Competition and New Product Introductions: Evidence from the Pharmaceutical Industry*

Yuanfang Chu, Sudipto Dasgupta, Fangyuan Ma

First Draft: November 2023

This Version: August 2024

Abstract: Firms view the timing of new product launches as real options, taking into consideration the uncertainty of the product's net value. The cost of cannibalizing existing products plays a crucial role in determining the net present value of a new launch. This paper demonstrates that for innovative products that may cannibalize existing offerings, the timing decisions are highly sensitive to competitors' actions. In the pharmaceutical industry, incumbent firms often delay the launch of improved products until generic entry threats rise, which lowers the cost due to cannibalization. The effect is more pronounced in therapeutic areas with unpredictable generic entry and among firms specialized in the commercialization of innovations. Our findings highlight how competition can foster innovation by accelerating the commercialization of new products.

Keywords: Innovation; Product Launch; Competition; Creative Destruction; Real Option.

* Yuanfang Chu and Sudipto Dasgupta are at the Chinese University of Hong Kong. Fangyuan Ma is at the Peking University. Emails: yuanfangchu@cuhk.edu.hk; s.dasgupta@cuhk.edu.hk; fangyuanma@phbs.pku.edu.cn. We thank Thomas Bourveau, Ling Cen, William Cong, Tony Cookson, Francesco D'Acunto, Xuelin Li, Linlin Ma, Song Ma, Honglin Ren, Tao Shu, Michael Weber, Alminas Zaldokas, and the audiences at the CUHK brownbag and Renmin University for helpful comments. We are responsible for the remaining errors.

I. Introduction

Innovation, a key driver of economic growth, generates new products and enhances productivity. The commercialization of innovation is crucial, as it generates monetary incentives for innovators and enhances consumer welfare. Despite its significance, the process of bringing innovative products to the market remains understudied. This paper addresses this gap by examining the timing of new product launches following the completion of innovation. We investigate how competition influences the speed at which innovative products reach the market, providing insights into the relationship between competition, innovation, and growth.

In granular product markets, successful innovators typically hold a temporary monopolistic position due to technological barriers or intellectual property protection. The intangible knowledge accumulated from prior innovations grants them a comparative advantage for follow-up innovations. However, incumbent innovators could hold back introducing new products that improve upon their existing offerings due to the concern of cannibalizing current profits. The extent of such cannibalization is uncertain and depends on competitors' actions. Specifically, the negative impact of cannibalization is substantial when the existing product holds a monopolistic market position. However, this impact is largely mitigated when a competitor enters the market, reducing the expected revenue for the incumbent. As a result, incumbent innovators tend to delay the introduction of new products, especially improved ones, until the threat of generic entry is sufficiently high – choosing the timing of new launches as if holding a real option.

In this paper, we explore how firms' decisions to launch new products are influenced by market entry threats to their existing offerings, and whether these effects stem from concerns about cannibalization. Our focus is on the pharmaceutical industry for two main reasons. First, FDA disclosure requirements and commercial databases provide detailed product information, including approval and launch dates, specific attributes (such as active ingredients, strength,

form, and associated patents), and market sales. Second, we can observe the escalation of entry threats faced by incumbents, i.e., the brand-name manufacturers, from potential entrants, i.e., generic drug makers.[2] Through Paragraph IV applications, generic manufacturers can challenge brand-name drug patents before they expire, aiming to enter the market. Actual market entry usually occurs several years later if patent litigation favors the challenger or if the parties settle on a "pay for delay" agreement.[3] This ability to identify an increase in the threat of entry as opposed to the actual entry allows us to investigate the cannibalization effect of new product launches in response to competitive pressure, rather than the effect of increased competition alone.

The timing of Paragraph IV events is primarily influenced by the Food and Drug Administration's (FDA's) policy of granting 180 days of exclusivity in the generic market to the first filer who successfully enters. This rule encourages generic makers to file patent challenges at the earliest time that FDA regulation permits, typically in the fourth year since FDA approval. At this time, FDA-granted market exclusivity for the brand-name drug is about to expire, leaving patent protection as the only safeguard. In a logit regression predicting Paragraph IV events, the dummy indicator of the fourth year since FDA approval for the brand-name drug is the strongest predictor, outperforming factors such as the drug's historical sales, patent strength, recent record of new product launches, and therapeutic category. However, the timing of Paragraph IV challenges for individual drugs is overall difficult to predict, as all these factors together explain only about 10% of the variation. The remaining randomness primarily

[2] Brand-name drugs are newly discovered medications developed through extensive research and clinical trials. Generic drugs are created to be biological equivalent copies of existing brand-name drugs after their patents expire. Brand-name drugs undergo full clinical trials, while generic drugs have an abbreviated approval process since the safety and efficacy of the active ingredient has already been established. At the granular level of each therapeutic molecule, the most significant competitive threats to brand-named drugs come from their generic counterparts.

[3] Paragraph IV challenges, under the Hatch-Waxman Act of 1984, play a major role in generic entry, accounting for fifty-five percent of initial generic actions. Source: FDA's research report of "marketing of first generic drugs approved by U.S. FDA from January 2010 to June 2017".

stems from technological hurdles and the business opportunities generic companies face across different drug markets.

We conduct a stacked difference-in-difference analysis using Paragraph IV events from 2010 to 2019. For each challenged drug, we identify matches from a cohort of unchallenged drugs with the closest ex-ante likelihood of facing a challenge, estimated from the logit regression using drug-quarter panel data. Additionally, the control drugs must be produced by a different firm. Our analysis focuses on a window starting two years before each Paragraph IV event and extending to either three years after the event or until the actual entry if it occurs earlier.

Using this matched sample, we examine incumbent firms' decisions about new product launches. Our findings reveal that threats from generic entry, as indicated by Paragraph IV challenges, significantly increase both the likelihood and number of new drug product launches. Before patent challenges, the treated and control groups displayed parallel trends of product launching. The economic magnitudes of these effects are sizable. For instance, after Paragraph IV events, challenged firms are 2.8 percent more likely per quarter to launch new drug products, which represents 39.4% of the unconditional launch rate of 7.1 percent.

Moreover, we find that the incremental new launches are primarily concentrated in the same therapeutic categories as the challenged drugs, suggesting that entry threats prompt firms to introduce related new products. These related products have the potential to substitute demand for existing ones, which might have been delayed without the competitive threat. Our analysis further reveals that among these related products, the effect is particularly strong for innovative ones, as indicated by the presence of new patents claiming drug substances. In contrast, there is no significant effect for related products based on the same patents as the challenged ones, or those with only minor additional patents, such as those claiming

formulations, polymorphs, or dosage forms. This suggests that cannibalization concerns are most pronounced for novel products that could render current offerings obsolete.

Importantly, these findings are unlikely to be explained by a positive demand shock that simultaneously motivates competitors to enter the market and prompts brand-name firms to introduce related new products. First, we do not find that Paragraph IV events are associated with a significant increase in the total sales of challenged drug line or therapeutic category, which suggests that it is unlikely that demand shocks coincide with the patent challenges. Second, our baseline results are more pronounced among Paragraph IV events occurring in the fourth year after the drug gets approved. As previously mentioned, the timing of these challenges is largely influenced by FDA policies and is relatively exogenous to demand shocks affecting each individual drug market. Taken together, our findings should be interpreted as firms' strategic reactions to generic competitors' intentions to enter the market.

Furthermore, the evidence reveals insights into the nature of real options for product introduction. First, the new launches occur immediately in the year following Paragraph IV challenges. This immediacy indicates that affected firms swiftly "exercise" their real options upon the resolution of competitive uncertainty. Second, the effects are predominantly driven by those approved by the FDA before patent challenges. This suggests that companies may withhold the market launch of such products, even when technologically ready, due to concerns about potential cannibalization of existing profits. Finally, the effects are more significant in therapeutic categories with less predictable generic entry threats, indicated by a low R-square in category-level regressions predicting Paragraph IV events. This aligns with the notion that the value of real options increases with the underlying uncertainty stemming from competitors' actions.

We next examine the cannibalization effect of new products introduced by the incumbent firm. Although Paragraph IV challenges signal potential generic entry threats, actual

entry, if it occurs, typically happens several years later. During this interval, sales of the challenged drug are not affected by the competitor's eventual entry but can be influenced by the incumbent's related new products. We find a significant decrease in both sales amount and quantity of the challenged drug after Paragraph IV events, specifically when related new products are launched in response. This decline does not occur when no related new products are introduced after the events. This finding suggests that market demand shifts away from the challenged drug product when the incumbent introduces related new products in response to entry threats.[4]

Finally, we explore which types of firms are more strategic in timing their innovative product launches. Since patenting is the primary method of protecting intellectual property in the pharmaceutical industry, we use patent portfolios to assess firms' innovative strength. It is well-established that there is a disparity between the scientific and economic value of patents. This gap arises from a patent's ability to block competition (e.g., Abrams, Akcigit, and Grennan (2019); Czarnitzki, Hussinger, and Leten (2020); Argente et al. (2023)) and its potential for abnormal commercialization, such as supporting multiple product developments.

We propose to measure a patent's abnormal commercialization value based on this gap, which presumably reflects its strategic value in the product market. Specifically, we classify a patent as having high commercial value if there is a large disparity between its scientific value, measured by forward citations, and economic value, following the method of Kogan, Papanikolaou, Seru, and Stoffman (2017). Our analysis reveals that firms holding a portfolio of commercially valuable patents are more responsive to entry threats in their decisions to launch innovative products. This supports the notion that drug companies specializing in commercialization are more strategic in their timing of product launches. In contrast, firms

[4] However, despite the risk of cannibalization, firms facing entry threats launch new products immediately rather than waiting for actual market entries. A possible reason for this is revenue smoothing. Waiting to launch the new products until entry could lead to severe revenue loss when entry eventually occurs.

with a portfolio of scientifically valuable patents show a weaker response to entry threats, indicating that these firms, which focus more on fundamental research, are less strategic in their timing of new product introductions.

Overall, our findings suggest that in the absence of competitive threats, there could be a significant gap between the technology frontier and the novelty of products offered in an economy. This wedge arises from innovators' product market considerations, creating a disconnection between innovation and economic growth. This issue extends beyond the pharmaceutical industry, affecting all industries where the accumulation of knowledge grants incumbent innovators a technological advantage in developing follow-up products. Our research indicates that fostering competition, including from imitators, speeds up the pace at which industry leaders bring their innovative products to the consumer market.

Our paper contributes to the literature on the impact of competition on innovation and growth, a topic on which there is an extensive theoretical literature. For example, Aghion, Bloom, Blundell, Griffith, and Howitt (2005) show that the effect of more competition on steady-state growth has an inverted-U shape. Aghion, Harris, Howitt, and Vickers (2001) demonstrate that the effect of imitation on innovation typically has an inverted-U shape but can be negative. There is also a set of empirical studies using the pharmaceutical setting to examine this issue, such as Higgins and Graham (2009), Garfinkel and Hammoudeh (2020), Branstetter et al. (2022), Thakor and Lo (2022), and Li, Lo, and Thakor (2024). The prior literature almost exclusively focuses on innovators' incentives, assuming an automatic generation of monetary rewards for successful innovators. However, little attention has been paid to the commercialization process, a critical step in connecting innovation with growth. Our paper provides evidence that commercialization of innovation is systematically delayed due to the real option embedded in product launch decisions, which stems from the unpredictability of

competition dynamics. In other words, our findings underscore an important yet understudied channel through which competition affects innovation and growth.

In this regard, our work connects with the strategic patenting literature (e.g., Czarnitzki, Hussinger, and Leten (2020) and Argente, Baslandze, Hanley, and Moreira (2023)), which emphasizes that patents might be filed merely to fend off competing innovation and that not all technological developments are commercialized. Our paper complements the previous finding by showing that that even among the technologies (patents) that are eventually commercialized, there is a persistent delay for innovation to reach the consumer market, which can be reduced by intensified competition. An important implication of our work is that competition, or the ease of imitation, can reduce the negative effect of strategic patenting on economic growth.

Our paper also contributes to the recent literature on product innovation and creative destruction. While classical arguments recognize that incumbents are concerned about cannibalization of their existing products and thus lack incentives to introduce improvements, recent work by Garcia-Macia, Hsieh, and Klenow (2019) finds that most growth stems from improving existing products rather than creating new ones, with incumbents' own-product improvements being more important than new entrants' creative disruption. This raises the question of what factors incentivize incumbent innovators to conduct self-destroying follow-up innovations. Argente, Lee, and Moreira (2024) proposes that competition from innovative rivals encourages creative destruction, generating a self-perpetuating, innovation-obsolescence product introduction cycle. They provide evidence for this in the retail goods industry using Nielsen-Kilts grocery scanner data. Our findings support their argument in the pharmaceutical industry, one of the most innovation-intensive industries. Furthermore, our results indicate that competitive forces do not necessarily need to come from innovative competitors—entry threats from imitators, such as generic makers, also stimulate product innovation by reducing the cannibalization concern.

Finally, our paper adds to the literature on product life cycles. Hoberg and Maksimovic (2022) find that the life cycle of firms' product portfolios, measured through textual analysis of 10-K filings, significantly impacts firms' investment decisions. Hajda and Nikolov (2022) show that the product cycle critically explains cash flow dynamics, corporate policies, and industry structure using product-level data from the retail industry. Our paper provides further insights into the evolution of the product life cycle by examining firms' product launch decisions. By leveraging the transparency of pharmaceutical products, our analysis investigates the granular details of each product, including their innovative features and the commercialization timelines. The evidence from our paper enhances our understanding of the interaction between corporate decisions and competitive dynamics.

II. Institutional Background

2.1 Therapeutic Products

In the pharmaceutical industry, the details of new products are highly transparent. To bring therapeutic products to market, FDA approval is mandatory. This involves disclosing crucial details such as active ingredients, strength, formulation, and unit count, to ensure compliance with safety and efficacy standards. In addition, patenting serves as the major method for drug companies to safeguard their intellectual property, offering insight into firms' innovation achievements. While the FDA does not directly assess patents, it mandates firms to list all relevant patents for each approved therapeutic product in the so-called Orange Book, enabling a clear connection between a company's technological innovation and its products.

A pharmaceutical product typically features active ingredients, routes of administration (e.g., oral, topical, or injection), strength (e.g., 50 mg or 100 mg per tablet), dosage form (e.g., capsules, tablets, or inhalers), and packaging. In the drug industry, new products are generally classified as either truly innovative or minor improvements. Truly innovative products introduce new drug substances or ground-breaking therapies, representing significant

advancements. Minor-improvement products, on the other hand, involve incremental changes to existing drugs, such as adjustments in dosage forms, formulations, or delivery methods. A key way to distinguish between these types is to check for new patents claiming drug substances. New drug substance patents typically indicate higher levels of innovation, while patents for formulation or dosage changes suggest minor improvements.

2.2 Competitor Entry

A significant feature of the pharmaceutical industry is that the timing of increased entry threat from competitors into granular product markets, which often precede the actual entries, is observable. Since the Hatch-Waxman Act enactment in 1984, generic drug producers can gain FDA approval for market entry by demonstrating both the bioequivalence of their generic drug to brand-name drugs and addressing each patent of the brand-name drug when submitting their application with one of four types of certifications. Entry can occur after all patents expire through the Paragraph III certification, or before patents expire through the Paragraph IV certification. Filing a Paragraph IV signals a heightened intention for generic producers to enter the market, although entry typically takes place several years later pending the resolution of patent litigation in court. Our test design focuses on Paragraph IV events, which represent 55% of initial generic entries.

In the Paragraph IV certification process, generic producers declare that the patents held by brand-name producers are not infringed, unenforceable, or invalid. If the brand-name drug manufacturer, as the patent holder, disputes the Paragraph IV certification, they can file a patent infringement suit against the generic applicants within 45 days of notification. In such cases, the FDA will delay generic approval until the court issues a final judgment favoring the generic producer. The first generic producer filing for Paragraph IV certification may receive a 180-day marketing exclusivity reward upon successfully entering the market, which encourages generic makers to file Paragraph IV as early as they are technologically ready and permitted

by the FDA. The FDA does not allow generic makers to file Paragraph IV challenges until the brand-named drug's administrative market exclusivity is about to expire.[5] Specifically, the most common type of market exclusivity for New Chemical Entity (NCE) restricts generic makers from filing Paragraph IV challenges for four years.[6] This rule leads to a clustering of Paragraph IV filings in the fourth year since brand-named drug approval, which has been found in the literature (e.g., Grabowski et al., 2015) and confirmed in our Figure 1. However, the technological hurdle for generic firms in drug production introduces unpredictability, making the timing of specific drugs to be challenged largely uncertain.

Each Paragraph IV challenge pertains to a specific version of a drug. Generic producers are not automatically approved to enter the markets of other versions within the drug product line. If brand-name producers introduce new versions of the drug with added patent protection after the Paragraph IV challenge, these versions aren't immediately under threat unless generic makers file additional Paragraph IV challenges against them.

III. Data

We construct a sample of therapeutic products marketed in the U.S. from 2010 to 2019 by collecting data from multiple sources. First, we collect the information on therapeutic products from the historical data files of the FDA's National Drug Code Directory using the FDA Web Archive and the Internet Archive Wayback Machine. This data source provides comprehensive details including drug names, labeler's name, FDA approval dates, and drug characteristics (e.g., active ingredients, strength, dosage forms). We define a "product" as each version of a drug product with distinct characteristics, including active ingredients, strength, dosage form,

[5] The administrative market exclusivity is granted by the FDA and is independent of patent protection. It can expire before or after the patent expiration day.

[6] For NCEs, the generic entries are generally forbidden for five years, while generic makers are allowed to file Paragraph IVs since the fourth year of drug approval. The other three types of exclusivities include the seven-year Orphan Drug Exclusivity (ODE), the three-year New Clinical Investigation exclusivity, and the six-month Pediatric Exclusivity (PED). Our sample of Paragraph IV events involves 71.4% with NCE exclusivity and 17.5% with ODE exclusivity.

and unit counts. We also refer to such a drug product as a "package" or "drug version." The products sharing the same active ingredients belong to the same product line, referred to as a "drug." In addition, we collect the patent number and expiration dates of each brand-name drug from the FDA Orange Book. The information about the economic value of patents, number of forward citations, issuing dates, and Cooperative Patent Classification (CPC) are from Kogan, Papanikolaou, Seru, and Stoffman (2017).[7] Furthermore, we collect information on Paragraph IV events from the FDA's official website. Our full sample includes all the brand-name drugs whose patents are challenged by generic manufacturers through Paragraph IV between 2010 and 2019 and those that have not experienced Paragraph IV by the end of 2019.

Second, we gather data on the price and quarterly sales for each drug product (also called package) from IQVIA. While IQVIA offers the drug price at various stages of the supply chain, we focus on the manufacturer selling price, which refers to the price at which a drug manufacturer sells its products to wholesalers or other intermediaries. Additionally, this database provides information on the Anatomical Therapeutic Chemical (ATC) Classification, as well as the date when each drug version was introduced to the U.S. market. We merge the IQVIA data with the FDA data based on the calendar quarter, drug name, and drug characteristics. Observations with missing or zero price or quarterly sales data were excluded from the analysis. The availability of IQVIA data limits our sample period from the first quarter of 2010 to the fourth quarter of 2019. The price and sales figures are adjusted for inflation using 2010 as the benchmark year.

Third, we match the drug's labeler name with the company name in Compustat. If the labeler cannot be found in Compustat, we check whether it is a firm's subsidiary by searching the labeler's name in the WRDS Subsidiary database. We use the gvkey of the parent company

[7] The data is collected from: https://github.com/KPSS2017/Technological-Innovation-Resource-Allocation-and-Growth-Extended-Data. It provides an updated data series till 2022 following Kogan, Papanikolaou, Seru, and Stoffman (2017).

if the labeler is identified as a subsidiary. The financial data is collected from Compustat Fundamentals Quarterly and stock return data is from CRSP daily. In the empirical analysis, we take the natural logarithm of the continuous data and winsorize at the 1st and 99th percentile to mitigate the impact of extreme outliers.

The overall sample consists of 851 different brand-name drugs manufactured by 147 unique U.S. listed companies, among which 300 drugs are challenged by generic applicants with Paragraph IV certifications from 2010 to 2019. These challenged drugs have 1,026 different product versions manufactured by 82 companies. In Table 1, Panel A shows the distribution of drugs in the level-one ATC category. The categories that exhibit the highest number of drugs are nervous system, antineoplastic and immunomodulating agents, and alimentary tract and metabolism, collectively accounting for 44.2% of the drugs in the overall sample. For the sample of brand-name drugs with paragraph IV challenges from 2010 to 2019, these categories remain the dominant therapeutic areas.

[Insert Table 1 about Here.]

In Panel B of Table 1, we show that firms often do not launch new drug products immediately upon FDA approval, especially for products sharing the same active ingredient with existing ones. The average (median) time gap between FDA approval and the quarter in which the therapeutic product is introduced to the U.S. market is approximately 1.8 quarters (one quarter) for the new drugs with brand-new active ingredients. However, the time gap is much longer for new versions of existing drugs, with 4.9 (2) quarters as the mean (median) value. This pattern is consistent with firms' delay of launching improved products that could potentially cannibalize the demand for existing products.

IV. Empirical Specification

We use the propensity score matching approach to match each challenged drug with control drugs that have the closest propensity of being challenged. In the first stage, we conduct logit

regression to predict the likelihood of being challenged through Paragraph IV in the next quarter. The dependent variable takes the value of one if drug *i* is challenged in the next quarter *t+1* and zero otherwise. The explanatory variables include: (1) a dummy variable indicating whether the current quarter *t* falls in the fourth year since FDA's approval, (2) a dummy variable indicating whether the average annual sales over the past three years is above 250 million USD,[8] (3) the number of unexpired patents covering the drug *i* in quarter *t*, (4) the proportion of patents claiming the drug substance among all the unexpired patents in quarter *t*, (5) firm size measured by the natural logarithm of total assets in quarter *t*, and (6) a group of variables indicating the numbers of new versions within drug line and number of new drugs within the company launched during each of the past eight quarters.[9] We include the year fixed effects and level-one ATC fixed effects.

The results of the first stage are presented in Table 2. We find that a drug is more likely to be challenged in the next quarter if the current quarter falls in the fourth year after the drug's approval. This aligns with the argument put forth by Grabowski, Brain, Taub, and Guha (2015) that generic makers frequently file Paragraph IV challenges at the earliest point in time following FDA regulations, as the first challenger is potentially eligible for obtaining a 180-day marketing exclusivity. Among all the predictors, the fourth-year indicator has the strongest explanatory power as indicated as the pseudo R-squared. Additionally, the indicator of average annual sales exceeding $250 million also predicts patent challenges positively, suggesting that generic makers are more interested in targeting profitable products, which is consistent with the findings in Grabowski, Long, Mortimer, and Boyo (2016) and Grabowski, Long, Mortimerb and Bilginsoy (2021). Furthermore, we find that a larger number of valid patents

[8] The cutoff of $250 million follows from Grabowski, Long, Mortimer, and Boyo (2016) and Grabowski, Long, Mortimerb and Bilginsoy (2021), who find that Paragraph IV challenges are more frequent and occur early for new molecular entities (NMEs) with annual sales over $250 million. This cutoff maps to approximately the 10th percentile of the matched sample.

[9] The indicators that perfectly predict challenging events are automatically excluded from the regression.

covering the drug and a greater fraction of patents claiming the drug's substance are positively associated with the likelihood of patent challenges, indicating that more innovative products protected by a larger portfolio of patents are more likely to be targeted by the generic makers. Finally, we investigate whether generic makers' decisions to challenge patents are influenced by the brand-name maker's recent product launch activities. An incumbent's introduction of related products might deter entry by signaling a potential shift in marketing effort away from existing offerings, thereby reducing the expected revenue for generics to enter the current markets. Conversely, launching new products could indicate that the brand-name manufacturer has less to lose from generic entry and hence less likely engage in costly litigation, potentially encouraging generic makers to file challenges. In our logit regression analysis, we find that the numbers of drug versions introduced recently does not significantly affect Paragraph IV filings. However, the number of new drugs launched in the current quarter is positively associated with patent challenges.

Although five variables demonstrate statistical significance in predicting Paragraph IV challenges, these factors collectively explain only 9.7% of the variation in the likelihood of being challenged in the subsequent quarter, as indicated by the pseudo R-squared in the last column of Table 2. The remaining variability may be attributed to the technological challenges encountered by generic makers as they strive to understand the requisite technology for manufacturing therapeutically equivalent generic versions. The generic makers may also time their market entry based on the overall business opportunities across their product lines, introducing additional uncertainty from the incumbent's perspective.

[Insert Table 2 about here.]

Based on the logit regression, we construct a matched sample to perform stacked difference-in-difference tests. For each challenged drug, we identify three matches from the unchallenged drugs with the closest ex-ante likelihood, estimated from the logit regression in

column (6) of Table 2, of being challenged during the quarter before the event. Additionally, we require the control drugs to be produced by a different firm. Our analysis focuses on a window beginning two years before each Paragraph IV event and extending up to three years afterward, or until the actual entry of generic competition if it occurs sooner. If a control drug gets challenged during the three years after the paragraph IV date, the observations since the quarter of control drug's own challenge are excluded. The treated drug and control drugs in each event cohort are required to have at least two quarters with non-missing data in both the pre-event window and post-event window. Our final matched sample contains 129 Paragraph IV events from 2010 to 2019 with 129 treated drugs and 338 control drugs.

The treated and control firms are well-balanced in the matched sample. As shown in Panel A of Table 3, there is no significant difference between the treated and control drugs in terms of their propensity score of being treated, and the variables utilized in the first stage (with one exception), during the quarter preceding Paragraph IV events. Furthermore, Figure OA1 demonstrates that the fitted density of the estimated propensity score for treated and control firms closely resemble each other. Taken together, these findings indicate that the treated and control drugs face similar likelihood of being challenged.

For our baseline test to assess whether treated firms respond to patent challenges by launching new products, we collapse the matched sample to the cohort-firm-quarter level where a "cohort" refers to one Paragraph IV event.[10] Our regression specification is outlined as follows.

$$y_{c,i,t} = \beta \times Treat_{c,i} \times Post_{c,t} + X_{c,i,t-1} + \delta_{c,i} + \eta_{c,t} + \varepsilon_{c,i} \qquad (1)$$

where *c* denotes cohort, *i* denotes firm, and *t* denotes quarter. $\delta_{c,i}$ denotes the cohort-firm fixed effects and $\eta_{c,q}$ denotes the cohort-quarter fixed effects. $Treat_{c,i}$ indicates firms that

[10] The sample size is reduced by only 4% because of the collapsing.

experience Paragraph IV challenge and $Post_{c,t}$ indicates the cohort-quarters of and after the quarter of Paragraph IV challenge. $X_{c,i,t-1}$ refers to a vector of control variables, including firm size, market-to-book ratio, ROA, cash holding, and leverage ratio.

Our primary dependent variables are the indicators of launching new drug products in the subsequent quarter. We categorize these new products into two groups: those in the same four-digit ATC therapeutic category as the existing product, termed "related new products," and those in other categories. Related new products are more likely to cannibalize demand for existing products. Within the related products, we further differentiate "innovative" products—those protected by an additional patent claiming a new drug substance—from "non-innovative" ones, which are covered by the same patents as current products or only minor additional patents (e.g., formulations, polymorphs, or dosage forms). Our dependent variables include both dummy indicators and counts of each type of new product launched during the quarter. The summary statistics of these dependent variables in the matched sample are reported in Panel B of Table 3. Firms introduce new products with a quarterly likelihood of 7.1 percent, and the average number of new products launched per quarter is 0.095.

[Insert Table 3 about here.]

The coefficient of our main interest is β in Equation (1), which captures the incremental likelihood (number) of new product introductions due to the intensified threats from generic competitors entering the market. Since therapeutic categories are accounted for in the first-stage estimation of propensity scores, treated and control drugs within the same cohort largely belong to the same category. Consequently, cohort-time fixed effects adjust for time-varying demand fluctuations across therapeutic categories, while cohort-firm fixed effects account for cross-sectional differences in firms' pace of new product introductions. Thus, β in specification (1) represents the treatment effect of Paragraph IV events.

V. Empirical Results

5.1 Baseline

Table 4 presents our baseline findings. In Columns (1) to (2), we find that following the escalation of generic entry threats signalled by Paragraph IV challenges, there is a notable increase in both the probability and quantity of new drug versions introduced by treated firms compared to control firms. Specifically, Column (1) suggests that treated firms exhibit a 2.8% higher likelihood of launching drug products. This effect is statistically significant at the 5 percent level and represents 39.4 percent of the unconditional launching rate of 7.1%. Additionally, as indicated in Column (2), they introduce an average of 0.063 more new versions of treated drugs, which is 66.3 percent of the unconditional average of 0.095.

More importantly, we find pronounced effect for related new drug products in the same therapeutic category. As shown in Column (3) of Table 4, the challenged firms are 2.2% more likely to launch related new products than the matched unchallenged firms after the Paragraph IV events, which corresponds to 100 percent of the unconditional launching rate of 2.2%. Such effect is statistically significant at the 5 percent level. Besides, Column (4) indicates that the challenged firms introduce 0.057 more improved drug versions compared to the unchallenged firms, which is 1.5 times the unconditional average of 0.037. This effect is statistically significant at the 1 percent level. In contrast, as shown in Columns (5) to (6), we do not find a significant increase in the likelihood of launching or the number of unrelated new products in the other therapeutic category following the Paragraph IV events. These non-innovative drug versions share the same set of patents as the existing versions of the treated drug, typically involving different packaging to serve diversified customer needs.

These findings indicate that the threat of competition accelerates the introduction of new drug products related to the challenged product, which have the potential to substitute existing ones in demand. In other words, in the absence of competition, firms are hesitant to launch new drugs that could cannibalize demand from their current products. However,

competitive pressures in one therapeutic area do not directly impact the company's products in the unrelated market segments.

Furthermore, within the related new drugs, we find significant increase in the likelihood and number of innovative products, as shown in Columns (7) to (8). Column (7) suggests that the likelihood of introducing innovative related new drugs increases by 1.3%, which accounts for 3.25 times of the unconditional rate of 0.4%. Similarly, as indicated in Column (8), the number of innovative related new drugs also shows a 188% increase. Such effects are statistically significant at the 1 percent level. In contrast, in Columns (9) to (10), we do not observe a significant increase in the likelihood of introducing non-innovative but related new drugs, nor do their numbers increase.

The findings suggest that generic entry threats are particularly important in driving the launch of innovative products. While both types of new products could compete with existing drugs, the innovative ones are more likely to make current offerings obsolete and thus face greater concerns about cannibalization. Therefore, competition plays a crucial role in advancing the commercialization of innovative products.

For the rest of our analyses, we focus on new products in general, the related new products, and the innovative related products, as the introduction of these products is the most responsive to competitive threats from generic makers.

[Insert Table 4 about here.]

Next, we examine the dynamic effects of the entry threats. We replace the indicator of $Post_{i,t}$ in the baseline regression with a group of cohort-year indicators relative to the event time.[11] The omitted base period is the year before the Paragraph IV challenge, i.e., [t-4, t-1]. As shown in Table 5, the coefficient on the interaction of $Treat_{i,c}$ and the indicator of period

[11] Since there are relatively few drug products introduced each quarter, we focus on the annual rate of product launches to compare differences between the treated and control groups.

[t-8, t-5] is insignificant throughout all dependent variables, suggesting that there is no diverging trend between the treated and control firms before the events. In untabulated tables, we examine the robustness of these results by using [t-8, t-5] as base period and find that the indicator of [t-4, t-1] remains insignificant in the regression.

Furthermore, Table 5 indicates that the treatment effect occurs in the first year after Paragraph IV challenges, especially for the related and innovative products. The effect remains significant for an additional two years. The immediacy of the treatment effect aligns with our argument that firms promptly exercise their real option to launch new products in response to increased entry threats.

[Insert Table 5 about here.]

5.2 Alternative Explanation

An alternative interpretation of our findings suggests that the timing of Paragraph IV coincides with an unobserved positive demand shock in the market of the challenged drug. This hypothetical demand shock simultaneously influences both the incumbent's decision to introduce more products and the generic maker's decision to enter the market. In this section, we rule out this alternative explanation through three approaches.

First, if positive demand shocks were driving our findings, we would expect increased introductions not only of innovative products but also of non-innovative ones, since both types are assumed to cater heightened consumer demand and generate profit for the producer. However, our analysis, outlined in Columns (9) to (10) of Table 4, reveals no significant increase in the latter type, which contradicts the argument of demand-driven product launch decisions.

Second, leveraging regulation-induced incentives, we demonstrate that the baseline effect is more pronounced within a subset of patent challenges that are the least likely to be driven by demand shocks. As previously mentioned, generic manufacturers are motivated to

file Paragraph IV challenges as early as possible to potentially secure 180-day market exclusivity in the generic market. For most drugs in our dataset, this earliest opportunity arises in the fourth year since FDA approval. As illustrated in Figure 1, there is a notable clustering of Paragraph IV challenges during this period. Importantly, compared to challenges in other years, those occurring in the fourth year are less likely to be induced by a surging market demand in the therapeutic area. We partition the regression sample into two groups based on whether the Paragraph IV challenge occurs in the fourth year following FDA approval of the treated drug. As presented in Table 6, the treatment effect is statistically more significant and more substantial for the challenges occurring in the fourth year, suggesting that an unobserved demand shock is unlikely to be the driving force of our findings.

[Insert Figure 1 about here.]

[Insert Table 6 about here.]

Third, we directly investigate market demand in each drug market indicated by the realized sales amounts. If positive demand shocks were responsible for our findings, we would expect a strong positive association between sales in the therapeutic market segment and the occurrence of Paragraph IV events. First, we aggregate sales at the drug-quarter level, summing sales from all drug versions sharing the same active ingredients. Before the generic enters the market, the combined sales of all versions that are offered by the branded drug and sharing the same active ingredients reflect the market demand for that granular therapeutic segment. In Figure 2, we plot the quarterly sales and sales growth of each drug under Paragraph IV challenges, starting eight quarters before the challenge and extending eight quarters afterwards, or until the actual entry if it occurs earlier. However, we find no significant changes surrounding the event time, contradicting the presence of a positive demand shock coinciding with the Paragraph IV.

[Insert Figure 2 about here.]

Next, we investigate this pattern using panel regressions with all quarterly observations of brand-named drugs before generic entries, as detailed in Table 7, Panel A. In Column (1), we find that drug sales exhibit high stickiness, with sales from the previous quarter explaining approximately 91% of the variation in quarterly sales. Furthermore, after controlling for the past sales, the indicator of Paragraph IV challenge during the current quarter does not show any significant impact on drug sales. This lack of significance persists even after controlling for quarter fixed effects, drug fixed effects, and category-quarter fixed effects, as reported in Columns (2) to (4). Additionally, the insignificance of the Paragraph IV effect remains over at least the subsequent four quarters, as shown in Columns (5) to (6).[12]

Further, we aggregate drug sales at the four-digit ATC therapeutic level to assess whether broader market demand relates to Paragraph IV challenges. Panel B of Table 7 shows a similar pattern to Panel A, with past sales accounting for 90% of the current quarter sales and patent challenges proving insignificant in explaining current and future sales of the ATC category.

These findings suggest that the generic makers' decisions to file Paragraph IVs are unlikely to coincide with unforeseen positive demand shocks, which past sales data does not predict. This supports the validity our baseline empirical model, where treated and control drugs are matched based on factors including their past sales.

Finally, we conduct a comparison of quarterly sales changes between treated and control drugs using a Difference-in-Difference approach similar to our baseline regressions. Our focus is restricted to a window surrounding Paragraph IV events and before the actual entry occurs. Within the matched sample of cohort-drug-quarter observations, we regressed

[12] In Online Appendix Table OA1, we explore the sales dynamics of drugs that faced patent challenges during our sample period. We analyse a window that starts two years before the Paragraph IV event and extends up to two years afterward, or the occurrence of actual entry if it comes sooner. Compared to the quarter before the event, neither the previous nor subsequent quarters show much significant differences in dollar sales or sales growth.

quarterly sales on the interaction term of Treat and Post, controlling for cohort-drug fixed effects and cohort-quarter fixed effects. As illustrated in Column (1) of Table 7, Panel C, we find no significant impact of Paragraph IV events on drug sales. This result holds after controlling for sales from the previous quarter, as shown in Column (2). Additionally, in Columns (3) to (6), we continue to find no significant impact of Paragraph IV on the future drug sales over the next one to four quarters. These observations suggest that despite the introduction of new versions in response to patent challenges, the overall demand for the affected product line does not undergo significant changes. This further suggests that the demand for the challenged versions is cannibalized by the introduced new versions, a phenomenon we investigate in detail in Section 5.4.

Taken together, our analysis does not reveal any evidence suggesting that patent challenges are linked to an increase in unforeseen demand for the affected drugs. Therefore, our findings of incremental product launches should be interpreted as strategic responses by firms to the threat of market entry, rather than being influenced by omitted variables related to changing market conditions or customer demand.

[Insert Table 7 about here]

5.3 Real Option Features

The evidence presented thus far suggests that incumbent companies respond swiftly to entry threats by introducing new products. This implies that they delay the launch of new products when there is no competitive pressure, treating product launch as real option which is exercised when the expected cannibalization costs are reduced due to a higher likelihood of competitive entry.

To delve deeper into this phenomenon, we differentiate between new drug products approved by the FDA before and after the Paragraph IV challenges. Our analysis focuses on whether each type of new product launch reacts differently to entry threats. Table 8 indicates

that entry threats only influence the propensity of launching products that were already approved by the FDA before Paragraph IV. Conversely, there is no notable difference in the likelihood or quantity of launches for products approved after Paragraph IV events between the treated and control groups. This finding suggests that the incremental launches of new products are likely those that were postponed when entry threats were absent, despite being technically ready for market.

[Insert Table 8 about here.]

Furthermore, we explore whether the baseline effect is more pronounced when the real option of timing product launches holds greater value. Typically, the total value of a new product to the company consists of its standalone value and the negative impact it has on the company's other products. Thus, the real option value linked to the launch decision hinges on uncertainty surrounding both the market demand for the new product and the magnitude of these side effects. For products closely related to existing offerings, uncertainty about market demand is limited, whereas the scale of side effects can vary greatly based on competitors' actions. Specifically, in the absence of competitor entry, the cannibalization effects of launching a new product can be substantial, particularly given the innovative firm's dominant position in the current product's market. However, when a competitor is poised to enter the market, existing product demand is already under pressure, which mitigates the cannibalization concern of new product introductions. Hence, the value of real options increases when the decision of generic competitors to enter the market becomes more unpredictable.

To gauge this uncertainty, we estimate logistic models following the same specifications as in Table 2, column (6), separately for each level-one ATC category, and derive the pseudo-R-squared for each regression. A lower pseudo-R-squared value suggests greater unpredictability in generic makers' moves, indicating higher uncertainty and consequently greater value in real options. We divide the regression sample into two types of cohorts based

on whether the therapeutic category of the treated drug in each cohort is associated with an R-squared value higher or lower than the sample median. Table 9 presents our results. We find a statistically significant influence of generic entry threats on decisions to launch new products only in the subgroup where the R-squared is lower than the median. However, the effect is not significant in the subgroup where generic makers' actions are more predictable. These findings underscore that firms' postponement of new product launches is driven by real options embedded in the uncertainty surrounding competitor actions, highlighting the pivotal role of uncertainty in determining real option values.

[Insert Table 9 about here.]

5.4 Cannibalization

We now explore why the escalation of entry threats triggers the exercise of the real options of new product launches. The generic competitor's intention to enter the market mitigates concerns about cannibalization from new product launches, as heightened competition reduces the future revenue from existing products. This resolves the uncertainty surrounding the real option value positively, prompting the firm to exercise the option by introducing products to the market.

To assess whether the introduction of new products indeed cannibalizes the demand for existing ones, we analyze the sales of the particular drug products under challenge surrounding Paragraph IV. Our analysis focuses on the period before generic manufacturers' entry into the market, when the brand-name drug maker still holds a monopolistic position in the drug market. During this time, sales of the challenged drug products are influenced only by the incumbent's own product offerings, but not by those of the competitors. We anticipate that sales of challenged drug products will decline following Paragraph IV challenges if related new drugs in the same therapeutic category are launched by the incumbent in response. Conversely, there

should be no changes in the sales of challenged drugs if the Paragraph IV events are not accompanied by the introduction of new products.

We test these predictions in a triple-difference framework, comparing the treatment effect in cohorts with an abnormally high number of new therapeutic products with the other cohorts. The regression specification is outlined as follows.

$$y_{c,i,t} = \alpha_1 \times Treat_{c,i} \times Post_{c,t} \times Abn.NewProducts\_ATC4_c$$
$$+\alpha_2 \times Treat_{c,i} \times Post_{c,t} + X_{c,i,t-1} + \delta_{c,i} + \eta_{c,t} + \varepsilon_{c,i} \dots\dots (2)$$

The dependent variables are the natural logarithm of quarterly sales, the number of units sold in a quarter, and the price for each version of a drug. Since IQVIA provides price and quarterly sales data for each version (or package) of a drug, we expand the baseline model from cohort-firm-quarter level to cohort-drug product-quarter level and include cohort-drug product fixed effects and cohort-quarter fixed effects. We introduce the variable, $Abn.NewProducts\_ATC4_c$, which serves as a dummy indicator for Paragraph IV challenges associated with an abnormally high number of related new products in the same four-digit ATC category launched by the treated drug. We measure this abnormal number through the difference-in-difference calculation of the average increase in the number of related products of the treated drug after the Paragraph IV challenge, minus the average increase in the number of related products of the control drugs in the same cohort. $Abn.NewProducts\_ATC4_c$ takes the value of one if the abnormal number exceeds the 75th percentile and zero otherwise.[13]

We anticipate the coefficient α_1 in equation (2) to be negative for sales or quantity of the challenged versions, reflecting demand substitution between these products and newly

[13] We can measure the abnormal launch rates of related innovative products using a similar approach. However, due to the quarterly launch rate of related innovative products being as low as 0.4%, the measurement is subject to significant noise, making it difficult to discern clear patterns. Therefore, we focus on *Abn.NewProducts_ATC4* for the triple-difference analysis.

introduced ones. On the other hand, α_2 should be insignificant for sales and quantity, as the "threat" of entry itself does not exert direct demand pressure until actual entry occurs.

Consistent with these predictions, we find in Columns (1) to (2) of Table 10 that the triple difference involving $Abn.NewProducts\_ATC4_c$ is negative and statistically significant at the 5% level for both sales and quantity. Furthermore, an F-test on the sum of coefficients of the triple interaction $Treat_{c,i} \times Post_{c,t} \times Abn.NewProducts\_ATC4_c$ and $Treat \times Post$ yields significant results, with the F statistics of 4.87 for sales and 5.87 for quantity. This indicates that dollar sales and the unit sales of the challenged versions decline for these cohorts associated with the introduction of improved versions. Conversely, the interaction term of $Treat_{c,i} \times Post_{c,t}$ is not significant, suggesting that the Paragraph IV events without new product introductions do not directly impact market demand. These findings strongly support our argument that demand for challenged drugs are diverted by the newly introduced products, particularly those falling within the same therapeutic category.

In the regression of drug prices reported in Column (3) of Table 10, the triple interaction term of $Treat_{c,i} \times Post_{c,t} \times Abn.NewProducts\_ATC4_c$ is positive and significant, while the interaction term $Treat_{c,i} \times Post_{c,t}$ remains insignificant. This suggests an abnormal price increase after Paragraph IV filings that are followed by the introduction of related new drugs. This pricing strategy may arise because only loyal customers remain in the market for the challenged drug, rather than switching to new products. As a result, the incumbent can charge higher prices to these loyal customers to maximize the revenue from this segment of the market.

[Insert Table 10 about here.]

Despite the risk of cannibalization, incumbents tend to introduce new products when the threat of market entry becomes significant, rather than waiting for generic competitors to actually enter the market. This strategy helps reduce potential revenue losses to generic entrants, as the demand for generic versions is closely tied to the market size of their branded

counterparts. By cannibalizing their own branded products, incumbents can mitigate the overall revenue losses from the entry of generics. Additionally, if the market size of current branded products shrinks significantly, it may effectively deter new entrants or limit the number of competitors in the long run.

5.5 Heterogeneity

We examine how baseline effects differ across firms with varying innovation profiles. To assess a firm's innovative strength, we analyze its patent portfolio, as patenting is the primary means of protecting intellectual property in the pharmaceutical industry. We evaluate both the economic value of a firm's patent portfolio, which indicates the monopolistic rents these patents can advance and protect, and their scientific value, which reflects the potential for inspiring further research and innovation. These two aspects of patents often diverge. As highlighted by the literature (e.g., Abrams, Akcigit, and Grennan (2019); Czarnitzki, Hussinger, and Leten (2020); Argente et al. (2023)), firms may strategically patent technologies without commercializing them to block the potential competition from other innovators. Additionally, the economic value of patents is closely linked to the development of products derived from them and the firm's product market strategies, which need not be associated with their scientific impact.

We hypothesize that the wedge between the scientific and economic values of patents reflects their abnormal commercialization potential, driven by the strategic value they offer to the patent holder in the product markets. Following Kogan, Papanikolaou, Seru, and Stoffman (2017), we measure the scientific value of patents using forward citations and the economic value based on market reactions to patent approval announcements.

As detailed in Columns (1) and (2) of Table 11, economic value is positively associated with forward citations across all patents held by pharmaceutical companies. However, this relationship is not perfectly aligned, as indicated by a relatively low R-squared in the regression.

These findings are consistent with the analysis by Kogan et al.'s (2017) focusing on various industries. Additionally, Columns (3) and (4) show that among the patents associated with marketed pharmaceutical products, the link between economic and scientific value is even weaker and statistically insignificant. However, there is a significantly positive relationship between economic value and the number of products associated with these patents, even after controlling for their scientific value. This suggests that the disparity between economic and scientific value arises from the commercial potential of the technologies covered by the patents. Finally, Columns (5) and (6) reveal a pronounced positive association between patents' economic value and the number of products launched within two years following Paragraph IV filings. This finding underscores that the gap between economic and scientific value of patents is largely driven by their ability to support strategic actions in the product market, especially facing entry threats.

[Insert Table 11 about here.]

Building on these analyses, we measure a patent's abnormal commercialization potential using the residuals from the regression reported in Table 11, Column (2). In this regression, the economic value of patents regressed on their forward citations, controlling for category-year interacted fixed effects and firm fixed effects. A patent is classified as having high commercial value if its residual term is positive. For each firm in our matched sample, we count the number of patents with high commercial value in the year preceding Paragraph IV events and normalize this count by firm size. Firms that rank in the top quartile based on this measure are identified as holding a portfolio of patents with "high commercialization value."

In Panel A of Table 12, we investigate whether baseline effects vary across firms with different levels of patent commercialization value. Although we observe no significant heterogeneity in the overall tendency of firms to launch new products or those within the same therapeutic category, as shown in Columns (1) to (4), firms holding patents with high

commercialization value exhibit a heightened responsiveness to entry threats in terms of launching innovative related products, as detailed in Columns (5) and (6). This finding supports the idea that firms with stronger commercialization capabilities are more strategic in timing their launch of innovative products.

We observe a contrasting pattern when evaluating firms based on the scientific value of their patent portfolios. For each patent, we measure its abnormal scientific value as the forward citation adjusted by the average forward citations of all patents issued in the same year of our sample. We then count the number of patents with a positive abnormal scientific value in the year prior to Paragraph IV events and normalize this count by firm size. Firms ranked in the top quartile based on this measure are classified as holding a portfolio of patents with high scientific value. As shown in Panel B of Table 12, these firms exhibit lower sensitivity in their new product launches to entry threats. This indicates that firms with a stronger focus on scientific innovations are less strategic in timing their product introductions.

[Insert Table 12 about here.]

Finally, we explore the heterogeneity across firms of different sizes and varying degrees of financial constraints. Large firms are defined as those whose total sales in the year prior to Paragraph IV challenges exceed the 75th percentile, indicated by the dummy variable $HighSales$. As shown in Panel A of Table 13, triple difference regressions reveal that while the interaction term $Treat_{c,i} \times Post_{c,t}$ is positively significant, the triple interaction term $Treat_{c,i} \times Post_{c,t} \times HighSales_{c,i}$ is negative and mostly insignificant. Additionally, F-tests indicate that the sum of coefficients for those two interaction terms is also statistically insignificant for five out of six dependent variables of product launches. These findings suggest that the strategic responses to entry threats through new product launches are similar across both large and small firms. However, responses appear slightly stronger among smaller firms,

which may be more sensitive to competitor entries in individual drug markets due to their small product portfolio size.

We assess firms' financial constraints using the Kaplan-Zingles (KZ) index (Kaplan and Zingales, 1997; Lamont et al., 2001). The dummy variable *HighKZ* denotes financially constrained firms whose KZ index in the year preceding the Paragraph IV challenge exceeds the 75th percentile of our sample distribution. In Panel B of Table 13, similar to Panel A, we find that the triple interaction term is statistically insignificant for Columns (1) to (5) and negatively significant in Column (6). Furthermore, F-tests indicate that the sum of the two interaction terms is not statistically different from zero for five out of six dependent variables. These findings indicate that unconstrained firms tend to be marginally more responsive to competitors' actions, possibly due to their greater financial flexibility, which allows them to implement product market strategies swiftly. These results hold robustly when using alternative measures such as the Hadlock-Pierce index (Hadlock and Pierce, 2010) and the Whited-Wu index (Whited and Wu, 2006).

[Insert Table 13 about here.]

VI. Conclusion

In this paper, we explore how competitor entry threats influence firms' strategies for commercializing their innovative products. We argue that firms often delay introducing innovative products due to concerns about cannibalization. Therefore, the timing of new product introductions is treated as a real option given the underlying uncertainty of the net value new products creates. A key factor prompting firms to exercise this option is the threat of competitor entry, which alleviates cannibalization concerns and strengthens the strategic advantage of deterring competitors from launching new products. These effects are particularly pronounced in markets where entry threats are unpredictable and among firms adept at commercializing their innovations. Our findings underscore that competitive pressures

accelerate the commercialization of innovation, fostering creative destruction and tightening the connection between innovation and economic growth.

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Table 1 Summary statistics

In Panel A, we show the distributions of drugs, packages, and firms in each ATC1 category in the overall sample. In Panel B, we show the time gap (in number of quarters) between the FDA approval date and the launching date for a drug version that has the same active ingredients as the existing drugs or for the new drugs with brand-new active ingredients.

Panel A. Distribution of drugs in the ATC1 in the overall sample before matching

		(1)	(2)	(3)	(4)	(5)	(6)
		All Drugs in the Overall Sample			Drugs with PIV in [2010-Q1, 2019-Q4]		
	ATC1 Categories	#[Drugs]	#[Packages]	#[Firms]	#[Drugs]	#[Packages]	#[Firms]
A	Alimentary tract and metabolism	112	415	44	55	170	34
B	Blood and blood forming organs	13	39	11	6	15	8
C	Cardiovascular system	98	710	35	25	138	27
D	Dermatological	50	163	15	15	39	14
G	Genito-urinary system and sex hormones	65	202	25	16	33	22
H	Systemic hormonal preparations	21	112	17	8	18	15
J	Anti-infective for systemic use	90	283	30	27	46	20
L	Antineoplastic and immunomodulating agents	117	305	40	42	112	30
M	Musculo-skeletal system	24	97	17	9	13	14
N	Nervous system	147	1,105	52	64	370	40
P	Antiparasitic products, insecticides, and repellents	6	14	5	3	4	5
R	Respiratory system	33	155	13	7	22	9
S	Sensory organs	60	135	16	19	35	9
T	Diagnostic Agents	3	10	3	0	0	1
V	Various	12	47	10	4	11	6
	Total	851	3,792	147	300	1,026	82

Panel B: Delay of launch (in number of quarters) since FDA approval

N	Mean	S.D.	Min	p-25th	Median	p-75th	Max
1. New versions with same active ingredient as existing drugs							
415	4.945	6.039	0	1	2	6	28
2. New drugs with brand-new active ingredient							
95	1.768	2.219	0	0	1	3	14

Table 2. Predictability of the paragraph IV events

In this table, we use a logistic regression model to examine the likelihood of Paragraph IV challenge in the subsequent quarter *t+1*, considering the following variables: (1) a dummy variable indicating whether quarter *t* falls in the fourth year since FDA's approval, (2) a dummy variable indicating whether the average annual sales in the past three years is above 250 million USD, (3) the number of unexpired patents covering the drug in quarter *t*, (4) the proportion of patents claiming the drug substance among all the unexpired patents in quarter *t*, (5) firm size measured by the natural logarithm of total assets in quarter t, (6) the number of drug versions per firm-quarter from *t-7* to *t*, and (7) the number of new drugs per firm-quarter from *t-7* to *t*. The dependent variable takes the value of one if a drug is challenged in the next quarter and zero otherwise. We include the year fixed effects and level-one ATC fixed effects. Z statistics are reported in the brackets. ***, **, and * indicate the 1%, 5%, and 10% levels of significance, respectively.

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent variable			*d_1stpiv_t+1*			
D[4th year since approval]	1.981**	1.960**	1.941**	1.892**	1.809**	1.783**
	(13.638)	(13.455	(13.283	(12.842	(11.235	(10.986
D[annual sales > 250m]		0.646**	0.511**	0.492**	0.581**	0.592**
		(3.363)	(2.546)	(2.452)	(2.790)	(2.821)
#[valid patents]			0.047**	0.051**	0.046**	0.044**
			(2.725)	(2.978)	(2.414)	(2.341)
%[substance patents]				0.475**	0.482**	0.493**
				(2.375)	(2.247)	(2.290)
Log(Total Assets)					-0.011	-0.018
					(-0.310)	(-0.500)
#[New Version]_t						-0.034
						(-0.436)
#[New Version]_t-1						-0.083
						(-0.724)
#[New Version]_t-2						-0.018
						(-0.245)
#[New Version]_t-3						0.031
						(0.613)
#[New Version]_t-4						0.014
						(0.255)
#[New Version]_t-5						-
#[New Version]_t-6						0.008
						(0.164)
#[New Version]_t-7						-0.133
						(-1.014)
#[New Drugs]_t						0.551**
						(2.478)
#[New Drugs]_t-1						-
#[New Drugs]_t-2						-
#[New Drugs]_t-3						0.772
						(0.712)
#[New Drugs]_t-4						-
#[New Drugs]_t-5						0.081
						(0.072)
#[New Drugs]_t-6						-
#[New Drugs]_t-7						-0.465
						(-0.425)
Observations	10,612	10,612	10,612	10,612	9,142	8,745
Pseudo R^2	0.085	0.090	0.093	0.095	0.091	0.097

Table 3. Summary for the matched sample

Panel A presents the results of T-test conducted in the matched sample. The matching process is described in Section IV. We calculate the mean value of the following variables for treated drugs and control drugs in the matched sample in the quarter before paragraph IV events: (1) the value of the propensity score, and (2) the variables used in the first stage of propensity score matching. We examine the statistical significance of the differences in mean values between the treated and control groups. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively. Panel B presents the summary statistics for dependent variables and control variables in the baseline regressions.

Panel A. Balance test for the matched sample

	Treated	Control	Dif.	T statistics
1. Propensity score	0.033	0.032	0.000	0.010
2. Variables used in the first stage:				
D[4th year since approval]	0.171	0.202	-0.031	-0.642
D[annual sales of last 3 years > 250m]	0.155	0.123	0.032	0.871
#[valid patents]	4.419	4.362	0.057	0.149
%[substance patents]	0.318	0.371	-0.053	-1.315
Log(Total Assets)	9.773	9.554	0.219	0.903
#[New Version]_t	0.078	0.047	0.031	0.460
#[New Version]_t-1	0.093	0.171	-0.078	-0.977
#[New Version]_t-2	0	0.176	-0.176	-2.209**
#[New Version]_t-3	0.124	0.078	0.047	0.625
#[New Version]_t-4	0.202	0.083	0.119	1.167
#[New Version]_t-5	0	0	0	.
#[New Version]_t-6	0.155	0.075	0.080	1.010
#[New Version]_t-7	0.078	0.138	-0.061	-0.718
#[New Drugs]_t	0.054	0.083	-0.028	-0.867
#[New Drugs]_t-1	0	0	0	.
#[New Drugs]_t-2	0	0	0	.
#[New Drugs]_t-3	0.008	0.003	0.005	0.633
#[New Drugs]_t-4	0	0	0	.
#[New Drugs]_t-5	0	0	0	.
#[New Drugs]_t-6	0	0	0	.
#[New Drugs]_t-7	0	0.003	-0.003	-1.000

Panel B. Summary statistics for dependent variables and control variables in the baseline regressions

	Mean	Median	S.D.
1. Dependent variables:			
D[All New Products]	0.071	0	0.257
D[New Products in ATC4]	0.022	0	0.147
D[New Products in Other ATC]	0.051	0	0.219
D[Innovative New Products in ATC4]	0.004	0	0.065
D[Non-innovative New Products in ATC4]	0.018	0	0.132
#[All New Products]	0.095	0	0.409
#[New Products in ATC4]	0.037	0	0.304
#[New Products in Other ATC]	0.058	0	0.271
#[Innovative New Products in ATC4]	0.012	0	0.216
#[Non-innovative New Products in ATC4]	0.026	0	0.216
2. Control variables:			
Firm Size	9.697	10.662	2.313
M/B	2.349	1.969	1.688
ROA	0.005	0.014	0.071
Cash Holding	36.195	1.252	205.164
Leverage Ratio	0.315	0.259	0.24

Table 4. Baseline result: introduction of new products

This table reports the OLS regression results using the matched sample. For each Paragraph IV event from 2010 to 2019, we identify matches from a cohort of unchallenged drugs with the closest ex-ante likelihood of facing a challenge, as estimated in the regression reported in the last column of Table 2. The control drugs must be produced by a different firm. The event window spans from eight quarters before to twelve quarters after each event. In columns (1) and (2), dependent variables are the dummy indicator or the number of new therapeutic products launched per firm-quarter. In columns (3) to (6), we distinguish new products which are in the same ATC4 category as the sample drug from other new products in the different ATC category. In the last four columns, we further decompose the new products in the ATC4 category into innovative new products, protected by additional patents claiming drug substance, from non-innovative proliferations, which have the same set of patents as the sample drug or are not protected by new substance patents. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	All New Products		*New Product in ATC4*		*New Product Other ATC*		*Innovative New Products in ATC4*		*Non-innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.028**	0.063***	0.022**	0.057***	0.008	0.006	0.013***	0.047***	0.009	0.010
	(2.077)	(2.808)	(2.524)	(3.205)	(0.696)	(0.419)	(2.943)	(3.301)	(1.194)	(0.847)
l. Firm Size	0.041***	0.064***	0.015**	0.040***	0.027**	0.024*	0.009***	0.023***	0.006	0.017
	(3.485)	(3.455)	(2.360)	(2.921)	(2.561)	(1.841)	(3.017)	(2.819)	(1.133)	(1.583)
l. M/B	0.003	0.006	0.002	0.008	0.000	-0.002	0.001	0.003	0.001	0.005
	(0.897)	(0.771)	(0.939)	(1.195)	(0.178)	(-0.614)	(1.007)	(0.826)	(0.516)	(0.916)
l. ROA	-0.038	-0.121	0.009	-0.074	-0.042	-0.046	0.012	-0.010	-0.002	-0.064
	(-0.633)	(-0.771)	(0.217)	(-0.554)	(-0.852)	(-0.738)	(0.386)	(-0.085)	(-0.073)	(-1.042)
l. Cash Holding	0.000	0.000	0.000	0.000**	-0.000**	-0.000*	0.000	0.000	0.000	0.000*
	(0.333)	(1.219)	(1.534)	(2.174)	(-2.298)	(-1.915)	(1.127)	(1.195)	(1.202)	(1.780)
l. Leverage Ratio	-0.094***	-0.140***	-0.019	-0.031	-0.081***	-0.109***	-0.006	-0.017	-0.013	-0.013
	(-3.944)	(-3.262)	(-1.192)	(-0.891)	(-4.373)	(-4.742)	(-0.699)	(-0.768)	(-0.935)	(-0.480)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.050	0.038	0.050	0.004	0.043	0.052	0.001	-0.019	0.046	-0.013

Table 5. Dynamics of the treatment effect

This table presents the pre-treatment effects and post-treatment effects of Paragraph IV challenges on the introduction of new therapeutic products. For each Paragraph IV, the event window spans from eight quarters before to twelve quarters after each event. Considering the lower frequency of new product introduction, we present the pre-treatment and post-treatment effects on the year level. In columns (1) and (2), the dependent variables are a dummy indicator or the number of new therapeutic products introduced per firm-quarter. In columns (3) and (4), the dependent variables are a dummy indicator or the number of new products that are in the same ATC4 category as the sample drug. In the last two columns, the dependent variables are a dummy indicator or the number of innovative new products which are protected by additional patents claiming drug substance and in the same ATC4 as the sample drug. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Products in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * [t-8, t-5]*	0.009	0.009	0.016	0.016	-0.006	-0.031
	(0.403)	(0.246)	(1.167)	(0.548)	(-0.848)	(-1.395)
*Treat * [t, t+4]*	0.026	0.053*	0.033***	0.062***	0.008*	0.031*
	(1.301)	(1.712)	(2.766)	(2.791)	(1.812)	(1.847)
*Treat * [t+5, t+8]*	0.020	0.058**	0.028***	0.067***	0.013**	0.038**
	(1.061)	(1.999)	(2.669)	(3.039)	(2.555)	(2.178)
*Treat * [t+9, t+12]*	0.062***	0.110***	0.032***	0.075***	0.012**	0.036**
	(2.954)	(3.360)	(2.648)	(3.218)	(2.182)	(2.015)
l. Firm Size	0.040***	0.064***	0.015**	0.040***	0.009***	0.024***
	(3.462)	(3.443)	(2.374)	(2.943)	(3.022)	(2.833)
l. M/B	0.003	0.006	0.002	0.008	0.001	0.003
	(0.947)	(0.805)	(0.945)	(1.207)	(1.043)	(0.832)
l. ROA	-0.039	-0.121	0.010	-0.072	0.012	-0.008
	(-0.646)	(-0.771)	(0.239)	(-0.538)	(0.393)	(-0.066)
l. Cash Holding	0.000	0.000	0.000	0.000**	0.000	0.000
	(0.363)	(1.261)	(1.520)	(2.191)	(1.179)	(1.311)
l. Leverage Ratio	-0.094***	-0.139***	-0.020	-0.030	-0.006	-0.014
	(-3.950)	(-3.216)	(-1.219)	(-0.862)	(-0.637)	(-0.616)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	8,299	8,299	8,299	8,299	8,299	8,299
Adjusted R^2	0.060	0.057	0.080	0.031	0.016	0.012

Table 6. Subsample tests: patent challenge induced by administrative incentives

In this table, we partition the matched sample into two subsamples based on whether a paragraph IV challenge occurs in the 4th year after the treated drug is approved by the FDA. The results of each subsample are presented in Panel A and Panel B respectively. In each panel, the model we use is the same as the baseline model. The event window spans from eight quarters before to twelve quarters after each event. In each panel, the dependent variables include (1) a dummy indicator or the number of new therapeutic products introduced per firm-quarter, (2) a dummy indicator or the number of new therapeutic products that are in the same ATC4 category as the sample drug, and (3) a dummy indicator or the number of innovative new products which are protected by additional patents claiming drug substance and in the same ATC4 as the sample drug. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A. PIV occurs in the 4th year since FDA approval

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.077***	0.122***	0.041***	0.096***	0.020**	0.072**
	(3.080)	(2.792)	(2.890)	(3.090)	(2.480)	(2.420)
l. Firm Size	0.064***	0.089**	0.019	0.041	0.015**	0.041*
	(2.744)	(2.367)	(1.627)	(1.657)	(2.004)	(1.849)
l. M/B	0.006	0.007	0.007	0.011	0.007**	0.014*
	(0.752)	(0.499)	(1.533)	(1.216)	(2.168)	(1.860)
l. ROA	-0.144	-0.369	-0.022	-0.171	0.016	-0.147
	(-0.896)	(-0.601)	(-0.167)	(-0.312)	(0.132)	(-0.264)
l. Cash	-0.000	-0.000	0.000	0.000	-0.000	0.000
	(-1.026)	(-0.104)	(0.378)	(0.700)	(-0.010)	(0.452)
l. Leverage	-0.115**	-0.231**	-0.039	-0.097	-0.052**	-0.130*
	(-2.195)	(-2.406)	(-1.117)	(-1.266)	(-1.986)	(-1.867)
Cohort-Firm	YES	YES	YES	YES	YES	YES
Cohort-Time	YES	YES	YES	YES	YES	YES
Observations	2,174	2,174	2,174	2,174	2,174	2,174
Adjusted R^2	0.020	-0.040	0.053	-0.092	-0.118	-0.144

Panel B. PIV occurs in the other years

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.006	0.035	0.014	0.040*	0.010*	0.034**
	(0.362)	(1.356)	(1.267)	(1.895)	(1.850)	(2.235)
l. Firm Size	0.029**	0.049**	0.012*	0.036**	0.006**	0.014*
	(2.182)	(2.346)	(1.672)	(2.293)	(2.166)	(1.961)
l. M/B	0.002	0.005	0.001	0.007	-0.000	-0.001
	(0.470)	(0.536)	(0.316)	(0.801)	(-0.248)	(-0.331)
l. ROA	0.004	-0.041	0.024	-0.043	0.013	0.032
	(0.065)	(-0.366)	(0.552)	(-0.496)	(0.618)	(0.765)
l. Cash	0.000	0.000	0.000	0.000**	0.000*	0.000*
	(0.498)	(1.348)	(1.494)	(2.108)	(1.767)	(1.756)
l. Leverage	-0.080***	-0.106**	-0.013	-0.010	0.008	0.016
	(-3.087)	(-2.345)	(-0.687)	(-0.278)	(0.988)	(0.836)
Cohort-Firm	YES	YES	YES	YES	YES	YES
Cohort-Time	YES	YES	YES	YES	YES	YES
Observations	6,116	6,116	6,116	6,116	6,116	6,116
Adjusted R^2	0.059	0.062	0.047	0.033	0.044	0.032

Table 7. Market demand around Paragraph IV events

Panel A reports the panel regression of quarterly sales of each drug, summing up the sales of all versions introduced by the brand-named drug firm sharing the same active ingredients, on the sales of previous quarter, and an indicator of Paragraph IV events. Each column controls for different fixed effects as indicated in the bottom of the table. T-statistics are reported in the parathesis based on the robust standard errors for Column (1), standard errors clustered on quarter level in Column (2), and errors double clustered on drug and quarter levels in Columns (3) to (6). Panel B reports the panel regression of quarterly sales of all drugs in an ATC4 category on the sales of previous quarter, and an indicator of Paragraph IV events among drugs in an ATC4 category. Each column controls for different fixed effects as indicated in the bottom of the table. T-statistics are reported in the parathesis based on the robust standard errors for Column (1), standard errors clustered on quarter level in Column (2), and errors double clustered on ATC4 and quarter levels in Columns (3) to (6). Panel C reports the regression in the matched sample at cohort-drug-quarter level where sales information is available. The regression specification resembles the baseline as reported in Table 4. The drug sales from the previous quarters are further controlled for in Columns (2) to (6). Each column controls for the cohort-quarter and cohort-drug fixed effects. T-statistics are reported in the parathesis based on stand errors double clustered on the cohort-drug and cohort-quarter levels. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A. Overall sample (all the drugs before matching)

	(1)	(2)	(3)	(4)	(5)	(6)
			Drug Sales in quarter			
	[q]	*[q]*	*[q]*	*[q]*	*[q+2]*	*[q+4]*
Drug Sales [q-1]	0.880***	0.884***	0.796***	0.797***	0.031	0.110**
	(460.186)	(14.799)	(9.579)	(9.696)	(1.068)	(2.573)
PIV [q]	0.001	0.002	-0.001	-0.001	-0.001	-0.000
	(0.342)	(1.588)	(-0.733)	(-0.440)	(-0.373)	(-0.011)
Drug Sales [q]					-0.212***	-0.168***
					(-3.314)	(-3.259)
Drug Sales [q+1]					1.067***	0.029
					(20.203)	(1.408)
Drug Sales [q+2]						-0.126***
						(-2.980)
Drug Sales [q+3]						1.031***
						(23.118)
Drug FE	NO	NO	YES	YES	YES	YES
Quarter FE Effects	NO	YES	YES	YES	YES	YES
ATC1*Qtr FE	NO	NO	NO	YES	NO	NO
Observations	21,960	21,960	21,954	21,954	20,258	18,671
Adjusted R^2	0.906	0.909	0.916	0.916	0.941	0.943

Panel B. Total Sales at ATC4 Level in the Overall sample (all the drugs before matching)

	(1)	(2)	(3)	(4)	(5)	(6)
			Sales_ATC4 in a quarter			
	[q]	*[q]*	*[q]*	*[q]*	*[q+2]*	*[q+4]*
Sales_ATC4 [q-1]	0.874***	0.882***	0.772***	0.787***	0.071**	0.104***
	(33.240)	(14.130)	(8.103)	(9.042)	(2.065)	(3.246)
PIV [q]	0.002	0.004	-0.006	-0.004	-0.002	0.004
	(0.216)	(0.557)	(-0.603)	(-0.454)	(-0.361)	(0.815)
Sales_ATC4 [q]					-0.289***	-0.100***
					(-3.646)	(-3.462)
Sales_ATC4 [q+1]					1.105***	0.054
					(33.629)	(1.118)
Sales_ATC4 [q+2]						-0.264***
						(-2.840)
Sales_ATC4 [q+3]						1.078***
						(32.250)
ATC4 FE	NO	NO	YES	YES	YES	YES
Quarter FE Effects	NO	YES	NO	YES	YES	YES
Observations	7,371	7,371	7,371	7,371	6,903	6,443
Adjusted R^2	0.901	0.908	0.911	0.916	0.940	0.938

Panel C. PSM Matched Sample

	(1)	(2)	(3)	(4)	(5)	(6)
			Drug Sales in quarter			
	[q]	*[q]*	*[q+1]*	*[q+2]*	*[q+3]*	*[q+4]*
*Treat * Post*	0.004	-0.001	-0.001	0.000	0.000	0.001
	(0.707)	(-0.267)	(-0.858)	(0.054)	(0.021)	(0.279)
Drug Sales [q-1]		0.709***	-0.060	-0.023	0.043	0.254***
		(13.238)	(-1.210)	(-0.394)	(0.582)	(4.003)
Drug Sales [q]			0.879***	-0.148**	-0.147**	-0.338***
			(16.488)	(-2.111)	(-2.130)	(-4.083)
Drug Sales [q+1]				0.953***	-0.062*	-0.017
				(11.682)	(-1.943)	(-0.702)
Drug Sales [q+2]					0.932***	-0.030
					(12.366)	(-1.259)
Drug Sales [q+3]						0.881***
						(19.718)
l. Firm Size	0.007	0.001	0.001	0.001	0.000	0.000
	(1.466)	(0.534)	(1.308)	(0.574)	(0.104)	(0.157)
l. M/B	0.001	-0.000	-0.000	0.000	0.001**	0.001***
	(0.704)	(-0.011)	(-0.173)	(0.520)	(2.054)	(2.916)
l. ROA	0.028	0.018	0.002	0.004	0.003	0.010
	(1.418)	(1.497)	(0.274)	(0.800)	(0.903)	(1.271)
l. Cash Holding	-0.001	-0.005	-0.001	-0.002	-0.003	-0.006
	(-0.122)	(-1.586)	(-0.241)	(-0.901)	(-1.174)	(-1.646)
l. Leverage Ratio	-0.012	-0.013	-0.006	-0.006	-0.001	-0.002
	(-0.974)	(-1.518)	(-0.863)	(-0.885)	(-0.337)	(-0.877)
Cohort-Drug FE	YES	YES	YES	YES	YES	YES
Cohort-Quarter FE	YES	YES	YES	YES	YES	YES
Observations	7,032	7,032	6,882	6,720	6,565	6,398
Adjusted R^2	0.691	0.893	0.906	0.906	0.909	0.933

Table 8. New products approved before vs. after the entry threat

This table explores the introduction of new therapeutic products approved by the FDA before or after the generic entry threat. In each panel, the dependent variables include (1) a dummy indicator or the number of new therapeutic products introduced per firm-quarter, (2) a dummy indicator or the number of new therapeutic products that are in the same ATC4 category as the sample drug, and (3) a dummy indicator or the number of innovative new products which are protected by additional patents claiming drug substance and in the same ATC4 as the sample drug. We categorize new products into two group based on whether they are approved by the FDA before or after the occurrence of the Paragraph IV event. The results are presented in Panel A and Panel B respectively. The event window spans from eight quarters before to twelve quarters after each event. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A. New products launched before PIV

	(1)	(2)	(3)	(4)	(5)	(6)
	Approved before PIV					
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.037***	0.074***	0.025***	0.062***	0.013***	0.074**
	(2.806)	(3.367)	(2.892)	(3.432)	(2.989)	(2.521)
l. Firm Size	0.022**	0.046***	0.012*	0.037***	0.007***	0.034**
	(2.315)	(2.662)	(1.950)	(2.740)	(2.636)	(2.570)
l. M/B	-0.000	0.002	0.003	0.008	0.001	0.006
	(-0.087)	(0.227)	(0.998)	(1.192)	(1.142)	(0.715)
l. ROA	-0.004	-0.081	0.016	-0.065	0.015	0.104
	(-0.069)	(-0.530)	(0.383)	(-0.488)	(0.517)	(0.445)
l. Cash Holding	0.000	0.000	0.000	0.000**	0.000	0.000
	(0.292)	(1.310)	(1.316)	(2.068)	(0.316)	(0.970)
l. Leverage Ratio	-0.072***	-0.106**	-0.020	-0.032	-0.009	-0.030
	(-3.291)	(-2.490)	(-1.295)	(-0.918)	(-1.152)	(-0.622)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.079	0.049	0.064	0.015	0.012	-0.033

Panel B. New products launched after PIV

	(1)	(2)	(3)	(4)	(5)	(6)
	Approved after PIV					
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	-0.008	-0.011	-0.002	-0.008	0.000	-0.000
	(-1.148)	(-1.265)	(-0.979)	(-1.462)	(0.348)	(-0.075)
l. Firm Size	0.018***	0.018**	0.003*	0.003	0.002	0.003
	(2.797)	(2.411)	(1.731)	(1.417)	(1.505)	(1.207)
l. M/B	0.003*	0.004*	-0.000	-0.000	-0.000	-0.000
	(1.700)	(1.802)	(-0.090)	(-0.072)	(-0.007)	(-0.042)
l. ROA	-0.028	-0.040	-0.005	-0.005	-0.003	-0.030
	(-0.830)	(-1.066)	(-0.446)	(-0.425)	(-0.304)	(-0.628)
l. Cash Holding	0.000	0.000	0.000	0.000	0.000	0.000
	(0.170)	(0.157)	(1.138)	(0.655)	(1.329)	(1.499)
l. Leverage Ratio	-0.021	-0.034**	0.000	-0.004	0.003	0.009
	(-1.514)	(-2.035)	(0.120)	(-0.673)	(0.802)	(0.916)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.032	0.019	0.013	-0.006	-0.019	-0.109

Table 9. Subsample test: uncertainty of generic competitor's entry

In this table, we examine whether new therapeutic products are more likely to be launched when a high extend of uncertainty gets resolved. We run the same logit model of predicting PIV as the one in the last column of Table 2 for *each ATC1 category* and use the R^2 as the measure of uncertainty. Low R^2 suggests that the occurrence of Paragraph IV challenge in the subsequent quarter *t+1* is hard to predict. Once the PIV happens, the event can resolve a high extend of uncertainty. In each panel, the dependent variables include (1) a dummy indicator or the number of new therapeutic products introduced per firm-quarter, (2) a dummy indicator or the number of new therapeutic products that are in the same ATC4 category as the sample drug, and (3) a dummy indicator or the number of innovative new products which are protected by additional patents claiming drug substance and in the same ATC4 as the sample drug. We classify the cohorts in the matched sample into two groups based on whether the treated drug in a cohort belongs to an ATC1 category with R^2 lower than the median value across all the cohorts. The results are presented in Panel A and Panel B respectively. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A. R^2 <= Median

	(1)	(2)	(3)	(4)	(5)	(6)
	R^2 <= median					
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.035*	0.072***	0.021**	0.060***	0.011**	0.045***
	(1.932)	(2.629)	(2.179)	(3.097)	(2.260)	(2.683)
l. Firm Size	0.050***	0.073***	0.013*	0.036**	0.007**	0.026**
	(3.326)	(3.219)	(1.654)	(2.339)	(1.975)	(2.144)
l. M/B	0.004	0.006	0.002	0.007	0.003*	0.007**
	(1.060)	(0.980)	(0.781)	(1.520)	(1.689)	(2.134)
l. ROA	-0.032	-0.163	-0.020	-0.149	0.006	-0.079
	(-0.411)	(-0.723)	(-0.414)	(-0.786)	(0.138)	(-0.417)
l. Cash Holding	-0.000	0.000	0.000	0.000	0.000	0.000
	(-0.028)	(0.642)	(1.059)	(1.522)	(0.564)	(0.638)
l. Leverage Ratio	-0.092***	-0.147***	-0.022	-0.040	-0.013	-0.043
	(-3.183)	(-3.061)	(-1.053)	(-1.086)	(-1.189)	(-1.455)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	4,918	4,918	4,918	4,918	4,918	4,918
Adjusted R^2	0.029	0.017	0.058	0.013	-0.005	-0.034

Panel B. R^2 > Median

	(1)	(2)	(3)	(4)	(5)	(6)
	R^2 > Median					
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.025	0.056	0.023	0.052	0.014*	0.047*
	(1.200)	(1.462)	(1.372)	(1.528)	(1.788)	(1.840)
l. Firm Size	0.018	0.045	0.016	0.047*	0.008**	0.016
	(0.991)	(1.333)	(1.466)	(1.703)	(1.991)	(1.525)
l. M/B	0.001	0.005	0.002	0.008	-0.002	-0.008
	(0.091)	(0.226)	(0.383)	(0.410)	(-0.798)	(-1.079)
l. ROA	-0.055	-0.067	0.056	0.043	0.023	0.110
	(-0.568)	(-0.352)	(0.664)	(0.244)	(0.488)	(1.278)
l. Cash Holding	0.000	0.001	0.000*	0.001	0.000	0.000
	(1.638)	(1.377)	(1.861)	(1.349)	(0.823)	(0.124)
l. Leverage Ratio	-0.104**	-0.142	-0.023	-0.034	0.003	0.020
	(-2.465)	(-1.629)	(-0.827)	(-0.439)	(0.175)	(0.516)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	3,229	3,229	3,229	3,229	3,229	3,229
Adjusted R^2	0.082	0.067	0.035	-0.014	0.007	-0.005

Table 10. Demand cannibalization for the challenged drug products

In this table, we examine whether launching new therapeutic products is associated with the changes in the quarterly sales (*Log(Sales)*), number of counting units sold (*Log(Qty.)*), and unit price of the challenged product (*Log(Price)*). For each Paragraph IV event, the event window starts from the eighth quarter before to the twelfth quarter after the event. We use *Abn.NewProducts_ATC4* to identify the paragraph IV challenges associated with an abnormally large number of new products in the same ATC4 category as the sample drug launched by the treated firms. Here, the abnormal number of new products is measured using the difference-in-difference approach, which calculates the difference between the average increase in the number of new products in the same ATC4 category as the treated drug launched by treated firms and the average increase in the number of new products in the same ATC4 category as the control drugs introduced by the control firms after the PIV event. *Abn.NewProducts_ATC4* takes the value of one if the abnormal number for a specific cohort exceeds the 75th percentile of the distribution across all cohorts, and zero otherwise. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-product fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-product and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively. We present the results of F tests which examine whether the coefficient of *Treat * Post* and the coefficient of the triple interaction sum up to zero. We show the sum of these coefficients, F statistics, and the p-value.

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.NewProducts_ATC4*	-0.615**	-0.604**	0.094***
	(-2.358)	(-2.361)	(3.089)
*Treat * Post*	0.166	0.102	0.006
	(1.076)	(0.675)	(0.315)
l. Firm Size	0.167	0.101	0.029
	(1.438)	(0.837)	(1.446)
l. M/B	-0.024	-0.005	-0.011***
	(-0.736)	(-0.145)	(-2.924)
l. ROA	0.741*	0.845*	0.027
	(1.706)	(1.862)	(0.416)
l. Cash Holding	-0.001**	-0.001**	0.000
	(-1.990)	(-2.007)	(1.521)
l. Leverage Ratio	0.127	0.017	0.106***
	(0.430)	(0.055)	(2.890)
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	12,616	12,616	12,616
Adjusted R^2	0.896	0.921	0.999
Sum of Coefficients (1) and (2)	-0.466**	-0.502**	0.100***
F statistics	4.87	5.87	17.50
P-value	0.028	0.016	0.000

Table 11. Patent value and product market strategies

Dependent variable is the natural logarithm of one plus a patent's nominal economic value, denoted as *Log(1+EconValue)*. In the left-panel, the sample includes all the un-expired patents held by the firms in the matched sample in the period of 2010 to 2019. *Log(Market cap)* equals the natural logarithm of a firm's market capitalization on the day before the patent's granting day. In the right-panel, the sample exclusively includes the un-expired patents associated with the brand-name drugs that are manufactured by the matched firms and on-sale in the U.S. market in the period of 2010 to 2019, rather than encompassing all the patents owned by the firms. We examine the relation between the patents commercial value and the total number of new therapeutic products introduced (*#all products*), the number of new therapeutic products introduced in two years before or after the firm's PIV event (*#products_[t-8, t-1]* and *#products_[t, t+8]*), and the number of new therapeutic products introduced in three years before or after the firm's PIV event (*#products_[t-12, t-1]* and *#products_[t, t+12]*). CPC3 denote the three-digit USPTO technology classification classes. 'Year' refers to the patent granting year. In all specifications, standard errors are clustered at the granting year level.

	(1)	(2)	(3)	(4)	(5)	(6)
	Log(1+EconValue)		*Log(1+EconValue)*			
Sample:	*Full sample*		*Commercialized patents*			
Log(1+citation)	0.033***	0.010**	0.019	0.017	0.017	0.017
	(6.336)	(2.425)	(0.854)	(0.760)	(0.753)	(0.756)
#all products				0.007*		
				(1.760)		
#products_[t-8, t-1]					0.000	
					(0.014)	
#products_[t, t+8]					0.030**	
					(2.148)	
#products_[t-12, t-1]						-0.001
						(-0.042)
#products_[t, t+12]						0.029**
						(2.117)
Log(Market Cap.)	0.662***					
	(36.565)					
CPC3*Year fixed effect	YES	YES	YES	YES	YES	YES
Firm fixed effects	NO	YES	YES	YES	YES	YES
Observations	57,145	57,145	1,215	1,215	1,215	1,215
Adjusted R^2	0.722	0.740	0.813	0.814	0.814	0.814

Table 12: Heterogeneity test: innovation profiles

In this table, we examine whether the introduction of new therapeutic products is affected by patent commercial value and patent citations. For each Paragraph IV, the event window starts from the eighth quarter before to the twelfth quarter after the event. In Panel A, we introduce the concept 'abnormal commercial value'. It represents the residual term obtained from regressing patent commercial value on patent citations and market capitalization. We count the number of patents with positive abnormal commercial value held by each of our sample firms in the year before Paragraph IV challenges and normalize it by firm size. The firms ranked in the top quartile are identified as having 'high commercial value' of the patent portfolio, as signified by the dummy variable *HighComValue.* In Panel B, we introduce the concept 'abnormal citation'. For each patent, the abnormal citation equals the number of citations minus the average number of citations for all patents issued in the same year in our sample. We construct a dummy variable, denoted *HighCitation*, to identify the firms with the number of patents with positive abnormal citation (normalized by firm size) in the year before the Paragraph IV event higher than the 75^{th} percentile value of the number of patents with positive abnormal citations for all firms in our sample. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively. We present the results of F tests which examine whether the coefficient of *Treat * Post* and the coefficient of the triple interaction sum up to zero. We show the sum of these coefficients, F statistics, and the p-value.

Panel A. Commercial value of a firm's patent portfolio

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post * HighComValue*	0.022	0.026	-0.000	0.002	0.044*	0.116*
	(0.395)	(0.209)	(-0.005)	(0.017)	(1.781)	(1.719)
*Post * HighComValue*	-0.026	-0.093	-0.020	-0.091	-0.028*	-0.097*
	(-0.967)	(-1.469)	(-1.017)	(-1.561)	(-1.906)	(-1.858)
*Treat * Post*	0.019	0.046*	0.020**	0.050***	0.008*	0.031**
	(1.245)	(1.916)	(2.035)	(2.687)	(1.763)	(2.089)
l. Firm Size	0.036***	0.057***	0.013**	0.037**	0.008***	0.022**
	(2.815)	(2.790)	(2.072)	(2.581)	(2.607)	(2.502)
l. M/B	0.002	0.004	0.001	0.007	0.002	0.005
	(0.454)	(0.599)	(0.252)	(1.065)	(1.361)	(1.376)
l. ROA	-0.086	-0.151	0.019	-0.073	0.007	-0.033
	(-1.204)	(-0.814)	(0.389)	(-0.466)	(0.193)	(-0.228)
l. Cash Holding	0.000	0.000	0.000**	0.000***	0.000	0.000
	(0.364)	(1.472)	(2.081)	(2.738)	(1.445)	(1.566)
l. Leverage Ratio	-0.081***	-0.138***	-0.012	-0.044	-0.010	-0.035
	(-3.043)	(-2.679)	(-0.740)	(-1.040)	(-0.941)	(-1.269)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	7,539	7,539	7,539	7,539	7,539	7,539
Adjusted R^2	0.046	0.034	0.050	0.005	0.012	-0.014
Sum of Coefficients	0.041	0.060	0.020	0.052	0.052**	0.148**
F Statistics	0.63	0.36	0.42	0.25	4.84	5.20
P-value	0.426	0.548	0.516	0.615	0.028	0.023

Panel B. Scientific value of a firm's patent portfolio

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post * HighCitation*	-0.034	-0.149*	-0.019	-0.127*	-0.026*	-0.097*
	(-0.806)	(-1.951)	(-0.595)	(-1.929)	(-1.658)	(-1.841)
*Post * HighCitation*	0.028	0.064**	0.002	0.047*	0.012***	0.039***
	(1.420)	(2.008)	(0.157)	(1.864)	(2.633)	(3.184)
*Treat * Post*	0.026	0.073***	0.024**	0.072***	0.016***	0.056***
	(1.589)	(2.821)	(2.309)	(3.713)	(3.086)	(3.458)
l. Firm Size	0.038***	0.062***	0.014**	0.041***	0.009***	0.026***
	(2.927)	(2.975)	(2.163)	(2.797)	(2.907)	(2.771)
l. M/B	0.002	0.007	0.001	0.009	0.002	0.006*
	(0.618)	(0.841)	(0.435)	(1.292)	(1.468)	(1.668)
l. ROA	-0.087	-0.150	0.020	-0.071	0.005	-0.037
	(-1.226)	(-0.807)	(0.405)	(-0.450)	(0.141)	(-0.253)
l. Cash Holding	0.000	0.000	0.000**	0.000**	0.000	0.000
	(0.070)	(1.034)	(1.982)	(2.355)	(0.594)	(0.573)
l. Leverage Ratio	-0.078***	-0.125***	-0.009	-0.028	-0.008	-0.026
	(-3.095)	(-2.722)	(-0.566)	(-0.780)	(-0.825)	(-1.074)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	7,539	7,539	7,539	7,539	7,539	7,539
Adjusted R^2	0.047	0.034	0.049	0.005	0.010	-0.016
Sum of Coefficients	-0.008	-0.076	0.005	-0.056	-0.010	-0.041
F Statistics	0.05	1.25	0.03	0.86	0.54	0.74
P-value	0.822	0.264	0.874	0.355	0.461	0.390

Table 13: Heterogeneity test: firm size and financial constraints

In this table, we examine the effects of generic entry threats on the introduction of new therapeutic products across heterogenous firms based on the triple-difference analysis setting. For each Paragraph IV, the event window starts from the eighth quarter before to the twelfth quarter after the event. In Panel A, we introduce a dummy indicator, *HighSale*, for firms with big sizes. It equals one for the firms with total sales in the quarter before Paragraph IV (*t-1*) higher than the 75-percentile value of all firms' total sales in our sample, and zero otherwise. In Panel B, we introduce a dummy indicator, *HighKZ*, for firms with financial constraints. It equals one for the firms with the value of KZ index in the quarter before Paragraph IV (*t-1*) higher than the 75-percentile value across all firms' KZ index in our sample, and zero otherwise. We construct the KZ index following Lamont, Polk, and Saaá-Requejo (2001). We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, and leverage ratio. All specifications include cohort-firm fixed effects and cohort-quarter fixed effects. Standard errors are clustered at the cohort-firm and cohort-quarter levels. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively. We present the results of F tests which examine whether the coefficient of *Treat * Post* and the coefficient of the triple interaction sum up to zero. We show the sum of these coefficients, F statistics, and the p-value.

Panel A: Firm size

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post * HighSale*	-0.021	-0.005	-0.006	0.011	-0.021*	-0.028
	(-0.575)	(-0.084)	(-0.255)	(0.272)	(-1.814)	(-0.888)
*Post * HighSale*	0.018	0.016	-0.003	-0.000	0.011*	0.010
	(0.945)	(0.394)	(-0.251)	(-0.010)	(1.686)	(0.324)
*Treat * Post*	0.036**	0.065**	0.024*	0.053**	0.020***	0.056***
	(1.993)	(2.297)	(1.919)	(2.298)	(3.023)	(3.017)
l. Firm Size	0.042***	0.066***	0.014**	0.040***	0.009***	0.023**
	(3.537)	(3.258)	(2.205)	(2.618)	(2.883)	(2.203)
l. M/B	0.003	0.006	0.003	0.008	0.001	0.003
	(0.842)	(0.741)	(0.970)	(1.190)	(0.955)	(0.819)
l. ROA	-0.039	-0.120	0.009	-0.074	0.012	-0.011
	(-0.634)	(-0.771)	(0.214)	(-0.553)	(0.378)	(-0.088)
l. Cash Holding	0.000	0.000	0.000	0.000**	0.000	0.000
	(0.394)	(1.231)	(1.537)	(2.147)	(1.330)	(1.297)
l. Leverage Ratio	-0.092***	-0.138***	-0.019	-0.031	-0.006	-0.017
	(-3.887)	(-3.240)	(-1.208)	(-0.887)	(-0.632)	(-0.739)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.050	0.038	0.050	0.003	0.002	-0.019
Sum of Coefficients	0.014	0.060	0.018	0.065**	-0.001	0.028
F Statistics	0.25	1.95	1.34	4.21	0.02	1.41
P-value	0.620	0.163	0.248	0.041	0.892	0.236

Panel B. Financial Constraints

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post * HighKZ*	-0.010	-0.068	-0.008	-0.050	-0.011	-0.059**
	(-0.246)	(-1.225)	(-0.353)	(-1.236)	(-1.210)	(-2.158)
*Post * HighKZ*	0.008	0.002	-0.002	-0.000	-0.003	-0.003
	(0.403)	(0.069)	(-0.157)	(-0.005)	(-0.536)	(-0.160)
*Treat * Post*	0.037**	0.088***	0.027***	0.074***	0.017***	0.063***
	(2.352)	(3.323)	(2.653)	(3.371)	(3.165)	(3.397)
l. Firm Size	0.012	0.038*	0.015**	0.048***	0.010***	0.033***
	(1.047)	(1.780)	(2.183)	(2.849)	(2.976)	(2.873)
l. M/B	0.005	0.011	0.006**	0.015**	0.003*	0.007**
	(1.180)	(1.379)	(2.152)	(2.108)	(1.934)	(2.017)
l. ROA	0.023	-0.056	0.025	-0.073	0.012	-0.021
	(0.376)	(-0.330)	(0.589)	(-0.503)	(0.407)	(-0.157)
l. Cash Holding	-0.000	0.000	0.000	0.000**	0.000	0.000
	(-0.029)	(0.951)	(1.367)	(2.045)	(0.838)	(0.917)
l. Leverage Ratio	-0.116***	-0.158***	-0.026*	-0.041	-0.009	-0.022
	(-4.490)	(-3.468)	(-1.681)	(-1.133)	(-1.032)	(-0.879)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.050	0.038	0.050	0.003	0.002	-0.019
Sum of Coefficients	0.014	0.060	0.018	0.065**	-0.001	0.028
F Statistics	0.25	1.95	1.34	4.21	0.02	1.41
P-value	0.620	0.163	0.248	0.041	0.892	0.236

Figure 1. Timing of paragraph IV challenge relative to the FDA approval date
In this figure, we show the distribution of the time gap, measured in number of years, between FDA approval date of a challenged drug and the date when the paragraph IV challenge occurs. The time gap between n and n+1 years is denoted as the n^{th} year in the horizontal axis.

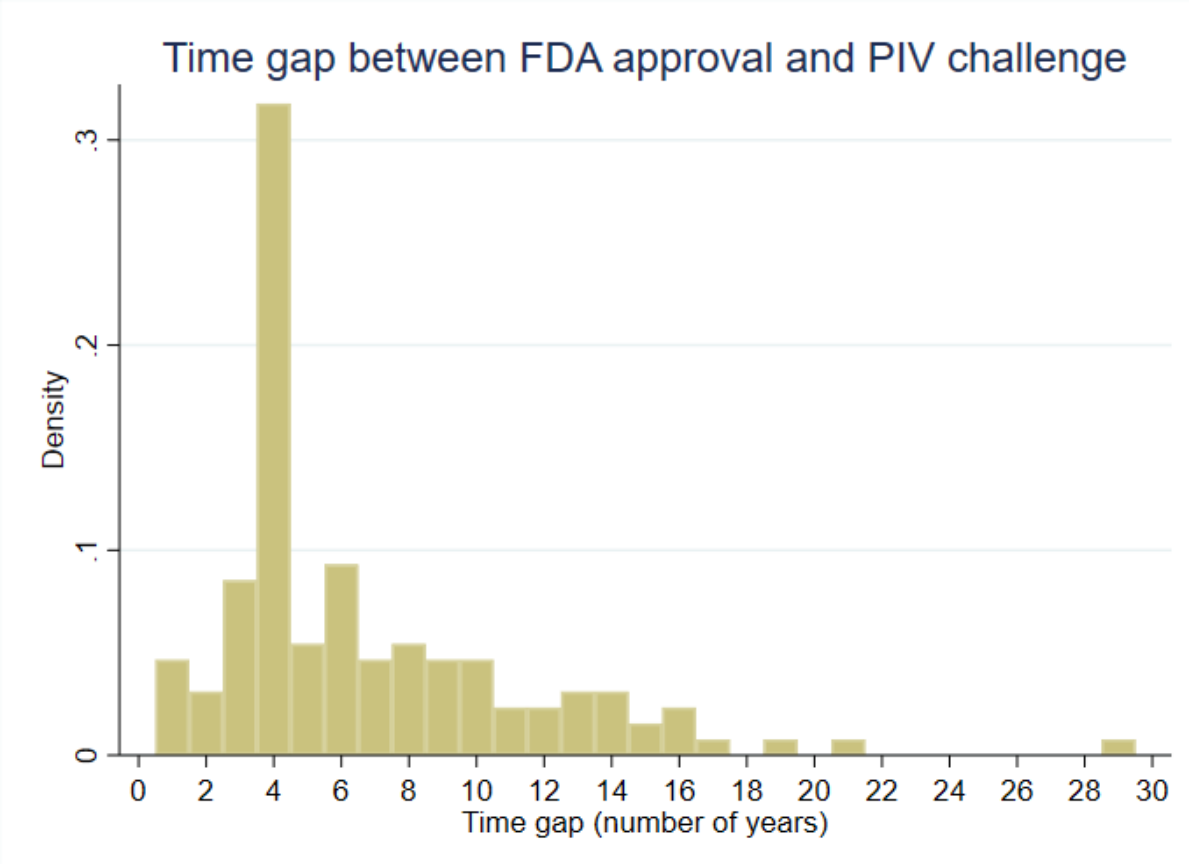


Figure 2-a. Quarterly Sales Growth of the Treated Drugs around Paragraph IV Events
For each treated drug in the matched sample, we aggregate the sales of all drug versions with the same active ingredients in a quarter and calculate the drug-level sales growth from quarter *q-1* to quarter *q*. The following figure shows the average sales growth for all the treated drugs from eight quarters before PIV to eight quarters after PIV.

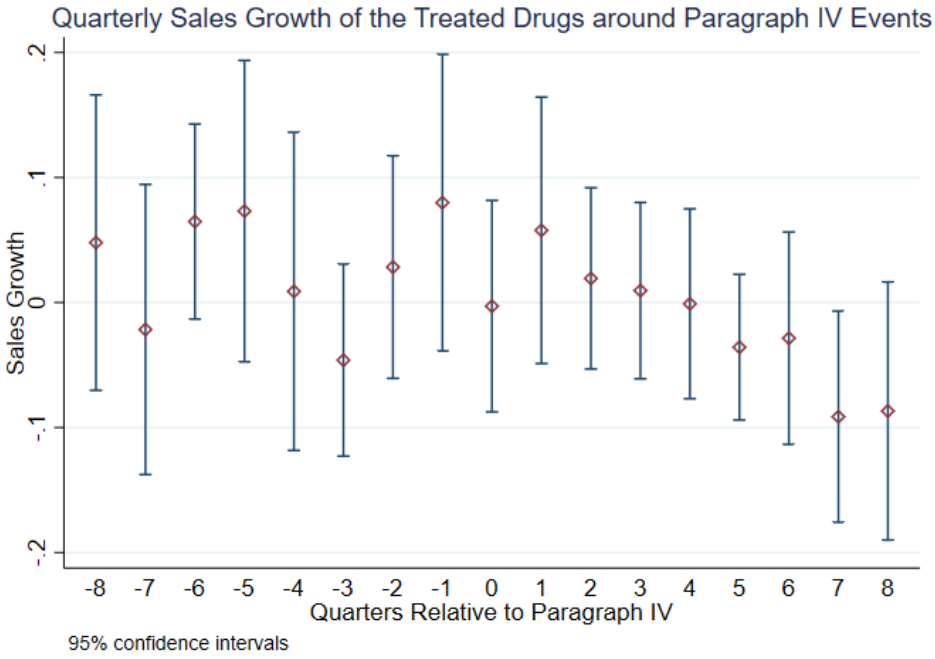
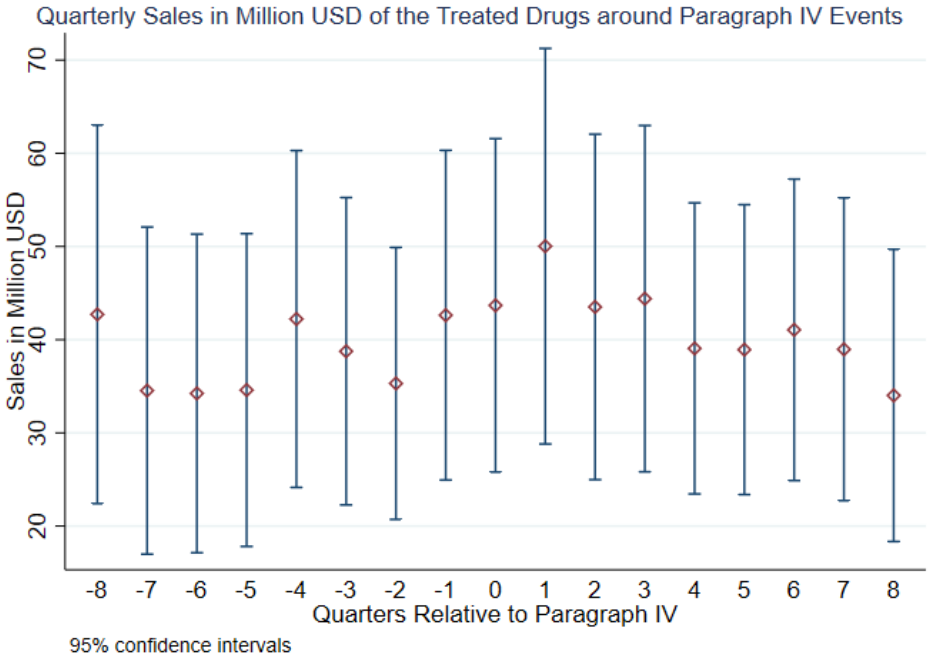


Figure 2-b. Quarterly Sales of the Treated Drugs around Paragraph IV Events
For each treated drug in the matched sample, we aggregate the sales of all drug versions with the same active ingredients in a quarter. The following figure shows the average sales in million US dollar for all the treated drugs from eight quarters before PIV to eight quarters after PIV.



Online Appendix

Competition and New Product Introductions: Evidence from the Pharmaceutical Industry

by

Yuanfang Chu, Sudipto Dasgupta, and Fangyuan Ma

Table OA1. Dynamics of Sales or Sales Growth of Treated Drugs

This table reports the dynamics of sales growth and dollar value of sales for the drug markets that experienced Paragraph IV challenges during our sample period. We aggregate the sales of all the drug versions offered by the brand-named drug company that share the same active ingredients. For each patent challenge event, we focus on a window starting from eight quarters before the event and extending up to eight quarters afterwards, or the actual entry if it occurs earlier. The dummy indicator of the quarter before the event is left out as the base. Each column includes different fixed effects and standard errors are clustered at varying levels as indicated in the bottom of the table. T-statistics are reported in brackets. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

	(1)	(2)	(3)	(4)	(5)	(6)
	Sales Growth			Drug Sales in Million USD		
D[t-8]	-0.032	-0.018	-0.018	0.084	-0.917	-0.917
	(-0.382)	(-0.229)	(-0.268)	(0.006)	(-0.074)	(-0.086)
D[t-7]	-0.101	-0.098	-0.098	-8.092	-8.317	-8.317
	(-1.222)	(-1.192)	(-1.274)	(-0.644)	(-0.646)	(-0.885)
D[t-6]	-0.015	-0.019	-0.019	-8.398	-7.740	-7.740
	(-0.212)	(-0.268)	(-0.354)	(-0.677)	(-0.611)	(-0.855)
D[t-5]	-0.007	0.007	0.007	-8.032	-7.973	-7.973
	(-0.080)	(0.083)	(0.085)	(-0.653)	(-0.636)	(-0.954)
D[t-4]	-0.071	-0.050	-0.050	-0.410	-1.187	-1.187
	(-0.814)	(-0.583)	(-0.533)	(-0.032)	(-0.094)	(-0.167)
D[t-3]	-0.126*	-0.120*	-0.120*	-3.873	-4.573	-4.573
	(-1.775)	(-1.726)	(-1.916)	(-0.317)	(-0.372)	(-0.712)
D[t-2]	-0.052	-0.040	-0.040	-7.325	-6.413	-6.413
	(-0.692)	(-0.565)	(-0.685)	(-0.632)	(-0.554)	(-1.127)
D[PIV]	-0.083	-0.075	-0.075	1.053	1.053	1.053
	(-1.130)	(-1.085)	(-1.157)	(0.083)	(0.084)	(0.695)
D[t+1]	-0.022	-0.009	-0.009	7.401	7.772	7.772
	(-0.276)	(-0.121)	(-0.140)	(0.530)	(0.612)	(1.226)
D[t+2]	-0.061	-0.053	-0.053	0.885	1.707	1.707
	(-0.867)	(-0.783)	(-0.933)	(0.068)	(0.146)	(0.214)
D[t+3]	-0.070	-0.061	-0.061	1.770	2.392	2.392
	(-1.014)	(-0.919)	(-1.184)	(0.137)	(0.206)	(0.301)
D[t+4]	-0.081	-0.072	-0.072	-3.563	-2.283	-2.283
	(-1.142)	(-1.061)	(-1.100)	(-0.299)	(-0.218)	(-0.253)
D[t+5]	-0.116*	-0.096	-0.096*	-3.698	-2.418	-2.418
	(-1.740)	(-1.550)	(-1.787)	(-0.311)	(-0.231)	(-0.264)
D[t+6]	-0.108	-0.106	-0.106*	-1.572	0.057	0.057
	(-1.479)	(-1.486)	(-1.805)	(-0.130)	(0.005)	(0.006)
D[t+7]	-0.171**	-0.164**	-0.164**	-3.659	-2.420	-2.420
	(-2.339)	(-2.336)	(-2.407)	(-0.302)	(-0.230)	(-0.278)
D[t+8]	-0.167**	-0.164**	-0.164**	-8.612	-7.754	-7.754
	(-2.111)	(-2.117)	(-2.061)	(-0.722)	(-0.750)	(-0.791)
Firm FE	NO	YES	YES	NO	YES	YES
Robust S.E.	YES	YES	NO	YES	YES	NO
Cluster S.E.	NO	NO	Firm	NO	NO	Firm
Observations	1,254	1,254	1,254	1,899	1,899	1,899
Adjusted R^2	0.003	0.058	0.058	-0.006	0.191	0.191

Figure OA1. Matching results

These figures show the quality of propensity score matching. The upper figure presents the mean difference value of each variable used in the first stage of the matching process between the treated and control firms both before and after matching. The middle (lower) figure presents the fitted density of the propensity score in the full (matched) sample. The propensity scores are estimated using the last model in Table 2.