Paying off the Competition: Contracting, Market Power, and Innovation Incentives*

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Abstract

This paper explores the relationship between a firm's legal contracting environment and its innovation incentives. Using granular data from the pharmaceutical industry, we examine a contracting mechanism through which incumbents maintain market power: "pay-for-delay" agreements to delay the market entry of competitors. Exploiting a shock where such contracts become legally tenuous, we find that affected incumbents subsequently increase their innovation activity across a variety of project-level measures. Exploring the nature of this innovation, we also find that it is more "impactful" from a scientific and commercial standpoint. The results provide novel evidence that restricting the contracting space can boost innovation at the firm level. However, at the extensive margin we find a reduction in innovation by new entrants in response to increased competition, suggesting a nuanced effect on aggregate innovation.

Keywords: Drug Development, Pharmaceutical Industry, Contracting, 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, rewarding firms by limiting their competition, may encourage further innovation to reap monopoly profits. On the other hand, an incumbent firm under such protection may feel no need to innovate further with a guaranteed revenue stream from its product. Furthermore, the extent of protection may change an incumbent firm's strategic actions—such as licensing 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 boosting innovation by changing market competition, such as antitrust enforcement and patent policy.

In this paper, we examine how the legal contracting environment, which regulates the endogenous actions by firms to maintain their market power, affects innovation incentives. We provide evidence from a contracting mechanism used by innovative firms to deter competitors. Our setting is the pharmaceutical industry, which is a sector known for developing innovative products through its research and development (R&D) activities. In this industry, firms that are first to pass clinical trials and obtain Food and Drug Administration (FDA) approval enjoy several years of marketing exclusivity, during which no other firm can directly compete against that drug. However, after their marketing exclusivity expires, other firms may launch generic versions of the specific drug through 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"—with entering generic manufacturers, whereby the generic firm agrees to delay its product launch in exchange for cash. These agreements effectively provide an endogenous tool through which

incumbent firms can reduce the competition that they face.[1]

Testing how these agreements affect the competitive environment and innovation incentives is challenging, however, since generic entry and signing pay-for-delay agreements are contemporaneous endogenous decisions by both incumbents and entrants. To overcome these concerns, we use a Supreme Court ruling in 2013—*FTC v. Actavis*—which increased the legal risk of engaging in pay-for-delay agreements as a natural experiment. The ruling stated that under antitrust law, the Federal Trade Commission (FTC) could target such agreements, granting the FTC broader bargaining power in these antitrust settlements. Consistent with the increased legal risk, we document a sharp decline in the number of pay-for-delay agreements after the ruling, starkly reversing the previous trend. Furthermore, we show that the ruling did not seem to change the incentives of generic entrants, who filed at the same rate both before and after the ruling.[2] 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.

Using detailed project-level data on public pharmaceutical firms and their drug development portfolios, we conduct a difference-in-differences (diff-in-diff) analysis by exploiting incument firm's heterogeneity in the exposureto the ruling. Specifically, 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. We measure a firm's innovation activities by the number of new drug trials initiated and existing projects suspended in each therapeutic area it operates in.[3] These measures,

[1]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).

[2]This supports the view that generic firms did not enter to engage in pay-for-delay settlements; rather, these firms enter markets for profitable competition against branded (incumbent) drugs.

[3]A therapeutic category is a group of disease indications sharing high pathological correlations. Drugs

analyzing innovations across distinct R&D areas within firms, capture both the exploration of novel ideas and abatement of ongoing development. Furthermore, our data and setting permit us to measure real innovation activity through project decisions, rather than relying solely on patent-related metrics.[4]

Our analysis shows that affected firms *increased* their innovation activity following the ruling by raising project initiation rates and lowering suspension rates in therapeutic areas with drugs losing exclusivity.[5] The effects are economically significant, with affected firms increasing drug initiations by 5.7% as a fraction of previous portfolio size in areas facing imminent exclusivity expiration, and decreasing the rate of project suspensions by 2.8%. These magnitudes are equivalent to more than half of the unconditional average initiation and suspension frequencies.[6] Using granular fixed effects, we show that the results hold both within firms, when comparing project decisions in affected versus unaffected areas within a given firm, as well as across firms, when comparing the project decisions of different firms operating in the same therapeutic area. The results suggest that the relationship between generic competition and innovation is mediated by the ability of incumbent firms to protect their monopoly power through pay-for-delay agreements. Such contracting arrangements allow firms to resolve the uncertainty of product competition and reduce the need to maintain their competitive edge with new drugs. However, after this channel becomes legally risky, firms need to rely on innovation activities to escape neck-and-neck competition (e.g. Aghion

aimed at a specific category are plausibly close substitutes, and hence close competitors. We follow the Center for Medicare & Medicated Services' ICD-10 medical classification assessment and group diseases in the same subchapter level as the therapeutic category.

[4]We supplement our analysis with quality measures based on patents. We explain the institutional details that make patent counts a problematic measure of innovation in this setting.

[5]In untabulated results, we confirm that incumbent firms indeed reduced their levels of innovation following *realized* Paragraph IV generic entry *before FTC v. Actavis*. This relationship significantly reverses itself following this ruling. Put differently, when an incumbent pharma 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, consistent with our DID analysis.

[6]In subsequent tests, we show that these suspensions are voluntary and not due to drugs performing poorly in clinical trials. We also find that the affected firms are more likely to acquire projects from other firms, consistent with firms choosing to in-source existing projects as an alternative to in-house innovation (see, e.g., Krieger et al. (2022b)).

et al., 2005).[7]

We validate these results in several ways. First, we demonstrate that the parallel trend assumption likely holds in our setting, as the treatment and control groups do not exhibit significant differences in the main outcome variables before the shock. Second, we show that the loss in marketing exclusivity does not universally lead to changes in innovation; it crucially depends on the ability of firms to contract via pay-for-delay agreements.[8] In particular, we conduct a placebo test to demonstrate that the changes on innovation, following the loss of exclusivity, manifest for affected firms only after the *FTC v. Actavis* ruling. Instead, we do not observe any significant differences in initiations or suspensions if firms lost market exclusivity before the ruling. This result reiterates that firms resort to innovation when it becomes infeasible to fend off the competition with strategic contracting. We additionally show that our results are robust to numerous additional specifications and alternative sample selection criteria.[9]

We leverage additional data to delve deeper into our results. First, we conduct heterogeneity analyses and document that innovation responses vary based on incumbent firm's development portfolio strength, with stronger effects for firms with *weaker* pipelines. This is consistent with firms not feeling the need to bolster their R&D portfolios when they can stave off competitive entry through contracting; however, when their ability to contract is weakened, these firms without promising therapies in development have a pressing need to develop new drugs. Second, using patent-level data, we find evidence that affected firms pursue *higher-quality* innovation: the citations received by the affected firms' patents increase

[7]In untabulated results, we find that the increase in innovation concentrates among the less financially constrained treatment group—firms with relatively low outstanding debt or sufficient cash reserves. The weaker responses from more-constrained firms suggest that our effects are not due to pay-for-delay payments exacerbating financial constraints and thus dampening pre-ruling innovation. If cash spent on pay-for-delay agreements constrained firms and hindered innovation, a stronger effect in more-constrained firms would be expected.

[8]As a relevance test, we validate that our treatment variable—the loss of marketing exclusivity—does lead to generic manufacturers attempting to enter the market through additional Paragraph IV filings.

[9]In particular, we re-run our analysis with a propensity score-matched sample, using count regression models, dropping all control variables, and with different sample selection restrictions, among other robustness tests. We find consistent results with each of these tests.

and the economic value of new patents issued by those firms increases.

In the final part of our analysis, we explore the overall impact on innovations within a therapeutic category, in order to examine effects at the extensive margin and estimate the aggregation effects of firm decisions. At the overall therapeutic category level, we find a 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 may dampen entry into the area by *new* (non-generic) developers. This suggests that the ability of incumbent firms to stave off generic competition has implications not only for the decision to innovate by themselves but also for the decision to innovate by 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), and our results shed new light on the new channels through contracting agreements.

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; Cohen et al., 2019). Our paper contributes to these strands of the literature by providing evidence that the relationship between competition and innovation can depend on the contracting arrangements available to incumbent firms within the property rights and antitrust law system. Specifically, our results indicate that policy fostering greater competition leads to greater innovation only if strategic 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.[10] 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. Branstetter et al. (2022) 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. 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), leading to more of a focus on higher-value innovation.[11] 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).

While our paper also explores the setting of generic entry in the pharmaceutical industry, it differs by providing novel evidence on the effect of the contracting environment in mediating the effect of competition on innovation. The findings suggest that existing evidence on the relationship between competition and innovation may hinge crucially on the legal environment and the ability of firms to write contracts with competitors, such as pay-for-delay agreements in the case of the drug development industry. Our evidence thus points to an overlooked but important factor related to the legal contracting space that plays a role in the innovation decision-making process.

[10] 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.

[11] 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.

2 Institutional Setting and Conceptual Framework

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. We then provide a simple theoretical framework to help guide our empirical analyses and hypotheses.

2.1 Generic Entry in the Pharmaceutical Industry

The current regulatory landscape in the pharmaceutical industry, shaped by the Hatch-Waxman Act of 1984, aims to bolster consumer choice through increased competition. Prior to the enactment of this law, the FDA required generic drugs to replicate most of the original clinical trials in order to gain market approval, resulting in significant development costs. After the passage of the Hatch-Waxman Act, generic developers only need to demonstrate bioequivalence (the same clinical benefit) to the original drug, 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 framework has facilitated greater entry of cost-effective generic substitutes, intensifying competition for incumbent producers.[12]

Under the Hatch-Waxman Act, the timing of generic entry depends on the marketing exclusivity and patent protection of a new brand drug. A developing firm typically initiates the patent application early in the drug trial process. Generally, the term of each patent will last about 20 years from its application. If a drug survives a sequence of clinical trials, typically lasting 8 years (e.g. DiMasi and Grabowski, 2007), the firm will submit a New Drug Application (NDA) to the FDA for market approval. Upon approval, the FDA will grant exclusive marketing rights to the new product, preventing any possible generic entrants for

[12]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. Lo and Thakor (2022) and Lo and Thakor (2023) provide reviews describing the competitive structure of the industry.

a period of 3 to 7 years. As described in more detail below, marketing exclusivity endows the recipient with monopoly power, surpassing the strength of patent protection.

Once the marketing exclusivity period for an incumbent brand-name drug is over, in accordance with Hatch-Waxman, a competing generic drug may enter the marketplace. 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 the 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, advantageous to the brand-name owner, instigates an automatic 30-month stay on the FDA's approval of the generic drug. FDA approval may only occur following the first court ruling favoring the manufacturer or through a reached settlement. Upon generic approval, the generic provider is granted 180 days of market exclusivity, becoming the sole competitor with the branded drug.[13]

Once the litigation process starts, 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.[14] 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. Settle-

[13]In the event of a Para-IV case loss, the generic manufacturer assumes a Paragraph III filing status, committing to await the expiration of the relevant patent before seeking final ANDA approval.

[14]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.

ment terms may specify the generic product's market entry timing and the royalties owed by the generic manufacturer. Alternatively, the brand-name producer may opt for a settlement through a "pay-for-delay" agreement, involving a direct payment to the generic manufacturer in exchange for refraining from entering the market for an extended period.[15] A 2010 FTC study (FTC, 2010) suggests that agreements with compensation typically prolong generic entry by nearly 17 months compared to agreements without payments. Correspondingly, Helland and Seabury (2016) find that Para-IV challenges reduce drug prices and increase quantity, but this effect is reversed when a settlement is reached.

As an example, several generic drug makers filed ANDAs that threatened the exclusivity of the drug Androgel in 2003. Androgel's owner, Solvay Pharmaceuticals,[16] 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."

2.2 The *FTC v. Actavis* Ruling

Pay-for-delay agreements were a commonly used strategy in the 2000s (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, enabling 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.[17] This decision was arguably unexpected, since

[15]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.

[16]Solvay was later acquired by Abbott Laboratories and is now owned by AbbVie Inc., a spin-off from Abbott.

[17]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

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 several pharmaceutical firms for non-cash delay strategies, such as promising no authorized generic launches or providing other first generic arrangements. The *FTC v. Actavis* ruling also granted more bargaining leverage to the FTC. In a 2015 FTC settlement, for instance, Cephalon Inc. and Teva Pharmaceutical, in addition to providing $1.2 billion in monetary relief for drug buyers, agreed to prohibit entering any future pay-for-delay deals. Firms now face a substantial increase in legal risk related to antitrust enforcement if they participate in pay-for-delay agreements subsequent to this ruling.

As evidence of 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.[18] As the table shows, pay-for-delay agreements dropped sharply after the ruling. This is also visible 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. Finally, the last row of the table shows that the *FTC v. Actavis* ruling had no significant impact on the frequency of Para-IV first filings, as the number of Para-IV filings remained flat around the ruling. We formally demonstrate this effect in our subsequent analysis. This implies that the ruling did not change the incentives of generic producers to enter into the market. Put differently, their entrance is motivated by the potential profits of launching products, rather than engagement in pay-for-delay agreements.

— Insert Table 1 and Figure 2 Here —

making them much more legally tenuous. See Edlin et al. (2015) for an overview of the effects of the ruling.

[18]The aggregated data come from the FTC's annual report on Medicare Modernization Act agreement filings.

2.3 Conceptual Framework

We now describe a simple conceptual framework to develop our hypotheses and guide the empirical analysis. Consider a setting with two players: an incumbent drug development firm, I, and a potential entrant, E. Firm I has an existing drug product which generates a cash flow of $L > 0$. At the beginning of the game, 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 of R&D success. With probability q, the investment successfully produces a new drug that replaces I's existing drug. This new drug produces a cash flow equal to $H > L$, and since it is a novel drug with marketing exclusivity, E cannot launch a generic drug.

However, with probability $1 - q$, R&D for the new drug fails the development process and I still receives a cash flow equal to L from its existing drug. This existing drug is also vulnerable to generic entry. Conditional on research failure, E randomly enters the market with some exogenous probability α by filing a generic drug application. If E enters, both I and E split the market and earn oligopoly profit $M < L/2$ respectively. We consider a simple pay-for-delay strategy, allowing the incumbent I to make a take-it-or-leave-it (TIOLI) offer to E to not enter the market. We solve the model through backward induction and leave the details of the proof to the Appendix. Our empirical results will test the following proposition:

Proposition 1. *Incumbents will increase their R&D investments after pay-for-delay agreements become infeasible.*

The intuition is as follows. Without pay-for-delay agreements, 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. With the possibility of using a pay-for-delay agreement, the incumbent will always pay the entrant because the monopoly profit is greater than the

oligopoly profit. When incumbent firms can make use of these agreements, 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 ex-ante R&D investment.

3 Data Description

3.1 Drug Development Data

Our main data come from Biomedtracker (BMT), a database that covers detailed information on drug trials for biopharmaceutical companies in the United States. For each firm, the database contains a history of pipeline development dating back as far as the 1980s (although coverage is more complete after 2000).

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 drug 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. For each event, the database also includes the current phase and the likelihood of its eventual approval, calculated using a combination of historical data and analyst estimates. In pharmaceutical development, drugs target the specific symptoms of a disease, known as indications or therapeutic categories. Since a drug may potentially apply to more than one indication, trial information is subdivided at the indication level. We therefore define each combination of a drug and indication as a project. We use the Center for Medicare & Medicaid Services' ICD-10 medical classification assessment grouped at the first subchapter level to define a therapeutic category (referred to as an "ICD" hereafter). Examples of categories include "malignant neoplasms of the breast" and "disorders of the gallbladder, biliary tract, and pancreas."

We conduct our main analysis at the firm-therapeutic category level, which allows us to explore project decisions of distinct R&D units within a firm (Henderson, 1994), as well as decisions within given therapeutic areas across different firms. We examine a variety of outcome variables to characterize detailed project decisions by biopharma firms. For each therapeutic category within a firm, we explore the number of projects that are initiated and suspended. Since innovative sectors like the biopharma industry are characterized by an active market for ideas (e.g. Gans and Stern, 2003a,b), 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. Our data also allow us to define a number of pipeline control variables for therapeutic categories within a firm, including the total number of active ongoing projects, the average probability of final approval across projects, and the cumulative number of approved projects.

3.2 Marketing Exclusivity and Paragraph IV Entry Data

We use information on the marketing exclusivity expiration date for each incumbent (brand-name) drug to measure exposure to the *FTC v. Actavis* ruling. We obtain this data from the FDA Orange Book, sourced from the National Bureau of Economic Research's (NBER) data repository. For each drug's trade name, there may be multiple product numbers depending on dosage and strength. If there is more than one product expiring in the same year under the same trade name, we consolidate this information at the trade name level. We then manually match the exclusivity loss information to drug owners and the associated disease categories by trade names. In total, we can match 991 drugs with unique trade names that expired between 2003 and 2022.

We also collect 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 about the generic-seeking certification, including product name, dosage form, strength, the reference branded drug, and the first filing date of the generic

drug application. This information is available from March 2004. We complement this data with information from paragraphfour.com, a database that compiles detailed information on Paragraph IV cases. For each branded drug, we eliminate repetitions related to dosage form and strength by retaining the earliest generic filing at the drug level. We reason that the profit lost by the brand-name owner begins with the first generic entry, and the marginal impact of subsequent generic entry diminishes over time.[19] 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.

3.3 Patent Data and Financial Information

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.[20] 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

[19] 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.

[20] This adjustment method is commonly known as the "fixed effect" approach (Lerner and Seru, 2017).

plus the patents from other firms cited by the firm's patents filed over the past five years.

Finally, in order to explore investments and the financial conditions of firms in our sample, we manually match the firms in the BMT database to Compustat. We gather data on R&D expenditures, cash holdings, debt levels, earnings, and total assets. Additionally, we also include lags of these variables (scaled by total assets) as controls.

3.4 Summary Statistics

Our sample period runs from 2009 to 2016, which yields a balanced sample period before and after the shock in 2013. Beginning our sample in 2009 also allows us to avoid any confounding effects of the financial crisis. However, our results remain robust when beginning our sample in 2009, which corresponds to the first year with complete Para-IV Entry information.[21]

Table 2 provides summary statistics for the main variables in our analysis. Our sample consists of 3,319 unique firm-ICD combinations with 13,773 annual observations, and includes 483 public firms and 122 disease categories. On average, the rate at which a firm initiates new projects in a given therapeutic area is (*Initiation Rate*) 9.9%, and the rate at which a firm's projects fail (*Suspension Rate*) is 4.5%. This relatively large turnover rate is consistent with the low average probability of eventual approval for drugs each project—23% over our sample—consistent with the high degree of scientific risk that has been documented with drug development (e.g., Wong et al. (2019)).

— Insert Table 2 Here —

4 Empirical Methodology

The *FTC v. Actavis* ruling reduced the ability of firms to engage in pay-for-delay agreements to protect the profits of drugs whose marketing exclusivity has expired. As a result, firms with drug exclusivity set to expire in the period immediately after the ruling will be the

[21] 2016 corresponds to the last year for which we have data coverage from the BMT database.

most affected by the restricted ability to contract with incoming generic entrants. In order to explore this, we run the following main difference-in-differences (DiD) specification for firm i operating in ICD j in year t:

$$Y_{i,j,t} = \alpha + \beta Treated_{i,j} \times Post_t + \gamma Controls_{i,j,t} + \mu_{i,j} + \lambda_t + \varepsilon_{i,j,t}. \quad (1)$$

In equation (1), the treatment variable, $Treated_{i,j}$, takes a value of one if firm i has a drug with an exclusivity period expiring between 2013 and 2016 (the period following *FTC v. Actavis*) in ICD j, and zero otherwise.[22] $Post_t$ is a dummy variable which takes a value of one if the year is subsequent to the *FTC v. Actavis* ruling in 2013. $Y_{i,j,t}$ is the outcome variable of choice for firm i in ICD j in year t. We focus on two set of variables to measures innovation activities. $Initiations_{i,j,t}$ is the number of trials initiated by firm i for early-stage projects (preclinical or phase 1) in ICD j at time t. This measures a company's active exploration of new projects. $Suspensions_{i,j,t}$ is the number of projects in any phase suspended by company i in ICD j at time t. This measures the abandonment (or halting) of ongoing projects by the company. In the regression analyses, we either normalize these variables by lagged portfolio size ($Num\,Drugs_{i,j,t-1}$) or take logs. Normalizing by portfolio size captures the propensity to initiate or suspend a project as a firm's drug portfolio expands or shrinks, while taking logs accounts for potential skewness of the outcome variable. However, our results are robust to using raw counts of initiations and suspensions using either OLS or Poisson regressions.

$Controls_{i,j,t}$ is a vector of control variables. We include several variables that we refer to as "pipeline" controls, which characterize the nature of a firm's research pipeline. $Avg\,LOA_{i,j,t}$ is the average probability of eventual FDA approval for all of company i's projects in ICD j, which is a proxy for the viability of the firm's development portfolio. $Num\,Drugs_{i,j,t}$ is the number of active projects for company i's projects in ICD j, capturing portfolio size. $Num\,Approved_{i,j,t}$ is the cumulative number of approved drugs by firm i in

[22] 43 firms have drugs with market exclusivity expiring in at least one ICD. Within this treated group, each firm is exposed to the shock in around 2.5 ICDs out of an average of 8.2 total active disease categories.

ICD j until year t, which controls for a firm's expertise (i.e. built-up knowledge capital) in a given area. We also include a number of standard firm-level controls to account for differences in firm characteristics. This includes the logarithm of total assets $log(TA)$ to proxy for firm size, profitability $EBIT/TA$ (measured through earnings before interest and taxes scaled by total assets), cash holdings scaled by total assets $Cash/TA$, R&D expenditures scaled by total assets $R\&D/TA$, and leverage ratio $Debt/TA$. All control variables are lagged by one year except for $log(TA)$.[23]

Equation (1) is estimated at the firm-ICD-year level, which allows precise identification and enables us to explore both variation across firms (innovation within affected firms compared to innovation within unaffected firms) as well as variation within firms (innovation in affected areas compared to innovation in unaffected areas within the same firm). We include firm-ICD fixed effects $\mu_{i,j}$ to control for unobserved firm characteristics in a given category. In the baseline analysis, we control for broad time-trends using year fixed effects λ_t, but show the results are robust to including a variety of more granular fixed effects. We double-cluster standard errors at the firm level and the ICD level.

In the Appendix Table C.1, we formally validate the relevance condition of drug exclusivity loss, confirming that it does lead to significantly more generic entry. We validate this by using the number of Para-IV filings—the decision of a generic manufacturer to enter into an area—as the outcome variable. We instead normalize the raw number of certifications by (one plus) the cumulative number of approved drugs rather than the active projects since generic makers only target approved products. Our results indicate that affected firms experienced significant challenges from generic entrants in exclusivity-losing categories in the year of exclusivity loss. The economic magnitude is substantial, indicating an increased entry rate by 7.4%, which is over nine times larger than the unconditional average (0.8%). This magnitude strongly supports the notion that exclusivity loss leads to increased competition for incumbent firms. Consistent with this, among all unique treated firm-ICD combinations,

[23] A possible concern is that some of the control variables may also be affected by the shock and thus become "bad controls" once included. We show that our results are very similar without any control variables.

63% of them experienced realized Para-IV filings from 2013 to 2016. Furthermore, we find that Para-IV filings do not significantly increase for treated firms relative to control firms after the ruling. This is consistent with the evidence in Table 1 and Figure 2, that we do not find evidence that generic manufacturers are making entry decisions explicitly to sign pay-for-delay agreements, but rather because it is profitable to bring a generic drug to the marketplace.

The validity of the DiD 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 holds in our setting. Second, as noted earlier, the final ruling from the U.S. Supreme Court was relatively unexpected, preventing self-selection. Finally, drug development process is both lengthy and risky (e.g. Wong et al., 2019), lasting an average of 8 years before approval and receovomh exclusivity.. Firms are therefore effectively unable to select their treatment intensity, as the choice to begin the project had been made several years earlier before the shock. Our identification strategy is similar in spirit to that used in Krieger et al. (2022a), 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. We address additional identification challenges in Section 5.3.

5 Results

5.1 Project Decisions

We begin our analysis by examining new project initiations via equation (1). The results are provided in Table 3. Overall, we find that affected firms increase their number of new project initiations in disease categories with exclusivity-expiring drugs in the post-ruling period. Column (1) in Table 3 shows that the initiation rate increased by 5.7% after the shock, which is greater than half of the unconditional sample mean (9.9%). Consistent with

this, column (2) shows that the yearly number of initiations increases by 6.6%.

— Insert Table 3 Here —

In columns (3) and (4) of Table 3, we replace year fixed effects (FEs) with more granular firm-by-year FEs. This allows us to compare compare the difference between two therapeutic areas within the same firm and in the same year, one suffering competitive threats due to generic entry and the other being unaffected. The effects continue to hold with this specification. This helps to establish that our results are not driven by unobservable differences across firms, as the counterfactual is project decisions within the same firm.[24] Furthermore, the results suggest that firms increased innovation specifically in the areas affected by generic entry following the ruling, rather than in different areas, which is consistent with incumbent firms having built up "knowledge capital" in those areas and thus finding it advantageous to continue research in them (see, e.g., Krieger et al. (2022b) for theory and evidence).

In columns (5) and (6), we replace the firm-by-year FEs with therapeutic category-by-year FEs. This analysis allows us to compare two competing firms developing in the same disease area at the same time, but with one of them losing marketing exclusivity in the post-period. This helps to alleviate concerns 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 broadly spur R&D efforts in that area. The effects remain and become even stronger when controlling for category-specific time trends.

We next examine the decision to suspend or abandon the development of existing projects as another aspect of innovation decisions. The results for project suspensions are provided in Table 4. After the shock, we find that affected firms significantly decrease their suspensions of existing projects—i.e. they increase their chance of continuing work on current drugs in development.[25] We estimate the overall treatment effects in columns (1) and (2) as

[24]The firm-year FEs will absorb all firm-level controls.

[25]Furthermore, we find evidence that these suspension decisions are voluntary—i.e. firms are choosing to discontinue work on existing projects—and are not due to the drugs being scientific "failures," i.e. failing to meet endpoints in clinical trials. In columns (1) and (2) of Appendix Table C.2, we find negative and

before, and find that the annual propensity of project suspension in an affected therapeutic area significantly decreases by 2.8%, more than 60% of the unconditional sample average (4.5%), and the yearly number of suspensions also significantly decreases by 10.3%. The remaining columns show that the results are consistent with either within-firm or across-firm comparisons, and are in line with the previous results that affected firms boosted their innovation activity following the ruling.

— Insert Table 4 Here —

In total, these findings indicate that, when contracting is restricted due to the reduced viability of pay-for-delay agreements, firms respond by intensifying their innovation efforts. This effect is consistent 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 write contracts to protect their monopoly power. The elimination of pay-for-delay agreements introduce uncertainties of future cash flows due to potential generic entries, and incumbent firms hedge this risk with innovation efforts, as pointed out in our conceptual framework by Proposition 1. Together, our results imply that the legal contracting environment is critical to understanding the innovation decisions of firms in a competitive environment, and that an unrestricted contracting environment may not be optimal for encouraging firm innovation.

5.2 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 $Treat_{i,j}$ with individual year indicators instead of $Post_t$. We include all individual years except the year before shock (2012) as the reference

significant effects when examining suspensions that do not have any preceding negative trial events. We define negative trial events as trial updates that reduced the estimated probability of approval or FDA-issued clinical holds (potentially due to safety concerns). Instead, we do not find any significant effects on trials following negative events, i.e. suspensions driven by scientific reasons.

year.

$$Y_{i,j,t} = \alpha + \sum_{k=2009, k\neq 2012}^{2016} \beta_k Treat_{i,j} \times \mathbf{1}(t = k) + \gamma Controls_{i,t} + \mu_{i,t} + \lambda_{j,t} + \varepsilon_{i,t}.$$

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. This suggests that the parallel trends assumption holds for our setting.

— Insert Figure 3 Here —

5.3 Robustness

In this section, we perform a variety of robustness tests for our main results.

5.3.1 General Exclusivity Loss and the Ability to Contract

A potential concern is that our results are driven by a broad effect that applies to any firm losing marketing exclusivity on their drugs—a firm may choose to increase innovation in response to market entry pressures irrespective of the ruling and the ability to engage in pay-for-delay contracts. 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. Nonetheless, to alleviate this concern, we run an alternative version of our main specification that replaces our treatment variable with a dynamic variable that captures a firm's exposure to exclusivity losses at any point during the sample rather than the static window from 2013 to 2016. More specifically, we define a new treatment variable, $Loss\,Roll_{i,j,t}$, which takes a value of one if firm i has a drug in indication category j that is set to lose exclusivity from t to $t+3$. We then run an equivalent

specification to equation (1) using this alternative treatment variable:

$$Y_{i,j,t} = \alpha + \beta_1 Loss\,Roll_{i,j,t} \times Post_t + \beta_2 Loss\,Roll_{i,j,t} + \gamma Controls_{i,j,t} + \mu_{i,j} + \lambda_t + \varepsilon_{i,j,t}. \quad (2)$$

Note that, different from equation (1), $Loss\,Roll_{i,j,t}$ has time-series variation within a given firm-ICD combination and thus will not be absorbed by $\mu_{i,j}$. This specification allows us to examine the ruling's effects on innovation incentives, parsed out from any confounding factors due to exclusivity expiring more generally. In particular, if the results we find are due to the contracting incentives related to the use of pay-for-delay agreements, we should find significant results on the interaction term β_1 in equation (2), and a null effect for β_2, which serves as a placebo as it captures the period when firms were freely able to contract.

Table 5 confirms that this is the case. The sign and significance for the $Loss\,Roll_{i,j,t} \times Post_t$ coefficients are close to our original specification, confirming that our previous findings are due to changes in innovation incentives induced by the ruling rather than the general expiration of exclusivity. Furthermore, the coefficients for $Loss\,Roll_{i,j,t}$ (non-interacted) are insignificant and close to zero, suggesting that firms do not significantly respond to the market entry pressure *before* the ruling. This finding echoes our economic interpretation: when firms were freely able to contract with entrants and delay them, marketing exclusivity loss did not provide any additional incentives to innovate.

— Insert Table 5 Here —

5.3.2 Alternative Specifications

Our results are also robust to a number of alternative specifications.

First, our treatment variable is a binary variable that indicates whether or not a therapeutic area within a firm has at least one drug which faces exclusivity loss. However, intuitively, if the effects we document are due to the loss of exclusivity, they should be larger

if a firm-ICD has *more* drugs that are losing exclusivity.[26] In order to test this, we re-run our tests replacing our original treatment variable with a measure of treatment intensity. More specifically, we define $Treat\,Num_{i,j,t}$ as the number of drugs in ICD j within firm i that will lose exclusivity in the post-period. We also re-run the dynamic treatment specification from Table 5, replacing *Loss Roll* with *Loss Roll Num*, defined as the number of drugs that will lose from year t to $t+3$. The results are provided in Table 6, and indicate that firm-ICDs with a greater number of exclusivity-expiring drugs experience greater increases in innovation in the post-period.

— Insert Table 6 Here —

Second, our main outcome variables examine the rate of project initiations or suspensions, as well as the logarithm of the number of initiations or suspensions. However, as has been documented by the econometrics literature (e.g., Cameron and Trivedi (1986), Cameron and Trivedi (2013), Cohn et al. (2022)), the use of logarithms with count variables in linear regression models may introduce bias. To address this potential concern, for robustness we re-estimate our main results using the number of initiations and suspensions as outcome variables via OLS and Poisson models. The results, included in Appendix Table C.3, are robust to doing so.

Third, a potential concern is that our inclusion of lagged firm and project characteristics as control variables may bias our inferences. In particular, it may be that some of the control variables are also affected by the shock. To show that this is not the case, in Appendix Table C.4, we show that our results are very similar when excluding any control variables.

5.3.3 Sample Construction

We perform a number of other robustness checks related to the construction of our sample.

[26] In the sample, 74% of the treated firm-ICDs has one drug losing exclusivity, and 20% have two. The maximum is four.

First, although the DiD 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.[27] In Panel A of Table 7, we perform a balance check for the matched sample in 2012, and confirm that there exist no significant differences in the financial characteristics between the two groups. In Panel B, we then show that our main results hold for this matched sample.

— Insert Table 7 Here —

Second, Appendix Table C.5 shows that our results are robust to an extended sample period starting in 2005, the date from which we have the earliest Para-IV entry and exclusivity loss data.

Third, there may be a concern that the treatment group consists of large pharmaceutical firms with recently approved drugs, yet 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 Appendix Table C.6. The results are again consistent.

Finally, it is possible that the disease categories in our treatment group received unobserved technology shocks that are concurrent with *FTC v. Actavis*. Appendix Table C.7 show that our results remain robust even if we restrict ourselves to the sample of ICDs with at least one drug losing exclusivity from 2013. We note that the granular time-varying fixed effects in Tables 3 and 4 should also alleviate these last two concerns.

[27] We first predict the propensity of treatment based on the number of active projects and approved drugs in 2012. Each treated firm-ICD is matched with up to three control observations with a propensity difference cutoff of 0.001. For each matched pair, we further require that (i) the difference of 2012 average likelihood of approval cannot exceed 20% and (ii) they are in the same ICD.

5.3.4 Other Regulatory Events

Another possible concern is that our effects are confounded with alternative regulatory events that occurred during our sample period in the drug development industry. The first such event is the introduction by the FDA of a new expedited evaluation pathway called the Breakthrough Therapy Designation (BTD) program in July 2012. The goal was to facilitate and accelerate the approval of therapies that have demonstrated substantial improvements over available treatments (e.g., Garfinkel and Hammoudeh (2020)). The second event is the amendment of the 1983 Orphan Drug Act to address potential abuses in 2013. Under the Orphan Drug Act, drug companies developing drugs targeting rare diseases will receive fee waivers, tax credits, and additional market exclusivity. It was argued that firms tried to "game the system" by intentionally narrowing down the indication scope of their drugs to target orphan diseases, which could then be approved as a treatment for broader diseases after accruing the benefits from the Orphan Drug Act. To stop this strategy, the FDA constrained an approved orphan drug's eligibility for targeting other indications.

While these events overlap with the timing of the *FTC v. Actavis*, we argue that they are unlikely to disproportionately affect firms losing future marketing exclusivity, which would have to be the case if they are confounding factors. To further establish this point, in Appendix Table C.8, we show that our treatment group does not exhibit any significant difference in terms of Breakthrough Therapy or orphan drug designations relative to the control group after the shock.

5.4 Heterogeneity: Pipeline Strength

Our main results estimate the average treatment effects for firms losing market exclusivity in a given disease category. In this section, we explore heterogeneity in how strongly firms respond to the restricted ability to contract with pay-for-delay agreements. In particular, we explore whether the firm has promising projects under development in the area exposed to the shock. With a robust drug pipeline, it can rely on that existing pipeline to produce

marketable drugs in response to competition and thus has less of a need to start new projects. Conversely, a firm without a strong pipeline should have a stronger incentive to develop new drugs once it can no longer contract with competitors to delay them from entering.

To explore this, we split our sample based on measures of pipeline strength. Specifically, we define pipeline strength, $Strength_{i,j,t}$, as the expected number of drugs that will eventually be approved: $Avg\,LOA_{i,j,t} \times Drug\,Num_{i,j,t-1}$.[28] We then split the sample based on pre-shock pipeline strength in 2012, defining dummy variables that indicate whether a firm-ICD is in the lowest tercile of pipeline strength ($L\,Strength$), the middle tercile ($M\,Strength$), or the highest tercile ($H\,Strength$). We run our main specification interacted with these tercile dummies.

The results are provided in Table 8. Overall, we find that the incentive to initiate new drug trials is strongest for treated firm-ICDs with weaker development pipelines, consistent with stronger incentives to develop new drugs after the ruling. Firms also suspend projects less frequently in treated ICDs with stronger pipelines, in line with firms being less likely to abandon projects in areas that show more promise. In Appendix Table C.9, we confirm that the reduced likelihood of suspension is concentrated in areas with at least one Phase 3 project. These late-stage projects have a larger continuation value with the highest likelihood of approval (Krieger et al., 2022b).

— Insert Table 8 Here —

Our heterogeneity analyses are also consistent with firms not feeling the need to bolster their R&D portfolios when they can stave off competitive entry through contracting. However, when the ability to contract is weakened, affected firms without promising trials in development have the most pressing need to develop new drugs.

[28] We find similar results when defining pipeline strength using only $Avg\,LOA_{i,j,t}$.

5.5 Additional Outcomes

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

5.5.1 External Innovation

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 results may understate or overstate the project decision incentives of a firm, since acquisitions are an alternative to initiating a new project within the firm.

To explore this, we re-estimate equation (1) with $Drug$, $Acq_{i,j,t}$, 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. Therefore, our results are not driven by the incentives of killer acquisitions, as in (Cunningham et al., 2021). In Table 9, we find that affected firms also source drugs from other firms when exposed to generic entry following the ruling.[29] The coefficient estimates imply that a treated firm increases acquisition rate by almost 12%. The number of acquisitions also significantly increases by 20%. This suggests that firms use acquisitions as another mechanism to increase their net innovative activity in response to a diminished ability to protect their monopoly power, consistent with these firms pursuing late-stage projects as a more timely response to negative shocks (e.g. Krieger et al., 2022b; Bena and Li, 2014).

— Insert Table 9 Here —

[29] In Appendix Figure B.1, we provide the coefficient dynamics for acquisitions, and show that the parallel trends assumption holds.

5.5.2 Patent-related Innovation Outcomes

While our main focus is on the drug development activities, we also supplement our analysis with patent-related outcomes 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.

We note that patent *counts* are problematic in our setting beyond the disadvantages that they may not correspond to actual innovation (Freilich, 2019). 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 (Hemphill and Sampat, 2012). These new patents tended to be minor modifications or mixtures of delivery methods of older drugs.[30]

Instead, we examine several measures of the *value* of a firm's new patents. First, we explore two commonly used proxies for 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 (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, providing another view into the novelty of the innovations.

Panel A of Table 10 provides the summary statistics for these measures for the 12,570 patents filed by the sample firms between 2009 and 2016. On average, each patent receives 4.3 (unadjusted) future citations and is (nominally) worth $80 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. Panel B of Table 10 provides regression results at the patent level that compare the patent characteristics before and after

[30]Consistent with this, in our untabulated results we find insignificant effects when using patent counts as our outcome variable at the firm level.

exposure to *FTC v. Actavis* for firms with exclusivity-expiring drugs compared to control firms.

— Insert Table 10 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 30% 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). Examining the market value of patents in columns (3) and (4), affected firms' new patents significantly increase in value by roughly 10% relative to patents issued by other firms, with or without adjusting for inflation. Finally, in the last column of Table 10, 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.

5.5.3 Firm-level Outcomes

We next examine broader firm-level outcomes around the FTC v. Actavis ruling. To do so, we define our $Treated$ variable at the firm level, which takes a value of one if a firm has a drug with exclusivity expiring in the post-ruling period, and zero otherwise. The results are presented in Table 11.

— Insert Table 11 Here —

We first examine a variety of financial outcomes. in column (1), we analyze R&D expenditures to assess overall firm spending on innovation, as well as cash holdings and the capital structure to understand how firms are financing their increased innovation activities. Consistent with the increase in project initiations and acquisitions, we observe a relative increase

in R&D expenditure, accounting for 13% of total assets for the affected firms. Hand-in-hand with this increase in R&D expenses, cash holdings significantly decrease and leverage goes up (columns 2 and 3). This suggests that firms are drawing down their cash reserves and increasing their debt to fund new R&D, aligning with the project innovation being financed by a combination of internal cash and external debt. Lastly, in column (4) we document that affected firms' profitability significantly declines. This is consistent with affected firms losing monopoly profits due to generic entry and also increasing their investment spending. Furthermore, any new project initiated will take years to possibly be approved and generate cash flows.

Finally, we present an additional validation test to confirm that the *FTC v. Actavis* ruling did indeed reduce incumbent firms' ability to contract with entrants. The details of most settlement terms are confidential and not publicly available, which prevents us from directly observing whether a firm signs a pay-for-delay agreement. Therefore, even though Table C.1 confirms that affected firms do face more generic challenges after the shock, we cannot directly measure whether pay-for-delay settlements still exist. Put it differently, while we can observe the existence of a settlement between an incumbent drug maker and a generic entrant, we cannot determine whether pay-for-delay activities are involved.

To address this issue and provide additional evidence of the effects of the *FTC v. Actavis* ruling on pay-for-delay settlements, we take an alternative approach and focus on the Para-IV cases that result in court decisions. We manually collect additional variables from the "Legal Proceedings" sections of 10-K filings, extracting any mentions of generic litigation cases. Since companies do not fully disclose all cases, we also supplement our data with manually collected information from news articles via Law360 and LexisNexis. We define a variable, $Court, Num_{i,t}$, as the number of Para-IV court cases for firm i in year t that conclude with a court ruling. The idea is that, given a restricted ability to contract via pay-for-delay settlements, the number of cases with court rulings should be expected to increase for the affected firms after *FTC v. Actavis*. Column (5) of Table 11 confirms that, following

the *FTC v. Actavis* ruling, affected firms become more inclined to wait for court rulings (rather than settling), which typically result in direct entry by competitors, as previously noted.

6 Overall Innovation

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 by 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.[31]

We explore this issue by examining a variety of outcomes over our sample period at the aggregated therapeutic category level. More specifically, we examine the total number of project suspensions, $Suspensions_{j,t}$, and acquisitions of new projects, $Drug\,Acq_{j,t}$. 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, $Inc\,Initiations_{j,t}$, and drug project initiations by new entrants, $Ent\,Initiations_{j,t}$. 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 developing their own brand-name drugs. We include fixed effects by therapeutic category and year, as well as several controls, including

[31] Indeed, motivating entrants was the rationale behind the FDA introducing a marketing exclusivity period for newly approved drugs.

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. We run a similar diff-in-diff specification, except that our treatment variable $Treat_j$ is defined at the overall therapeutic category level.

The results are given in Table 12. Consistent with our firm-level analysis, we find that the therapeutic categories affected by the *FTC v. Actavis* ruling have a relatively smaller number of drug suspensions and a greater number of drug acquisitions. However, we do not find a significant positive effect on new project initiations in column (3). Once we decompose the aggregate initiations, incumbents indeed respond by increasing their initiations significantly (column 4), consistent with our previous results.

— Insert Table 12 Here —

However, we find negative effects with respect to new entrants in the therapeutic area after examining the extensive margin. 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. 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.[32]

Our results are broadly consistent with previous empirical and theoretical work about

[32]See, for example, Krieger et al. (2022b) 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.

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, whereas *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. Segal and Whinston (2007) argue that antitrust policy affects the dynamics between incumbents and potential new innovators in a more nuanced way. Limiting the ability of incumbents to create market barriers via contracting (e.g. pay-for-delay agreements) permits new entrants to replace the previous incumbents. However, potential entrants may not respond because they worry about their own monopoly profits once they successfully become the new incumbents.

7 Conclusion

In this paper, we examine the relationship between competition, the contracting environment, and innovation by exploring a specific contracting mechanism that firms may use to maintain their market power: pay-for-delay agreements. We investigate this using detailed data from the pharmaceutical industry and focus on a Supreme Court ruling that made such agreements legally risky and subject to antitrust enforcement. After the ruling, we find that generic entry threats motivate incumbent firms to innovate. Moreover, treated firms pursue more "impactful" innovation, both from a scientific and commercial standpoint, following the ruling. These results suggest that strategic settlements, such as pay-for-delay agreements, reduce firms' incentives to innovate. However, we also demonstrate that the ruling had a negative effect on firm entry into areas with heavy generic competition, indicating that the effects on competition at the extensive margin may differ.

Overall, our results provide evidence of the complex relationship between competition and innovation. This has implications for using antitrust law to promote innovation. Specifically,

the results suggest that a nuanced approach must be taken in regulation aimed at influencing competition. If the regulatory goal is to stimulate innovation, it is not sufficient to enact laws and regulations that increase competition. Instead, the promotion of increased competition must be accompanied by initiatives that restrict the contracting options for incumbents, preventing them from nullifying the regulatory attempt to enhance competition. Only when this is done can increased competition stimulate innovation.

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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.

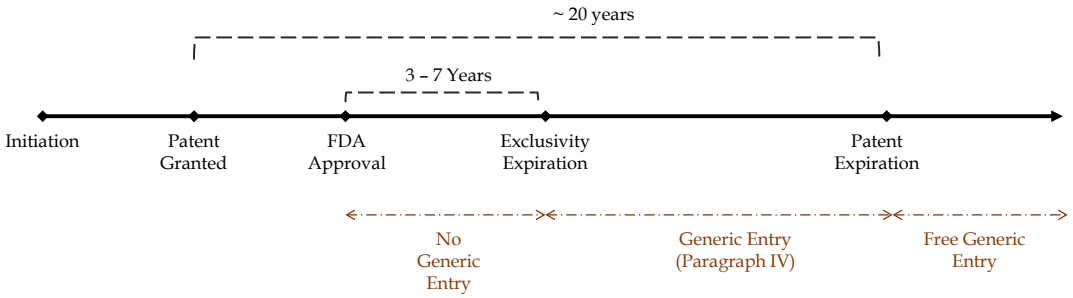


Figure 2: Pay-for-Delay Settlements over Time

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.

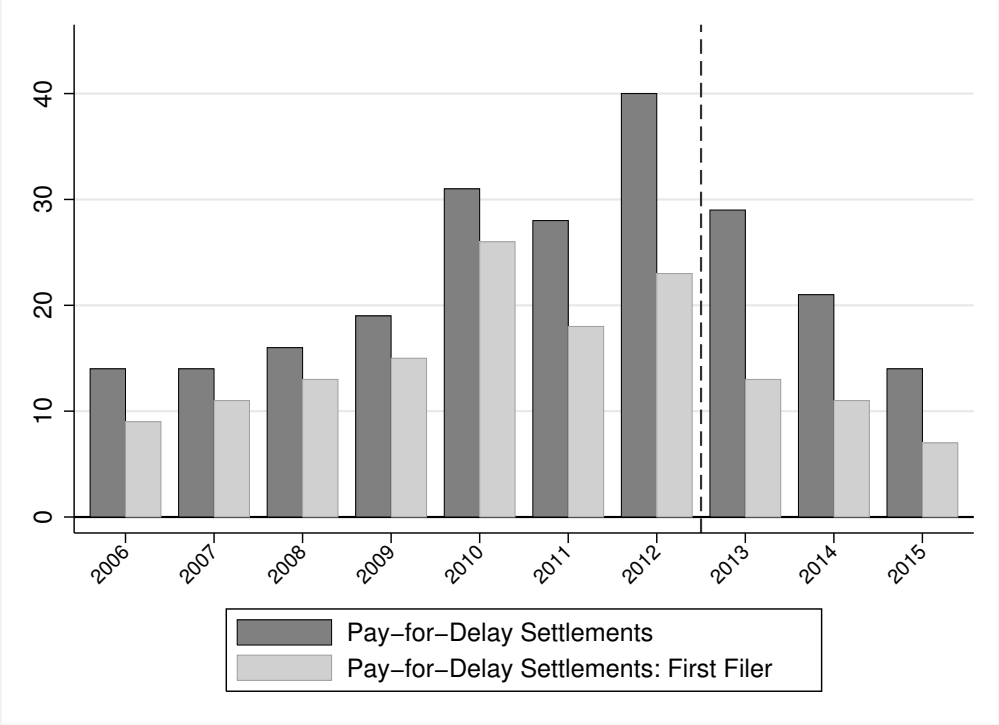
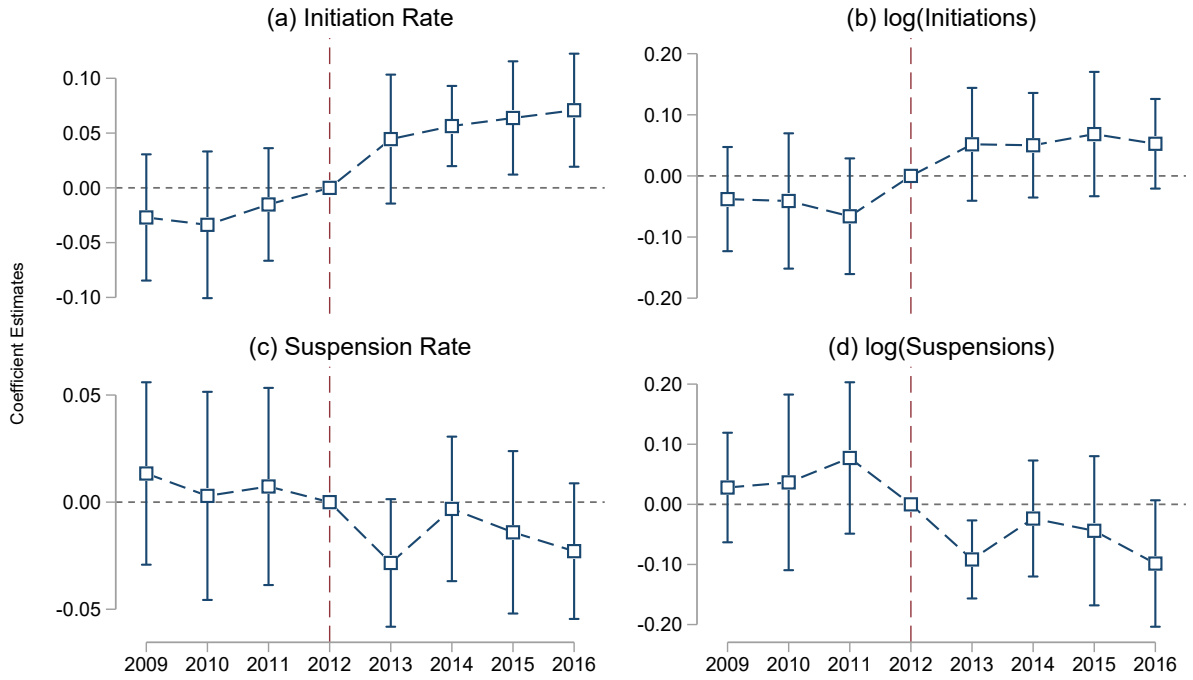


Figure 3: Parallel Trends: Initiations and Suspensions

This figure provides coefficient dynamics for the diff-in-diff estimation in Tables 3 and 4 by estimating the following equation:

$$Y_{i,j,t} = \alpha + \sum_{k=2009, k\neq 2012}^{2016} \beta_k Treat_{i,j} \times \mathbf{1}(t = k) + \gamma Controls_{i,t} + \mu_{i,t} + \lambda_{j,t} + \varepsilon_{i,t}.$$

$\mathbf{1}(t = k)$ 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. Year of 2012 (the year before the shock) is dropped as the reference year. Outcome variables are indicated in figure captions. 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 from the FTC's annual report on Medicare Modernization Act Agreement Filings, which document settlement information. The first row counts the number of settlements with first generic filers. The second 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.

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
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
Brand-name Drugs with First Para-IV Filers	38	34	44	58	59	45	40	40	44	40	40

Table 2: Summary Statistics

This table provides the summary statistics for the main variables at the firm-ICD level. $Post_t$ is a dummy variable that takes a value of one if year t is 2013 or later. $Initiations_{i,j,t}$ is the number of new drug initiations for firm i's ICD j in year t. $Suspensions_{i,t}$ is the number of suspensions of drug trials for firm i's ICD j in year t. $Num\,Drugs_{i,j,t}$ is the number of active drugs being developed for firm i's ICD j in year t. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) divided by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) divided by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $Drug\,Acq_{i,j,t}$ is the number of drug acquisitions in firm i's ICD j in year t. $Drug\,Acq\,Rate_{i,j,t}$ is number of drug acquisitions ($Drug\,Acq_{i,j,t}$) divided by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $Avg\,LOA_{i,j,t}$ is the average likelihood of approval of active drug projects for firm i's ICD j in year t. $Num\,Approved$ is the cumulative number of drugs approved by date t for firm i's ICD j. The statistics include the number of observations (N), Mean ($Mean$), standard deviation (Std), 10th percentile ($p10$), 50th percentile ($Median$), and 90th percentile ($p90$).

Variables	N	Mean	Std. Dev.	p10	Median	p90
$Initiations$	13,695	0.220	0.619	0.000	0.000	1.000
$Suspensions$	13,695	0.161	0.544	0.000	0.000	1.000
$Drug\,Num$	13,695	2.279	2.598	1.000	1.000	5.000
$Initiation\,Rate$	13,695	0.099	0.276	0.000	0.000	0.353
$Suspension\,Rate$	13,695	0.045	0.163	0.000	0.000	0.125
$Drug\,Acq$	13,695	0.181	0.852	0.000	0.000	0.000
$Drug\,Acq\,Rate$	13,695	0.068	0.272	0.000	0.000	0.000
$Avg\,LOA$	13,695	22.874	22.634	0.000	15.727	59.000
$Num\,Approved$	13,695	0.171	0.487	0.000	0.000	1.000

Table 3: Effects of Exclusivity Loss After *FTC v. Actavis* on Project Initiations

This table provides estimation results for project initiations using equation (1) at the firm-ICD-year level. $Treated_{i,j}$ is equal to one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is the number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Initiation\,Rate$	(4) $\log(Initiations)$	(5) $Initiation\,Rate$	(6) $\log(Initiations)$
$Treated \times Post$	0.057***	0.066***	0.047***	0.064***	0.076***	0.090***
	(4.338)	(3.139)	(3.558)	(2.997)	(5.228)	(4.864)
Controls	Y	Y	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	–	–	–	–
Firm-Year FE	N	N	Y	Y	N	N
Category-Year FE	N	N	N	N	Y	Y
N	13,118	13,118	12,522	12,522	13,089	13,089
Adj. R^2	0.30	0.42	0.31	0.39	0.30	0.42

Table 4: Effects of Exclusivity Loss After *FTC v. Actavis* on Project Suspensions

This table provides estimation results for project suspensions using equation (1) at the firm-ICD-year level. $Treated_{i,j}$ is one if firm i's ICD j 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. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) *Suspension Rate*	(2) log(*Suspensions*)	(3) *Suspension Rate*	(4) log(*Suspensions*)	(5) *Suspension Rate*	(6) log(*Suspensions*)
Treated × *Post*	−0.028**	−0.103**	−0.022*	−0.075*	−0.023**	−0.099**
	(−2.588)	(−2.545)	(−1.960)	(−1.938)	(−2.116)	(−2.550)
Controls	Y	Y	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	–	–	–	–
Firm-Year FE	N	N	Y	Y	N	N
Category-Year FE	N	N	N	N	Y	Y
N	13,118	13,118	12,522	12,522	13,089	13,089
Adj. R^2	0.03	0.28	0.00	0.22	0.00	0.26

Table 5: Alternative Specification: Rolling-Window Exclusivity Loss

This table provides estimation results for project initiations and suspensions using a rolling-window measure of exclusivity loss at the firm-ICD-year level. $Loss\,Roll_{i,j,t}$ equals one if firm i's ICD j has a drug with exclusivity expiring from t to $t+3$, and zero otherwise. $Post_t$ is a dummy variable that takes a value of one if year t is 2013 or later. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) over (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions.Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$Loss\,Roll$	−0.023	−0.053	0.007	0.017
	(−1.632)	(−1.621)	(0.724)	(0.824)
$Loss\,Roll \times Post$	0.053***	0.060*	−0.024**	−0.083**
	(3.031)	(1.957)	(−2.428)	(−2.106)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.30	0.42	0.03	0.28

Table 6: Alternative Specification: Treatment Intensity

This table provides estimation results by defining the treatment variable as the number of drugs losing exclusivity. Panel A replicates the main results, where $Treated\,Num_{i,j,t}$ is the number of drugs that will lose exclusivity from 2013 to 2016 for firm i's ICD j. Panel B replicates Table 5, where $Loss\,Roll\,Num_{i,j,t}$ is the number of drugs that will lose exclusivity from t to $t+3$ for firm i's ICD j. $Post_t$ is a dummy variable that takes a value of one if year t is 2013 or later. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) over (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Main Results

	(1) *Initiation Rate*	(2) log(*Initiations*)	(3) *Suspension Rate*	(4) log(*Suspensions*)
Treated Num × *Post*	0.033***	0.030*	−0.021***	−0.081***
	(3.661)	(1.873)	(−3.116)	(−3.196)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.30	0.42	0.03	0.28

Panel B: Rolling-Window Specification

	(1) *Initiation Rate*	(2) log(*Initiations*)	(3) *Suspension Rate*	(4) log(*Suspensions*)
Loss Roll Num	−0.007	−0.022	0.000	0.009
	(−0.837)	(−1.138)	(0.079)	(0.539)
Loss Roll Num × *Post*	0.032***	0.037*	−0.014**	−0.059**
	(2.969)	(1.879)	(−2.029)	(−2.085)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.30	0.42	0.03	0.28

Table 7: Robustness: Propensity Score Matched Sample

This table provides estimation results based on a propensity-score matched sample. For each treated firm-ICD observation, we match up to three control observations in the same ICD based on the 2012 values of $Avg\,LOA$, $Num\,Drugs$ and $\log(Num\,Approvals)$. Panel A shows the balance test for the matched sample based on variable values in 2012. Panel B provides the main results estimated using this matched sample. $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) over (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Balance Test in 2012

	Observations		*Mean*				
	Control	*Treat*	*Control*	*Treat*	*Diff.*	*t-stat*	*p-value*
$Avg\,LOA$	169	69	46.103	48.921	−2.819	−0.750	0.451
$Drug\,Num$	169	69	3.947	4.334	−0.387	−0.950	0.352
$Num\,Approved$	169	69	0.480	0.507	−0.028	−0.300	0.761
$Log(TA)$	169	69	9.647	9.535	0.112	0.300	0.764
$EBIT/TA$	169	69	0.002	0.067	−0.065	−0.700	0.483
$Cash/TA$	169	69	0.231	0.201	0.030	0.900	0.359
$R\&D/TA$	169	69	0.158	0.109	0.049	1.000	0.314
$Debt/TA$	169	69	0.299	0.263	0.037	0.850	0.389

Panel B: Regression Results

	(1) *Initiation Rate*	(2) $\log(Initiations)$	(3) *Suspension Rate*	(4) $\log(Suspensions)$
$Treated \times Post$	0.058***	0.121***	−0.027*	−0.085**
	(4.576)	(3.837)	(−1.850)	(−2.552)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	1,749	1,749	1,749	1,749
Adj. R^2	0.18	0.40	0.06	0.28

Table 8: Heterogeneity: Pipeline Strength

This table provides estimation results for heterogeneous effects based on pipeline strength. $Treated_{i,j}$ is one if firm i's ICD j has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise. Development portfolio strength, $Strength_{i,j,t}$ is defined as $Avg\,LOA_{i,j,t} \times DrugNum_{i,j,t-1}$. We then split the sample based on pre-shock pipeline strength $Strength_{i,j,2012}$ and sort the observations into terciles, indicated by $L\,Strength$ (Lowest), $M\,Strength$ (Medium), and $H\,Strength$ (Highest). $Post_t$ is a dummy variable that takes a value of one if year t is 2013 or later.$Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) over (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double-clustered at the firm and ICD levels. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively. The difference between the coefficients for $H\,Strength \times Treated \times Post$ and $L\,Strength \times Post$ is provided in the bottom rows.

	(1) $InitiationRate$	(2) $Log(Initiation)$	(3) $SuspensionRate$	(4) $Log(Suspension)$
$L\,Strength \times Treated \times Post$	0.228**	0.238***	0.010	0.042
	(2.099)	(2.928)	(0.293)	(0.741)
$M\,Strength \times Treated \times Post$	0.071	0.204**	−0.033	−0.035
	(1.392)	(2.475)	(−0.678)	(−0.429)
$H\,Strength \times Treated \times Post$	0.042**	0.053*	−0.020	−0.092**
	(2.324)	(1.966)	(−1.545)	(−2.045)
$L\,Strength \times Post$	0.016	0.042*	0.004	0.024
	(0.695)	(1.817)	(0.300)	(1.443)
$M\,Strength \times Post$	−0.033**	−0.012	0.026***	0.056***
	(−2.387)	(−1.006)	(3.100)	(3.588)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.30	0.42	0.03	0.28
$High - Low$	−0.186*	−0.185***	−0.029	−0.133*
	(−1.697)	(−2.758)	(−0.848)	(−1.869)

Table 9: Drug Acquisitions

This table provides estimation results for drug acquisitions and different types of project suspensions using equation (1) at the firm-ICD-year level. $Treated_{i,j}$ is one if firm i's ICD j 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. $Drug\,Acq\,Rate_{i,j,t}$ is number of drug acquisitions ($Drug\,Acq_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Drug\,Acq)_{i,j,t}$ is the logarithm of one plus drug acquisitions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Drug\,Acq\,Rate$	(2) $\log(Drug\,Acq)$
$Treated \times Post$	0.120***	0.199**
	(2.815)	(2.580)
Controls	Y	Y
Firm-Category FE	Y	Y
Year FE	Y	Y
N	13,118	13,118
Adj. R^2	0.07	0.14

Table 10: 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 2009 to 2016. Panel A summarizes the main variables, and Panel B provides the estimation results. $Treated_i$ 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 the year is 2013 or later. $Cites$ is the number of forward citations received by the patent. $Adj\,Cites$ is the number of forward citations divided by the average citations received by patents filed in the same year and same technology class. $Mkt\,Val$ is the market value (in millions of dollars) of the patent based on stock returns. $RMkt\,Val$ is the real market value (in millions of 1982 dollars) of the patent based on stock returns. $Pct\,Knowledge$ 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 $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. We include the filing firm FEs, filling year-quarter FEs, and (3 digit) CPC code FEs. t-statistics are reported in parentheses, and robust standard errors are double clustered at the CPC and filing year-quarter level. . ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Summary Statistics

Variables	N	Mean	Std	p25	p50	p75
$Cites_{k,t}$	12,570	4.290	10.379	0.000	1.000	12.000
$Adj\,Cites_{k,t}$	12,570	0.683	1.541	0.000	0.132	1.864
$Mkt\,Val_{k,t}$	12,570	79.712	141.821	2.162	18.400	243.688
$RMkt\,Val_{k,t}$	12,570	33.068	58.419	0.915	7.559	100.383
$Pct\,Knowledge_{k,t}$	12,570	0.381	0.425	0.000	0.125	1.000

Panel B: Regression Results

	(1) $\log(Cites)$	(2) $\log(Adj\,Cites)$	(3) $\log(MktVal)$	(4) $\log(RMkt\,Val)$	(5) $Pct\,Knowledge$
$Treated \times Post$	0.304***	0.131***	0.105**	0.100**	−0.031**
	(6.744)	(6.747)	(2.494)	(2.602)	(−2.247)
Controls	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y
Year-Qtr FE	Y	Y	Y	Y	Y
CPC FE	Y	Y	Y	Y	Y
N	12,272	12,272	12,272	12,272	12,272
Adj. R^2	0.22	0.23	0.86	0.86	0.19

Table 11: Firm-level Outcomes

This table provides estimation results for firm-level outcomes. $Treated_i$ 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 the year is 2013 or later. $R\&D/TA$ is R&D expenditures over total assets for firm i in year t. $Cash/TA_{i,t}$ is cash holdings over total assets for firm i in year t. $Debt/TA_{i,t}$ is debt over total assets for firm i in year t. $EBIT/TA_{i,t}$ is earnings before interest and taxes over total assets for firm i in year t. $Court\,Num_{i,t}$ is the number of firm i's cases which end up with a court ruling in year t. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$, each defined at the firm-level. t-statistics are reported in parentheses, and robust standard errors are clustered at the firm level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $R\&D/TA$	(2) $Cash/TA$	(3) $Debt/TA$	(4) $EBIT/TA$	(5) $Court\,Num$
$Treated \times Post$	0.129**	−0.063***	0.143**	−0.261**	0.143*
	(2.398)	(-2.758)	(1.974)	(-2.263)	(1.875)
Controls	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y
N	2,458	2,463	2,449	2,460	2,463
Adj. R^2	0.61	0.72	0.64	0.69	0.04

Table 12: Overall Effect on Innovation by Therapeutic Area

This table shows results at the therapeutic category level j. $Treated_j$ takes a value of one if ICD 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 ICD j. $Drug\,Acq_{j,t}$ is the number of acquisitions of drugs from other companies in ICD j. $Initiations_{j,t}$ is the total number of new drug trial initiations in ICD j. $Inc\,Initiations_{j,t}$ and $Ent\,Initiations_{j,t}$ are the numbers of initiations by incumbents and new entrants, respectively. $Entrants_{j,t}$ is the number of firms entering into therapeutic ICD j. Regressions are run from 2009 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 ICD level. Category and year fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Suspensions_{j,t}$	(2) $Drug\,Acq_{j,t}$	(3) $Initiations_{j,t}$	(4) $Ent\,Initiations_{j,t}$	(5) $Inc\,Initiations_{j,t}$	(6) $Entrants_{j,t}$
$Treated_j \times Post_t$	−1.925***	0.804*	0.229	−0.785***	1.014*	−0.755***
	(−3.613)	(1.800)	(0.447)	(−2.677)	(1.972)	(−2.887)
$Num\,Drugs_{j,t-1}$	0.058*	0.035*	0.032	0.012	0.020	0.006
	(1.875)	(1.737)	(0.477)	(0.632)	(0.265)	(0.464)
$Avg\,LOA_{j,t-1}$	−0.004	−0.000	−0.029**	−0.004	−0.025**	−0.002
	(−0.588)	(−0.051)	(−2.524)	(−0.492)	(−2.222)	(−0.285)
$Num\,Firms_{j,t-1}$	−0.068	0.010	0.127	−0.079**	0.207**	−0.087***
	(−1.365)	(0.409)	(1.652)	(−2.285)	(2.494)	(−2.668)
Category FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y
N	1,190	1,190	1,190	1,190	1,190	1,190
Adj. R^2	0.87	0.38	0.88	0.65	0.70	0.64

Appendix

A Proof of Proposition 1

We solve the model through backward induction. I will always pay if it is possible, as E's reservation price equals to future profits $M/2$. Gains from transacting exist because

$$\underbrace{L}_{\text{Monopoly Profit}} - \underbrace{M}_{\text{TIOLI Offer}} > \underbrace{M}_{\text{Oligopoly Profit}}.$$

Given this decision, the value function of the incumbent under pay-delay-agreement is:

$$V_P = \max_{0 \leq q \leq 1} \quad q \times H + (1-q)\,\alpha\,(L-M) + (1-q)\,(1-\alpha)\,L - \frac{cq^2}{2}.$$

The first-order condition generates

$$q_P = \frac{H - L + \alpha M}{c}.$$

When pay-for-delay is not possible, the value function is simply

$$V_{NP} = \max_{0 \leq q \leq 1} \quad q \times H + (1-q)\,\alpha M + (1-q)\,(1-\alpha)\,L - \frac{cq^2}{2},$$

which implies that

$$q_{NP} = \frac{H - \alpha M - (1-\alpha)\,L}{c}.$$

The difference between these two innovation efforts is:

$$q_{NP} - q_P = \frac{\alpha\,(L - 2M)}{c} > 0.$$

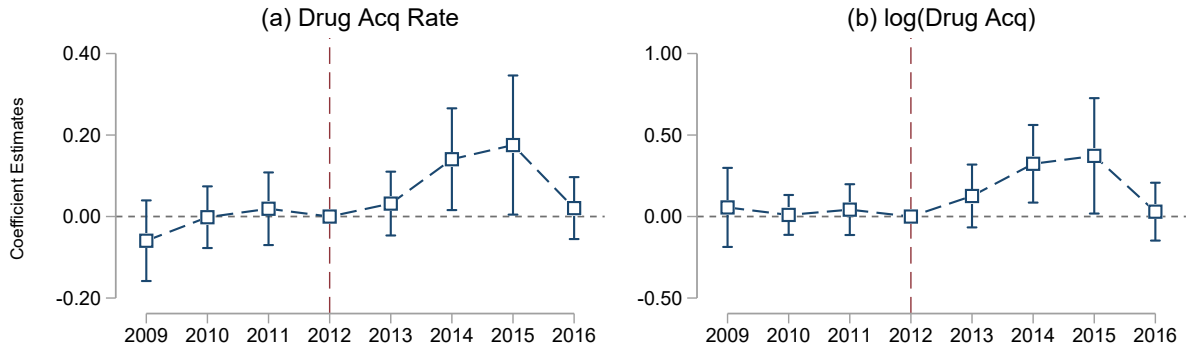
B Appendix Figures

Figure B.1: Coefficient Dynamics: Acquisitions

This figure provides coefficient dynamics for acquisitions the diff-in-diff estimation in Tables 9 by estimating the following equation:

$$Y_{i,j,t} = \alpha + \sum_{k=2009, k\neq 2012}^{2016} \beta_k Treat_{i,j} \times \mathbf{1}(t = k) + \gamma Controls_{i,t} + \mu_{i,t} + \lambda_{j,t} + \varepsilon_{i,t}.$$

$\mathbf{1}(t = k)$ 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. Year of 2012 (the year before the shock) is dropped as the reference year. Outcome variables are indicated in figure captions. 95% confidence interval bands are shown along with the point estimates.



C Appendix Tables

Table C.1: Exclusivity Loss and Paragraph-IV Filings

This table provides estimation results for showing Para-IV generic filings and the loss of exclusivity. $Loss_{i,j,t}$ is one if at one of firm i's drug loses exclusivity in ICD j at year t, and zero otherwise. $Post_t$ is one year t is greater or equal to 2013, and zero otherwise. $ParaIV_{i,j,t}$ is the number of Para-IV certifications challenging firm i's approved drugs in ICD j in year t. *ParaIV Rate* is the number of Para-IV certifications ($Para\,IV_{i,j,t}$) scaled by the lagged cumulative number of drugs approved ($Num\,Approved_{i,j,t-1}$). $\log(ParaIV)_{i,j,t}$ is the logarithm of one plus Para-IV filings. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $ParaIV\ Rate$	(2) $\log(ParaIV)$	(3) $ParaIV\ Rate$	(4) $\log(ParaIV)$
$Loss_t$	0.074**	0.055**	0.055	0.055*
	(2.096)	(2.059)	(1.471)	(1.826)
$Loss_t \times Post_t$			0.042	0.014
			(0.825)	(0.309)
$Loss_{t-1}$	0.001	0.013		
	(0.023)	(0.487)		
$Loss_{t-2}$	−0.010	−0.009		
	(−0.819)	(−0.854)		
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	11,487	11,487	13,194	13,194
Adj. R^2	0.01	0.01	0.01	0.01

Table C.2: Suspension Types

This table provides estimation results for different types of project suspensions using equation (1) at the firm-ICD-year level. $Treated_{i,j}$ is one if firm i's ICD j 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. $Voluntary\,Suspensions$ is the number of suspensions without any preceding negative trial events. $Failure\,Suspensions$ is the number of suspensions with preceding negative trial events, which include negative trial results and clinical holds. The rate and logarithm of voluntary and failure suspensions are defined in the same way as the other tables. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Voluntary\,Suspension\,Rate$	(2) $\log(Voluntary\,Suspensions)$	(3) $Failure\,Suspension\,Rate$	(4) $\log(Failure\,Suspensions)$
$Treated \times Post$	−0.021*	−0.095**	−0.007	−0.016
	(−1.810)	(−2.213)	(−1.242)	(−1.467)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.02	0.26	0.00	0.00

Table C.3: Robustness: Count Variable Specifications

This table provides estimation results using count models with the raw number of initiations and suspensions as dependent variables. OLS regression results are shown in columns (1) and (4), Poisson regression results without fixed effects in columns (2) and (5), and a Poisson regression with fixed effects in columns (3) and (6). $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiations_{i,j,t}$ is number of initiations. $Suspensions_{i,j,t}$ is number of suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	OLS	Poisson	Poisson	OLS	Poisson	Poisson
	(1)	(2)	(3)	(4)	(5)	(6)
	Initiations	*Initiations*	*Initiations*	*Suspensions*	*Suspensions*	*Suspensions*
$Treated \times Post$	0.117**	0.324***	0.256***	−0.267**	−0.489***	−0.395**
	(2.429)	(2.825)	(3.512)	(−2.590)	(−2.834)	(−2.183)
Controls	Y	Y	Y	Y	Y	Y
Firm-Category FE	Y	N	Y	N	Y	Y
Year FE	Y	N	Y	N	Y	Y
N	13,118	13,695	5,250	13,118	13,695	5,078
Adj. R^2	0.48	–	–	0.28	–	–

Table C.4: Robustness: No Control Variables

This table provides robustness checks for our main results by dropping all the control variables. $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) over (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspension)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. No control variables are included. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$Treated \times Post$	0.048***	0.094***	−0.026**	−0.073*
	(4.195)	(4.966)	(−2.259)	(−1.788)
Controls	N	N	N	N
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	16,601	19,344	16,601	19,344
Adj. R^2	0.30	0.40	0.03	0.25

Table C.5: Robustness: Extended Time Period

This table provides robustness checks for our main results with an extended sample period from 2005 to 2016. $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$Treated \times Post$	0.068***	0.074**	−0.032***	−0.110***
	(4.754)	(2.417)	(−3.172)	(−3.140)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	16,730	16,730	16,730	16,730
Adj. R^2	0.26	0.36	0.02	0.25

Table C.6: Robustness: Restricted Sample of Firms with Approved Drugs

This table provides robustness checks for our main results with a restricted sample of firms with approved drugs only. $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$Treated \times Post$	0.058***	0.069***	−0.021**	−0.086**
	(4.786)	(3.667)	(−2.126)	(−2.108)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	6,362	6,362	6,362	6,362
Adj. R^2	0.21	0.44	0.05	0.30

Table C.7: Specification with Restricted Sample: Therapeutic Categories with Exclusivity Losses

This table provides robustness checks for our main results with a restricted sample of categories with exclusivity losses only. $Treated_{i,j}$ is one if firm i's ICD j 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. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$Treated \times Post$	0.069***	0.088***	−0.023**	−0.097***
	(4.035)	(2.815)	(−2.334)	(−2.643)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	7,476	7,476	7,476	7,476
Adj. R^2	0.31	0.39	0.04	0.31

Table C.8: Robustness: Null Effects of Other Regulatory Reforms

This table provides robustness checks by studying outcome variables related to concurrent shocks. $Treated_{i,j}$ is one if firm i's ICD j 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. $BTD\,Rate_{i,j,t}$ is the number of drugs with new Breakthrough Therapy Designations (BTDs) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(BTD)_{i,j,t}$ is the logarithm of one plus new BTDs. $Orphan\,Rate_{i,j,t}$ is number of new orphan drug designations ($Orphan_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Orphan)_{i,j,t}$ is the logarithm of one plus orphan drug designations. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $BTD\,Rate$	(2) $\log(BTD)$	(3) $Orphan\,Rate$	(4) $\log(Orphan)$
$Treated \times Post$	−0.007	−0.008	−0.000	0.004
	(−0.471)	(−0.293)	(−0.122)	(0.648)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.14	0.20	0.11	0.10

Table C.9: Heterogeneity: Phase 3 Drugs

This table provides estimation results for heterogeneous effects based on whether a firm has Phase 3 drugs. $Treated_{i,j}$ is one if firm i's ICD j has a drug with exclusivity expiring from 2013 to 2016, and zero otherwise. We then split the sample based on whether the firm i has at least one Phase 3 drug in ICD j in 2012, indicated by $P3$ (at least one). $Post_t$ is a dummy variable that takes a value of one if year t is 2013 or later. $Initiation\,Rate_{i,j,t}$ is number of initiations ($Initiations_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Initiations)_{i,j,t}$ is the logarithm of one plus new drug trial initiations. $Suspension\,Rate_{i,j,t}$ is number of suspensions ($Suspensions_{i,j,t}$) scaled by the (lagged) number of active drugs ($Num\,Drugs_{i,j,t-1}$). $\log(Suspensions)_{i,j,t}$ is the logarithm of one plus new drug trial suspensions. Control variables include $\log(TA)$ and the lagged values of $Avg\,LOA$, $Num\,Drugs$, $\log(Num\,Approvals)$, $EBIT/TA$, $Cash/TA$, $R\&D/TA$, and $Debt/TA$. t-statistics are reported in parentheses, and robust standard errors are double clustered at the firm and ICD level. Fixed effects are included in all specifications, as indicated. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1) $Initiation\,Rate$	(2) $\log(Initiations)$	(3) $Suspension\,Rate$	(4) $\log(Suspensions)$
$P3 \times Treated \times Post$	−0.029	−0.046	−0.039***	−0.174***
	(−1.209)	(−0.966)	(−2.997)	(−4.596)
$Treated \times Post$	0.065***	0.087***	−0.008	−0.017
	(5.304)	(2.763)	(−0.777)	(−0.588)
$P3 \times Post$	0.030**	0.004	−0.008	−0.017
	(2.049)	(0.248)	(−0.719)	(−1.033)
Controls	Y	Y	Y	Y
Firm-Category FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
N	13,118	13,118	13,118	13,118
Adj. R^2	0.30	0.42	0.03	0.28