

# Paying off the Competition: Market Power and Innovation Incentives\*

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## Abstract

Using granular data from the pharmaceutical industry, we explore how a firm’s market power affects its innovation incentives. We focus on a particular mechanism through which incumbents maintain market power: “pay-for-delay” agreements to delay the market entry of competitors. When unfettered in the use of these agreements, we show that incumbents reduced their innovation in response to potential entry by direct competitors. But after such agreements became legally tenuous, incumbents *increased* their innovation after competitive entry, and this innovation is of higher “quality”. However, we find a reduction in innovation by new entrants in response to increased competition.

**Keywords:** Drug Development, Pharmaceutical Industry, Monopoly, Antitrust, Market Power, Competition, Innovation

**JEL Classifications:** D42, D43, G31, K21, L41, L43, L65, O31, O32.

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# 1 Introduction

The effect of competition among firms on innovation is a critical issue for policymakers, given the importance of innovation as a driver of economic growth. However, the relationship between increased competition and innovation is not clear-cut in the literature (e.g. Aghion et al., 2005). On the one hand, measures such as greater patent protection to reward firms for their innovation by limiting their competition may encourage further innovation in order to reap monopoly profits. On the other hand, an incumbent firm with an existing product under such protection may feel no need to innovate further if it can already rely on a guaranteed revenue stream from the product. Furthermore, the extent of protection may change the endogenous actions incumbent firms undertake—such as R&D or contracting—to deter competitors, leading to unclear effects on innovation at the intensive and extensive margins. Understanding the interaction between these forces is crucial for ascertaining the effect of policies aimed at increasing innovation by changing the degree of competition in a market, such as antitrust enforcement and patent policy.

In this paper, we explore this issue by providing evidence from a legal mechanism through which innovative firms may maintain their market power, and its ramifications for innovation. We do so in the setting of a particular sector known for developing innovative products through its research and development (R&D) activities—the pharmaceutical industry. In this industry, firms that are first to pass clinical trials and obtain Food and Drug Administration (FDA) approval for their drugs enjoy marketing exclusivity for a number of years, during which no other firm can directly compete against that drug. However, after their marketing exclusivity expires, other firms may enter the market by launching generic versions of the specific drug, through what is known as a Paragraph IV filing. In order to continue their monopoly over marketed drugs, incumbent pharmaceutical firms have regularly entered into “pay-for-delay“ agreements—also known as “reverse payments”—settlements with entering generic manufacturers, whereby the generic firm agrees to delay its product launch in exchange for a cash amount. These agreements effectively provide an endogenous tool through

which incumbent firms can reduce the competition that they face.<sup>1</sup>

Using detailed data on public pharmaceutical firms and their drug development portfolios from 2005 to 2016, we construct a *firm-specific* measure of the amount of competition that each incumbent faces through Paragraph IV generic drug entry filings. We show that unconditionally over our sample period, incumbent firms responded to potential entry from direct competitors by reducing their innovation activity and initiating a smaller number of new drug trials.<sup>2</sup> The results suggest that firms appear to reduce their levels of innovation when faced with increased competition.

We then explore the effect of a Supreme Court ruling in 2013, *FTC v. Actavis*, which increased the legal risk of engaging in pay-for-delay agreements. The ruling stated that under antitrust law, the Federal Trade Commission (FTC) could target such agreements, and granted the FTC broader bargaining power in these types of antitrust settlements. Consistent with the increased legal risk, we document a sharp decline in the number of pay-for-delay agreements after the ruling, a stark reversal of the previous trend. Furthermore, we show that the ruling did not appear to change the incentives of generic entrants, which filed at the same rate both before and after the ruling.<sup>3</sup> The ruling can therefore be interpreted as an unexpected regulatory change that reduced the ability of incumbent firms to enter into agreements to impede new competition.

Our initial result, that incumbent firms reduce their levels of innovation when faced with increased competition, reverses itself following this ruling. Put differently, when a pharma

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<sup>1</sup>This is consistent with papers in the Law and Economics literature that have argued, and provided evidence, that these agreements are anticompetitive. See, for example, Hovenkamp et al. (2002), Rosenthal (2002), Drake et al. (2015), and Xie and Gerakos (2020).

<sup>2</sup>As we discuss in the paper, our setting affords us to measure real innovation activity through project decisions, rather than having to rely solely on measures related to patents. We later supplement our analysis with various project-related and patent-related measures to better understand the nature of the innovation that affected firms undertake.

<sup>3</sup>This supports the view that generic firms did not enter for the purpose of engaging in pay-for-delay settlements; put differently, these firms enter into a market because it would be profitable to compete against the branded (incumbent) drugs. In subsequent analyses, we use hand-collected data from 10-K filings and searches of news articles to find mentions of litigation faced by affected incumbent companies. We show that the number of litigated court cases with rulings where generic drugs were allowed to enter (i.e. cases that are not settled) went up.

firm observes a generic entry filing against one of its products after the ruling, it *increases* its number of new drug trial initiations and *decreases* its number of suspensions of existing projects. This suggests that the initial negative relationship between generic competition and innovation is driven primarily by the ability of incumbent firms to protect their monopoly power through pay-for-delay agreements. Such agreements allow firms to resolve the uncertainty of product competition and reduce the need to maintain their competitive edge with novel drugs. However, after this channel becomes legally risky, firms need to rely on innovation activities to escape neck-and-neck competition (e.g. Aghion et al., 2005).

While the above results are suggestive, they are subject to concerns about endogeneity and reverse causality, since generic entry and signing pay-for-delay agreements are contemporaneously endogenous decisions made by both incumbents and entrants. In order to address these concerns, we use the *FTC v. Actavis* ruling as a natural experiment, and conduct a differences-in-differences (diff-in-diff) analysis by exploiting firm heterogeneity in the exposure of incumbent firms to the ruling. Specifically, incumbent firms with drugs slated to lose marketing exclusivity in the years immediately following the ruling had increased exposure to generic entry, and thus, to the court ruling. Furthermore, since the expiration date of marketing exclusivity for these drugs had been predetermined at the end of the drug approval process, which spans a number of years (e.g. DiMasi and Grabowski, 2007), the institutional framework alleviates concerns of self-selection into the treatment group. This diff-in-diff analysis shows that affected firms had a relative increase in innovation through a higher number of new trial initiations, and a lower number of suspensions. We show that the results also hold at a more granular level of analysis, when considering treated therapeutic units within firms.

We validate these results through a number of additional tests. First, we replicate the same exercise at the firm-therapeutic-category level and document that these effects also hold both across different categories within a single firm as well as across different firms within a

single category.<sup>4</sup> Second, using data on drug sales, we find that these effects are centered on two groups: firms with drugs with high sales whose exclusivity was set to expire after the Supreme Court ruling, and firms with a large number of drugs whose exclusivities were set to expire after the ruling. Both of these effects are consistent with the hypothesized responses of firms that are the most affected by the law. Third, we provide a host of robustness tests showing that our results are driven by the diminished ability of firms to engage in pay-for-delay agreements, and not by sample selection concerns.<sup>5</sup>

We then leverage our data to explore the *nature* of firms’ innovation decisions, in order to provide further color on our main results. First, using patent-level data, we find evidence that affected firms pursue *higher-quality* innovation—the citations received by the affected firms’ patents increase, the economic value of new patents issued by those firms increases, and the new patents are less reliant on the firms’ existing knowledge base. Second, using additional project-level data, we find that the affected firms are more likely to acquire projects from other firms, which is consistent with firms choosing to in-source existing projects from other firms as an alternative to in-house innovation. Furthermore, affected firms are more likely to pursue “breakthrough” therapies or therapies that target rare diseases. When put together, these results suggest that affected firms not only increase their innovation when faced with an increased threat of generic entry, but choose more “impactful” innovation from a scientific as well as commercial standpoint. Third, we find that the affected firms increased their R&D expenditures and decreased their cash holdings following the ruling, which is consistent with firms spending to expand their net innovation activities.

In the final part of our analysis, we explore the overall impact on innovations within

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<sup>4</sup>A therapeutic category is a group of indications sharing high pathological correlations. Drugs aimed at a specific category are plausibly close substitutes, and hence close competitors. We follow the Center for Medicare & Medicaid Services’ ICD-10 medical classification assessment and group diseases in the same subchapter level as the therapeutic category.

<sup>5</sup>In particular, we perform a placebo test by counterfactually assuming the ruling occurred in 2009, and using firms with drug exclusivities expiring between 2009 and 2012 as the pseudo-treatment group. We obtain no significant results via this test for our outcome variables. We also re-run our analysis on a propensity score-matched sample and a restricted sample of firms with approved/active drug projects, and find consistent results with these samples.

a therapeutic category, in order to examine effects at the extensive margin and estimate the aggregation effects of individual firm decisions. At the level of therapeutic category, we find an overall decrease in suspensions as well as an increase in new trial initiations by incumbent firms exposed to competition risk by the Supreme Court ruling. However, we also find that the enhanced ability of generic producers to enter an area may dampen entry into the area by *new* firms. This suggests that the ability of incumbent firms to stave off generic competition has implications not only for the decision to innovate by incumbents but also for the decision to innovate by new (non-generic) potential innovators. Our results are consistent with theories predicting that the effect of antitrust policy on innovation is not clear-cut, e.g. Segal and Whinston (2007), but our results shed new light on the reasons for this, and imply that the effects of optimal policy related to antitrust law on innovation will be nuanced.

This paper is related to the broad theoretical and empirical literature that explores the relationship between competition and innovation: see Tirole (1988); Aghion et al. (2001, 2005); Gans et al. (2002); Gans and Stern (2003b), among many others; Ahn (2002) provides a review of the literature. Also related is the literature on the optimal design of a property rights system with respect to innovation incentives (e.g. Klemperer (1990); Gilbert and Shapiro (1990); Hopenhayn et al. (2006); Acemoglu and Akcigit (2012); Williams (2013), among others). Our paper contributes to these strands of the literature by providing evidence that the relationship between competition and innovation can depend on the tools available to incumbent firms within the property rights and antitrust law system. Specifically, our results indicate that increased competition leads to reduced innovation as long as incumbents have access to tools to keep competition at bay, but it increases innovation once these tools have either been exhausted or are otherwise unavailable. However, this increase in innovation at the intensive margin is accompanied by a possible decline in innovation at the extensive margin.

Our paper is directly connected to the literature that explores competitive effects in the

biopharmaceutical industry, particularly with regard to the effect of generic manufacturers on incumbent firms. Higgins and Graham (2009) argue that generic penetration carries a long-term growth concern for the ex ante R&D incentives of incumbent firms.<sup>6</sup> Branstetter et al. (2016) examine the welfare consequences of Paragraph IV generic entry in the pharmaceutical industry and estimate that generics increase consumer surplus but reduce producer surplus. Thakor and Lo (2022) explore the effect of increased competition in the biopharmaceutical industry induced by easier generic entry through the Hatch-Waxman Act, finding that affected firms increased their R&D but decreased their levels of innovation (measured through patents).<sup>7</sup> Branstetter et al. (2014) estimate the effect of generic entry on incentives for early-stage pharmaceutical innovation and find that an increase in generic penetration reduces early-stage innovation in therapeutic markets. Garfinkel and Hammoudeh (2020) use FDA breakthrough designation therapy indications as a shock to pharmaceutical competition and find evidence consistent with such shocks discouraging rivals' innovation in an area along the lines of Aghion et al. (2005).

Our paper also examines the effect of generic entry on pharmaceutical innovation, but it highlights the importance of the legal environment in mediating the relationship between generic competition and innovation. Like these earlier papers, we also find a negative relationship between generic entry and innovation, but we have the novel finding that this relationship is driven by the ability of incumbents to engage in pay-for-delay settlements with generic entrants. In particular, we document a *reversal* of this result when pay-for-delay agreements are impeded.

The remainder of this paper is organized as follows. In Section 2, we provide a brief theoretical framework to motivate our analysis. Section 3 describes the institutional background related to the pharmaceutical industry, generic entry, and the *FTC v. Actavis* ruling.

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<sup>6</sup>Also related are papers that examine the behavior of incumbent firms when faced with the threat of entry. See, for example, Goolsbee and Syverson (2008); Parise (2018), who examine this topic using data from the airline industry.

<sup>7</sup>Grabowski and Vernon (1992) examines market share and entry for a sample of drugs following the enactment of the Hatch-Waxman Act, and demonstrates that generic entry does significantly increase competition for incumbent producers. Grabowski (2007) provides an overview.

Section 4 describes our data sources. Section 5 describes our empirical methodology, and provides the results for our Paragraph IV panel regressions. Section 6 contains our diff-in-diff methodology and results. Section 7 examines the aggregated effects at the level of therapeutic area. Section 8 concludes.

## 2 Conceptual Framework

In this section, we briefly describe a simple theoretical framework to guide our hypotheses and empirical analysis. The full model and proofs are included in the Internet Appendix.

Consider a setting with two players: an incumbent drug development firm,  $I$ , and a potential entrant,  $E$ . There are two periods,  $t = 1$  and  $t = 2$ , and the discount rate is set to zero for simplicity. At the beginning of the first period,  $E$  randomly enters the market with some exogenous probability  $\alpha$  by filing a generic drug application. At the beginning of the second period, if  $E$  had previously entered, it will enter with the same probability  $\alpha$ . After  $E$  enters, there is a given probability  $\lambda$  that the FDA approves the generic drug that period.

Firm  $I$  has an existing drug product which generates cash flows of  $L > 0$ . After observing whether  $E$  enters at  $t = 1$ ,  $I$  decides how much to invest in R&D. It can choose an investment level  $q$  at a cost of  $c(q) = cq^2/2$ . A greater investment leads to a higher chance the R&D will succeed—with probability  $q$ , the investment successfully produces a new drug that replaces  $I$ 's existing drug. This new drug produces cash flows equal to  $H > L$ , and since it is a novel drug with marketing exclusivity,  $E$  cannot launch a generic drug in either period. However, with probability  $1-q$ , R&D for the new drug fails and  $I$  still receives cash flows equal to  $L$  from its existing drug. This existing drug is also vulnerable to generic entry—if the FDA approves  $E$ 's generic drug, the existing drug's profit is zero.

In the baseline model, we consider a simple pay-for-delay strategy that the incumbent firm  $I$  can undertake. After observing that  $E$  has chosen to enter at  $t = 1$  but before making any R&D investments,  $I$  can choose to pay  $E$  a fixed reservation price  $p$ .<sup>8</sup> This will guarantee

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<sup>8</sup>In the Internet Appendix, we provide parametric restrictions for  $p$  such that the price is not too high



that there will be no generic drugs launched in either period even if the innovation by  $I$  fails. With this basic modeling setup, we obtain the following two hypotheses.

**Hypothesis 1 (H1):** Without the possibility of pay-for-delay agreements, the incumbent firm will invest more in innovation when it observes an entry by a generic firm in the first period.

**Hypothesis 2 (H2):** When an incumbent firm is able to use pay-for-delay agreements, then it will pay the competitor and reduce its R&D investments when it observes an entry by a generic firm in the first period.

The intuition is as follows. The benefits of investment in innovation include two components. First, it can deter potential generic entry, which is an “escape the competition” effect. Second, it can increase the profitability of the incumbent firm’s product from  $L$  to  $H$ . H1 follows because realized entry by  $E$  at  $t = 1$  increases the forward probability of generic entry, which makes  $I$  more willing to invest in innovation in order to deter competition. However, when firms can make use of pay-for-delay agreements, the incumbent firm  $I$  will pay the generic firm  $E$  when it enters, therefore eliminating the possibility of competitive threats in the second period. At the same time, the first component of the benefits to innovation—deterring future entry—is eliminated and therefore firms will only invest in order to generate higher profitability. This diminishes the marginal returns from innovation, and as a result firms will decrease their R&D investment, leading to H2.<sup>9</sup>

Finally, suppose that we relax the assumption that the payment price  $p$  is exogenously given, and instead allow bargaining between  $I$  and  $E$ , where  $I$  makes a take-it-or-leave-it (TIOLI) offer to  $E$ . This results in the following hypothesis:

**Hypothesis 3 (H3):** Pay-for-delay agreements will be more prevalent for high-sales incumbent drugs. In particular, there exists a cutoff  $L^*$  such that the incumbent will pay if

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for the incumbent to pay. We also endogenize the price in an extension.

<sup>9</sup>Risk aversion on the part of the incumbent firm, which has been documented in the pharmaceutical industry (i.e. Krieger et al. (2022)), would also exacerbate this effect.

$$L \geq L^*.$$

In this case,  $E$ 's reservation price is determined by the expected future value of profits the generic drug will produce. The transaction will occur so long as the loss of the incumbent drug's monopoly profits is larger than  $E$ 's expected cash flows. Therefore, the more profitable the existing drug, the more likely it is that  $I$  will pay  $E$ .

### 3 Institutional Setting

In this section, we review the institutional setting related to generic entry in the pharmaceutical industry, as well as the *FTC v. Actavis* court ruling.

#### 3.1 Generic Entry in the Pharmaceutical Industry

The current regulatory regime in the pharmaceutical industry for generic and brand-name drugs is a consequence of the passage of the Hatch-Waxman Act of 1984. Intended to benefit consumers by increasing drug choices through competition, this legislation dramatically changed the terms under which a generic product could be approved in the same market as an existing branded drug. Prior to the enactment of this law, the FDA required generic drugs to replicate much of the original clinical trial testing in order to gain market approval, resulting in significant development costs. After the passage of the Hatch-Waxman Act, these restrictions were eased, and generic developers only needed to prove bioequivalence to the original drug (i.e. that the generic delivers the same clinical benefit), thus allowing generic manufacturers to bypass portions of the drug trial process. The Hatch-Waxman Act also introduced a provision whereby generic producers could more easily challenge the patent protection of brand-name drugs once their marketing exclusivity had expired. Overall, this facilitated the increased entry of generic products in drug markets and allowed them to provide low-cost substitutes for consumers, exposing incumbent producers to significantly

higher levels of competition.<sup>10</sup>

Under the provisions of the Hatch-Waxman Act, the timing of generic entry depends on the marketing exclusivity and patent protection of a new drug. A developing firm will typically first apply for a patent early in the drug trial process. Generally, the term of each patent will last about 20 years from its application. If a drug survives clinical trials—typically lasting 8 years (e.g. DiMasi and Grabowski (2007))—the firm will submit a New Drug Application (NDA) to the FDA in order to gain approval to market the drug to consumers. If the drug is approved, the FDA will grant exclusive marketing rights to the new product, meaning that no generic producer can apply for a competing product. The length of exclusivity typically lasts 3 to 7 years. As described in more detail below, marketing exclusivity endows the recipient with monopoly power, and it is much stronger than patent protection.

Under Hatch-Waxman, a generic manufacturer must file an Abbreviated New Drug Application (ANDA) with one of four Paragraph certifications when seeking generic approval. Each Paragraph certification corresponds to different conditions of patent availability and expiration. Among them, only Paragraph IV (Para-IV) certification applies to the case when a branded product’s patent has not expired. By filing a Para-IV entry certification, the generic maker declares that its product does not infringe on a patent or that patent is invalid. Figure 1 illustrates the timeline of generic entry during a brand-name drug’s post-approval lifespan.

— Insert Figure 1 Here —

After being notified of a Para-IV ANDA, an incumbent pharmaceutical company often sues the generic maker for patent infringement. This litigation process is beneficial for the brand-name owner. It triggers an automatic 30-month stay on the FDA’s approval of the generic drug—the FDA may only approve the ANDA upon the first court ruling in favor

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<sup>10</sup>See Grabowski (2004, 2007) and Thakor and Lo (2022) for details of the provisions and the law, and evidence of its effect on pharmaceutical competition. Berndt and Aitken (2011) show that generic entry is economically important in the industry, while Reiffen and Ward (2005) provide evidence that generics dramatically decrease the market share of brand pioneers.

of the manufacturer, or if a settlement is reached. Once the generic is approved to enter into the market, it is awarded 180 days of market exclusivity as the sole generic provider in competition with the branded drug.<sup>11</sup>

Following the initiation of litigation, the incumbent drug owner often seeks a settlement before the court decision. This is not only because litigation is costly and time-consuming, but also because the courts usually rule in favor of the generic application.<sup>12</sup> If the brand-name and generic manufacturers enter into a settlement, it may specify the generic product's time of entry into the market, as well as the royalties owed by the generic manufacturer. However, the brand-name producer may instead choose to settle with the generic manufacturer by offering a direct payment through a "pay-for-delay" agreement.<sup>13</sup> In exchange, a generic manufacturer agrees to refrain from entering the market for an additional amount of time.<sup>14</sup>

As an example, several generic drug makers filed ANDAs that threatened the exclusivity of the drug Androgel in 2003. Androgel's owner, Solvay Pharmaceuticals,<sup>15</sup> sued the generic companies for patent infringement, but the litigation process exceeded the FDA's 30-month stay and Actavis Inc. (formerly Watson Pharmaceuticals) had its generic version approved in January 2006. In September 2006, Solvay persuaded Actavis to delay its product launch until 2015, and in the meantime to help promote Androgel. In exchange, Solvay made annual payments of \$19 to 30 million to Actavis for "promotion costs."

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<sup>11</sup>If the generic manufacturer loses its Para-IV case, it then *de facto* becomes a Paragraph III filing, in which case the applicant agrees to wait until the relevant patent expires before it seeks final ANDA approval.

<sup>12</sup>An FTC study (FTC, 2002) documents that generic applications prevailed in 73% of the patent litigation that was ultimately resolved by a court decision from 1992 to June 2002.

<sup>13</sup>The FTC considers a variety of non-pecuniary exchanges to be equivalent to payments. For example, the aforementioned 180-day market exclusivity of first filers does not apply to the brand-name pharmaceutical company's "authorized generic" or "AG". An incumbent company could postpone entry by promising not to launch an AG and erode a generic product's profits.

<sup>14</sup>An FTC study in 2010 (FTC, 2010) indicates that "agreements with compensation on average prohibit generic entry for nearly 17 months longer than agreements without payments". Consistent with these agreements being collusive, Helland and Seabury (2016) document that Para-IV challenges lower drug prices and increase quantity, but the effect is reversed if a settlement is reached.

<sup>15</sup>Solvay was later acquired by Abbott Laboratories and is now owned by AbbVie Inc. after being spun off.

### 3.2 The *FTC v. Actavis* Ruling

Pay-for-delay agreements were a commonly used strategy in the 2000s (see Bulow (2004)). In the early 2010s, the Federal Trade Commission (FTC) argued that pay-for-delay agreements effectively allowed brand-name producers and generic manufacturers to form a cartel that enabled them to share a monopolistic market profit. This eventually led to the landmark decision *FTC v. Actavis* in 2013, in which the Supreme Court held that the FTC could litigate pay-for-delay agreements under antitrust law.<sup>16</sup> This decision was arguably unexpected, since prior to the ruling, both the District Court and the Eleventh Circuit Court dismissed the FTC's claims, while the final Supreme Court decision was split 5-to-3.

Since the ruling, the FTC has aggressively targeted pay-for-delay agreements. It has successfully sued a number of pharmaceutical firms for non-cash delay strategies, such as promising no authorized generic (AG) launches or providing other first generic arrangements. The *FTC v. Actavis* ruling also granted more bargaining leverage to the FTC. For example, in addition to \$1.2 billion in monetary relief to compensate drug buyers, Cephalon Inc. and Teva Pharmaceutical agreed to a prohibition on entering any kind of future pay-for-delay deals in a 2015 FTC settlement. Firms now incur a substantial increase in legal risk stemming from antitrust enforcement if they have engaged in pay-for-delay agreements after this ruling.

As evidence for the effect of the ruling, Table 1 summarizes the yearly number of drugs with first Para-IV generic filers, final settlements, and pay-for-delay agreements.<sup>17</sup> As the table shows, the *FTC v. Actavis* ruling did not change the intensity of Para-IV first filings—the number of Para-IV filings remains flat around the ruling. This suggests that the ruling did not change the decisions of generic producers to enter into the marketplace. Put differently, generic producers are likely not entering solely to engage in pay-for-delay agreements, but

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<sup>16</sup>No. 12-416, 570 U.S. \_\_\_(2013). While the ruling did not ban pay-for-delay agreements, it made clear that such agreements could fall under the FTC's antitrust regulatory powers under rule of reason, thus making them much more legally tenuous. See Edlin et al. (2015) for an overview of the effects of the ruling.

<sup>17</sup>The aggregated data come from the FTC's annual report on Medicare Modernization Act agreement filings.

rather are entering the market because it is profitable to do so.

— Insert Table 1 Here —

In contrast, pay-for-delay agreements drop sharply after the ruling. This is also seen graphically in Figure 2. In the years leading up to 2013, the number of pay-for-delay settlements showed a strong increasing trend. However, after 2013, this trend reverses itself. This effect holds when including all pay-for-delay agreements, as well as only agreements with generic first filers (the first generic company to file for Para-IV entry). For example, in 2015, there were only 7 settlements with first filers, the lowest number since 2006.

— Insert Figure 2 Here —

## 4 Data Description

Our analysis is based on a sample of public firms in the pharmaceutical and biotechnology industries. We first extract detailed firm-specific drug development and trial information from an industry competitive intelligence database. We then construct financial variables for these firms through the Compustat database. We supplement this sample with additional data on Para-IV certification filings and updates on exclusivity and litigation efforts.

### 4.1 Drug Development Data

Our main data come from the Biomedtracker (BMT) database, an industry competitive intelligence database that covers drug trial information in detail for the universe of public and private biopharmaceutical companies in the U.S. For each firm, the database contains pipeline development history dating as far back as the 1980s (although the coverage is more complete after 2000). In pharmaceutical development, drugs target the specific symptoms of a disease, known medically as indications. Since each drug may potentially apply to multiple indications, and thus may be approved by the FDA at different times, trial information

is subdivided at the indication level. We therefore define each combination of drug and indication as a project.

The FDA drug development approval process consists of three clinical trial phases—phase 1, 2, and 3—and a final NDA/BLA (new drug application/biologic license application) FDA approval phase. In the BMT database, the history for each project covers events across all of these phases, including drug trial initiation, phase trial updates, trial suspensions, regulatory information, marketing decisions, partnerships, acquisitions, and patent updates. Upon each event, the database also includes the phase of the FDA approval process for the indication, and the likelihood of its eventual approval, calculated using a combination of historical data and analyst estimates. Given each firm’s research portfolio, defined as the set of ongoing projects, we include its size (the total number of ongoing projects) and the average probability of final approval as control variables.

We examine a variety of outcome variables to characterize detailed project choice decisions by biopharma firms. For each firm, we explore the number of projects it initiates and suspends. Since innovative sectors like the biopharma industry are characterized by an active market for ideas (e.g. Gans and Stern (2003b,a)), in which firms frequently acquire R&D-related assets from each other, we also construct a variable that tracks the external projects acquired by each firm.

Finally, for the aggregate analysis of the impact on competition in a given disease area, we map the BMT indications to the Center for Medicare & Medicated Services’ ICD-10 medical classification assessment and group them at the first subchapter level to form a therapeutic category. Examples of categories are “malignant neoplasms of breast” and “disorders of gallbladder, biliary tract and pancreas.”<sup>18</sup>

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<sup>18</sup>This provides us with a total of 157 categories from the ICD-10 assessment of the sample firms.

## 4.2 Paragraph IV Entry Data

In our analysis, we use the Para-IV generic entry applications associated with each incumbent firm. We obtain the set of Para-IV certifications from the FDA’s website. Each observation includes detailed information on the generic-seeking certification, such as product name, dosage form, strength, the reference branded drug, and the first filing date of the generic drug application. On a prospective basis, this information dates back to March of 2004. We supplement this with data from paragraphfour.com, which is a database that compiles detailed information on Paragraph IV cases. For each branded drug, we eliminate repetitions due to dosage form and strength by keeping the earliest generic filing at the drug level. We reason that the profit that is lost by the brand-name owner begins at the first generic entry, and the marginal impact of subsequent generic entry becomes smaller over time.<sup>19</sup> Using the trade names of branded drugs, we manually match each listed product to a pharmaceutical company in BMT. In total, 431 branded drugs with non-missing filing dates are matched in our sample.

## 4.3 Financial Information

In order to explore the investments and financial decisions of the firms in our sample, we manually match the firms in the BMT database to Compustat. We restrict our analysis to a sample period from 2005 to 2016, due to the availability of Para-IV Entry information. This provides us with a dataset at the firm-year level of 572 public firms with over 3,618 firm-year observations. We collect information on R&D expenditures, cash holdings, debt levels and earnings, as well as total assets. The first four variables, after being scaled by total assets, are used as outcome variables to quantify the impact of generic threats on a company’s financial performance. Additionally, in most regressions, we include lags of these variables as controls.

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<sup>19</sup>In particular, the first ANDA filer’s settlement is key to the process, and often dictates what happens to any later Para-IV filers. Furthermore, later settlements are often not relevant. We thank Greg Glass for pointing this out.



## 4.4 Patent Data

As an alternate measure to better understand the nature of the firm’s innovation decisions, we also examine measures related to patents issued by each firm. We match our sample firms to their patents using data from Kogan et al. (2017), and utilize their measure of the economic value of patents. In particular, Kogan et al. (2017) measure excess stock returns around patent issuance to estimate the value that the market places on new patents.

We also explore another commonly used proxy for the value of patents—the future citations received by each patent—which reflects the impact and importance of the patent. In addition to the raw number of citations, we create an adjusted citation count by dividing each patent’s future citations by the average citations of all patents filed in the same year and the same technology class, following Hall et al. (2001). This adjustment corrects for truncation errors, as patents filed closer to the end of the sample tend to receive fewer citations since the citations are yet to be observed in the data.<sup>20</sup> We also calculate the percentage of citations made by patents that are based on the applicant firm’s existing knowledge base, in order to explore the exploitation of innovation. Following Benner and Tushman (2002), a firm’s existing knowledge base is defined as a firm’s patents filed over the past five years plus the patents from other firms cited by the firm’s patents filed over the past five years.

## 4.5 Marketing Exclusivity Data

We use information on the expiration date of exclusivity for each brand drug in order to measure the treatment intensity of incumbents to the *FTC v. Actavis* ruling. We obtain this data from the FDA Orange Book, taken from the National Bureau of Economic Research’s (NBER) data repository. Like the data for Para-IV entries, there may be multiple product numbers under each drug’s trade name, depending on dosage and strength. We collapse this information at the level of the trade name if there is more than one product expiring in the same year, and we then match drug owners in BMT by the trade name. In total, we match

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<sup>20</sup>This adjustment method is commonly known as the “fixed effect” approach (Lerner and Seru, 2017).

991 drugs with unique trade names expiring from 2003 to 2022.

## 5 Generic Entry and Innovation Outcomes

We begin this section by providing results that examine the reactions of pharmaceutical firms to Para-IV generic entry.

### 5.1 Empirical Methodology

In our first specification, we run panel regressions to explore the reaction of incumbent firms to entries from generic firms. In order to do so, we construct a variable at the firm-year level that measures how affected a firm is by potential generic threats. More specifically, we define a variable— $ParaIV_{i,t}$ —as the number of firm  $i$ 's brand-name drugs for which there is generic entry through a Para-IV certification in year  $t$ . With this measure, we estimate the following panel regression from 2005 to 2016:

$$\begin{aligned} Y_{i,t} = & \alpha + \beta_1 ParaIV_{i,t-1} + \beta_2 ParaIV_{i,t-1} \times Post_t \\ & + \beta_3 ParaIV_{i,t-2} + \beta_4 ParaIV_{i,t-2} \times Post_t + \gamma Controls_{i,t} + \mu_i + \lambda_t + \varepsilon_{i,t} \end{aligned} \quad (1)$$

In equation (1), we include two lags of  $ParaIV_{i,t}$  in order to account for variations in the timing of responses following Para-IV certification, and the awareness that the litigation process that begins after an ANDA may take more than one year. We interact these lags with  $Post_t$ , which is a dummy variable that takes a value of 1 if year  $t$  is 2013 or later, and 0 otherwise. These interaction terms allow us to explore whether this relationship between competition and innovation is affected by increased antitrust enforcement induced by *FTC v. Actavis*, which diminished the ability of these firms to engage in pay-for-delay agreements.

$Y_{i,t}$  is the outcome variable of choice for firm  $i$  in year  $t$ . We focus on two variables as measures of innovation.  $Initiation_{i,t}$  is the number of trials initiated by company  $i$  for

early-stage projects (preclinical or phase 1) at time  $t$ . This measures a company’s active exploration of new projects.  $Suspension_{i,t}$  is the number of projects in any phase suspended by company  $i$  at time  $t$ . This measures the abandonment (or halting) of ongoing projects by the company.

$Controls_{i,t}$  is a vector of control variables. We include several variables that we refer to as “pipeline” controls, that characterize the condition of a firm’s research pipeline.  $AvgChance_{i,t}$  is the average probability of eventual FDA approval for all of company  $i$ ’s projects, which is a proxy for the viability of the firm’s development portfolio.  $P1_{i,t}$ ,  $P2_{i,t}$  and  $P3_{i,t}$  are counts of a firm’s active projects in phase 1, 2 and 3, respectively. These variables are included to control for the stage of research of a firm’s development portfolio. We also include the natural logarithm of total assets  $\log(TA)$  to proxy for firm size and other financial variables, profitability  $EBIT/TA$  (measured through earnings before interest and taxes), cash holdings  $Cash/TA$ , R&D expenditures  $R\&D/TA$ , and leverage ratio  $Debt/TA$ . All control variables are lagged by one year except for  $\log(TA)$ .

## 5.2 Summary Statistics

Panel A of Table 2 provides summary statistics for the main variables. A typical pharmaceutical firm in our sample initiates two new drug projects in a given year and suspends or terminates 1.5 existing projects every year. This relatively large number of terminations is consistent with the low average approval probability for each project, which is 18% over our sample, implying that more than 80% of the projects in development will eventually fail. The average firm in our sample has around 11 projects in its development pipeline across all phases, and its average annual R&D expenditures are about 54.5% of its total assets. This is consistent with the need for a diversified development portfolio and high R&D expenditures due to the high attrition rate for drug projects.

— Insert Table 2 Here —

Panel B of Table 2 provides the distribution of Para-IV generic filings. In a given year, the majority of firms do not receive generic challenges. This is because a firm will usually only have a small number of approved products losing exclusivity, and furthermore generic manufacturers will selectively target the most profitable ones. Conditional on generic entry, the majority of firms have one product facing Para-IV entry in a given year. GlaxoSmithKline plc had 9 marketed products facing Para-IV entry in 2008, the maximum value in our sample.

### 5.3 Results

We begin by exploring the response of firms to generic competition over our sample period. Table 3 provides the estimation results for equation (1). Column (1) shows that over our full sample, firms significantly decreased their initiation of new projects in response to an increase in Para-IV generic filings that directly affect an incumbent pharmaceutical firm's products. This effect holds particularly for two-year lagged Para-IV filings. In column (3), consistent with this effect, we find that firms facing generic entry also increased their suspensions of existing projects, both for one-year and two-year lagged filings. These results suggest that incumbent pharmaceutical firms respond to increased competitive pressures stemming from Para-IV entry by reducing their innovative activities.

— Insert Table 3 Here —

However, in columns (2) and (4), we find that our previous result reverses itself during the period after the ruling. In particular, in the post-ruling period, we find a relative *increase* in trial initiations and a *decrease* in trial suspensions when firms face an increase in Para-IV entry. The magnitudes are statistically and economically significant. For example, column (2) shows that before the court ruling, a firm facing generic entry in the previous two years reduced its number of new project initiations by 0.4 and 0.7, on average, respectively. In contrast, a firm facing a generic entrant after 2013 responded by initiating an additional 1.3 and 1.0 drugs, which are both larger than the prior reduction. These increases in initiations

are also more than 50% of the sample average. Similarly, a firm facing generic competition after 2013 suspended an average of 1.4 fewer projects over the following two years. This magnitude is also comparable to the unconditional mean number of suspensions over the sample.

These results suggest that, following increased antitrust risk when pay-for-delay agreements became less feasible, firms responded to increased competition by increasing their net innovation activity. This effect is consistent with hypothesis H1 in Section 2, with firms feeling a need to “escape the competition” with increased levels of innovation (e.g. Aghion et al. (2005)), given a diminished legal ability to protect their monopoly power. However, before these legal changes, incumbent pharmaceutical firms responded to increased competitive pressures stemming from Para-IV entry by *reducing* their innovative activities. This is consistent with hypothesis H2 in Section 2. A rationale for these effects is as follows. Without the use of pay-for-delay agreements, there is *ex ante* uncertainty about competition before realized entry, and thus incumbent firms hedged this uncertainty with innovation efforts. But when this uncertainty can be resolved with pay-for-delay agreements, firms no longer need to hedge and can reduce their innovative activities. Together, our results imply that the ability of incumbent firms to enter into contracts with newly entering rivals to stave off competition may be a key factor in driving the previously demonstrated negative relationship between competition and innovation.

## 6 Diff-in-Diff around *FTC v. Actavis*

While the previous results are suggestive of the effect of the increase in antitrust enforcement following the *FTC v. Actavis* ruling, they are subject to concerns about potential endogeneity and reverse causality.<sup>21</sup> In order to overcome these concerns, we run a diff-in-diff analysis, exploiting firm exposure to the ruling.

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<sup>21</sup>For example, firms may be able to endogenously affect the Paragraph IV filings intensity through strategies such as “evergreening” their patents (Hemphill and Sampat (2012)). We discuss this issue in further detail shortly.

## 6.1 Empirical Methodology

The *FTC v. Actavis* ruling reduced the ability of firms engaging in pay-for-delay agreements to protect the profits of drugs whose period of FDA marketing exclusivity has expired. As a result, those firms whose drugs are set to expire in the period immediately after the ruling will be the most affected. Consequently, we define a treatment variable,  $ExcluLoss_{2013-2016,i}$ , which takes a value of one if firm  $i$  has a drug with an exclusivity period expiring between 2013 and 2016, and zero otherwise. In our sample, 176 drugs had their marketing exclusivity expire during this period, which provides us with 60 firms in the treatment group. Among the 60 treated firms in our sample, 42 are realized compliers, i.e., their exclusivity-expiring drugs experienced Para-IV generic entry afterward, which further validates the relevance of our treatment variable around the *FTC v. Actavis* ruling. We then run the following diff-in-diff regression:

$$Y_{i,t} = \alpha + \beta_1 ExcluLoss_{2013-2016,i} \times Post_t + \gamma Controls_{i,t} + \mu_i + \lambda_t + \varepsilon_{i,t}. \quad (2)$$

In equation (2), as before,  $Post_t$ , is a dummy variable which takes a value of one if the year is subsequent to the *FTC v. Actavis* ruling. The validity of the diff-in-diff framework in this case hinges on the observation that firms did not self-select into the treatment group in anticipation of the ruling. We believe that this observation holds in our setting. First, we will show that the parallel trends assumption likely holds in our setting. Second, as noted earlier, the final ruling from the U.S. Supreme Court was relatively unexpected, preventing self-selection. Finally, since the drug development process is both lengthy and risky (e.g. Wong et al. (2019)), lasting an average of 8 years before a drug is potentially approved and able to gain exclusivity. This makes it effectively impractical for firms to be able to choose their treatment intensity, as the choice to begin the project had been made several years

earlier.<sup>22</sup>

Based on our conceptual framework, innovation efforts by the treatment group should be concentrated on clinical trials conducted in disease groups related to the drugs with marketing exclusivity expiring between 2013 and 2016. Put differently, the initiations and suspensions made by our treated firms in response to the shock should be specifically in the disease categories associated with the drugs affected by generic entry. In order to explore this and further establish the channels behind our effects, we expand our analysis to examine effects at the level of the firm-therapeutic category, which allows us to explore decisions of distinct R&D units *within* a firm (Henderson and Cockburn, 1994). In our sample, an average firm operates in 7.28 ICD categories, each of which is defined as a therapeutic area. Exploiting different combinations of fixed effects in equation (2) at the therapeutic area level, we are able to explore innovation within a given firm’s affected therapeutic areas in response to the increased threat of generic entry, relative to other areas within the same firm as well as other firms operating within the same area. In particular, we define  $ExcluLoss_{2013-2016_{i,j}}$  as taking a value of one if firm  $i$ ’s therapeutic category  $j$  has a drug with exclusivity period expiring between 2013 and 2016, and zero otherwise.  $Initiations_{i,j,t}$  and  $Suspensions_{i,j,t}$  are defined similarly as before, except that the number is counted for firm  $i$ ’s therapeutic category  $j$  at  $t$ .

## 6.2 Results: Project Innovation Outcomes

The results estimating equation (2) at the firm-year level are given in the first two columns of Table 4. We find that firms in the treatment group—those with exclusivity-expiring drugs in the post-ruling period—increase the number of their new project initiations, and decrease the number of their suspensions relative to the control group following the *FTC v. Actavis* court ruling. In particular, a firm affected by the court ruling initiates 1.75 more new

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<sup>22</sup>Our identification strategy is similar in spirit to that used in Krieger et al. (2022), which examines heterogeneity in pharma firm responses to the introduction of Medicare Part D based on differences in remaining exclusivity periods and drug shares across elderly populations.

drug projects and suspends 1.99 fewer projects, on average, relative to the control group.<sup>23</sup> These results are consistent with our previous results that firms increase their net innovation activities following a reduction in their ability to engage in pay-for-delay agreements with future entrants.

— Insert Table 4 Here —

We then confirm that our results are consistent at a more granular level. In Table 4, we replicate the diff-in-diff analysis at the firm-therapeutic area level. The results indicate that the increase in innovation activities occurs specifically within a firm’s therapeutic areas that are subject to the threat of generic entry. In columns (3) and (4), we include firm-category fixed effects along with year fixed effects. This allows us to examine the effects of generic entry threats for a given firm-therapeutic category relative to non-affected ones within a given year. It is also possible that the results are influenced by common shocks to certain therapeutic categories. For example, a scientific breakthrough in a particular area during our sample may spur R&D efforts in that area. To account for this, in columns (5) and (6), we include firm-category fixed effects and therapeutic category-year fixed effects, showing that the effects remain even when controlling for category-specific time trends. The estimated magnitudes are consistent across different specifications. Furthermore, firms increase their innovation activity in affected areas relative to unaffected areas in the same firm.

### 6.3 Parallel Trends

A critical assumption of any diff-in-diff setting is the parallel trends assumption, that there are no pre-trends between the treatment and control groups. In order to validate this assumption, we interact our treatment variable  $ExcluLoss_{2013-2016_i}$  with individual year indicators

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<sup>23</sup>In additional untabulated tests, we show that the change in suspensions are due specifically to suspension *decisions* made by the developing firm (i.e. voluntary suspensions), as opposed to trial failures that do not meet desired endpoints.



instead of  $Post_t$ .<sup>24</sup> This allows us to examine whether there are any differential effects between the treatment and control firms in the years before the ruling. The coefficients are plotted in Figure 3, along with their 95 percent confidence intervals. For both initiations and suspensions, the coefficients show no discernible pre-trends before the ruling. After the ruling, the coefficient estimates for initiations increase in magnitude and significance, while the coefficient estimates for suspensions decline and turn significant. This suggests that the parallel trends assumption holds for our setting. Figure 3 plots the coefficients at the firm level. In the Internet Appendix, we confirm that the graphs are similar if we plot them at the firm-category level.

— Insert Figure 3 Here —

## 6.4 Heterogeneity

To further solidify the channels driving our results, we examine heterogeneity in our main effect. In particular, hypothesis H3 of Section 2 predicts that firms with high-sales drugs that are affected by generic entry will respond more strongly to the ruling. Consistent with this hypothesis, Grabowski and Kyle (2007) show that profitable brand-name drugs attract more generic competition. As a result, incumbent firms whose exclusivity-expiring drugs have relatively high sales (i.e. “blockbuster” drugs) should be more affected by the ruling. Furthermore, firms with a relatively large number of exclusivity-expiring drugs should also be more affected by the ruling.

In order to explore this predicted effect, we split our treatment group based on these two criteria. To identify high-sales drugs, we collect the top 100 brand-name drugs by sales in 2012 and 2013 from drugs.com and match them to the respective firms that commercialized them. We then construct two variables:  $HSale_i$  takes a value of one if firm  $i$  has an exclusivity-expiring drug that is in the top 100 sales list (a blockbuster drug) and zero

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<sup>24</sup>We include all individual years except 2012, which serves as the reference year. The figures are qualitatively similar across other specifications.

otherwise, and  $LSale_i$  takes a value of one if firm  $i$  has an exclusivity-expiring drug that is not in the top 100 sales list and zero otherwise. There are a total of 19 treated firms for which  $HSale_i = 1$ , accounting for roughly one-third of the total; the rest of treated companies are  $LSale_i = 1$ . To identify firms with relatively large numbers of exclusivity-expiring drugs, we construct two additional variables.  $HNum_i$  takes a value of one if firm  $i$  has an above-median number of exclusivity-expiring drugs in 2013 to 2016 and zero otherwise, and  $LNum_i$  takes a value of one if firm  $i$  has a below-median number of exclusivity-expiring drugs in 2013 to 2016 and zero otherwise.<sup>25</sup>

The results are given in Table 5. As the table shows, the effects are concentrated on the firms likely to be the most exposed to the *FTC v. Actavis* ruling: firms with relatively higher sales, and the firms with the highest number of drugs with exclusivity expiring in the 2013 to 2016 period. The difference is substantial. For example, the high-sales affected group significantly increased their new project initiations by 3.8 drugs and decreased their suspensions of existing projects by 4.5 drugs, which are both roughly 2.2 times larger than the average treatment effects. On the other hand, the low-sales affected group's reactions are close in magnitude to 0 and are insignificant. The results for the high-number and low-number groups follow the same pattern.

— Insert Table 5 Here —

## 6.5 Robustness

We conduct a number of robustness checks for our main results. First, a potential concern is that firms which lose marketing exclusivity will always respond by innovating more, regardless of the availability of pay-for-delay agreements. However, we argue that before the *FTC v. Actavis* ruling, since firms can strategically use these payments to defend against generic entrants, the loss of marketing exclusivity poses a smaller concern. To show this, we perform a placebo test by counterfactually assuming that the ruling occurred in 2009, and

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<sup>25</sup>The median number of exclusivity-expiring drugs is two.

use the firms that lost exclusivity from 2009 to 2012 as the pseudo-treatment group.<sup>26</sup> In Table A.1 of the Internet Appendix, we find insignificant results for all of our main outcome variables.

Second, the count nature of clinical trials allows us to alternatively use a Poisson model. We use a linear regression model as our main specification since it permits a large array of fixed effects. However, in Table A.2, we show that our main results are robust to using such nonlinear models.

Third, although the diff-in-diff analysis does not require the treatment group and control group to be identical prior to the shock, there exists a concern that these two groups may differ in various dimensions that drive the differences in innovation activities after the shock. To alleviate this concern, we conduct our diff-in-diff analysis using propensity score matching to construct our treatment and control groups.<sup>27</sup> In Table A.3 of the Internet Appendix, we perform a balance check for the matched sample from 2009 to 2012, and confirm that there exist no significant differences in the financial characteristics between the two groups. We then show that our main results hold for this matched sample. A related concern is that the treatment group consist of large pharmaceutical firms with recently approved drugs, but the control group includes smaller biotech companies without any drugs on the market. To address this concern, we restrict the sample to firms with at least one drug approved after 2005 in the first two columns of Table A.4. The results are again consistent.

Finally, it is possible that the disease categories that have drug exclusivity expiring from 2013 to 2016 received technology shocks that were concurrent with *FTC v. Actavis*. If this is the case, then firms may have altered their innovation activities, but for a reason unrelated to competition. While our previous analysis including drug category-year fixed effects will control for such shocks, we additionally address this concern in two ways. First,

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<sup>26</sup>The cutoff is chosen so that the pseudo-treatment group does not overlap with the actual treatment group. In this analysis, we drop all firm-year observations after 2013 to perform a clean test.

<sup>27</sup>We match each firm in the treatment group to a firm in the control group based on firm size ( $\log(TA)$ ) and average chance of approval (*AvgChance*) in 2012, i.e. the year prior to the shock. We impose a 0.025 maximal difference and require that each treated firm have one matched neighbor.

in the last two columns of Table A.4, we replicate our estimation using a sample of firms with at least one active drug project in the affected disease categories. Second, in Table A.5 we include control variables that count the number of active projects in each ICD category (157 new variables in total), thus providing a more granular characterization of firm pipeline distribution in different areas. Our results continue to hold with both of these specifications.

## 6.6 Additional Outcomes

Our results thus far suggest that firms appear to increase their innovation activities once they have a diminished ability to fend off competition. In this section, we provide a number of additional analyses in this section to shed further light on the nature of the affected firms' innovation activities.

### 6.6.1 Patent-related Innovation Outcomes

We begin by using patent-related outcomes to supplement our previous measures of project starts and stops, in order to gauge whether the *quality* of affected firms' innovation changes. For example, a firm may choose to initiate more drug trials, resulting in a higher volume of innovation, but this may not reflect promising or novel drug candidates, or other significant innovation.

We note that patent *counts* are problematic in our setting beyond the disadvantages that patent counts may not correspond to actual innovation (Freilich, 2019) because biopharma companies commonly used “evergreening” strategies when they were able to freely use pay-for-delay agreements, in which firms would issue new patents on *existing* drugs to extend the patent protection length. This would permit incumbents to better negotiate with generic manufacturers (see e.g., Hemphill and Sampat (2012)). These new patents tended to be minor modifications of mixtures of delivery methods of older drugs.<sup>28</sup> We therefore instead

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<sup>28</sup>Consistent with this, in our untabulated results we find insignificant effects when using patent counts as our outcome variable at the firm level. An alternative measure is to use the citation-weighted number of patents, in which each patent is weighted by its own forward citations divided by the average citations

examine several measures of the *value* of a firm’s new patents, which allows us to account for this possibility. First, we explore two commonly used proxies of the impact and importance of patents: the future citations received by each patent and future citations adjusted for the average citations within the same technology class and year (e.g. Hall et al. (2001)). Second, we examine the economic value of new patents issued by firms as another measure of innovation quality (Kogan et al., 2017). Finally, we examine the extent to which a firm’s new patents exploit the firm’s existing knowledge base, as another view into the novelty of the innovations.

Panel A of Table 6 provides the summary statistics for these measures for the 17,971 patents filed by the sample firms between 2005 and 2016.<sup>29</sup> Panel B of Table 6 compares the patent characteristics before and after *FTC v. Actavis* exposure for the treatment group.

— Insert Table 6 Here —

The results for the patent citation measures are shown in columns (1) and (2). The results show that the raw number of citations increases by 38.3% for patents issued by treated firms relative to control firms after the shock. The results are similar when adjusting citation counts by average citations received by patents filed in the same year and technology class (column 2).

We provide the results using economic value of patents in columns (3) and (4) of Table 6. The results indicate that for affected firms after the *FTC v. Actavis* ruling, the market value of new patents significantly increases by 10.6% relative to patents issued by other firms. The results are similar when measuring patent value in real dollars to account for inflation (column 4).

Finally, in the last column of Table 6, we explore whether the new patents issued by

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of all patents issued in the same year (e.g., Hall et al. (2005); Kogan et al. (2017)). Patents issued in the treatment period (2013 to 2016), however, tend to suffer from truncation bias and have fewer citations. For example, the average biotech patent issued in 2016 has 0.7 citations.

<sup>29</sup>Each patent receives 5.5 (unadjusted) future citations and is worth \$72 million estimated from stock market returns. For our regressions, following the literature, we take the logarithm of citations and market values due to the skewness of these variables.

treated firms become less exploitative. We find that the new patents issued by treated firms become less exploitative, i.e., they rely less on the firm’s existing knowledge base. When taken together, these results reinforce our previous results on the increase in project starts and decrease in project stops, and provide evidence that this new innovation is higher quality—it has larger scientific and commercial value.

### 6.6.2 Project-related Innovation Outcomes

To add further color to the nature of the innovation activities conducted by firms, we also examine additional drug development project outcomes. We start with project acquisitions as an outcome variable. Innovative firms have a choice between “internal” and “external” innovation—i.e. conducting R&D in-house, or acquiring it from another firm. Thus, our previous results may understate or overstate the project decision incentives of a firm, since acquisitions are an alternative to the initiation of a new project within the firm. In order to explore this, we re-estimate equation (2) with  $DrugAcq_{i,t}$ , which is defined as the number of drugs acquired from other companies. We note that these are not whole-firm acquisitions, but rather acquisitions of the intellectual property rights of a *drug project*. Furthermore, we ensure that the acquired project is a *new brand-name drug* in development, rather than a competing generic drug.<sup>30</sup>

The first column of Table 7 provides the estimation results. Subsequent to the ruling, affected firms increase their acquisitions of projects from other firms. The coefficient estimate implies that a treated firm acquires an average of 1.2 additional drug projects compared to a control firm following the ruling, which is slightly larger than the unconditional average of 1.1 projects in the treatment group.<sup>31</sup> This suggests that firms use acquisitions as another mechanism to increase their net innovative activity in response to a diminished ability to

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<sup>30</sup>Therefore, our results are not driven by the incentives of killer acquisitions (Cunningham et al., 2021).

<sup>31</sup>We report the unconditional mean of the treatment group because it tends toward the inclusion of large pharmaceutical firms, which are the common acquirers in this industry. The existence of many smaller and financially constrained biotech firms over the whole sample will underestimate the overall propensity of acquisition in the sample.

protect their monopoly power, consistent with these firms pursuing late-stage projects as a timelier response to negative shocks (e.g. Krieger et al., 2021; Bena and Li, 2014).

— Insert Table 7 Here —

We then explore two regulatory designations that correspond to more novel drug candidates. First, we examine the number of drug projects developed by each firm that receive a “Breakthrough Therapy Designation” (BTD) from the FDA. This designation is awarded for drugs that are intended to treat serious conditions, and for which the preliminary evidence indicates they may be a significant improvement over existing treatments (see Garfinkel and Hammoudeh (2020)). Second, we examine the number of drug projects developed by each firm that receive an “Orphan Drug” designation from the FDA, which indicates that the drug is intended to diagnose or treat a rare disease. Both designations receive expedited review by the FDA as well as other regulatory benefits, and are designed to encourage developing firms to pursue more novel treatments. Columns (2) and (3) of Table 6 show that firms are more likely to pursue projects with both types of designation, which again reinforces the notion that treated firms, when they are less able to engage in pay-for-delay settlements, not only increase their innovation but choose more “impactful” innovation from a scientific and commercial standpoint.

### 6.6.3 Litigation Outcomes

A shortcoming of our analysis is that we do not directly measure the precise details of pay-for-delay settlements at the firm level, such as settlement terms and litigation costs, since these details are confidential. Even though we can observe whether there exists a settlement for generic entry, the terms of the settlement are thus unobservable, and we therefore cannot categorize it by whether pay-for-delay activities are involved.

To address this issue, and to provide more evidence of the effects of the *FTC v. Actavis* ruling on pay-for-delay settlements, we hand-collect additional variables from the “Legal

Proceedings” sections of 10-K filings, extracting any mentions of generic litigation cases. We identify cases at the brand-name drug and generic entrant level. Since companies do not fully disclose all cases, we also supplement our data with hand-collected information from news articles via Law360 and LexisNexis. With this data, we construct two additional measures. We first define  $CourtNum_{i,t}$  as the number of Para-IV court cases for firm  $i$  in year  $t$  which conclude with a court ruling.  $EntryRuling_{i,t}$  is then defined as the number of court cases for firm  $i$  in year  $t$  which conclude with a ruling in which the generic drug is allowed to enter into the market.

Given our hypothesis about the effect of the *FTC v. Actavis* ruling, in the absence of pay-for-delay settlements, the number of cases with court rulings and cases in which the generic drug allowed to enter the market is predicted to go up for the affected firms after the ruling. Table 8 provides the estimation results for the litigation outcomes with the diff-in-diff analysis. Both outcomes are significantly positive, confirming that the affected firms become more likely to wait for court rulings (rather than settling), which tend to lead to direct entry by competitors, as previously noted.

— Insert Table 8 Here —

#### 6.6.4 Financial Outcomes

We next examine broader firm-level financial outcomes around the *FTC v. Actavis* ruling. In particular, we examine R&D expenditures to see the overall firm investment, and also cash holdings and the capital structure to see the ways that firms are funding their increase in innovation outcomes. In line with an increase in project initiations and acquisitions, we see a relative increase in R&D expenditure of 17% of total assets for the affected firms, consistent with firms planning new projects. Hand-in-hand with this increase in R&D expenses, cash holdings significantly decrease and leverage goes up. This suggests that firms are drawing down their cash holdings and increasing their debt in order to fund new R&D, which is in line with in-house innovations and external acquisitions being financed by a combination



of internal cash and external (debt) financing. Lastly, consistent with affected firms losing monopoly profits from generic entries, we document that their profitability significantly decreases.

— Insert Table 9 Here —

## 7 Therapeutic Area Analysis

In the final part of our analysis, we explore the aggregate implications of these effects by examining the overall innovation activity in specific therapeutic categories. The aggregate effects are not *a priori* clear-cut. On the one hand, we have shown that incumbents increase their innovation activity in response to generic entry when hindered in their ability to use pay-for-delay agreements. On the other hand, increased innovative activity on the part of incumbents may serve as a deterrent to potential (non-generic) entrants, as it may be more difficult to compete against the incumbent's increased efforts. Furthermore, a diminished ability to protect monopoly power may weaken the ex ante incentives of firms that innovate in order to gain that monopoly power.<sup>32</sup>

We explore this issue by examining a variety of outcomes over our sample period at the aggregated therapeutic category level, which we index by  $j$ . More specifically, we examine the total number of project suspensions,  $Suspensions_{j,t}$ , and acquisitions of new projects,  $DrugAcq_{j,t}$ . Since we are particularly interested in the development of new drugs, we also count the total number of new drug project initiations,  $Initiations_{j,t}$ , and further subdivide this count into drug project initiations by incumbent firms,  $IncInitiation_{j,t}$ , and drug project initiations by new entrants,  $EntInitiation_{j,t}$ . Finally,  $Entrants_{j,t}$  is the number of firms entering into the therapeutic category with new drug projects. It should be emphasized that the entrants defined here are *not* the generic manufacturers aiming to produce their current drugs with Para-IV filings, but rather are firms that are developing their own brand-name

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<sup>32</sup>Indeed, motivating entrants was the rationale behind the FDA introducing a marketing exclusivity period for newly approved drugs.

drugs. We include fixed effects by therapeutic category and year, as well as several controls, including the lagged number of projects under development in the category, the number of incumbent firms operating in the category, and the average likelihood of approval for all current projects in the category.

With these outcome variables, we run a diff-in-diff specification. Our treatment variable is  $ExcluLoss_{2013-2016_j}$ , a binary variable that takes a value of one if area  $j$  has at least one approved product lose its market exclusivity between 2013 and 2016, and zero otherwise. We multiply this variable with the  $Post_t$  variable to construct the diff-in-diff estimator in this setting. Our results are robust to using alternative measures such as the realized number of Para-IV filings or the number of drugs losing their exclusivity in the post-treatment period.

The results are given in Table 10. Consistent with our firm-level analysis, we find that the therapeutic areas affected by the *FTC v. Actavis* ruling have a relatively smaller number of drug suspensions and a greater number of drug acquisitions. Interestingly, column (3) shows that the *total* number of initiations of new drugs in a given category increases in response to the shock, although the effect is insignificant. Examining this effect more closely, we find that in an affected area, incumbents respond by increasing their initiations significantly (column 4). However, we find negative effects with respect to new entrants in the therapeutic area after examining the extensive margin in columns (4) and (6). In particular, following the ruling, there is a *decline* in the number of new entrants into the affected area, as well as a decline in the number of drug trials initiated by entering firms. This result also sheds light on the structure of competition following the *FTC v. Actavis* ruling: while competition for *existing* drugs increases following the ruling, via increased generic competition, competition for *new* ideas declines, due to fewer entering firms.

— Insert Table 10 Here —

Put together, the results suggest an interesting consequence of the constraint on pay-for-delay agreements. On the one hand, at a more highly aggregated level, restricting pay-for-delay agreements seems to have increased innovation by firms already operating in a given

therapeutic area. On the other hand, new (non-generic) entrants appear to have diminished incentives to innovate in a therapeutic area in response to generic filings following the ruling. There are numerous potential reasons for this result. Unlike the incumbent companies that are motivated to maintain their market position, entrants may be concerned about their loss of profitability from increased generic activity, given the unavailability of pay-for-delay agreements that previously staved off generics from entering the market. Alternatively, it may be that the increased innovation activity by incumbent firms serves as a deterrent to new companies entering the space, given the incumbent's built-up stock of knowledge capital from bringing its earlier drug to market.<sup>33</sup>

Our results are broadly consistent with results pointed out in previous empirical and theoretical work about the dynamics of incumbent responses to increased competition. Lichtenberg and Philipson (2002) note that market competition in the pharmaceutical industry can take on the forms of both within-patent and between-patent competition. Generic replacement is an example of within-patent competition, while *better* novel drugs under new patents are an example of between-patent competition. These different types of competition have differing effects in terms of innovation outcomes. For example, Gilchrist (2016) finds that a one-year increase in the marketing exclusivity period of a newly approved drug increases subsequent entry by 0.2 drugs. Our results add the new insight that antitrust regulation in innovative sectors may result in one type of competition (within) increasing at the expense of the other (between).

Our findings also map to the theoretical work of Segal and Whinston (2007). While antitrust policy in innovative industries usually focuses on the trade-off between R&D incentives and monopoly pricing, there is also a dynamic tension between incumbents and potential new innovators. New inventors stand on the shoulders of the old ones and may replace them. However, once entrants successfully do so, they themselves become the targets of newcomers. Limiting the ability of incumbents to create market barriers permits new

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<sup>33</sup>See, for example, Krieger et al. (2021) for an example of how built-up knowledge capital can keep incumbents in a given space, but can cause new entrants to flee a space given a negative shock.

entry but does not guarantee it, because the same restrictions will apply to the new entrants once they succeed and gain market share.

## 8 Conclusion

In this paper, we examine the relationship between competition and innovation through exploring a particular legal mechanism by which firms may endogenously maintain their market power: pay-for-delay agreements. We explore this using detailed data from the pharmaceutical industry, using a Supreme Court ruling that made such agreements legally risky and subject to antitrust enforcement. Before the ruling, we find a negative relationship between competitive entry and innovation by incumbent firms, but this relationship reverses itself following the ruling. Furthermore, treated firms pursue more “impactful” innovation from a scientific and commercial standpoint following the ruling. These results suggest that firms that are able to protect their monopoly power through pay-for-delay agreements face dampened incentives to innovate, and that restricting such agreements through antitrust law may increase their innovation incentives. However, we also show that the ruling had a negative effect on firm entry into areas with heavy generic competition, suggesting that the effects on competition at the extensive margin may differ.

Overall, our results provide evidence for a complex effect of competition on innovation. This has implications for the use of antitrust law to promote innovation. In particular, the results suggest that a nuanced approach must be taken to regulation aimed at influencing competition. If the regulatory goal is to stimulate innovation, then it is not enough to enact laws and regulations that increase competition. Rather, the encouragement of increased competition has to be accompanied by initiatives that limit the contracting options for incumbents to nullify the regulatory attempt to elevate competition. Only when this is done can greater competition stimulate innovation.

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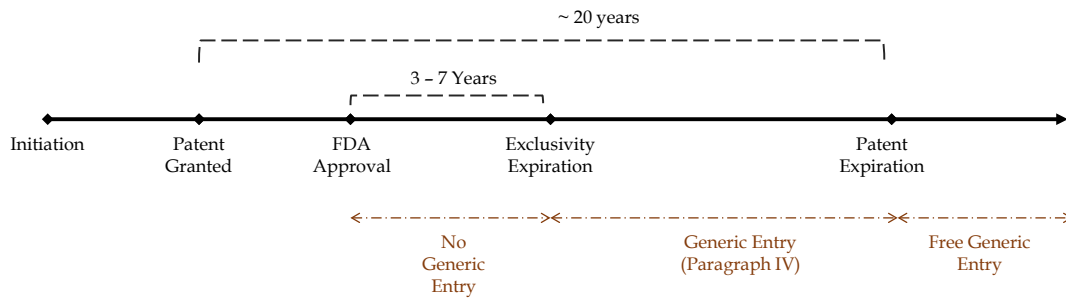


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# Figures

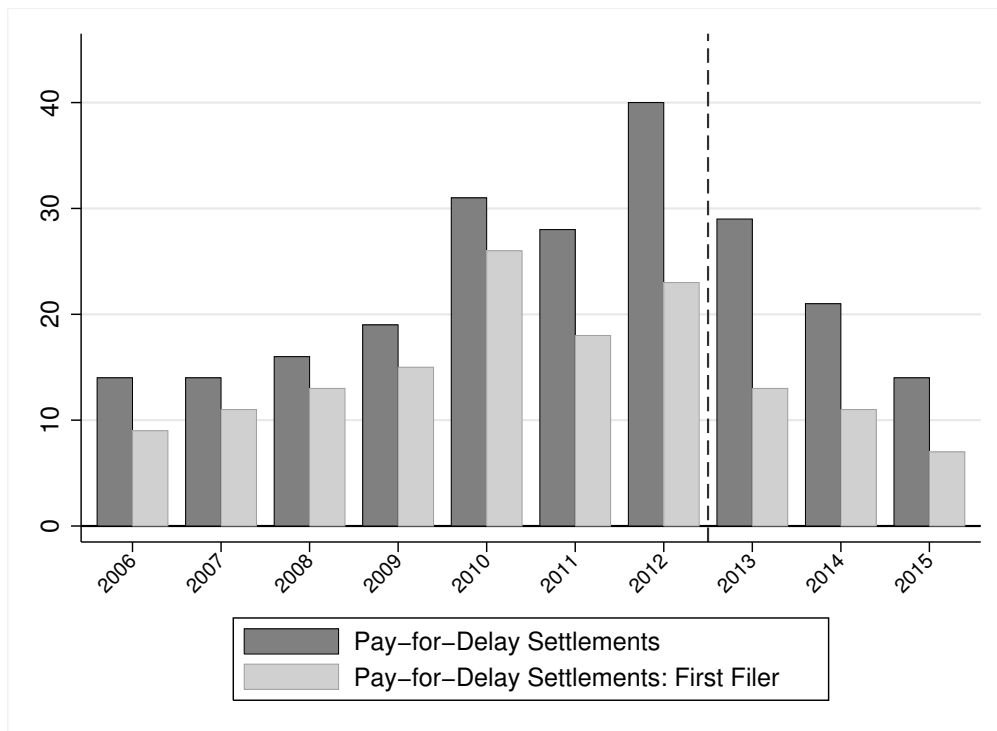
**Figure 1: Timeline of Generic Entry for a Given Drug**

This figure plots the timeline of generic entry for each brand-name drug.



## Figure 2: Pay-for-Delay Settlements over Time

This figure plots the trend of pay-for-delay settlements around the decision of *FTC v. Actavis* (dashed line). Data are from the FTC's annual report on Medicare Modernization Act Agreement Filings.

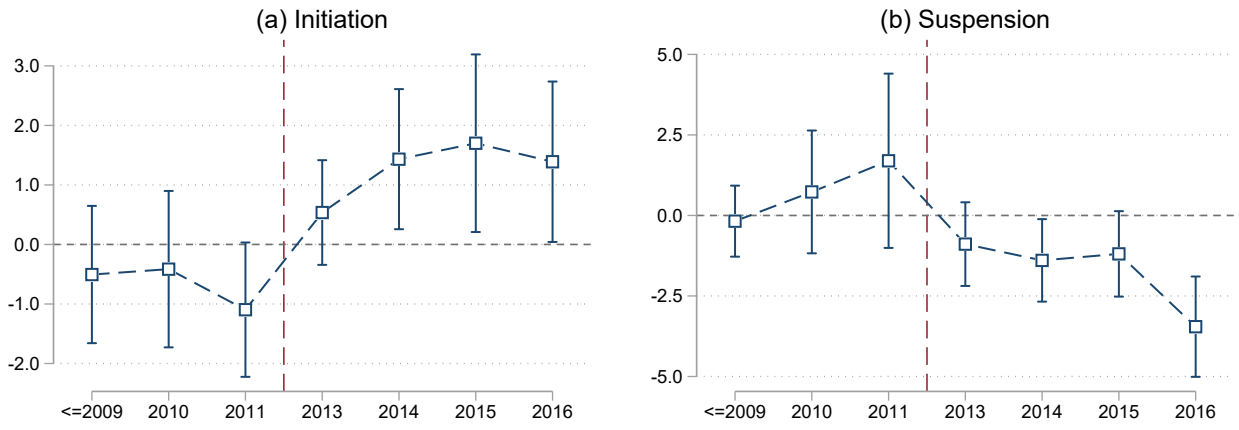


### Figure 3: Diff-in-Diff Coefficient Dynamics

This figure provides coefficient dynamics for the diff-in-diff estimation in Table 4 by estimating the following equation:

$$Y_{i,t} = \alpha + \sum_{k=2009, k \neq 2012}^{2016} \beta_1 ExcluLoss_{2013-2016}_i \times \mathbf{1}(t = k) + \gamma Controls_{i,t} + \mu_i + \lambda_t + \varepsilon_{i,t}.$$

$\mathbf{1}(t = k)$  is the indicator function that equals to one if the current year  $t$  is  $k$ . For example,  $\mathbf{1}(t = 2010)$  indicates that the current year is 2010. The left boundary year 2009 includes all sample years before 2009. 95% confidence interval bands are shown along with the point estimates.



# Tables

**Table 1: Pay-for-Delay Settlements over Time**

This table summarizes the number of brand-name drugs involved with Para-IV ANDA filings and their settlement information. In the first row, we count the number of brand-name drugs that receive Para-IV filings for the first time in each year. The Para-IV filing information is from the FDA’s website. For each branded drug, we aggregate over the dosage form and strength. The remaining rows are from the FTC’s annual report on Medicare Modernization Act Agreement Filings, which document settlement information. The second row counts the number of settlements with first generic filers. The third row counts the number of settlements with pay-for-delay agreements, including all generic filers. The last row only counts the number of pay-for-delay settlements with first generic filers.

<i>Year:</i>	<i>2005</i>	<i>2006</i>	<i>2007</i>	<i>2008</i>	<i>2009</i>	<i>2010</i>	<i>2011</i>	<i>2012</i>	<i>2013</i>	<i>2014</i>	<i>2015</i>
Brand-name Drugs with First Para-IV Filers	38	34	44	58	59	45	40	40	44	40	40
Settlements Involving First Filers	5	11	16	29	32	49	54	43	41	53	39
Pay-for-Delay Settlements	3	14	14	16	19	31	28	40	29	21	14
Pay-for-Delay Settlements Involving First Filers	2	9	11	13	15	26	18	23	13	11	7

**Table 2: Summary Statistics**

This table provides the summary statistics for the main variables. Panel A summarizes the variables at the firm level.  $Initiations_{i,t}$  is the number of new drug trial initiations for firm  $i$  in year  $t$ .  $Suspensions_{i,t}$  is the number of suspensions of drug trials firm  $i$  in year  $t$ .  $ExcluLoss2013-2016_i$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable that takes a value of one if year  $t$  is 2013 or later.  $AvgChance_{i,t}$  is the average likelihood of approval of a firm's drug portfolio.  $P1_{i,t}$ ,  $P2_{i,t}$  and  $P3_{i,t}$  are the number of active projects in a firm's phase 1, 2 and 3 drug portfolios, respectively. The financial variables are the natural log of total assets  $log(TA)_{i,t}$ , cash holdings  $Cash/TA_{i,t}$ , R&D expenditures  $R\&D/TA_{i,t}$ , and leverage ratio  $Debt/TA_{i,t}$ . The statistics include the number of observations ( $N$ ), Mean ( $Mean$ ), standard deviation ( $Std$ ), 25th percentile ( $p25$ ), median ( $p50$ ), and 75th percentile ( $p75$ ). In Panel B, the distribution of  $ParaIV_{i,t}$  is provided.  $ParaIV_{i,t}$  is the number of firm  $i$ 's drugs affected by Paragraph IV entrants.

**Panel A: Summary Statistics**

<i>Variables</i>	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>p25</i>	<i>p50</i>	<i>p75</i>
$Initiations_{i,t}$	3618	2.007	4.969	0.000	1.000	2.000
$Suspensions_{i,t}$	3618	1.507	5.067	0.000	0.000	1.000
$ExcluLoss2013-2016_i$ $\times Post_t$	3618	0.063	0.243	0.000	0.000	0.000
$AvgChance_{i,t}$	3618	17.853	14.032	8.000	15.200	24.333
$P1_{i,t}$	3618	3.072	8.440	0.000	1.000	2.000
$P2_{i,t}$	3618	5.269	13.670	0.000	2.000	4.000
$P3_{i,t}$	3618	2.622	7.348	0.000	1.000	2.000
$log(TA)_{i,t}$	3613	4.274	2.360	2.761	4.070	5.265
$Cash/TA_{i,t}$	3613	0.641	0.301	0.408	0.737	0.907
$R\&D/TA_{i,t}$	3606	0.545	0.712	0.151	0.322	0.599
$Debt/TA_{i,t}$	3584	0.391	1.005	0.000	0.033	0.299

**Panel B: Para IV Distribution**

$ParaIV_{i,t}$	0	1	2	3	4	> 4
<i>Count</i>	3,391	125	52	26	10	14
<i>Percentage</i>	93.73%	3.45%	1.44%	0.72%	0.28%	0.39%

**Table 3: Generic Entry and Innovation Activity, Before and After *FTC v. Actavis***

This table provides estimation results for innovation outcomes for equation (1) around the *FTC v. Actavis* ruling.  $ParaIV_{i,t}$  is the number of firm  $i$ 's drugs affected by Paragraph IV entrants in year  $t$ .  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Initiations_{i,t}$  is the number of new drug trial initiations.  $Suspensions_{i,t}$  is the number of suspensions of drug trials. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)
	$Initiations_{i,t}$	$Initiations_{i,t}$	$Suspensions_{i,t}$	$Suspensions_{i,t}$
$ParaIV_{i,t-1}$	-0.200 (-0.926)	-0.396* (-1.920)	0.911** (2.116)	1.104** (2.196)
$ParaIV_{i,t-1} \times Post_t$		1.257*** (3.027)		-1.376* (-1.851)
$ParaIV_{i,t-2}$	-0.584*** (-4.107)	-0.721*** (-4.030)	0.664* (1.799)	0.873*** (4.110)
$ParaIV_{i,t-2} \times Post_t$		1.045*** (2.874)		-1.391*** (-2.777)
Controls	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	3,319	3,319	3,319	3,319
Adj. $R^2$	0.87	0.88	0.80	0.82

**Table 4: Exclusivity Loss Diff-in-Diff Regressions: Project Initiations and Suspensions**

This table provides estimation results for innovation outcomes for equation (2). Columns (1) and (2) provide results at the firm-year level, while the remaining columns provide results at the firm-ICD-year level. *ExcluLoss*<sub>2013-2016</sub> is a dummy variable that takes a value of one if the firm or firm-ICD has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise. *Post*<sub>*t*</sub> is a dummy variable that takes a value of one if the year is 2013 or later. *Initiations*<sub>*i,t*</sub> is the number of new drug trial initiations. *Suspensions*<sub>*i,t*</sub> is the number of suspensions of drug trials. For the firm-level regressions, control variables include *log(TA)* and the lagged values of *AvgChance*, *P1*, *P2*, *P3*, *EBIT/TA*, *Cash/TA*, *R&D/TA*, and *Debt/TA*. Firm-ICD controls include the lagged number of drugs in each phase in a firm's specific ICD category (*P1*<sub>*i,j,t*</sub>, *P2*<sub>*i,j,t*</sub>, and *P3*<sub>*i,j,t*</sub>), as well as the lagged average probability of success for that ICD category (*AvgChance*<sub>*i,j,t*</sub>). Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)	(5)	(6)
	<i>Initiations</i> <sub><i>i,t</i></sub>	<i>Suspensions</i> <sub><i>i,t</i></sub>	<i>Initiations</i> <sub><i>i,j,t</i></sub>	<i>Suspensions</i> <sub><i>i,j,t</i></sub>	<i>Initiations</i> <sub><i>i,j,t</i></sub>	<i>Suspensions</i> <sub><i>i,j,t</i></sub>
<i>ExcluLoss</i> <sub>2013-2016</sub> $\times$ <i>Post</i> <sub><i>t</i></sub>	1.745*** (2.852)	-1.990*** (-3.627)	0.286** (2.195)	-0.086* (-1.899)	0.332** (2.368)	-0.088* (-1.899)
Observation Unit	Firm	Firm	Firm-ICD	Firm-ICD	Firm-ICD	Firm-ICD
Controls	Y	Y	Y	Y	Y	Y
Firm FE	Y	Y	N	N	N	N
Year FE	Y	Y	Y	Y	N	N
Category-Year FE	N	N	N	N	Y	Y
Firm-Category FE	N	N	Y	Y	Y	Y
N	3,549	3,549	24,666	24,666	24,665	24,665
Adj. <i>R</i> <sup>2</sup>	0.87	0.80	0.47	0.32	0.47	0.31



**Table 5: Exclusivity Loss and Affected Drug Importance**

This table provides estimation results for innovation value outcomes for equation (2), split based on the relative importance of affected drugs.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $HSale_i$  takes a value of one if company's exclusivity-expiring drug is in the top 100 sales (blockbuster drugs).  $LSale_i$  takes a value of one if company's exclusivity-expiring drug is not the in top 100 sales.  $HNum_i$  takes a value of one if company is above-median in terms of number of exclusivity-expiring drugs.  $LNum_i$  takes a value of one if company is below-median in terms of number of exclusivity-expiring drugs.  $Initiations_{i,t}$  is the number of new drug trial initiations.  $Suspensions_{i,t}$  is the number of suspensions of drug trials. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)
	$Initiations_{i,t}$	$Suspensions_{i,t}$	$Initiations_{i,t}$	$Suspensions_{i,t}$
$ExcluLoss_{2013-2016_i}$ $\times Post_t \times HSale_i$	3.826*** (3.479)	-4.497*** (-3.676)		
$ExcluLoss_{2013-2016_i}$ $\times Post_t \times LSale_i$	0.457 (0.654)	-0.438 (-1.557)		
$ExcluLoss_{2013-2016_i}$ $\times Post_t \times HNum_i$			3.735*** (3.148)	-3.631*** (-3.491)
$ExcluLoss_{2013-2016_i}$ $\times Post_t \times LNum_i$			0.025 (0.090)	-0.573** (-2.089)
Controls	All	All	All	All
Firm FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	3,549	3,549	3,549	3,549
Adj. $R^2$	0.87	0.80	0.87	0.80

**Table 6: The Effects of Exclusivity Loss on Patent Quality**

This table provides results for patent quality. Each observation is a unique patent, indexed by  $k$ . The sample consists of patents filed by the sample firms from 2005 to 2016. Panel A summarizes the main variables, and Panel B provides the estimation results.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if the patent developer  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Cites$  is the number of forward citations received by the patent.  $AdjCites$  is the number of forward citations divided by the average citations received by patents filed in the same year and same technology class.  $MktVal$  is the market value (in millions of dollars) of the patent based on stock returns.  $RMktVal$  is the real market value (in millions of 1982 dollars) of the patent based on stock returns.  $PctKnowledge$  is the percent of citations made by the patent that are based on the applicant firm's existing knowledge base. Existing knowledge base is defined as a firm's patents filed in the past five years, and other firms' patents cited by the firm's patents filed over the past five years. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . T-statistics are reported in parentheses, and heteroskedasticity robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

**Panel A: Summary Statistics**

<i>Variables</i>	<i>N</i>	<i>Mean</i>	<i>Std</i>	<i>p25</i>	<i>p50</i>	<i>p75</i>
$Cites_{k,t}$	17,971	5.488	13.507	0.000	1.000	5.000
$AdjCites_{k,t}$	17,971	0.707	1.608	0.000	0.151	0.699
$MktVal_{k,t}$	17,971	71.805	131.330	6.343	16.706	74.217
$RMktVal_{k,t}$	17,971	30.421	55.046	2.727	7.105	31.798
$PctKnowledge_{k,t}$	17,971	0.357	0.417	0.000	0.077	0.842

**Panel B: Regression Results**

	(1)	(2)	(3)	(4)	(5)
	$Log(Cites)_{k,t}$	$Log(AdjCites)_{k,t}$	$Log(MktVal)_{k,t}$	$Log(RMktVal)_{k,t}$	$PctKnowledge_{k,t}$
$ExcluLoss_{2013-2016_i}$	0.383***	0.170***	0.106***	0.101***	-0.034**
$\times Post_t$	(10.098)	(9.446)	(4.178)	(4.395)	(-2.273)
Controls	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y
N	17,794	17,794	17,794	17,794	17,794
Adj. $R^2$	0.20	0.18	0.84	0.84	0.18

**Table 7: The Effects of Exclusivity Loss on Other Drug-related Outcome Variables**

This table provides estimation results for other drug-related outcome variables.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $DrugAcq_{i,t}$  is the number of acquisitions of drugs from other companies in the year.  $BTD_{i,t}$  is the number of drug projects that receive Breakthrough Therapy designation in the year.  $OrphanDrug_{i,t}$  is the number of drug projects that receive Orphan Drug designation in the year. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)
	$DrugAcq_{i,t}$	$BTD_{i,t}$	$OrphanDrug_{i,t}$
$ExcluLoss_{2013-2016_i} \times Post_t$	1.185*** (3.139)	0.578*** (4.125)	0.494* (1.867)
Controls	Y	Y	Y
Firm FE	Y	Y	Y
Year FE	Y	Y	Y
N	3,549	3,549	3,549
Adj. $R^2$	0.25	0.35	0.57

**Table 8: The Effects of Exclusivity Loss on Litigation Outcomes**

This table provides estimation results for litigation outcomes.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if the firm has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable that takes a value of one if the year is 2013 or later.  $CourtNum_{i,t}$  is the number of cases which end up with a court ruling.  $EntryRuling_{i,t}$  is the number of cases where the generic drug is allowed to enter the market. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)
	$CourtNum_{i,t}$	$EntryRuling_{i,t}$
$ExcluLoss_{2013-2016_i} \times Post_t$	0.175** (2.495)	0.077** (2.280)
Controls	Y	Y
Firm FE	Y	Y
Year FE	Y	Y
N	3,549	3,549
Adj. $R^2$	0.04	0.03

**Table 9: The Effects of Exclusivity Loss on Financial Variables**

This table provides estimation results for financial outcomes.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if the firm has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable that takes a value of one if the year is 2013 or later. The financial variables include R&D expenditures  $R\&D/TA$ , cash holdings  $Cash/TA$ , leverage ratio  $Debt/TA$ , and profitability  $EBIT/TA$ . Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)
	$R\&D/TA_{i,t}$	$Cash/TA_{i,t}$	$Debt/TA_{i,t}$	$EBIT/TA_{i,t}$
$ExcluLoss_{2013-2016_i}$	0.174***	-0.067***	0.136**	-0.327***
$\times Post_t$	(3.114)	(-3.405)	(2.148)	(-2.776)
Controls	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	3,542	3,549	3,535	3,547
Adj. $R^2$	0.55	0.69	0.61	0.67

**Table 10: Overall Effect on Innovation by Therapeutic Area**

This table shows results at the therapeutic category level  $j$ .  $ExcluLoss_{2013-2016_j}$  takes a value of one if the area  $j$  has at least one approved product losing its marketing exclusivity between 2013 and 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Suspensions_{j,t}$  is the number of suspensions of drug trials in area  $j$ .  $DrugAcq_{j,t}$  is the number of acquisitions of drugs from other companies in area  $j$ .  $Initiations_{j,t}$  is the total number of new drug trial initiations in area  $j$ .  $IncInitiation_{j,t}$  and  $EntInitiation_{j,t}$  are the numbers of initiations by incumbents and new entrants, respectively.  $Entrants_{j,t}$  is the number of firms entering into therapeutic area  $j$ . Regressions are run from 2005 to 2016. Control variables include the lagged number of projects under development in the category, the average likelihood of approval for all current projects in the category, and the number of incumbent firms operating in the category. T-statistics are reported in parentheses, and robust standard errors are clustered at the category level. A constant term (not reported) is included in all regressions. Category and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

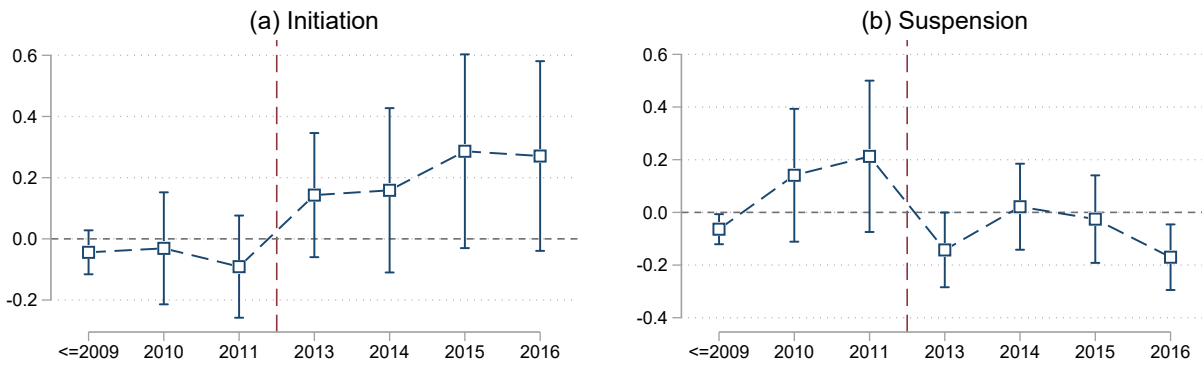
	(1)	(2)	(3)	(4)	(5)	(6)
	$Suspensions_{j,t}$	$DrugAcq_{j,t}$	$Initiations_{j,t}$	$EntInitiation_{j,t}$	$IncInitiation_{j,t}$	$Entrants_{j,t}$
$ExcluLoss_{2013-2016_j} \times Post_t$	-1.297*** (-2.734)	0.772* (1.890)	0.496 (0.953)	-1.197*** (-4.244)	1.694*** (2.964)	-1.183*** (-4.493)
$NumDrugs_{j,t-1}$	0.158*** (4.288)	0.027* (1.689)	0.056 (1.051)	0.001 (0.035)	0.055 (0.760)	-0.001 (-0.056)
$AvgAppProb_{j,t-1}$	-0.004 (-0.573)	-0.002 (-0.580)	-0.026*** (-3.564)	0.008 (0.967)	-0.034*** (-3.221)	0.011 (1.478)
$NumFirms_{j,t-1}$	-0.104** (-2.091)	0.010 (0.474)	0.102 (1.516)	-0.034 (-1.029)	0.137 (1.574)	-0.056* (-1.690)
Category FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y
N	1,649	1,649	1,649	1,649	1,649	1,649
Adj. $R^2$	0.82	0.33	0.84	0.64	0.62	0.63

# Internet Appendix (for online publication)

## Appendix A: Additional Results

**Figure A.1: Diff-in-Diff Coefficient Dynamics at the Firm-Category Level**

This figure provides coefficient dynamics for the diff-in-diff estimation in Table 4. The detail is similar to Figure 3 except that the estimation is performed at the firm-category level.



**Table A.1: Robustness—Placebo Test**

This table provides placebo estimation results for innovation outcomes. *ExcluLoss2009-2012* is a dummy variable that takes a value of one if the firm or firm-ICD has a drug with exclusivity expiring from 2009 to 2012, and zero otherwise. *PseudoPost* is a dummy variable that takes a value of one if the year is 2009 or later. *Initiations<sub>i,t</sub>* is the number of new drug trial initiations. *Suspensions<sub>i,t</sub>* is the number of suspensions of drug trials. Control variables include  $\log(TA)$  and the lagged values of *AvgChance*, *P1*, *P2*, *P3*, *EBIT/TA*, *Cash/TA*, *R&D/TA*, and *Debt/TA*. Regressions are run from 2005 to 2012. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)
	<i>Initiations<sub>i,t</sub></i>	<i>Suspensions<sub>i,t</sub></i>
<i>ExcluLoss2009-2012<sub>i</sub> × PseudoPost<sub>t</sub></i>	-0.049 (-0.129)	0.413 (1.025)
Controls	Y	Y
Firm FE	Y	Y
Year FE	Y	Y
N	1,806	1,806
Adj. <i>R</i> <sup>2</sup>	0.87	0.83



**Table A.2: Robustness—Poisson Model**

This table provides estimation results for innovation outcomes in a Poisson model. In the first two columns, a random effects model is estimated. In the last two columns, firm and year fixed effects are included.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Initiations_{i,t}$  is the number of new drug trial initiations.  $Suspensions_{i,t}$  is the number of suspensions of drug trials. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2012. T-statistics are reported in parentheses, and heteroscedasticity robust standard errors are included. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)
	$Initiations_{i,t}$	$Suspensions_{i,t}$	$Initiations_{i,t}$	$Suspensions_{i,t}$
$ExcluLoss_{2013-2016_i}$ $\times Post_t$	0.130*** (3.648)	-0.368*** (-9.489)	0.172*** (3.132)	-0.341*** (-5.351)
Controls	Y	Y	Y	Y
Firm FE	N	N	Y	Y
Year FE	N	N	Y	Y
N	3,586	3,586	3,020	2,719

**Table A.3: Robustness—Propensity Score Matching**

This table provides estimation results for innovation outcomes using a propensity score matched sample. We match on  $\text{Log}(TA)$  and  $\text{AvgChance}$  in 2012 based on the nearest neighbor for each treatment firm. We restrict our matched sample to a precision difference cutoff of 0.025. Panel A shows the summary statistics of financial variables from 2009 to 2012. Panel B shows the regression results.  $\text{ExcluLoss}_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $\text{Post}_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $\text{Initiations}_{i,t}$  is the number of new drug trial initiations.  $\text{Suspensions}_{i,t}$  is the number of suspensions of drug trials. Control variables include  $\text{log}(TA)$  and the lagged values of  $\text{AvgChance}$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $\text{EBIT}/TA$ ,  $\text{Cash}/TA$ ,  $\text{R\&D}/TA$ , and  $\text{Debt}/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

**Panel A: Summary Statistics for the Matched Sample from 2009 to 2012**

	<i>Control Obs.</i>	<i>Treat Obs.</i>	<i>Mean of Control</i>	<i>Mean of Treat</i>	<i>Diff.</i>	<i>t-stat</i>	<i>p-value</i>
<i>Log(TA)</i>	101	103	4.887	5.020	-0.134	-0.550	0.568
<i>EBIT/TA</i>	100	103	-0.398	-0.289	-0.110	-1.300	0.204
<i>Cash/TA</i>	100	103	0.636	0.576	0.060	1.500	0.136
<i>R&amp;D/TA</i>	100	103	0.422	0.369	0.054	0.800	0.433
<i>Debt/TA</i>	100	103	0.203	0.276	-0.074	-1.150	0.243

**Panel B: Regression Results for the Matched Sample**

	(1)	(2)
	<i>Initiations<sub>i,t</sub></i>	<i>Suspensions<sub>i,t</sub></i>
<i>ExcluLoss</i> <sub>2013-2016<sub>i</sub> × <i>Post<sub>t</sub></i></sub>	1.214* (1.732)	-0.725*** (-2.891)
Controls	Y	Y
Firm FE	Y	Y
Year FE	Y	Y
N	547	547
Adj. <i>R</i> <sup>2</sup>	0.71	0.39

**Table A.4: Robustness—Restricted Sample**

This table provides estimation results for innovation outcomes in restricted samples. In the first two columns, only firms with at least one drug approved after 2005 are included. In the last two columns, only firms with at least one active drug project in the affected disease categories are included.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Initiations_{i,t}$  is the number of new drug trial initiations.  $Suspensions_{i,t}$  is the number of suspensions of drug trials. Control variables include  $\log(TA)$  and the lagged values of  $AvgChance$ ,  $P1$ ,  $P2$ ,  $P3$ ,  $EBIT/TA$ ,  $Cash/TA$ ,  $R\&D/TA$ , and  $Debt/TA$ . Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)
	$Initiations_{i,t}$	$Suspensions_{i,t}$	$Initiations_{i,t}$	$Suspensions_{i,t}$
$ExcluLoss_{2013-2016_i} \times Post_t$	1.915*** (3.049)	-1.948*** (-3.478)	4.031** (2.645)	-2.687** (-2.458)
Controls	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	1,301	1,301	426	426
Adj. $R^2$	0.88	0.81	0.87	0.78

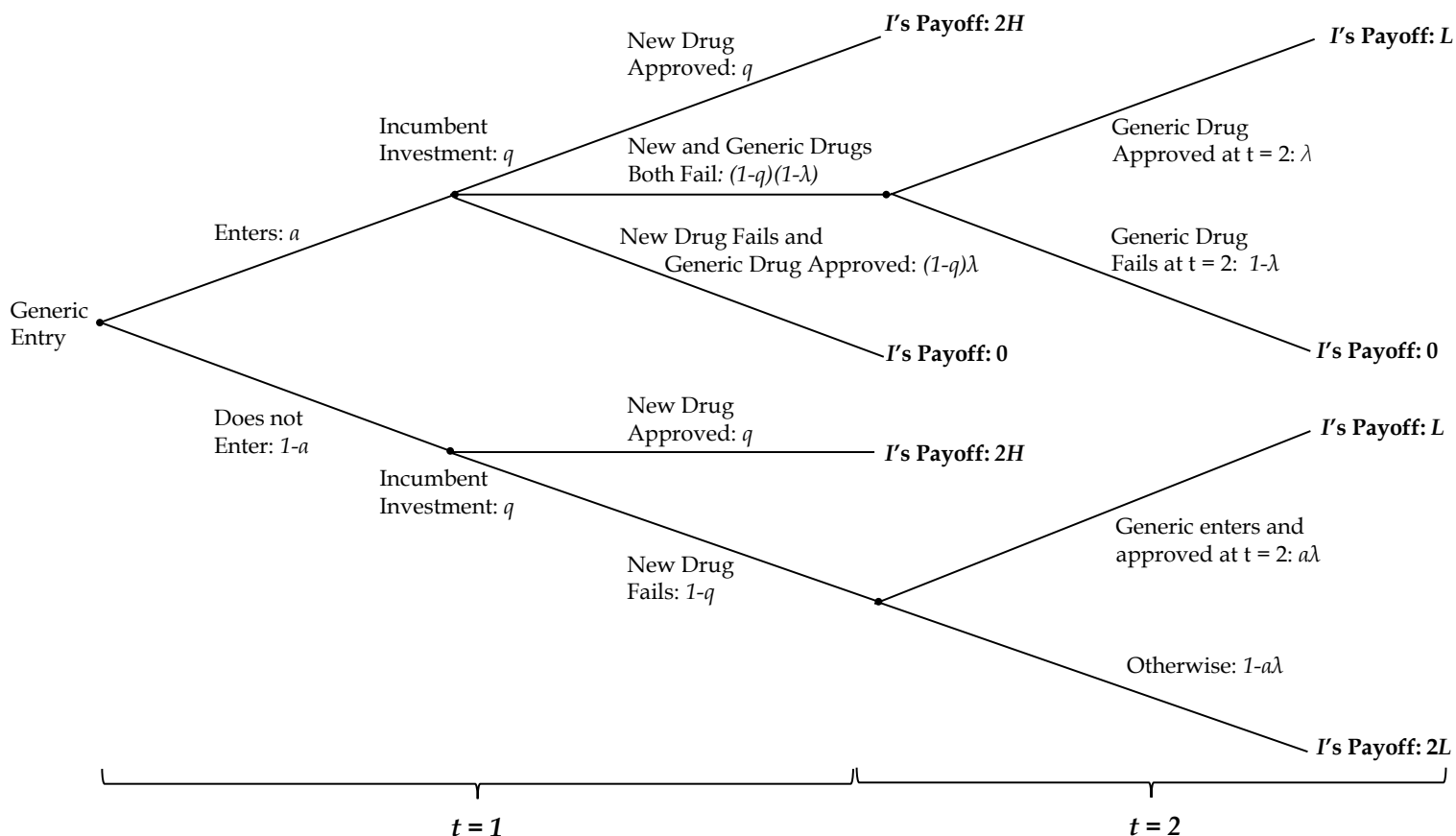
**Table A.5: Robustness—ICD Category Controls**

This table provides estimation results for innovation outcomes with additional ICD control variables. In addition to all the control variables included in the main specification, we add 157 control variables, each of which counts the number of active projects in a particular area.  $ExcluLoss_{2013-2016_i}$  is a dummy variable that takes a value of one if firm  $i$  has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise.  $Post_t$  is a dummy variable which takes a value of one if year  $t$  is 2013 or later.  $Initiations_{i,t}$  is the number of new drug trial initiations.  $Suspensions_{i,t}$  is the number of suspensions of drug trials. Regressions are run from 2005 to 2016. T-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. A constant term (not reported) is included in all regressions. Firm and year fixed effects are included in all specifications, as indicated. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)
	$Initiations_{i,t}$	$Suspensions_{i,t}$
$ExcluLoss_{2013-2016_i} \times Post_t$	0.543* (1.691)	-1.178*** (-3.353)
ICD Controls	Y	Y
Controls	Y	Y
Firm FE	Y	Y
Year FE	Y	Y
N	3,549	3,549
Adj. $R^2$	0.91	0.86

# Appendix B: Model

Figure A.2: Timeline



## Model Setup

There are two players, an incumbent (brand name) drug manufacturer,  $I$ , and a potential entrant  $E$ . The game has two periods, denoted by  $t = 1$  and  $t = 2$ , and the discount rate is zero.  $I$  decides whether to pay  $E$  and how much to spend on innovation in order to maximize total profits at an exogenously given  $t = 1$ . The timeline is shown in Figure A.2.

*Generic Entry:* At the beginning of  $t = 1$ ,  $E$  randomly enters with probability  $\alpha$  by filing a generic drug application. If it has not done so at  $t = 1$ , it randomly enters again with the same probability at  $t = 2$ . After it enters, in each period, there is a probability  $\lambda$  that the FDA approves the generic drug if  $I$  has not previously innovated a novel drug. The

approved generic drug will reduce the profits of the brand-name drug in each period to 0. Both  $\alpha$  and  $\lambda$  are exogenously given.

*Innovation:* After observing whether  $E$  enters at  $t = 1$ ,  $I$  decides how much to invest on innovation, which is denoted by  $q \in [0, 1]$ . The cost function of R&D investment is  $c(q) = cq^2/2$ . A greater investment in R&D leads to a higher likelihood of R&D success; specifically, With probability  $q$ , a novel drug is successfully developed and replaces the existing drug at  $t = 1$ . The novel drug generates cash flows of  $H$  and is protected by market exclusivity so that  $E$  cannot launch a generic drug in either  $t = 1$  and  $t = 2$ . With probability  $1 - q$ , the development fails and  $I$  stays with its initial drug, which generates a cash flow of  $L < H$  and is susceptible to generic entry in both periods.

*Pay-for-Delay:* If pay-for-delay strategies are allowed, after observing that  $E$  enters at  $t = 1$  but before making its R&D investment decision,  $I$  could pay  $E$  to withdraw its generic filing. This will guarantee that there will be no generic drugs launched in either period if innovation fails. For simplicity, we model this payment as a fixed reservation price  $p$  paid by  $I$  for  $E$  to quit development.

For simplicity, we assume that  $I$  can only invest or pay a realized entrant  $E$  at  $t = 1$ . This is for the ease of analysis; however the results still hold if we also allow actions at  $t = 2$ . After paying  $E$ , there will be no new potential entrants at  $t = 2$ . This reflects the fact that the litigation settlement process will put a stay on FDA's approval process. This could alternatively be modeled as a reduced chance of new entrants at  $t = 2$ .

We make the following assumption:

**Assumption 1.**  $p < p^* = \left(1 - \frac{2H}{c} + \frac{2+\lambda(1-\lambda)+(1-\lambda)^2}{2c}L\right) (2\lambda + (1 - \lambda)\lambda) L$ .

This assumption ensures that the price paid as part of the pay-for-delay strategy is such that the incumbent is willing to pay. We later relax this assumption, and allow for the price to be endogenously determined in a bargaining process.

## Analysis

We first examine the choice of  $I$  upon observing generic entry if  $I$  cannot engage in a pay-for-delay strategy.

**Hypothesis 1 (H1):** Without the possibility of pay-for-delay agreements, the incumbent firm will invest more in innovation when it observes entry by a generic firm in the first period.

*Proof.* If  $E$  enters at  $t = 1$ , the expected total profits of  $I$  are

$$V_1^E = \max_{0 \leq q \leq 1} q \times 2H + (1 - q) \lambda \times 0 + (1 - q) (1 - \lambda) (\lambda L + (1 - \lambda) 2L) - \frac{cq^2}{2}.$$

In the above equation, with probability  $q$ , the new drug is approved so the total payoff is  $2H$ . With probability  $(1 - q)\lambda$ , the new drug is not approved and the generic drug is approved at  $t = 1$ . If this is the case, the total profits are 0 for the incumbent. Lastly, with probability  $(1 - q)(1 - \lambda)$ , the new drug is not approved and the generic drug is not approved at  $t = 1$ . In the second period, if the generic is approved (with probability  $\lambda$ ), then the total profit is  $L$  for the incumbent. Otherwise, the total profit is  $2L$ . Solving the maximization problem generates:

$$q^E = \frac{2H - (1 - \lambda)(\lambda L + (1 - \lambda)2L)}{c}. \quad (3)$$

If  $E$  does not enter at  $t = 1$ , the expected total profits of  $I$  are

$$V_1^{NE} = \max_{0 \leq q \leq 1} q2H + (1 - q)(\alpha\lambda L + (1 - \alpha\lambda)2L) - \frac{cq^2}{2}.$$

In the above equation, with probability  $q$ , the new drug is approved so the total payoff is  $2H$ . With probability  $1 - q$ , the new drug is not approved. In the second period, if the generic drug enters and is approved (with probability  $\alpha\lambda$ ), then the total profit is  $L$  for the incumbent. Otherwise, the total profit is  $2L$ . Solving the maximization problem in this scenario generates:

$$q^{NE} = \frac{2H - (\alpha\lambda L + (1 - \alpha\lambda)2L)}{c}.$$

The investment is higher with  $E$  entering at  $t = 1$  (i.e.  $q^E > q^{NE}$ ) since

$$(1 - \lambda)(\lambda L + (1 - \lambda)2L) < \alpha\lambda L + (1 - \alpha\lambda)2L.$$

□

We first examine the choice of  $I$  upon observing generic entry in the case where  $I$  can engage in a pay-for-delay strategy.

**Hypothesis 2 (H2):** When an incumbent firm is able to use pay-for-delay agreements, then it will pay the competitor and reduce R&D investments when it observes entry by a generic firm in the first period.

*Proof.* Suppose  $I$  has paid  $E$  after it sees  $E$  make the decision to enter. Then the total profits of  $I$  are:

$$V_1^P = \max_{0 \leq q \leq 1} q2H + (1 - q)2L - p - \frac{cq^2}{2},$$

since  $q$  only affects the product profitability, which implies  $q^P = (2H - 2L)/c$ . As shown in the proof of **H1**, if  $E$  does not enter at  $t = 1$ , then

$$q^{NE} = \frac{2H - (\alpha\lambda L + (1 - \alpha\lambda)2L)}{c} > \frac{2H - 2L}{c} = q^P.$$

Therefore,  $I$ 's innovation investment will be lower if the generic firm enters and receives the pay-for-delay payment. It remains to be shown that  $I$  is willing to pay the price  $p$  instead of relying on innovation, i.e.  $V_1^P > V_1^E$ . This is equivalent to showing:

$$p < \left(1 - \frac{q^E + q^P}{2}\right) (2\lambda + (1 - \lambda)\lambda) L.$$

The right-hand side of the above equation is equivalent to

$$p^* = \left(1 - \frac{2H}{c} + \frac{2 + \lambda(1 - \lambda) + (1 - \lambda)^2}{2c} L\right) (2\lambda + (1 - \lambda)\lambda) L > 0.$$

□

Finally, we consider the case where the pay-for-delay price that  $I$  pays to  $E$  is endogenous. We endogenize the pay-for-delay price  $p$  using a simple bargaining protocol, where  $I$  makes a take-it-or-leave-it (TIOLI) offer to  $E$ . Define the cash flow that  $E$  receives from its generic drug in each period as  $x$ . Then the reservation price of  $E$  will be given as:

$$p = (1 - q^E) (\lambda 2x + (1 - \lambda)\lambda x).$$

Note that in the above equation, the generic firm can only receive profits when it rejects the offer (so  $I$  invests  $q^E$ ) and the new drug is not approved (with probability  $1 - q$ ). With this bargaining protocol, we have our last hypothesis.

**Hypothesis 3 (H3):** Pay-for-delay agreements will be more prevalent for high-sales incumbent drugs. In particular, there exists a cutoff  $L^*$  such that the incumbent will pay if  $L \geq L^*$ .

*Proof.* As shown in the proof of **H2**, the incumbent is willing to pay only if

$$p = (1 - q^E) (\lambda 2x + (1 - \lambda)\lambda x) < \left(1 - \frac{2H}{c} + \frac{2 + \lambda(1 - \lambda) + (1 - \lambda)^2}{2c} L\right) (2\lambda + (1 - \lambda)\lambda) L,$$



which is equivalent to:

$$x < L + \frac{2\lambda + \lambda(1 - \lambda)}{1 - q^E} L^2.$$

Now define  $f(L) = (2\lambda + \lambda(1 - \lambda)) L^2 + L$ . Since  $f(L)$  strictly increases for  $L > 0$ , there exists a  $L^*$  such that  $f(L^*) = x$  and  $f(L) > x$  for all  $L > L^*$ . Therefore, for all  $L > L^*$ , we have

$$x < f(L) < L + \frac{2\lambda + \lambda(1 - \lambda)}{1 - q^E} L^2.$$

□