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Competition, Cannibalization, and New Product Introductions: Evidence from the Pharmaceutical Industry

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Abstract

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Keywords: innovation, product launch, competition, creative destruction, real option
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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 innovation grants them a comparative advantage for follow-up innovation. However, incumbent innovators often hold back introducing related new products due to the concern of cannibalizing current profits, which could arise from the potential substitution of customer demand and internal competition for limited marketing resources. Ex ante, the strength of such cannibalization is uncertain and largely 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 from its existing products. 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.[1]

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 study centers on the pharmaceutical industry, a crucial sector that significantly

[1] To illustrate this, suppose the standalone NPV for a new product is \$10. The cost of cannibalization, C = \$12 without competitor entry, and C = \$6 if entry occurs and the entrant captures half of the incumbent's market. The ex-ante probability for entry is 0.6, and delaying the product launch to the next period will reveal (for sure) whether entry will occur. If the product is launched today, the expected total NPV is 0.6 x (\$10 - \$6) + (1-0.6) x (\$10 - \$12) = \$1.6. Although this is a positive number, the firm would be better off postponing the launch decision until the uncertainty is resolved. If entry occurs, the product is launched, generating an NPV of \$10 - \$6; if entry does not occur, the product would not be launched, resulting in an NPV of \$0. The expected total NPV of this strategy is 0.6 x \$4 + 0.4 x \$0 = \$2.4, which is higher than launching before uncertainty resolves.

impacts morbidity and mortality. This industry provides two key advantages for our analysis. 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 a brand-name drug's patents before they expire, aiming to enter the market. Actual market entry usually occurs several years later if patent litigation favors the challenger or the parties reach a settlement that allows for entry. [3] This ability to identify an increase in the *threat of entry* prior to the *actual entry* allows us to investigate the cannibalization effect of new product launches, that is, how firms' product launch activities in response to competition affect the sales of their existing products.

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 after four years since FDA approval. At this time, FDA-granted administrative 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 a four-year gap between the quarter and drug approval time 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.

[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. 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-name drugs come from their generic counterparts.

[3] Typically, a generic drug manufacturer either waits for the patents of a brand-name drug to expire before filing a Paragraph III application or files a Paragraph IV application before expiration by claiming that the existing patents are invalid or not infringed. 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".

The remaining randomness primarily stems from technological hurdles 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 three years after the challenge.

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 display parallel trends of product launch activity. The economic magnitudes of these treatment effects are sizable. For instance, after the 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 that could substitute for existing ones. 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 a new drug substance. 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. These patterns align with the argument that related new products, especially innovative ones, have been delayed in the absence of competitive threats and are introduced after existing products face challenges from competitors.

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 the challenged 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 during the quarter immediately following the completion of four years since FDA approval. As previously mentioned, the timing of these challenges is largely influenced by FDA policies and is relatively exogenous to demand shocks affecting each drug market. Taken together, our findings should be interpreted as firms' strategic reactions to escalated entry threats from competitors.

Furthermore, the evidence reveals insights into the nature of real options for product introduction. First, the effects are predominantly driven by drugs 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. Second, the effects are more significant in therapeutic categories with less predictable generic entry threats, indicated by a low pseudo-R^2 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 the sales amount and the quantity of the challenged drug after Paragraph IV events, especially 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.

Although delaying cannibalization costs until the uncertainty surrounding generic entry is fully resolved can enhance value, managers tend to introduce new products when the probability of generic entry becomes sufficiently high. This approach helps avoid a sharp decline in total revenue after generics enter the market. Consistently, we observe incremental new product introductions occurring

both immediately after Paragraph IV events, which signal a significant increase in the likelihood of entry, and after actual generic entries, which fully resolves the uncertainty about entry.[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 strengths. It is well-established that there is a disparity between the scientific and economic value of patents. This disparity 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 discrepancy, which presumably reflects the patent's strategic value in the product market. Specifically, we classify a patent as having high commercial value if its economic value, measured following Kogan, Papanikolaou, Seru, and Stoffman (2017), far exceeds the scientific value, measured by forward citations. 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 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, novel products may face significant delays in reaching the market after technological innovation is completed. These delays arise from innovators' product market considerations, creating a gap 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

[4] We argue that entry deterrence is unlikely to be the primary reason for firms to launch new products immediately after Paragraph IV events. First, credible threats of new product launches are likely to be equally effective in entry pre-emption, and such threats are particularly feasible in the pharmaceutical industry, where new product availability is transparently indicated by FDA approvals. Second, our analysis reveals that Paragraph IV events followed by incremental immediate new product launches are associated with a greater likelihood of generic entry within five years, suggesting that these launches are unlikely to deter such entries.

follow-up products.[5] 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 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.[6] Our paper provides evidence that the 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 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

[5] There are several notable examples of technology leaders delaying product launches due to concerns about cannibalization until competition intensified. Apple Inc. postponed the iPhone's launch until it perceived threats to the iPod from mobile phones capable of playing music. Microsoft developed Office for iPad long before its eventual release, likely to protect its Windows tablet business. Traditional automakers like General Motors, Ford, and Volkswagen refrained from fully committing to electric vehicles until Tesla's success posed a significant threat to their market share. Similarly, Intel, a pioneer in NAND-based SSD technology, delayed the introduction of advanced products like Optane Memory, despite announcing the technology in 2015, until it faced heightened competition in 2016 from NVMe SSDs and aggressive pricing by rivals.

[6] Mukeherjee, Thornquist, and Zaldokas (2022) offer an exception by proposing a measure of innovation based on equity market reactions to product announcements.

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) propose 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 growing literature on healthcare finance, focusing on the innovation, competition, and pricing policies of pharmaceutical companies. Krieger, Li, and Thakor (2022) demonstrate that drug firms increase R&D expenditures by acquiring external innovations when their existing products face negative shocks. Li, Liu, and Taylor (2023) reveal that common venture capital ownership enhances innovation efficiency among pharmaceutical startups. Bonaime and Wang (2024) show that mergers and acquisitions significantly influence drug prices. Aghamolla, Karaca-Mandic, Li, and Thakor (forthcoming) find that access to credit affects the quality of healthcare provided by hospitals. Additionally, Li, Lo, and Thakor (2024) illustrate that a firm's legal contracting environment impacts its innovation incentives. Our paper differs by providing evidence on the effect of competition on the commercialization strategies of pharmaceutical companies, which in turn affects their innovation incentives.

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 offering 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 controversial practice among brand-name drug companies is the introduction of new versions of products with minor improvements when the patents for the existing version are about to expire. These new versions are often linked to additional secondary patents claiming minor modification of formulation or dosage changes, effectively extending the patent protection. This practice, known as "product hopping," is widely criticized for offering little or no improvement in patient welfare. A key way to distinguish between truly innovative drug products and those based on minor improvements is to look for new patents claiming drug substances. These patents typically indicate greater novelty and more significant advancements in terms of both therapeutic value and social welfare.

2.2 Competitor Entry

A significant feature of the pharmaceutical industry is that the timing of increased entry threats 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 or the parties reach a settlement that allows for entry. 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-name drug's administrative market exclusivity is about to expire.[7] Specifically, the most common type of market exclusivity for the New Chemical Entity (NCE) restricts generic makers from filing Paragraph IV challenges for four years.[8] This rule leads to a clustering of Paragraph IV filings immediately after four years have passed since the brand-name drug's approval. As found in Figure 1, more than 30% of the initial patent challenges occur in the 16th quarter since drug approval. This is consistent with the findings in the literature (e.g., Grabowski et al., 2015). However, the technological hurdle for generic

[7] 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.

[8] For NCEs, generic entries are generally forbidden for five years, while generic makers are allowed to file Paragraph IVs after four years since 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.

firms in drug production introduces unpredictability, making the timing of specific drugs to be challenged largely uncertain.

[Insert Figure 1 about here.]

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, labelers' names, FDA approval dates, and drug characteristics (e.g., active ingredients, strength, dosage forms). In addition, we collect the patent number and expiration dates of each brand-name drug product 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).[9] 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.

Based on the information, we define a "product" as each version of a drug product with distinct characteristics, including active ingredients, strength, dosage form, and unit counts, which is also referred to as a "package" or "drug version." The products sharing the same active ingredients belong to the same "product line," also referred to as a "drug."

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

[9] 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).

Anatomical Therapeutic Chemical (ATC) Classification,[10] allowing us to identify the products with potential substitution of consumer demand. We also collect the date when each drug product was introduced to the U.S. market from IQVIA. 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 are 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 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. Table 1 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. Appendix A contains the definition of all the variables used for our analyses.

[Insert Table 1 about Here.]

IV. Empirical Specification

[10] The Anatomical Therapeutic Chemical (ATC) classification system is a hierarchical method used to categorize drugs based on their anatomical and therapeutic properties. The first digit indicates the anatomical group, while the second digit denotes the therapeutic or pharmacological subgroup. The third digit specifies the chemical substance, and the fourth digit further details its pharmacological properties. For example, the category "A10" refers to antidiabetic drugs, with "A10A" specifically indicating human insulin.

We use the propensity score matching approach to match each challenged drug with control drugs that have the closest propensity of being challenged. Our attention is restricted to the initial filing of Paragraph IV within each drug line. This approach follows the method used in the literature, such as Hemphill and Sampat (2011) and Hemphill and Sampat (2012). In our sample, 78% of the initial Paragraph IV filers cover the entire product line, i.e., all available products sharing the active ingredients at the time of the filing.

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* experiences its initial Paragraph IV challenge in the next quarter *t+1* and zero otherwise. The explanatory variables include: (1) a dummy indicator of a four-year gap between the quarter *t* and the drug's approval date, (2) a dummy variable indicating whether the average annual sales over the past three years is above 250 million USD,[11] (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 products, both within and outside the current product line, launched by the firm during each of the past eight quarters. We include the year dummies and one-digit ATC category dummies.

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 four years have just passed since 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 four-year indicator has the strongest explanatory power, as indicated by the pseudo-R^2.[12]

[11] The cutoff of $250 million follows from Grabowski, Long, Mortimer, and Boyo (2016) and Grabowski, Long, Mortimer 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. Approximately 10% of the observations in the matched sample exceed the $250 million cutoff.

[12] The logit regression of Paragraph IV events with single independent variable of the four-year indicator has pseudo-R^2 of 0.067.

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, Mortimer, and Bilginsoy (2021).

Furthermore, we find that a larger number of valid patents 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 in equilibrium.

Finally, we find that the group of variables representing the number of recently launched products only marginally increases the pseudo-R^2, with most variables being insignificant. This may be due to the co-existence of two opposing effects. On the one hand, an incumbent's introduction of new products could indicate a potential shift in marketing effort away from existing offerings, potentially reducing expected revenue from current products and discouraging generic entries.[13] On the other hand, launching new products might suggest that the brand-name manufacturer has less to lose from generic entry and, hence, is less likely to engage in costly litigation, which could encourage generic makers to file patent challenges. As a result, new product launches have largely insignificant effects on the patent-challenging behavior of generic firms.[14]

As observed in the last column of Table 2, these factors collectively explain only 9.7% of the variation in the likelihood of being challenged in the subsequent quarter. 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.

[Insert Table 2 about here.]

[13] In the U.S., the generic makers typically do not conduct their own advertisement activities; instead, they rely on the marketing effort of brand-name drug producers to build product reputation among customers (Shapiro (2018)).

[14] Consistent with this finding, it is also unlikely that the incumbent launches new products specifically to pre-empt generic entry since the mere threat of such launches has similar entry-deterring effects (a point that we will revisit in Section 5.5). In untabulated tests, we find that, after controlling for the other variables in Table 2, the number of pipeline products– defined as the count of a sample firm's new drug products that have obtained FDA approval but have not yet been launched– does not significantly predict Paragraph IV events.

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 baseline analysis focuses on a window beginning two years before each Paragraph IV event and extending up to three years afterward. If a control drug gets challenged during the three years after the paragraph IV date, the observations since the quarter of the control drug's 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 the 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 groups 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 during the quarter preceding Paragraph IV events. Additionally, Figure OA1 demonstrates that the fitted densities of the estimated propensity score for treated and control drugs closely resemble each other. Moreover, our matched sample reveals an insignificant difference in the number of pipeline products– measured by the count of a sample firm's new drug products that have received FDA approval but have not yet been launched – between the treated and control firms during the year before Paragraph IVs. Specifically, the treated drugs are associated with an average of 1.047 un-launched products in the same company, while control drugs have 1.159. The T-statistic for this difference is 0.884. Taken together, these findings indicate that the treated and control drugs face similar ex-ante likelihood of being challenged.

[Insert Table 3 about here.]

In our baseline analysis, we assess whether treated firms respond to patent challenges by introducing new products. As the product launching decisions are made by the company, we change the data structure of the matched sample from "cohort-drug-quarter" to "cohort-firm-quarter" by removing duplicated observations within each cohort-firm-quarter. This process reduces the sample size by only

3.3%, and the sample remains balanced between the treated and control firms, as shown in Online Appendix OA1. 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.e., patent challenging events), i denotes firm, and t denotes quarter. $\delta_{c,i}$ denotes the cohort-firm fixed effects and $\eta_{c,t}$ denotes the cohort-quarter fixed effects. $Treat_{c,i}$ indicates firms that experience Paragraph IV challenges 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. As shown in Panel B of Table 3, the average likelihood (number) of new product launches for our sample firms is 7.1 percent (0.095 products) per quarter. In addition, we categorize these new products into two groups: those in the same four-digit ATC therapeutic category as the current product in our matched sample – sharing the same anatomical group, therapeutic subgroup, chemical substance, and pharmacological properties – and those in other categories. We refer to the former group as "related new products" since they are more likely to substitute demand for existing products. Table 3, Panel B, suggests that our sample firms launch related (unrelated) new products at a quarterly rate of 2.2% (5.1%), with an average of 0.037 (0.058) products per quarter. Finally, within the related products, we 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). As revealed by Panel B of Table 3, innovative (non-innovative) related products are introduced at a quarterly rate of 0.4% (1.8%), with an average of 0.012 (0.026) products launched per quarter. Online Appendix B provides several examples that illustrate the potential demand substitution between related products and the novelty of innovative products.

The coefficient of our main interest is β in Equation (1), which captures the incremental likelihood (number) of new product introductions due to intensified threat of entry from generic competitors. 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 signaled 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 a pronounced effect for related new drug products, namely those in the same four-digit ATC category as the sample drug. As shown in Column (3) of Table 4, the challenged firms are 2.2% more likely to launch related new products than the control firms after the Paragraph IV events, which corresponds to 100 percent of the unconditional launching rate of 2.2%. Such an effect is statistically significant at the 5 percent level. Besides, Column (4) indicates that the challenged firms introduce 0.057 more related new drugs compared to the control firms, which is 1.54 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 therapeutic categories different from the sample drugs.

The economically sizable treatment effects on related products suggest that concerns about cannibalization from demand substitution may have prevented firms from introducing these products in the absence of entry threats. When patent challenges increase the likelihood of entry, the expected cost

of cannibalization decreases significantly, prompting firms to launch these products more aggressively. However, competitive pressures in one therapeutic area do not directly impact the company's product launches in the unrelated market segments.

Furthermore, within the related new drugs, we find a 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 the unconditional rate of 0.4%. Similarly, as indicated in Column (8), the number of innovative related new drugs also increases by 3.92 times of the sample average. These 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 innovative and non-innovative 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. As a result, competition plays a crucial role in advancing the commercialization of innovative products. In addition, the insignificant change in non-innovative product launches indicates that product-hopping behavior is not substantially influenced by Paragraph IV challenges. This is likely because product-hopping is primarily used to extend market exclusivity around Paragraph III events, which are more predictable and occur immediately after the expiration of existing patents.

[Insert Table 4 about here.]

In Online Appendix Table OA2, we conduct robustness analyses regarding the definition of innovative new products. While the presence of additional patents claiming new substances effectively identifies radical innovations, it limits our focus to a narrow group of new products. Thus, we introduce a broader definition of innovative products to include those with changes in key dimensions such as active ingredients, routes of administration (e.g., oral, topical, or injection), or dosage form (e.g., capsules, tablets, or inhalers). Changes in these dimensions are considered more innovative compared to modifications in other product features, such as strength (e.g., 50 mg or 100 mg per caplet) or packaging (e.g., number of units per package). As shown in the table, we continue to find a positive and

statistically significant effect of Paragraph IV filings on the introduction of innovative new products within the same four-digit ATC category. However, the launch of non-innovative related products remains unaffected by Paragraph IV filings.

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. Our findings in Table 4 are robust to using the matched sample at the "cohort-drug-quarter" level as reported in Online Appendix Table OA3.

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. 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 [*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. Similarly, in Figure 2, we report the coefficients of the interaction terms between the treated dummy and indicators of the semi-annual time intervals relative to the event time. The findings in Table 5 and Figure 2 suggest that new product launches begin to increase within a short window following Paragraph IV events, which indicate a significant increase in the likelihood of generic entry. These results are robust to switching the benchmark period to the window of [t-8, t-5] (untabulated).

[Insert Table 5 about here.]

[Insert Figure 2 about here.]

5.2 Alternative Explanation

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

First, leveraging regulation-induced incentives, we demonstrate that the baseline effect is more pronounced within a subset of Paragraph IV challenges that are the least likely to be driven by

unpredicted 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 16th quarter since FDA approval. As illustrated in Figure 1, there is a notable clustering of Paragraph IV challenges in this quarter. Importantly, compared to challenges in other years, those occurring in the 16th quarter are more likely to be pre-determined and less likely to be induced by a sudden surge in market demand within the therapeutic area. We partition the regression sample into two groups based on whether the Paragraph IV challenge occurs in the 16th quarter following FDA approval of the treated drug. As presented in Table 6, the treatment effect is statistically more significant and more pronounced for the challenges occurring in the 16th quarter, suggesting that an unobserved demand shock is unlikely to be the driving force of our findings.

[Insert Table 6 about here.]

Furthermore, we directly investigate market demand in each therapeutic category 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. To investigate this possibility, we aggregate sales at the category-quarter level, summing the sales from all drug products within the four-digit ATC category. In Figure 3, we plot the quarterly sales and sales growth of each category in a four-year window surrounding the occurrence of Paragraph IV challenges. However, we find no significant changes surrounding the event time, especially around a short window, contradicting the presence of an unobserved positive demand shock coinciding with Paragraph IV.

[Insert Figure 3 about here.]

We also investigate this pattern using panel regressions with all quarterly observations of category-level drug sales, 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 90% of the variation in quarterly sales.[15] However, after controlling for the past sales, the indicator of Paragraph IV challenge

[15] In untabulated tables, we continue to find such stickiness in sales at the drug level.

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 and drug 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 (8). 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 of our baseline empirical model, where treated and control drugs are matched based on factors including their past sales.

In Panel B of Table 7, we aggregate drug sales at the firm-category-quarter level by summing the quarterly sales of all products within a specific four-digit ATC category offered by a given company. The results are consistent with those found in Panel A. This suggests that the observed effects are not driven by company-specific demand shocks within certain therapeutic categories—such as those arising from a surge in the brand's market reputation—that could simultaneously influence both generic competition and the launch of new products.

[Insert Table 7 about here.]

In summary, our analysis does not reveal any evidence suggesting that patent challenges are linked to an unexpected increase in the market demand for the affected drugs. Furthermore, we argue that reverse causality—specifically, generic manufacturers file Paragraph IV challenges exactly when they expect incumbents to launch related new products—is not a plausible explanation. This is because the introduction of new products typically cannibalizes the demand for existing products, thereby reducing the potential gains from entering the market. Taken together, our findings of incremental product launches should be interpreted as strategic responses by firms to the threat of market entry, rather than being driven by omitted variables related to changing market conditions or simultaneity bias.

5.3 Real Option Features

The evidence presented thus far is consistent with incumbent companies responding swiftly to entry threats by introducing new products. In other words, they delay the launch of new products when there is no competitive pressure, treating product launch as a 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.[16]

[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 one-digit ATC category, and derive the pseudo-R^2 from each regression. A lower pseudo-R^2 value suggests greater unpredictability in generic makers' moves, indicating higher uncertainty and, consequently, greater value in real options for the incument. We

[16] In our matched sample, the treated and control firms have comparable numbers of product pipelines. As previously noted in Section IV, there is no significant difference in the number of approved but un-launched products between the treated and control groups. This suggests that our findings in Table 8 are not attributable to the fact that firms with stronger product pipelines attract more generic entries.

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 a pseudo-R^2 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 pseudo-R^2 is lower than the median. However, the effect is not significant in the subgroup where generic makers' actions are more predictable.[17] 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 due to substitution in either consumer demand or marketing resources. 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 the challenge surrounding Paragraph IV. Our analysis focuses on the period before generic manufacturers enter 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.

[17] One limitation of this test is that R^2 can be a noisy indicator of product market uncertainty, even though the average R^2 values for the two subsamples are notably different—0.118 compared to 0.276.

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 drug product (or package), we expand the baseline model from cohort-firm-quarter level to cohort-product-quarter level and include cohort-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 and before actual entry, 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.[18]

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 introduced ones. On the other hand, α_2 should be insignificant for sales and quantity, as the increase in entry likelihood 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. In contrast, the interaction term $Treat_{c,i} \times Post_{c,t}$ is not significant. This suggests that Paragraph IV events without related product launches do not directly affect market

[18] 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.

demand. However, when new products are introduced following these events, demand for the challenged drug is cannibalized.

Table 10 also shows 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. The F statistics of the sum of these two coefficients is 4.39 for sales and 5.06 for quantity. The point estimations indicate that dollar sales and unit sales of the challenged drug products decline by 35.2% and 36.9%, respectively, following the Paragraph IV events associated with an incremental introduction of related products by the treated firm.[19] These effects are substantial, given that the average quarterly sales of a branded drug are approximately 40 million U.S. dollars when the Paragraph IV challenge is filed.[20]

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. Our findings align with the literature on brand-name producers' pricing behavior following generic entry (e.g., Grabowski and Vernon, 1992; Frank and Salkever, 1997), which also identifies the "harvesting" pricing strategy – charging higher prices to the remaining loyal segment after generic entry.

[Insert Table 10 about here.]

[19] The sum of two coefficients for Log(Sales) and Log(Quantity) is -0.434 and -0.461, respectively. We convert these log changes to percentage changes as follows: exp(-0.434) - 1 = 0.352; exp(-0.461) - 1 = 0.369.

[20] To further understand the life cycle of therapeutic products and potential cannibalization costs, we plot the quarterly sales and sales growth of branded drugs in the Online Appendix Figure OA2. The sample for these plots focuses on the period after the market launch but before the filing of the first Paragraph IV challenge. As a large number of Paragraph IV challenges occur at the beginning of the fifth year, we restrict our attention to the initial four years since drug approval. The figure reveals that new drug products generate limited sales during the initial quarter but experience rapid sales growth within the first year. Growth slows in the second year but remains positive, and by the third year, sales stabilize. In the fourth year, these drugs persistently generate quarterly sales of close to 40 million U.S. dollars on average.

We further investigate the dynamics of the cannibalization effects by estimating difference-in-difference regressions in two subsamples: one consisting of events followed by an abnormally large number of related new product launches and the other without such launches. The post-period indicator is replaced with a set of semi-annual time interval indicators relative to the event time, with the one year before Paragraph IV events excluded as the benchmark period. The coefficients on the interaction terms between the semi-annual indicators and the treated dummy are reported in Figure 4.

Our results in Figure 4 show no significant divergence in sales between the treated and control groups prior to the patent challenge events in either subsample. Furthermore, among the sample of events followed by an abnormal launch of related products, both sales and quantities of the challenged drugs decline significantly, beginning six months after the events, relative to their control groups. The timing of this cannibalization effect closely aligns with the new product launches, with a brief delay, consistent with the time needed for new drug products to capture the attention of doctors and patients and gain their trust. In contrast, among the subsample of events without an incremental launch of related products, sales, quantity, and price all remain stable at pre-event levels.

[Insert Figure 4 about here.]

Lastly, we rule out the possibility that the observed cannibalization effect is driven by competing drugs introduced by other branded producers. In Online Appendix Table OA4, we estimate a triple-difference regression following Equation (2) using a sample that excludes cohorts where competing branded products in the same four-digit ATC category were introduced by other firms during the post-event window. The coefficients on the triple interaction terms remain significantly negative for both sales and quantity, indicating a decline in sales of the challenged drug following the firm's launch of related new products. This suggests that the cannibalization effect documented in Table 10 primarily arises from competition between the challenged drug and related new products launched by the same company.

5.5 Actual Entries

We now examine the timing of new product launches following Paragraph IV events and how the timing is related to the occurrence of actual market entries. After a Paragraph IV filing, the challenged brand-name companies typically file patent infringement lawsuits against the generic manufacturer, meaning

that actual market entry would not occur until the patent dispute is resolved in favor of the challenger or the parties reach a settlement that permits entry. Among the Paragraph IVs filed between 2010 and 2014, 60% result in actual generic entry within five years. (The events from 2015 to 2019 are excluded as they have less than five years of post-event data in our sample.) When entry does occur, it happens on average 15 quarters after the Paragraph IV filing. As shown in Figure 5, the majority of entries following Paragraph IV challenges occur between ten to twenty-four quarters after the filing.

[Insert Figure 5 about here.]

To understand the timing of new product launches relative to actual market entry, we extend the matched sample to a window from two years before the Paragraph IV filing to five years afterward, focusing on challenges filed between 2010 and 2014 to ensure a five-year post-event window. The post-event window is divided into two periods: the time after the Paragraph IV filing but before actual market entry, and the period following entry, if it occurs within five years. We estimate the baseline regressions in this sample, including interaction terms of the treated dummy with time indicators for both periods. As reported in Table 11, for five of the six main independent variables, the interaction with the post-Paragraph IV indicator shows a positive and significant coefficient, and the interaction with the post-entry indicator is also significant for four out of six dependent variables. The magnitudes of the coefficients on the two interaction terms are roughly similar. These results indicate that both the Paragraph IV filing and eventual market entry contribute to the incremental launch of new products. This aligns with the argument that related new products are more likely to be introduced when the likelihood of entry substantially increases—first due to the Paragraph IV filing, and later when uncertainty about entry is fully resolved with the actual market entry.

[Insert Table 11 about here.]

However, the fact that new products are launched immediately following the Paragraph IV filings, as shown in Table 5 and Figure 2, raises the question of why challenged firms do not delay these launches until closer to, or after, the actual market entry, which typically occurs after about three years. Such a delay could help avoid incurring cannibalization costs until it is proven to be necessary. We believe the reason firms do not further postpone the launches is that doing so would likely result in a sharp revenue decline once generic entry occurs. When Paragraph IV filings signal a sufficiently high

likelihood of entry, a manager focused on revenue smoothing would likely view an immediate product launch as optimal. Online Appendix C provides an illustrative example of the revenue-smoothing benefit for the immediate launching strategy.

An alternative explanation for the immediate product launches following Paragraph IV events is that introducing related new products could potentially discourage the generic entrant from entering the market. However, we believe that entry deterrence is unlikely to be the primary motivation for these immediate launches. This is because credible threats of new product launches are generally seen as equally effective in pre-empting entry, and such threats are particularly credible in the pharmaceutical industry, where new product availability is transparently signaled by FDA approvals. See Example 2 in Online Appendix C for an illustrative example of the effectiveness of threats to launch.

In Table 12, we explore whether immediate new product launches following Paragraph IV filings are associated with a reduced likelihood of eventual entry or delayed entry. We divide the patent challenges filed between 2010 and 2014 into two groups based on whether the treated firm launched an abnormally large number of related new products following the challenge but before entry. As shown in Panel A, among the challenges followed by abnormal launches, 78% of the treated drugs experienced eventual entry within five years, which is 58.5% higher than the likelihood of the matched control drugs. In contrast, among the cohort without abnormal launches, only 53.2% of the treated drugs faced generic entry within five years, exceeding the control group by 23.4%. Moreover, Panel B reveals that, among those challenges with eventual entry occurring during our sample period, abnormal launches of related new products by the challenged firm are associated with a shorter delay to entry. These statistics do not support the idea that new product launches deter or delay generic entry. Instead, the evidence is consistent with the view that immediate new product launches occur primarily when the Paragraph IV event signals a sufficiently high likelihood of eventual generic entry.

[Insert Table 12 about here.]

5.6 Heterogeneity

We examine how baseline effects differ across firms with varying innovation profiles. We hypothesize that firms with strong capabilities in commercializing their innovative products are more likely to

behave strategically in response to entry threats, whereas firms that focus primarily on fundamental scientific research are less likely to engage in such strategic behavior.

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 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. Therefore, we argue that the disparity between the economic and scientific values of patents reflects their abnormal commercialization potential, driven by the strategic value they offer to the patent holders 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 13, economic value is positively associated with forward citations across all patents held by pharmaceutical companies. This is consistent with Kogan et al. (2017) focusing on patents from 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 wedge between the 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 13 about here.]

Building on these analyses, we propose a new measure of firms' innovative strength based on their patents. Specifically, we first gauge a patent's abnormal commercialization potential using the directional residuals from the regression reported in Table 13, 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. Furthermore, 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 14, 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 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 holding patents with high commercialization capabilities can facilitate strategic timing of the 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 14, 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 14 about here.]

Finally, we examine firm heterogeneity by size and financial constraints. Large (financially constrained) firms, defined as those with total sales (the Kaplan-Zingales index index, following Kaplan and Zingales (1997) and Lamont, Polk, and Saaá-Requejo (2001)) above the 75th percentile in the year before Paragraph IV challenges, are captured by the *HighSales* (*HighKZ*) dummy. Panel A (B) of Online Appendix Table OA5 shows that while the interaction term of the treated dummy and post-event indicator is positively significant, the triple interaction term with the indicators of large or constrained firms is negative and mostly insignificant. F-tests also reveal that the sum of these interaction terms is insignificant for five out of six product launch outcomes. These findings suggest that responses to entry threats via new product launches are similar across large vs. small firms and financially constrained vs. unconstrained firms. However, smaller firms may be more sensitive to competitor entry due to their smaller portfolios, while financially unconstrained firms may be slightly more responsive due to greater financial flexibility to implement product-market strategies. These results are robust when using alternative measures, such as the Hadlock-Pierce index (Hadlock and Pierce, 2010) and the Whited-Wu index (Whited and Wu, 2006).

VI. Conclusion

In this paper, we explore how competition influence firms' decisions of 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 create. A key factor prompting firms to exercise this option is the threat of competitor entry, which alleviates cannibalization concerns and thus increases the net value associated with new product launches. These effects are particularly pronounced in markets where competitor entries 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.

Reference

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Table 1 Summary statistics

This table reports the distributions of drugs (i.e., therapeutic product lines characterized by active ingredients), drug products (i.e., therapeutic products characterized by active ingredients, routes of administration, strength, dosage form, and packaging), and firms (at the parent firm level) within each one-digit ATC category. Columns (1) to (3) show the statistics among the overall sample, and Columns (4) to (6) show the statistics among the subset of drugs experiencing Paragraph IV events from 2010 to 2019.

		(1)	(2)	(3)	(4)	(5)	(6)
		All Drugs in the Overall Sample			Drugs with PIV in [2010-Q1, 2019-Q4]		
	ATC1 Categories	#[Drugs]	#[Products]	#[Firms]	#[Drugs]	#[Products]	#[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

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 indicator of a four-year gap between the quarter and the drug's approval date, (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 and the number of new drugs 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 dummies and one-digit ATC dummies. 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			*Paragraph IV [t+1]*			
D[4 years after 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 products [*t-7, t*]	NO	NO	NO	NO	NO	YES
ATC1 & Year dummies	YES	YES	YES	YES	YES	YES
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 the T-test conducted in the matched sample (at the "cohort-drug-quarter" level) based on the logit regression in Column (6) of Table 2. The matching details are described in Section IV. We calculate the mean value of the following variables for treated drugs and control drugs in the matched sample during 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 among the regression sample (at the "cohort-firm-quarter" level).

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
# Drugs	129	338		

Panel B. Summary statistics for the regression sample

	Mean	Median	S.D.
1. Dependent variables:			
D[All New Products]	0.071	0	0.257
D[New Products in the Same 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 the Same 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
# Firms	Treat = 129	Control = 324	
# Observations	Treat = 2,634	Control = 6,488	

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 three unchallenged drugs with the closest ex-ante likelihood of facing a challenge, as estimated in the regression reported in Column (6) 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. The matched sample is aggregated at the cohort-firm-quarter level for regression analyses. 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 four-digit ATC 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 same ATC category into innovative new products, protected by additional patents claiming new drug substance, from other non-innovative ones, 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 Products in the Same ATC4*		*New Products in 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. 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 four-digit ATC category as the sample drug. In columns (5) and (6), 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 four-digit ATC 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 the Same 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 16th quarter since 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 occurring in the 16th quarter since FDA approval

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Products in the Same ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.079***	0.132***	0.045***	0.098***	0.021**	0.077**
	(2.917)	(2.875)	(2.924)	(2.853)	(2.496)	(2.328)
l. Firm Size	0.065***	0.088**	0.017	0.038	0.012	0.035
	(2.682)	(2.269)	(1.411)	(1.564)	(1.659)	(1.581)
l. M/B	0.010	0.014	0.008*	0.015*	0.007*	0.013
	(1.239)	(1.129)	(1.785)	(1.757)	(1.942)	(1.640)
l. ROA	-0.104	-0.366	0.025	-0.164	0.041	-0.139
	(-0.653)	(-0.537)	(0.196)	(-0.269)	(0.319)	(-0.222)
l. Cash Holding	-0.000	-0.000	0.000	0.000	-0.000	0.000
	(-1.186)	(-0.178)	(0.278)	(0.633)	(-0.039)	(0.453)
l. Leverage	-0.132**	-0.262***	-0.041	-0.113	-0.043	-0.113
	(-2.466)	(-2.800)	(-1.265)	(-1.491)	(-1.625)	(-1.532)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time	YES	YES	YES	YES	YES	YES
Observations	1,916	1,916	1,916	1,916	1,916	1,916
Adjusted R^2	0.011	-0.053	0.067	-0.086	-0.099	-0.149

Panel B. PIV occurring during the other times

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Products in the Same ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.008	0.034	0.014	0.042**	0.010*	0.034**
	(0.494)	(1.354)	(1.332)	(2.050)	(1.912)	(2.307)
l. Firm Size	0.029**	0.050**	0.013*	0.037**	0.007**	0.016**
	(2.176)	(2.384)	(1.776)	(2.354)	(2.459)	(2.201)
l. M/B	0.001	0.003	0.001	0.006	-0.000	-0.000
	(0.257)	(0.328)	(0.254)	(0.696)	(-0.018)	(-0.136)
l. ROA	-0.008	-0.046	0.012	-0.045	0.007	0.026
	(-0.122)	(-0.413)	(0.275)	(-0.529)	(0.336)	(0.620)
l. Cash Holding	0.000	0.000	0.000	0.000**	0.000	0.000
	(0.561)	(1.386)	(1.508)	(2.132)	(1.613)	(1.573)
l. Leverage	-0.076***	-0.101**	-0.012	-0.009	0.004	0.008
	(-2.949)	(-2.232)	(-0.677)	(-0.245)	(0.416)	(0.380)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time	YES	YES	YES	YES	YES	YES
Observations	6,374	6,374	6,374	6,374	6,374	6,374
Adjusted R^2	0.061	0.062	0.044	0.026	0.029	0.026

Table 7. Market demand around Paragraph IV events

This table reports the results of panel regressions using all drug products before matching. In Panel A, the dependent variable is the quarterly sales for each therapeutic category, calculated as the sum of sales for all drug products within each four-digit ATC category. The main independent variable is an indicator of whether there are Paragraph IV filings within that category. In Panel B, the dependent variable is the quarterly sales for each brand-name company within each therapeutic category, summed across all drug products offered by the company within each four-digit ATC category. The main independent variable is an indicator of whether any of the company's drugs in the category have faced Paragraph IV challenges. In both panels, each column controls for different fixed effects, as indicated at the bottom of the table. T-statistics are reported in parentheses, with standard errors based on the following specifications: robust standard errors in Column (1), standard errors clustered at the quarter level in Column (2), and double-clustered standard errors at both the drug and quarter levels in Columns (3) to (8). ***, **, and * denote statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A. Total sales at ATC4 level

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
					Segment (ATC4) Sales at quarter:			
	[t]	*[t]*	*[t]*	*[t]*	*[t+1]*	*[t+2]*	*[t+3]*	*[t+4]*
PIV [t]	0.002	0.004	-0.006	-0.004	0.005	-0.002	0.006	0.004
	(0.216)	(0.557)	(-0.603)	(-0.454)	(0.492)	(-0.361)	(1.619)	(0.815)
Sales_ATC4 [t-1]	0.874***	0.882***	0.772***	0.787***	-0.105*	0.071**	0.061**	0.104***
	(33.240)	(14.130)	(8.103)	(9.042)	(-1.716)	(2.065)	(2.617)	(3.246)
Sales_ATC4 [t]					1.008***	-0.289***	-0.016	-0.100***
					(21.853)	(-3.646)	(-0.333)	(-3.462)
Sales_ATC4 [t+1]						1.105***	-0.253***	0.054
						(33.629)	(-2.906)	(1.118)
Sales_ATC4 [t+2]							1.092***	-0.264***
							(35.327)	(-2.840)
Sales_ATC4 [t+3]								1.078***
								(32.250)
ATC4 FE	NO	NO	YES	YES	YES	YES	YES	YES
Quarter FE	NO	YES	NO	YES	YES	YES	YES	YES
Observations	7,371	7,371	7,371	7,371	7,138	6,903	6,673	6,443
Adjusted R^2	0.901	0.908	0.911	0.916	0.940	0.940	0.939	0.938

Panel B. Total sales at ATC4-firm level

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Firm-Segment (ATC4) Sales at quarter:							
	[t]	*[t]*	*[t]*	*[t]*	*[t+1]*	*[t+2]*	*[t+3]*	*[t+4]*
PIV [t]	0.002	0.001	-0.001	0.000	0.002	0.000	0.002*	-0.001
	(0.627)	(0.459)	(-0.552)	(0.248)	(0.483)	(0.111)	(1.762)	(-0.462)
Firm_ATC4 Sales [t-1]	0.882***	0.863***	0.852***	0.857***	-0.070*	0.038	0.023	0.107**
	(43.651)	(13.086)	(12.820)	(13.586)	(-1.956)	(1.637)	(0.931)	(2.354)
Firm_ATC4 Sales [t]					1.001***	-0.185***	-0.032	-0.155***
					(22.159)	(-4.494)	(-1.029)	(-3.575)
Firm_ATC4 Sales [t+1]						1.075***	-0.118***	0.051*
						(21.124)	(-3.460)	(2.021)
Firm_ATC4 Sales [t+2]							1.057***	-0.120***
							(19.916)	(-3.595)
Firm_ATC4 Sales [t+3]								1.040***
								(17.843)
Firm FE	NO	NO	YES	YES	YES	YES	YES	YES
ATC-4 FE	NO	YES	YES	YES	YES	YES	YES	YES
Quarter FE	NO	YES	NO	YES	YES	YES	YES	YES
Observations	20,230	20,230	20,229	20,229	19,490	18,751	18,026	17,316
Adjusted R^2	0.902	0.908	0.905	0.908	0.936	0.934	0.934	0.934

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

This table explores the market introduction of new therapeutic products approved by the FDA before or after the generic entry threat. Specifically, we categorize each of the following dependent variables into two groups based on whether the new product obtain FDA approval before or after the occurrence of the Paragraph IV event: (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. The results based on two types of the new products 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 approved by the FDA before PIV

	(1)	(2)	(3)	(4)	(5)	(6)
	Products Approved before PIV					
	All New Products		*New Products in the Same 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 approved by the FDA after PIV

	(1)	(2)	(3)	(4)	(5)	(6)
	Products Approved after PIV					
	All New Products		*New Products in the Same 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 partition the sample into two groups of therapeutic categories based on the predictability of generic entry threats. Specifically, we estimate the same logit model from Column (6) of Table 2 separately for each one-digit ATC category and use the pseudo-R^2 to assess the predictability of entry threats. The cohorts in our sample are divided based on whether the treated drug in each cohort falls within a one-digit ATC category with the pseudo-R^2 below or above the overall sample median. In each subsample, 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 four-digit ATC 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. Categories with less predictable generic entry threats (i.e., pseudo-R^2 <= Median)

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Products in the Same 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. Categories with more predictable generic entry threats (i.e., pseudo-R^2 > Median)

	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Products in the Same 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 related new 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 the event and extends up to the twelfth quarter after the event or until actual entry if it occurs earlier. The sample is at the cohort-product-quarter level. We use *Abn.NewProducts_ATC4* to identify the Paragraph IV events associated with an abnormally large number of related new product launched by the treated firms. Here, the abnormal number of related 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 four-digit ATC category launched by treated firms per quarter and the average increase in the number of such products introduced by the control firms per quarter after the event. *Abn.NewProducts_ATC4* takes the value of one if the abnormal number for a specific event 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 coefficients of *Treat * Post* and *Treat * Post * Abn.NewProducts_ATC4* 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*	-0.595**	-0.583**	0.081***
	(-2.320)	(-2.324)	(2.760)
*Treat * Post*	0.161	0.122	0.002
	(1.061)	(0.839)	(0.084)
l. Firm Size	0.129	0.088	0.034*
	(1.106)	(0.736)	(1.694)
l. M/B	-0.015	0.003	-0.012***
	(-0.446)	(0.096)	(-3.245)
l. ROA	0.698	0.835*	0.025
	(1.583)	(1.842)	(0.385)
l. Cash Holding	-0.001**	-0.001**	0.000
	(-2.233)	(-2.267)	(1.262)
l. Leverage Ratio	-0.023	-0.131	0.114***
	(-0.080)	(-0.443)	(3.179)
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	12,252	12,252	12,252
Adjusted R^2	0.910	0.928	0.999
Sum of first two Coefficients	-0.434**	-0.461**	0.082***
F statistics	4.386	5.058	13.153
P-value	0.036	0.025	0.000

Table 11. New product introduction after Paragraph IVs and actual entries

This table presents the responses of challenged firms to Paragraph IV filings and the eventual market entries, if any, as estimated using a matched sample. For each Paragraph IV event from 2010 to 2014, we identify three unchallenged drugs with the closest ex-ante likelihood of facing a challenge based on the regression results reported in Column (6) of Table 2. The control drugs must be produced by a different firm. The event window spans from eight quarters before the event and extends up to twenty quarters afterward. *PostPIV* refers to the period following the Paragraph IV filing but before actual market entry or up to five years if the entry has not occurred by that time. *PostEntry* indicates the period after actual market entry, if any within the five-year post-Paragraph-IV window. 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 four-digit ATC 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 four-digit ATC as the sample drug. In each column, 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 the Same ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * PostPIV*	0.014	0.057**	0.024**	0.072***	0.011***	0.045***
	(0.757)	(2.033)	(2.004)	(3.232)	(2.761)	(2.626)
*Treat * PostEntry*	0.026	0.083**	0.020	0.085***	0.017***	0.059***
	(0.935)	(2.035)	(1.423)	(3.144)	(2.862)	(2.864)
l. Firm Size	0.006	-0.000	0.006	0.009	0.002	0.004
	(0.591)	(-0.015)	(1.064)	(1.096)	(1.148)	(1.186)
l. M/B	-0.001	-0.007	-0.002	-0.006	-0.001	-0.002
	(-0.336)	(-1.104)	(-0.781)	(-1.063)	(-0.486)	(-0.768)
l. ROA	-0.016	-0.270	-0.019	-0.260	-0.045	-0.230
	(-0.168)	(-1.196)	(-0.382)	(-1.314)	(-1.570)	(-1.167)
l. Cash Holding	-0.000	0.000	-0.000	0.000	-0.000	0.000
	(-0.511)	(0.071)	(-0.373)	(0.388)	(-0.489)	(0.110)
l. Leverage Ratio	-0.083***	-0.117***	-0.022	-0.028	0.000	-0.003
	(-3.835)	(-3.617)	(-1.526)	(-1.171)	(0.060)	(-0.228)
Cohort-Firm FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	6,662	6,662	6,662	6,662	6,662	6,662
Adjusted R^2	0.063	0.064	0.077	0.021	0.080	-0.006

Table 12: The likelihood and speed of actual entry

This table presents the results of T-tests on the likelihood and speed of actual generic entry. Panel A focuses on a subset of the matched sample, including the Paragraph IV events that occurred between 2010 and 2014. This sample is divided into two groups based on whether the Paragraph IV event is associated with an abnormally large number of related new product launched by the treated firm during the period from the event up to five years later, or until the actual entry time if it occurs earlier. We report the fraction of treated and control drugs associated with generic approval within five years of the Paragraph IV event in each group. Columns (3) and (4) examine the statistical significance of the differences in likelihood between the treated and control groups. Panel B focuses on a subset of the matched sample in which the Paragraph IV events are followed by actual generic entries by 2019. This sample is also divided into two groups based on whether the Paragraph IV event is associated with an abnormally high number of related new drugs during the period from the event to the time of generic entry. We calculate the time span (in years) between the year of the Paragraph IV event and the year when the generic drug is approved by the FDA for both treated and control drugs in each group. In columns (3) and (4), we report the statistical significance of the differences in the time span between the treated and control groups. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Likelihood of entry within five years of the event year

	(1) Treated	(2) Control	(3) Difference-in-Likelihood	(4) T statistic
Abn.NewProducts_ATC4= 1	0.780	0.195	0.585***	8.931
Abn.NewProducts_ATC4= 0	0.532	0.298	0.234***	4.976

Panel B: Average time span (in number of years) from event year to the actual entry

	(1) Treated	(2) Control	(3) Difference-in-Time Span	(4) T statistic
Abn.NewProducts_ATC4= 1	3.625	5.115	-1.490***	-4.071
Abn.NewProducts_ATC4= 0	3.975	4.260	-0.285	-0.955

Table 13. Patent value and product market strategies

The 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 firms in our matched sample and on sale in the U.S. market from 2010 to 2019. 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 denotes 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 14: Heterogeneity test: innovation profiles

In this table, we examine whether firms with different innovation strengths exhibit heterogeneous responses to generic entry threats. Panel A focuses on firms' commercialization capabilities as indicated by their patent portfolio. We introduce the concept of the 'abnormal commercial value' of a patent as the residual term obtained from the regression reported in Column (2) of Table 13. For each firm in our sample, we count the number of patents with positive abnormal commercial value during 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.* Panel B focuses on firms' strength in conducting fundamental scientific research. We introduce the concept of 'abnormal citation' of a patent as the number of forward 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 75th percentile of 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 Products in the Same ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post **	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 Products in the Same 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

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 quarters, between the FDA approval date of a challenged drug and the date when the Paragraph IV challenge occurs. The quarter of approval is referred to as the 0^{th} quarter in the horizontal axis.

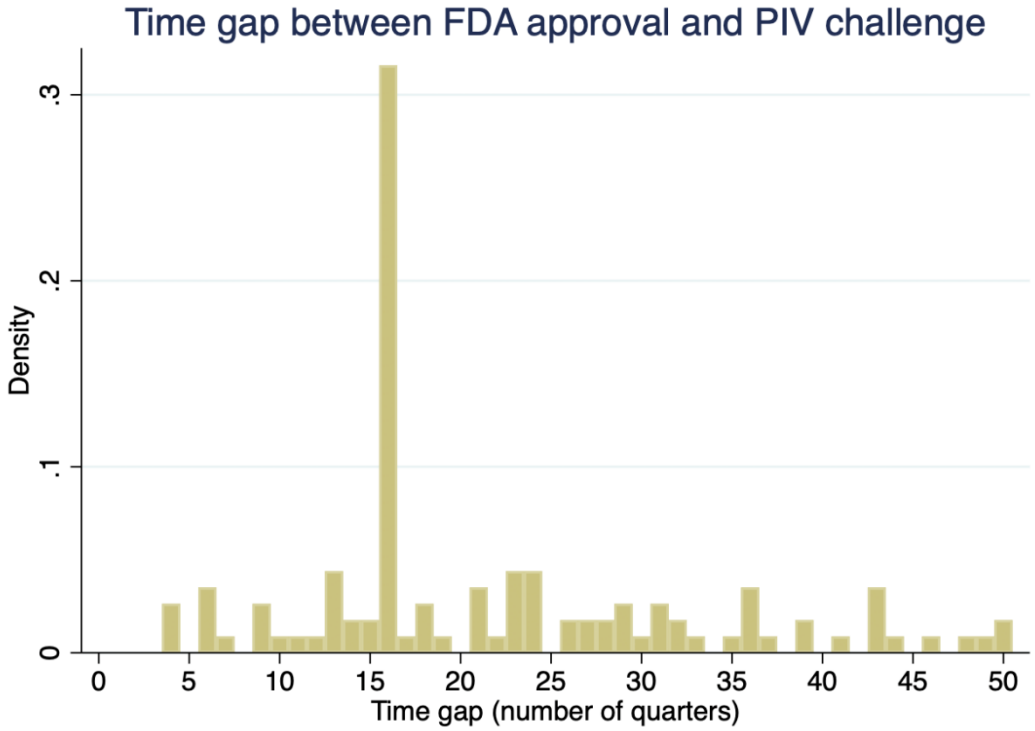


Figure 2. Dynamic effects of Paragraph IVs on new product launches

The figures represent the dynamic effects of Paragraph IV challenges. Specifically, we regress the dummy and number of new product launches on the interaction terms of the treated dummy and a set of semi-annual time interval indicators relative to the event time, with the year before the event excluded as the benchmark period. Each graph shows the coefficients on the interaction terms, including point estimates and 95% confidence intervals. In the top row, i.e., graphs (1) and (2), the dependent variables are a dummy indicator and the number of new therapeutic products introduced per firm quarter. In the middle row, i.e., graphs (3) and (4), the dependent variables are a dummy indicator and the number of new products that are in the same four-digit ATC category as the sample drug. In the bottom row, i.e., graphs (5) and (6), the dependent variables are a dummy indicator and the number of innovative new products which are protected by additional patents claiming drug substance and in the same four-digit ATC as the sample drug.

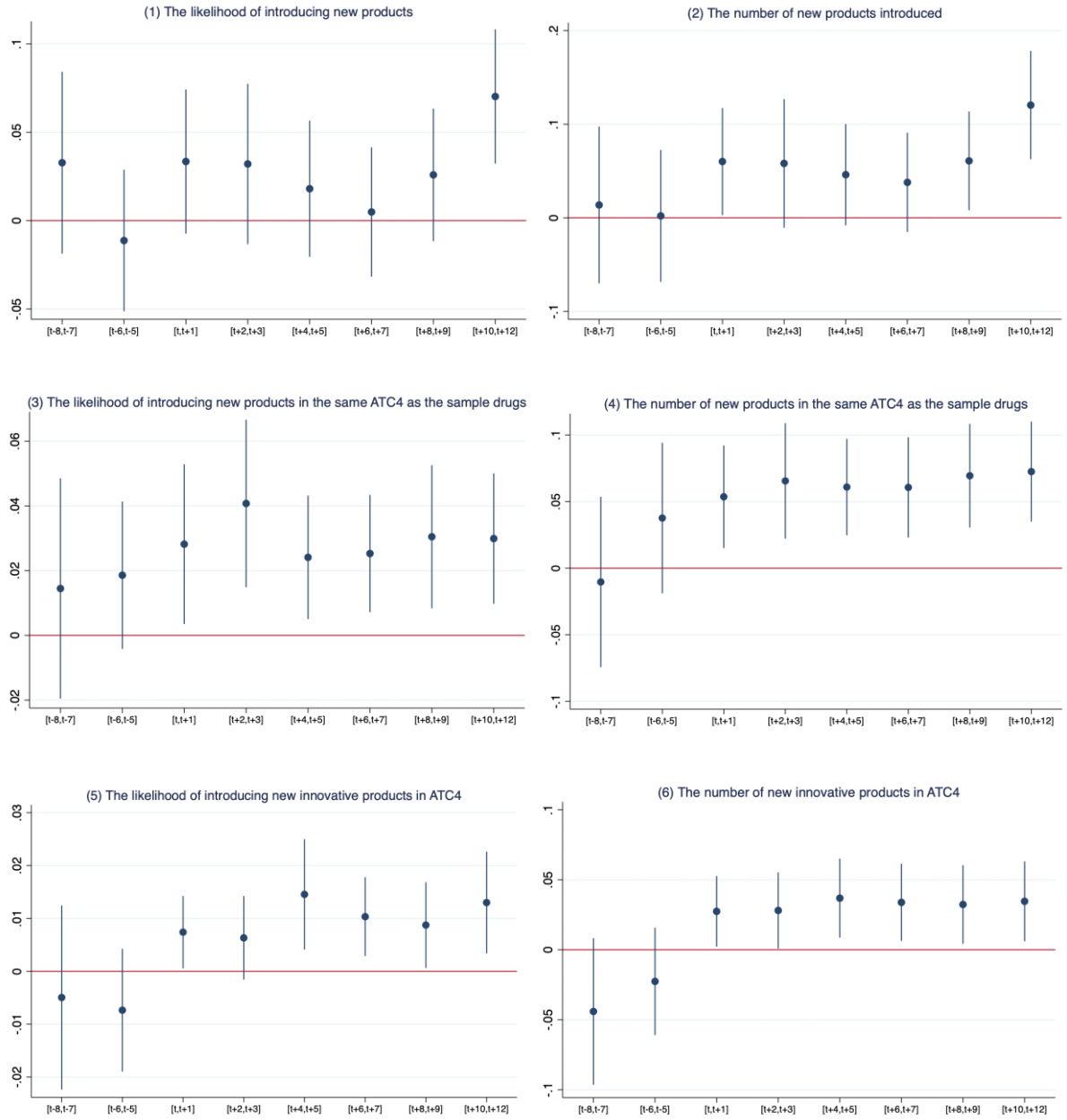
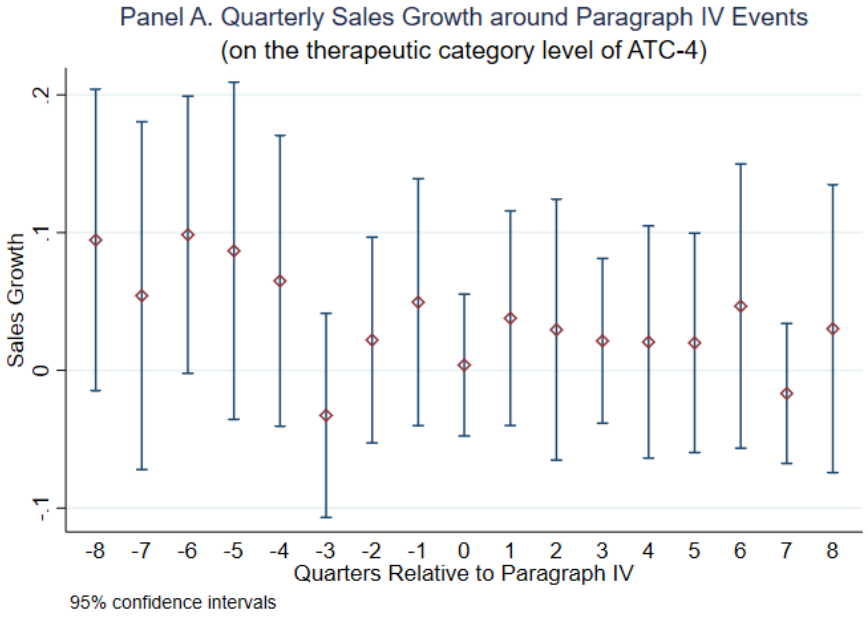


Figure 3. Drug sales surrounding Paragraph IV events
This figure presents the quarterly sales growth (Panel A) and the dollar amount of sales (Panel B) for each four-digit ATC category over a four-year window surrounding the occurrence of Paragraph IV events within the category. The dots represent the sample mean values, while the bars indicate the 95 percent confidence intervals.



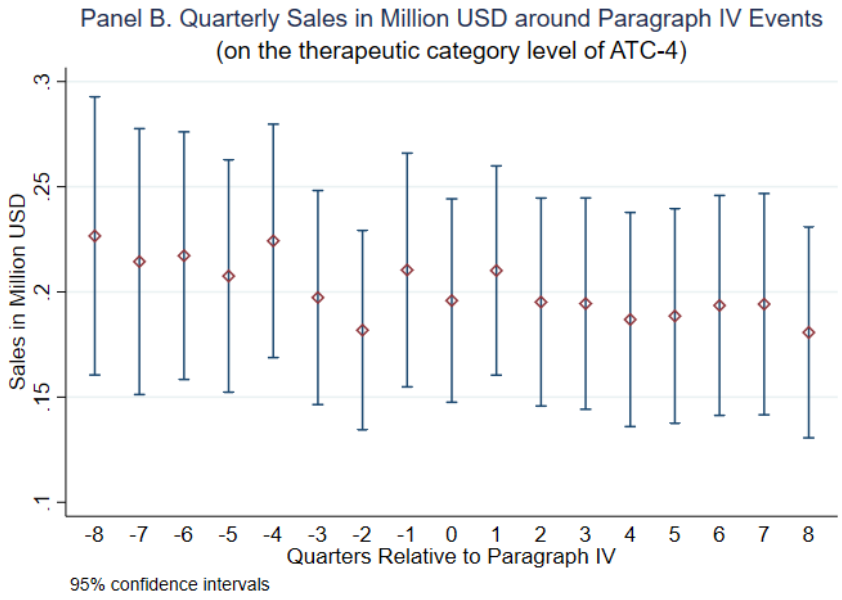


Figure 4: Dynamics of the Cannibalization Effects

The figures illustrate the dynamics of the cannibalization effects resulting from the introduction of related products by the challenged firms. We divide the sample into two subsamples: one where the challenged firm launched an abnormally large number of related new products during the period between the Paragraph IV challenge and the actual market entry compared to control firms, and another where no such launch occurred. In each subsample, we regress the quarterly sales, quantity, and price of the sample drug on the interaction terms of the treated dummy and a set of semi-annual time interval indicators relative to the event time, with the year before the event excluded as the benchmark period. Each graph shows the coefficients on the interaction terms, including point estimates and 95% confidence intervals. The left column, i.e., graphs (1), (2), and (3), displays results for the subsample where the treated firm launched a large number of related new products, while the right column, i.e., graphs (4), (5), and (6), shows results for the subsample without such launches.

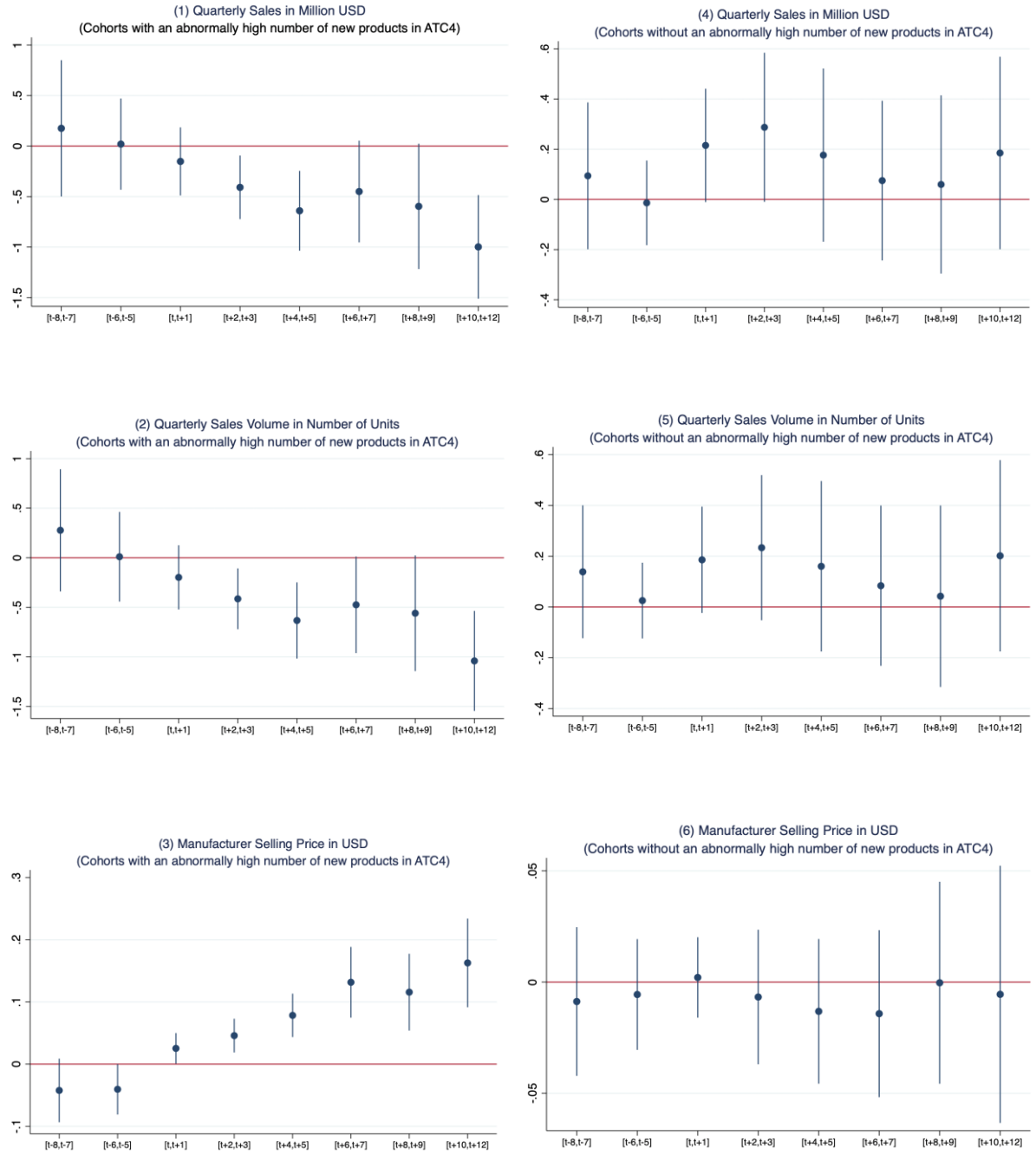
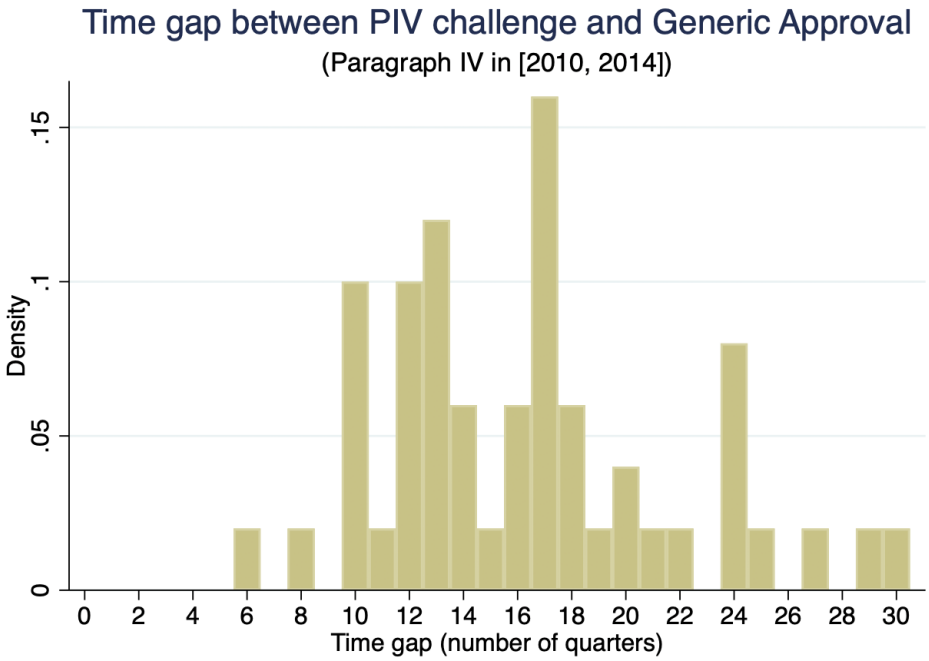


Figure 5: Timing of actual entry relative to Paragraph IV filings
In this figure, we show the distribution of the time gap, measured in quarters, between the Paragraph IV filing date of a challenged drug and the date when the generic maker eventually enters the market. The quarter of Paragraph IV filing is referred to as the 0^{th} quarter in the horizontal axis. The sample is restricted to the Paragraph IVs filed between 2010 and 2014.



Appendix: Variable Definitions

1. Dependent Variables

- *D[Paragraph IV] (t+1):* It is a dummy variable which takes the value of one if there is a Paragraph IV challenge for the brand-name drug *j* in the next quarter *t+1*, and zero otherwise.
- *D[All New Products]:* A dummy variable that takes the value of 1 if firm *i* in the matched sample launches new drug products in quarter *t*, and 0 otherwise.
- *#[All New Products]:* The number of new drug products introduced by firm *i* in quarter *t*.
- *D[New Products in the Same ATC4]:* A dummy variable that takes the value of 1 if firm *i* in the matched sample launches new drug products within the same four-digit ATC category as the sample drug in quarter t, and 0 otherwise.
- *#[New Products in the Same ATC4]:* The number of new drug products launched by firm *i* in quarter *t* within the same four-digit ATC category as the sample drug.
- *D[New Products in Other ATC]:* A dummy variable that takes the value of 1 if firm *i* in the matched sample launches new drug products outside the four-digit ATC category of the sample drug in quarter *t*, and 0 otherwise.
- *#[New Products in Other ATC]:* The number of new drug products launched by firm *i* in quarter *t* that are outside the four-digit ATC category of the sample drug.
- *D[Innovative New Products in ATC4]:* A dummy variable that takes the value of 1 if firm *i* in the matched sample launches new drug products within the same four-digit ATC category as the sample drug and these products are protected by additional patents claiming drug substance, i.e., those not previously applied to the existing product, in quarter *t*, and 0 otherwise.
- *#[Innovative New Products in ATC4]:* The number of new drug products launched by firm *i* in quarter *t* that are within the same four-digit ATC category as the sample drug and are protected by additional patents claiming drug substance.
- *D[Non-Innovative New Products in ATC4]:* A dummy variable that takes the value of 1 if firm *i* in the matched sample launches new drug products within the same four-digit ATC category as the sample drug but not protected by additional patents claiming drug substance, and 0 otherwise.
- *#[Non-Innovative New Products in ATC4]:* The number of new drug products launched by firm *i* in quarter *t* that are within the same four-digit ATC category as the sample drug but not protected by additional patents claiming drug substance.
- *Segment (ATC4) Sales:* The sum of sales (in billion USD) for all drug products within each four-digit ATC therapeutic category in each quarter.
- *Firm-Segment (ATC4) Sales:* The sum of sales (in billion USD) for all drug products manufactured by each firm within each four-digit ATC therapeutic category in each quarter.
- *Ln(Sales):* The natural logarithm of the sales (in USD) of product *j* produced by firm *i* in quarter *t*.
- *Ln(Qty):* The natural logarithm of the number of counting units sold of product *j* produced by firm *i* in quarter *t*.
- *Ln(Price):* The natural logarithm of the price of each product in quarter *t*.
- *EconValue:* The patent economic value, calculated based on market reactions to patent approval announcements, following Kogan, Papanikolaou, Seru, and Stoffman (2017).

2. Explanatory Variables

- *D[4 years after approval]:* It is a dummy indicator of a four-year gap between the current quarter *t* and the drug's approval date.
- *D[annual sales > 250m]:* It is a dummy variable indicating whether the average annual sales of drug *j* in the past three years is above 250 million USD.
- *#[valid patents]:* It equals the number of unexpired patents covering drug *j* in quarter *t*.
- *%[substance patents]:* It equals the proportion of patents claiming drug *j*'s substance among all the unexpired patents linked to drug *j* in quarter *t*.
- *Log(Total Assets):* It equals the natural logarithm of total assets in quarter *t*.

- *D[4 years after approval]:* A dummy variable indicating a four-year gap between the current quarter (*t*) and the drug's approval date.
- *D[annual sales > 250m]:* A dummy variable that takes the value of one if the average annual sales of drug *j* in the past three years exceed 250 million USD, and zero otherwise.
- *#[valid patents]:* The number of unexpired patents covering drug *j* in quarter *t*.
- *%[substance patents]:* The proportion of patents covering drug *j*'s substance among all unexpired patents related to drug *j* in quarter *t*.
- *Log(Total Assets):* The natural logarithm of the total assets in quarter *t*.
- *Treat:* A dummy indicator for treated firms in the sample.
- *Post:* A dummy indicator for quarters after the Paragraph IV events in the matched sample.
- *PostPIV:* A dummy indicator for quarters following the Paragraph IV event but before the actual market entry of generic drugs, if any within the sample period.
- *PostEntry*: A dummy indicator for quarters following the actual market entry of generic drugs, if any within the sample period.
- *PIV[t]*: A dummy variable that takes the value of 1 if there are Paragraph IV events within an ATC4 therapeutic category in quarter *t*, and 0 otherwise.
- *Abn.NewProducts_ATC4:* A dummy indicator of the Paragraph IV challenges associated with an abnormally large number of new products in the same four-digit ATC category launched by the treated firm. The abnormal number of new products is calculated using a difference-in-difference approach, measuring the difference between the average increase in the number of new products launched by treated firms per quarter and the average increase in the number of new products launched by control firms after the PIV events per quarter. *Abn.NewProducts_ATC4* takes the value of 1 if the abnormal number for a specific cohort exceeds the 75th percentile of the distribution across all cohorts.
- *citation:* The number of a patent's forward citations.
- *#all products:* The total number of new therapeutic products protected by each patent.
- *#products_[t-a, t+b]:* The number of new therapeutic products linked to a patent, introduced from *a* quarter before the firm's Paragraph IV event to *b* quarters after the event. Here, *t* denotes the quarter when the Paragraph IV event occurs.
- *Market Cap:* A firm's market capitalization on the day before the patent's granting day.
- *HighComValue:* The "abnormal commercial value" of a patent, defined as the residual term obtained from the regression reported in Column (2) of Table 11. For each firm during the year before Paragraph IV challenges, the number of patents with positive abnormal commercial value is counted and then normalized by firm size. Firms in the top quartile are identified as having 'high commercial value' of their patent portfolio, as indicated by the dummy variable *HighComValue*.
- *HighCitation*: The "abnormal citation" of a patent is the number of forward citations minus the average number of citations for all patents issued in the same year in our sample. A dummy variable, *HighCitation*, is constructed to identify firms with a higher number of patents with positive abnormal citations (normalized by firm size) in the year before the Paragraph IV event, exceeding the 75th percentile of the sample.
- *Firm Size*: The natural logarithm of firm *i*'s total assets in the last fiscal quarter, i.e., $Firm\ Size_{i,t-1} = \ln(at_{i,t-1})$.
- *Market-to-Book*$_{i,t-1}$: The market value of assets for firm *i* in quarter *t-1*, divided by its book value of assets, i.e., $Market\text{-}to\text{-}Book_{i,t-1} = (csho_{i,t-1} * prcc\_f_{i,t-1} + at_{i,t-1} - ceq_{i,t-1} - txdb_{i,t-1}) / at_{i,t-1}$.
- $ROA_{i,t-1}$: Firm i's operating income before depreciation in quarter *t-1*, divided by its total assets in quarter *t-2*, i.e., $ROA_{i,t-1} = oibdp_{i,t-1} / at_{i,t-1}$.
- *Cash Holding*$_{i,t-1}$: Firm i's cash and short-term investments in quarter *t-1*, divided by total assets in quarter *t-2*, i.e., $Cash\ Holding_{i,t-1} = che_{i,t-1} + dltt_{i,t-1}) / at_{i,t-2}$.
- *Leverage ratio*$_{i,t-1}$: The sum of firm i's total current liabilities and long-term debt, divided by total assets in quarter *t-1*, i.e., $Leverage\ ratio_{i,t-1} = (dlc_{i,t-1} + dltt_{i,t-1}) / at_{i,t-1}$.

Online Appendices for

Competition, Cannibalization, and New Product Introductions:

Evidence from the Pharmaceutical Industry

Online Appendix A: Supplementary Evidence

Table OA1: Balance test for the regression sample

This table presents the results of the T-test conducted in the regression sample (at the "cohort-firm-quarter" level), which is aggregated from the matched sample (at the "cohort-drug-quarter" level) based on the logit regression in Column (6) of Table 2. The construction details are described in Section IV. When there are multiple drugs within a cohort-drug-quarter, we take the average value for the reported variables. Below shows the mean value of each variable among the treated and control firms. 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.

	Treated	Control	Dif.	T statistics
1. Propensity score	0.033	0.032	0.000	0.011
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	0.122	0.033	0.888
#[valid patents]	4.419	4.364	0.054	0.142
%[substance patents]	0.318	0.373	-0.056	-1.373
Log(Total Assets)	9.773	9.541	0.231	0.954
# Firms	129	324		

Table OA2: Robustness: alternative definition of innovative products

This table presents a robustness test for the last four columns of Table 4. Specifically, the dependent variables in columns (1) and (2) are the dummy variable and the number of new products in the same four-digit ATC category as the sample drug, where the new products involve modifications in any of the following dimensions: active ingredients, routes of administration (e.g., oral, topical, or injection), and dosage form (e.g., capsules, tablets, or inhalers). The dependent variables in columns (3) and (4) are the dummy variable and the number of new products in the same four-digit ATC category, where the new products have the same active ingredients, routes of administration, and dosage form as the sample drug, but may differ in strength (e.g., 50 mg or 100 mg per tablet) and packaging (e.g., number of tablets per package). The regression sample and specification follow the same approach as in Table 4.

	(1)	(2)	(3)	(4)
	Innovative Related Products (differ in active ingredients, routes of administration, or dosage forms)		*Non-innovative Related Product (the other products in the same ATC4)*	
	Dummy	*Number*	*Dummy*	*Number*
*Treat * Post*	0.019***	0.054***	0.003	0.004
	(3.271)	(3.336)	(0.458)	(0.455)
l. Firm Size	0.010**	0.030**	0.005	0.009
	(2.026)	(2.491)	(1.169)	(1.624)
l. M/B	0.004*	0.009	-0.001	-0.002
	(1.718)	(1.488)	(-0.738)	(-0.860)
l. ROA	0.003	-0.060	0.007	-0.014
	(0.089)	(-0.456)	(0.205)	(-0.344)
l. Cash Holding	0.000**	0.000**	-0.000	-0.000
	(2.182)	(2.502)	(-1.263)	(-0.802)
l. Leverage Ratio	-0.016	-0.035	-0.003	0.004
	(-1.217)	(-1.082)	(-0.340)	(0.330)
Cohort-Firm FE	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290
Adjusted R^2	0.018	-0.014	0.047	0.006

Table OA3: Robustness for Table 4

This table reports the robustness analysis for the baseline regression reported in Table 4 using the matched sample at the cohort-drug-quarter level. The sample construction is detailed in Section IV. Regression specifications resemble Table 4. 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 Products in the Same ATC4*		*New Products in Other ATC4*		*Innovative New Products in ATC4*		*Non-innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post*	0.026*	0.061***	0.024***	0.059***	0.011	0.002	0.013***	0.048***	0.011	0.011
	(1.944)	(2.742)	(2.603)	(3.274)	(0.957)	(0.156)	(2.982)	(3.311)	(1.299)	(0.930)
l. Firm Size	0.038***	0.059***	0.015**	0.040***	0.026**	0.019	0.009***	0.023***	0.007	0.017
	(3.247)	(3.187)	(2.395)	(2.977)	(2.358)	(1.416)	(3.046)	(2.859)	(1.180)	(1.620)
l. M/B	0.003	0.005	0.002	0.008	-0.000	-0.003	0.001	0.003	0.001	0.005
	(0.677)	(0.600)	(0.913)	(1.176)	(-0.008)	(-0.886)	(0.998)	(0.818)	(0.490)	(0.900)
l. ROA	-0.045	-0.130	0.011	-0.069	-0.046	-0.061	0.012	-0.007	-0.001	-0.062
	(-0.742)	(-0.831)	(0.264)	(-0.522)	(-0.921)	(-0.936)	(0.407)	(-0.059)	(-0.029)	(-1.020)
l. Cash Holding	0.000	0.000	0.000	0.000**	-0.000**	-0.000**	0.000	0.000	0.000	0.000*
	(0.265)	(1.138)	(1.560)	(2.196)	(-2.194)	(-1.982)	(1.139)	(1.224)	(1.224)	(1.791)
l. Leverage Ratio	-0.092***	-0.139***	-0.020	-0.029	-0.080***	-0.110***	-0.006	-0.015	-0.014	-0.014
	(-3.853)	(-3.244)	(-1.212)	(-0.851)	(-4.250)	(-4.652)	(-0.646)	(-0.661)	(-0.993)	(-0.517)
Cohort-Drug 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	8,577	8,577	8,577	8,577	8,577	8,577	8,577	8,577	8,577	8,577
Adjusted R^2	0.078	0.067	0.104	0.049	0.080	0.094	0.030	0.026	0.106	0.034

Table OA4. Robustness for demand cannibalization test

This table shows the robustness test for the demand cannibalization effect documented in Table 10. Specifically, we exclude the cohorts where new branded products in the same four-digit ATC category are introduced by other brand-name companies during the post-event period. The specifications follow from Table 10.

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.NewProducts_ATC4*	-0.827**	-0.810**	0.145***
	(-2.131)	(-2.239)	(3.500)
*Treat * Post*	0.233	0.168	-0.058*
	(0.746)	(0.585)	(-1.860)
l. Firm Size	-0.048	-0.108	0.031
	(-0.290)	(-0.667)	(1.367)
l. M/B	-0.029	-0.015	-0.004
	(-0.661)	(-0.330)	(-0.831)
l. ROA	1.432**	1.693***	-0.107
	(2.355)	(2.723)	(-1.440)
l. Cash Holding	-0.000	-0.000	0.000
	(-0.876)	(-1.021)	(0.551)
l. Leverage Ratio	0.442	0.571	0.071*
	(0.900)	(1.186)	(1.797)
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	7,059	7,059	7,059
Adjusted R^2	0.897	0.917	0.999
Sum of first two Coefficients	-0.594**	-0.642***	0.086***
F statistics	6.331	8.188	13.272
P-value	0.012	0.004	0.000

Table OA5: Heterogeneity test: firm size and financial constraints

In this table, we examine whether firms with different sizes and degrees of financial constraints exhibit heterogeneous responses to generic entry threats. In Panel A, we introduce a dummy indicator for large firms, *HighSale*, which equals one for the firms with total drug sales in the quarter before Paragraph IV (*t-1*) higher than the 75-percentile value of our sample, and zero otherwise. In Panel B, we introduce a dummy indicator of financially constrained firms, *HighKZ*, which equals one for the firms with the value of the KZ index in the quarter before Paragraph IV (*t-1*) higher than the 75-percentile value of 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

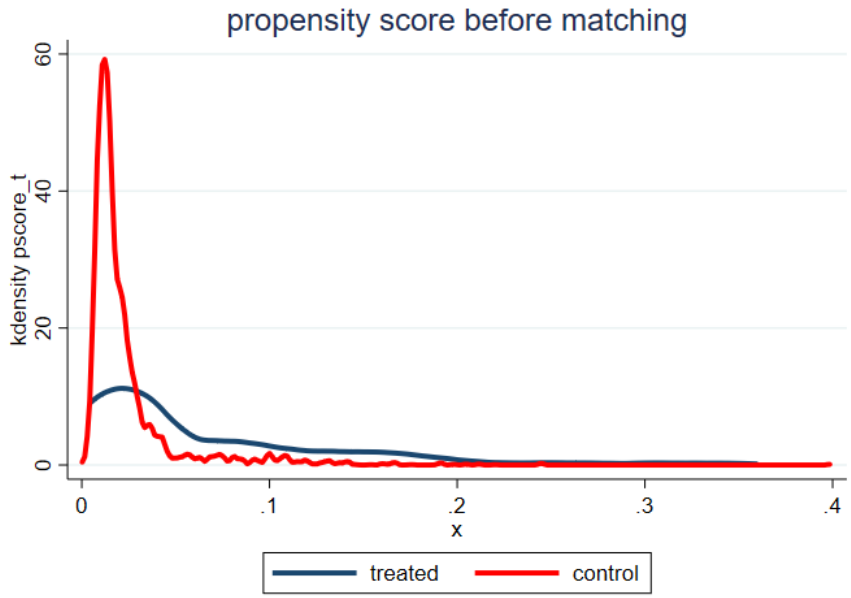
	(1)	(2)	(3)	(4)	(5)	(6)
	All New Products		*New Product in the Same ATC4*		*Innovative New Products in ATC4*	
	Dummy	*Number*	*Dummy*	*Number*	*Dummy*	*Number*
*Treat * Post * HighSale*	-0.021	-0.005	-0.006	0.011	-0.021*	-0.028
	(-0.575)	(-0.084)	(-0.255)	(0.272)	(-1.814)	(-0.888)
*Post * HighSale*	0.018	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 the Same 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	0.027	0.021	0.019	0.023	0.006	0.004
F Statistics	0.63	0.21	0.86	0.56	0.74	0.07
P-value	0.427	0.648	0.354	0.454	0.389	0.792

Figure OA1. Matching quality

These figures show the quality of propensity score matching. The upper (lower) figure presents the fitted density of the propensity score in the full (matched) sample. The propensity scores are estimated using the model reported in the last column of Table 2.



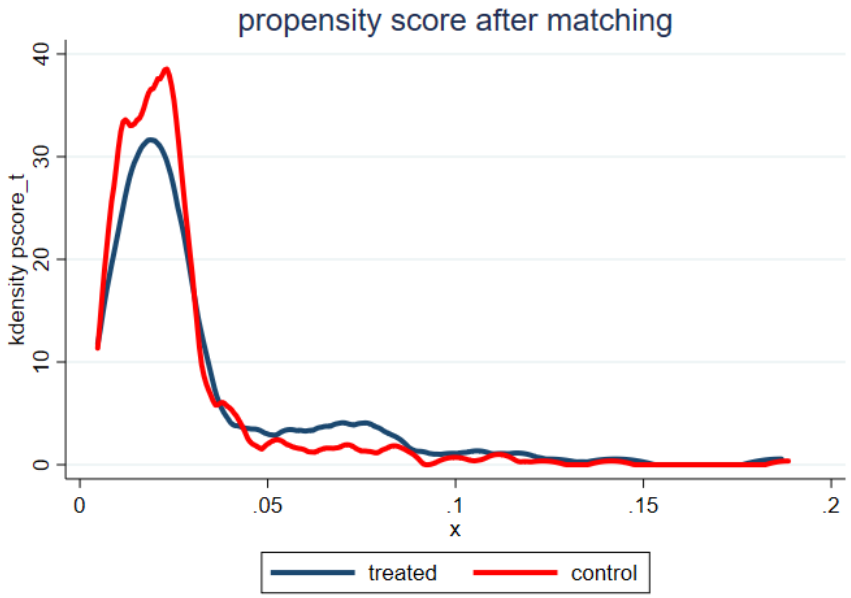
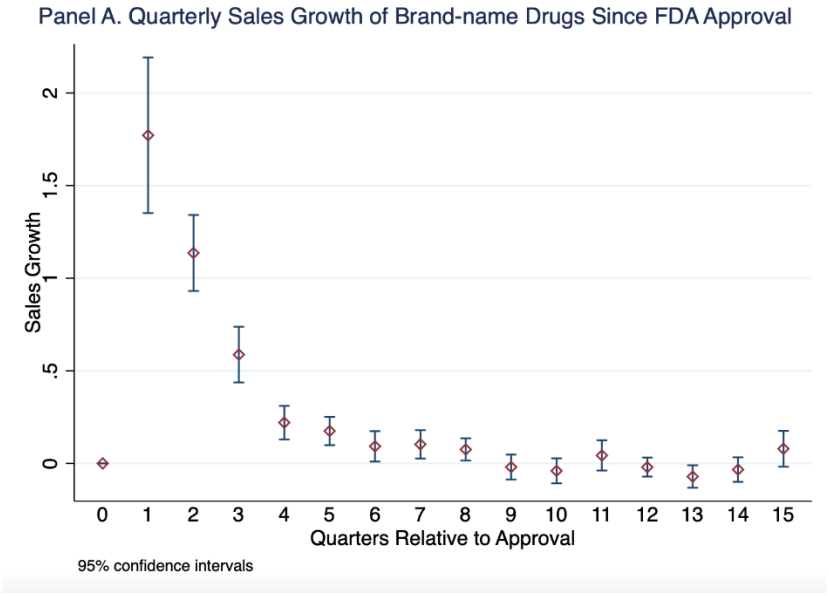
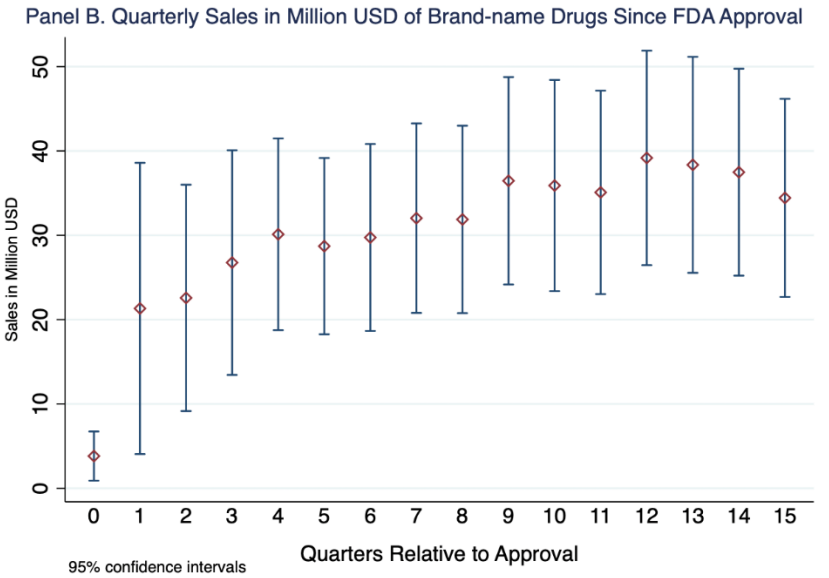


Figure OA2: Life-cycle of brand-name drugs for the first four years after approval

For each brand-name drug in our sample, we calculate the total quarterly sales of all versions within the drug line, grouped by active ingredients. Panel A (B) plots the growth rate of drug sales (dollar sales) per quarter over a four-year window following FDA approval. The sample for these plots covers the period after the drug's market launch but before the first Paragraph IV filing. The number of observations in the initial quarters after approval is limited, as market launches are typically delayed for a while after obtaining the approval. The numbers shown in the figure are based on the available data. The dots represent the sample mean values, and the bars indicate the 95% confidence intervals. Sales growth for the quarter in which approval is granted, i.e., quarter zero, is not measurable, so it is denoted as zero in Panel A.





Online Appendix B: Examples of new therapeutic products

Example 1: Innovative related new products.

Vraylar (cariprazine) and Saphris (asenapine) are both atypical antipsychotics manufactured by AbbVie. Saphris, approved by the FDA in 2009, is classified under ATC code N05A (Antipsychotics) and is indicated for the treatment of schizophrenia and acute manic or mixed episodes of bipolar I disorder. Vraylar, a newer atypical antipsychotic, received FDA approval in 2015. Also classified under N05A, Vraylar is indicated for the treatment of schizophrenia and bipolar disorder, including depressive episodes.

Both Vraylar and Saphris are effective substitutes, as they share the same classification and indications for the treatment of schizophrenia and bipolar disorder. Both drugs modulate similar neurotransmitter systems, particularly dopamine and serotonin receptors, which are crucial for addressing the symptoms associated with these conditions. This pharmacological similarity enables clinicians to select either drug based on individual needs of patients.

The innovativeness of Vraylar is largely attributed to its protection under two key patents: US7737142 and US7943621, both of which claim the drug's unique chemical properties as D3 and D2 dopamine receptor antagonists. Patent US7737142 describes novel (thio)carbamoyl-cyclohexane derivatives that preferentially target D3 and D2 receptors, which are important for modulating dopamine receptor activity. This specificity enhances treatment efficacy while potentially reducing side effects. US7943621 focuses on various salts of piperazine compounds, including hydrochloride and maleate forms, improving the drug's stability and bioavailability. Together, these patents highlight Vraylar's distinctive chemical composition and therapeutic potential, positioning it as a superior alternative to older treatments like Saphris. This combination of targeted action and optimized formulation contributes to Vraylar's innovation, ensuring its continued relevance in the treatment of complex psychiatric disorders.

Example 2: New product in the same four-digit ATC category

Zyprexa Zydis (ORAL SLD ODT) 15 mg and Zyprexa Relprevv (Dry RT Vial) 300 mg are two products under the Zyprexa brand, manufactured by Eli Lilly. Zyprexa Zydis, launched in 2001, is an orally

disintegrating tablet (ODT) used to manage symptoms of schizophrenia and bipolar disorder. It belongs to the ATC category N05A (Antipsychotics). Zyprexa Relprevv 300 mg, a long-acting injectable formulation introduced in 2015, is also indicated for the treatment of schizophrenia and bipolar disorder, offering rapid relief during acute episodes through extended-release dosing.

These two products are potential substitutes, as they both contain the same active ingredient, olanzapine, and treat similar psychiatric conditions. Despite differences in formulation and administration routes, both aim to manage the same symptoms and deliver therapeutic benefits to patients.

The innovation of Zyprexa Relprevv lies in its injectable formulation, which provides faster symptom relief compared to the orally disintegrating tablet of Zyprexa Zydis. The injectable form offers immediate therapeutic action, which is especially critical for patients in acute episodes, whereas the oral tablet, while convenient for daily maintenance, may take longer to achieve the same effects. This modification in the route of administration enhances the speed of treatment during emergencies and meets specific patient needs.

In terms of innovation, the degree of advancement and overall welfare improvement for patients is likely lower for Zyprexa Relprevv than the previous example of Vraylar. In our baseline analysis, which defines innovation based on the presence of additional patents claiming a new substance, Zyprexa Relprevv is not considered innovative relative to Zyprexa Zydis. However, under the broader definition of innovation used in Online Appendix Table OA2, Zyprexa Relprevv is classified as an innovative product.

Online Appendix C: Illustrative Examples

Example 1: Revenue Smoothing

A monopolistic incumbent offers a current product that has been generating $15 in revenue per period. At T=0, a potential entrant (e.g., a Paragraph IV challenger) reveals an 80% probability of entering the market at T=1. The incumbent has the option to launch a related new product, which could generate $10 in revenue per period on its own. However, the new product will cannibalize the current product's sales.

The revenue generated by the current product going forward depends on whether the potential entrant successfully enters the market and whether the incumbent decides to launch the new product. The following table summarizes the possible revenue scenarios:

	Entry	No Entry
New product launched	$0	$3
No new product	$6	$15

Assume both the current product and the new product generate revenue over three periods: T=0, T=1, and T=2. For simplicity, we ignore discounting in the following analysis.

1. If the incumbent is fully rational and cares only about maximizing expected revenue, it will prefer to postpone the decision of launching the new product until T=1.
    - If the entrant successfully enters the market at T=1:

      The incumbent will choose to launch the new product. This is because launching generates total revenue of $0 x 2 +$10 x 2 = $20 from T=1 to T= 2, whereas not launching results in a revenue of $6 x 2 = $12. Therefore, launching is the preferred option.
    - If the entrant does not enter the market at T=1:

      The incumbent will choose not to launch the new product. In this case, launching the new product generates total revenue of $3 x 2 +$10 x2 = $26 from T=1 to T= 2, while not launching generates $15 x 2 = $30. Thus, not launching the new product is the better option.
    - Thus, the postponing strategy at T=0 yields a total expected revenue of:

$15 + 0.8x$20 + 0.2 x$30 = $37.

- If the incumbent chooses to launch the new product at T=0, the total expected revenue is: ($10+$3) + 0.8 x ($10x2+$0x2) + 0.2 x ($10x2+$3x2) = $34.2.
- The value gain from postponing the launch (i.e., $37 - 34.2 = 2.8) reflects a reduction in cannibalization costs of ($15 - $3) + 0.2 x ($15-$3) x 2 = $16.8, minus the loss in the new product's revenue, which is $10 + 0.2 x$10 x2 = $14.

2. However, the postponement strategy will result in a sharp revenue drop at T=1 if entry occurs. A manager with a preference for smoothing revenue may therefore prefer to launch the new product at T=0. To illustrate this, we compare the revenue flows under the two strategies as shown below:

Strategy	Status at T=1	T=0	T=1	T=2
Launch new product if entry occurs at T=1	Entry	$15	$10	$10
	No Entry	$15	$15	$15
Launch new product at T=0	Entry	$13	$10	$10
	No Entry	$13	$13	$13

- In the case of entry at T=1, the postponement strategy results in a "revenue cliff" of $5 at T=1, as the revenue drops sharply from $15 at T=0 to $10 at T=1. In contrast, launching the new product at T=0 incurs a $2 revenue decline at T=0 and an additional $3 revenue decline at T=1.
- The "revenue cliff" under the postponement strategy is likely to attract investor attention and place significant pressure on the manager, as it signals a sharp revenue decline at a critical moment—when the incumbent is losing market power over the existing product and introducing a new one. As a result, the manager may prefer to recognize part of the revenue loss earlier (at T=0), even if this leads to slightly lower expected revenues compared to waiting for the uncertainty about entry to be fully resolved.
- When the probability of entry is sufficiently high at T=0, the expected revenue loss from launching immediately is relatively small (in this example, $2.8). In such cases, the manager may opt for the early launch strategy to avoid the larger potential impact of the revenue cliff.

Example 2: Threat of launching new products

An incumbent offers a current product that generates $15 in revenue in the absence of competitors and competing products. A potential entrant is considering entering the market, and the incumbent has the option to launch a related new product, which could generate $10 in revenue on its own. However, the new product would cannibalize the incumbent's existing product sales. The incumbent's revenue from the current product depends on whether the entrant successfully enters the market and whether the incumbent launches the new product. The entrant's revenue, if it successfully enters, also depends on whether the incumbent offers the competing new product. The following table summarizes the revenues for both the incumbent and the entrant under different scenarios:

Incumbent \ Entrant	Entry	No Entry
New product launched	$0 \ $3	$3 \ $0
No new product	$6 \ $9	$15 \ $0

The entrant faces a fixed cost to enter the market. It is common knowledge that this cost is uniformly distributed between $0 and $5. However, only the entrant knows its actual fixed cost, and there is no way for the entrant to communicate this information to the incumbent. The incumbent can choose to launch the new product either before or after the entrant makes its decision.

1. The incumbent's delayed decision as a Nash equilibrium

If the incumbent delays the decision to launch the new product, the entrant will choose to enter the market when its revenue gain from entry exceeds the fixed cost. In this case:

- If entry occurs, the incumbent will launch the new product, generating $10 in revenue. This is preferable to the $6 in revenue that would result from not launching the new product.
- If the entrant does not enter, the incumbent will refrain from launching the new product and will continue generating $15 in revenue from the current product, which is higher than the $13 in revenue from launching the new product that competes with the current one.

Anticipating the incumbent's reaction, the entrant expects to gain $3 from entering the market. As a result, the entrant will choose to enter whenever the fixed cost is less than $3. Thus, entry occurs with an ex-ante probability of 60%.

2. Immediate launch does not improve the incumbent's gains under symmetric information

If the incumbent launches the new product before the entrant makes its entry decision, it remains optimal for the entrant to base its decision on the realized fixed cost. The entrant will still choose to enter whenever the fixed cost is less than $3, which occurs with a 60% ex-ante probability.

The incumbent's expected gain from this immediate launch strategy is 0.6×$10+0.4×$13=$11.2.

However, the delayed strategy yields an expected gain of 0.6×$10+0.4×$15=$12.

Therefore, an immediate launch of the new product does not improve the incumbent's gains, as it does not reduce the likelihood of entry but incurs additional cannibalization costs. In this example, the immediate launch offers no additional benefit compared to a delayed but contingent decision because the threat of introducing the new product is credible under symmetric information.

3. Immediate launch to deter entry under information asymmetry

Suppose the incumbent has a 50% chance of having the new product ready to launch (the "ready type") and a 50% chance that the new product is not ready (the "unready type"). The entrant cannot distinguish between the two types unless the incumbent reveals it by launching the new product immediately.

- If the ready incumbent chooses to delay the launch, the entrant cannot distinguish it from the unready type. In this case, the entrant expects to gain 0.5 × $3 + 0.5 × $9 = $6 from entering. Since the entrant's fixed cost is always less than $5, entry will occur with 100% probability, and this incumbent will earn an expected gain of $10.
- However, if the ready type of incumbent launches the product to reveal its type, the entrant will choose to enter only if its fixed cost is less than $3, which occurs with a 60% probability. This strategy results in a higher expected gain for the incumbent: 0.6 × $10 + 0.4 × $13 = $11.2. This makes immediate launch the preferred strategy for the ready incumbent.

Therefore, if launching the new product is the only way for the incumbent to reveal its type to the entrant, the ready incumbent will opt to launch immediately. This new product launch serves to reduce the likelihood of entry by signaling the incumbent's type.

4. A preferred entry-deterring strategy: announcing the new product without actually launching

If the incumbent, with the new product ready, has an alternative strategy to convincingly reveal its type—even at a communication cost—it may prefer this alternative to launching the product immediately.

To see why, consider the scenario where the entrant learns about the incumbent's new product. The entrant would anticipate that the incumbent will launch the new product if entry occurs, which results in an expected gain of $3 from entering. Therefore, the entrant will choose to enter only when the fixed cost is less than $3, which happens with a 60% probability.

This suggests that, by revealing its type without launching, the incumbent's expected payoff is $0.6\times\$10+0.4\times\$15=\$12$. This expected payoff of $12 is higher than the $11.2 the incumbent would earn by launching the new product immediately.

Thus, the incumbent would prefer to pay a communication cost of up to $12 - $11.2 = $0.8 to reveal its type without launching the product.