.3%
Total	2,023	38.6%	35.6%	27.4%

Table A.3: **Determinants of the first generic: full sets of coefficients**

This table presents estimates of the effect of common ownership on the probability that a generic-drug manufacturer that files a Paragraph IV with the FDA will be the first Paragraph IV filer:

$$First_{jkm t} = \alpha + \beta \times Common\ Ownership_{jkt-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkm t},$$

where the dependent variable is a dummy variable indicating whether the generic manufacturer is the first generic that files the Paragraph IV with the FDA. *Common Ownership* is measured as the profit weight the top 20 generic shareholders put on the brand plaintiff one quarter prior to the year-quarter in which the first generic files the Paragraph IV (*Kappa20*). ϕ_j , ϕ_k , ϕ_l , and ϕ_s represent full sets of generic manufacturer, brand-name-firm, district-court, and time (year-quarter) fixed effects, respectively. Time is measured at the level of year-quarter in which the first generic files a Paragraph IV. See Table 4 for descriptions of control variables (the vector of X). Standard errors are clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Kappa20	0.453*** (0.052)	0.456*** (0.042)	0.493*** (0.063)	0.324*** (0.042)	0.276*** (0.066)
Ln(#Patents)		-0.016 (0.018)	-0.027 (0.016)	-0.035*** (0.009)	-0.017 (0.014)
Rank25		-0.054 (0.041)	-0.024 (0.049)	-0.026 (0.045)	0.062 (0.057)
Rank50		-0.063 (0.056)	0.004 (0.089)	-0.120* (0.061)	-0.222*** (0.063)
Rank75		-0.198*** (0.040)	-0.234*** (0.032)	-0.283*** (0.064)	-0.258*** (0.046)
Rank100		-0.065 (0.050)	-0.004 (0.046)	-0.040 (0.048)	0.012 (0.054)
Rank125		0.008 (0.106)	0.018 (0.085)	-0.015 (0.111)	-0.089 (0.092)
Rank150		-0.082 (0.080)	-0.093** (0.040)	-0.139 (0.084)	-0.118 (0.076)
Rank175		0.054 (0.121)	-0.008 (0.052)	0.043 (0.071)	0.067 (0.090)
Rank200		-0.103 (0.071)	-0.148 (0.102)	-0.152* (0.076)	-0.140** (0.065)
Route Exp		-0.005 (0.030)	-0.017 (0.036)	0.015 (0.026)	0.012 (0.031)
Therapy Exp		0.047** (0.022)	0.034*** (0.012)	0.038** (0.018)	0.049** (0.023)
Constant	0.336*** (0.014)	0.335*** (0.020)	0.346*** (0.014)	0.541*** (0.178)	0.769*** (0.215)
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓
N	1,597	1,597	1,597	1,597	1,597
Adj R ²	0.01	0.02	0.08	0.20	0.22

standard errors in parentheses

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

Table A.4: **Effect of common ownership on the likelihood of settlement: Full sets of coefficients**

This table presents estimates of the following regression model:

$$Settle_{jkms} = \alpha + \beta_1 \times Kappa20_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. *Kappa20* is the profit weight the top 20 generic shareholders put on the brand plaintiff as of the beginning of the quarter when a patent-infringement lawsuit is filed (see equation (15) for detailed descriptions). ϕ_j , ϕ_k , ϕ_l , and ϕ_s represent full sets of generic manufacturer, brand-name-firm, district-court, and time (year-quarter) fixed effects, respectively. Time is measured at the level of year-quarter in which the lawsuit is filed by the brand plaintiff. See Table 4 for descriptions of control variables (the vector of X). Standard errors in parentheses are clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Kappa20	0.254*** (0.066)	0.259*** (0.076)	0.274*** (0.083)	0.311*** (0.080)	0.312** (0.141)
First		0.111*** (0.033)	0.092*** (0.025)	0.094*** (0.023)	0.088*** (0.024)
Ln(#Patents)		0.014 (0.020)	0.018 (0.023)	0.010 (0.022)	0.015 (0.013)
Group		0.060*** (0.019)	0.027 (0.017)	0.033 (0.019)	0.028 (0.018)
Rank 25		-0.068 (0.045)	-0.107* (0.062)	-0.099 (0.076)	-0.029 (0.053)
Rank 50		-0.099** (0.039)	-0.206*** (0.060)	-0.216*** (0.071)	-0.244*** (0.056)
Rank 75		-0.056 (0.170)	-0.089 (0.132)	-0.058 (0.118)	-0.044 (0.105)
Rank 100		0.004 (0.063)	-0.116* (0.062)	-0.093** (0.040)	-0.127** (0.058)
Rank 125		0.155** (0.058)	0.128* (0.070)	0.076 (0.045)	0.137*** (0.044)
Rank 150		0.096*** (0.030)	0.094*** (0.019)	0.102** (0.042)	0.052 (0.078)
Rank 175		-0.029 (0.116)	-0.060 (0.093)	-0.046 (0.079)	-0.172 (0.172)
Rank 200		0.046 (0.071)	-0.067 (0.050)	-0.078 (0.066)	-0.078 (0.094)
Route Exp		-0.039** (0.019)	-0.033 (0.030)	-0.021 (0.032)	-0.034 (0.024)
Therapy Exp		-0.097*** (0.032)	-0.090*** (0.032)	-0.078* (0.045)	-0.062 (0.037)
Constant	0.366*** (0.024)	0.370*** (0.058)	0.132 (0.130)	0.301** (0.139)	0.026 (0.518)
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓
N	1,743	1,743	1,743	1,743	1,743
Adjusted R ²	0.00	0.03	0.08	0.10	0.25

standard errors in parentheses

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

Table A.5: **Effect of common ownership on the likelihood of settlement: Both generic and brand firms are publicly listed**

This table presents linear-probability-model estimates of the effect of common ownership on settlement.

$$Settle_{jkms} = \alpha + \beta_1 \times Common\ Ownership_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. In Panel A, *Common Ownership* is measured as *Kappa20* (see equation (15) for detailed descriptions). In Panel B, *Common Ownership* is measured as *Kappa20* $\geq 10\%$, which is an indicator variable coded as 1 if *Kappa20* is greater than or equal to 10%, and 0 otherwise. See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A. Kappa20					
Kappa20	0.326*** (0.071)	0.347*** (0.086)	0.376*** (0.110)	0.398*** (0.111)	0.450** (0.181)
N	1,089	1,089	1,089	1,089	1,089
Adj. R ²	0.01	0.06	0.10	0.10	0.24
Panel B. Kappa > 10%					
Kappa20 $\geq 10\%$	0.109*** (0.030)	0.118*** (0.036)	0.121*** (0.042)	0.127*** (0.041)	0.141* (0.069)
N	1,089	1,089	1,089	1,089	1,089
Adj. R ²	0.01	0.05	0.09	0.09	0.24
Controls		✓	✓	✓	✓
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓

Table A.6: **Effect of common ownership on the likelihood of settlement: Excluding branded drugs challenged by multiple first generics on the same day**

This table presents estimates of the effect of common ownership on settlement after excluding patent-protected drugs whose patents are challenged by multiple first-generic manufacturers on the same day. A patent-protected drug is defined at the formulation (e.g., tablet, capsule, and injection) under a brand name. Panel A presents linear-probability-model estimates of the effect of common ownership on settlement:

$$Settle_{jkms} = \alpha + \beta_1 \times Common\ Ownership_{jks-1} + X' \times \gamma_1 + \phi_j + \phi_k + \phi_l + \phi_s + \epsilon_{jkms},$$

where the dependent variable is an indicator variable coded as 1 if the two parties settle a litigation for at least one disputed patent, and 0 otherwise. *Common Ownership* is measured as *Kappa20* (see equation (15) for detailed descriptions). Panel B presents the second stage of instrumental variable (IV) estimates of the effect of common ownership on the likelihood of settlement in the post-2009Q2 period. *Kappa20* is instrumented by the percentile-rank transformed $\Delta Kappa20$ (see equation (21) and equation (22) for detailed descriptions). See Table 4 for descriptions of control variables (the vector of X). Standard errors are in parentheses clustered at the U.S. federal district court level.

	(1)	(2)	(3)	(4)	(5)
Panel A. Linear-probability-model estimates					
Kappa20	0.294*** (0.085)	0.306** (0.113)	0.342** (0.127)	0.375** (0.142)	0.443* (0.240)
N	1,371	1,371	1,371	1,371	1,371
Adj. R ²	0.01	0.02	0.08	0.10	0.25
Panel B. IV estimates					
Kappa120	0.120*** (0.036)	0.122*** (0.035)	0.101*** (0.033)	0.134* (0.070)	0.402** (0.200)
N	959	959	959	959	959
Controls		✓	✓	✓	✓
District Court FE			✓	✓	✓
Time FE			✓	✓	✓
Generic Firm FE				✓	✓
Brand Firm FE					✓