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Abstract

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Keywords: cannibalization, product Launch, competition, creative destruction
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1. Introduction

Cannibalization is a critical consideration in corporate capital budgeting decisions. It occurs when firms introduce new products that potentially erode the sales or profitability of their existing offerings. Classical valuation models emphasize the importance of accounting for cannibalization costs when calculating the Net Present Value (NPV) of a new project (e.g., Brealey, Myers, and Allen, 2011; Damodaran, 2007). Beyond these valuation concerns, cannibalization can fundamentally shape innovation incentives—it discourages incumbent firms from pursuing creative destruction, a phenomenon known as the "replacement effect" (Arrow, 1962). However, empirical evidence remains limited regarding how cannibalization concerns influence firms' product introduction decisions and, more broadly, their product lifecycle management strategies.

The industrial organization literature (e.g., Argente, Lee, and Moreira, 2024) suggests that the impact of cannibalization is closely related to competition. When firms decide on new product introductions, they face a fundamental trade-off between internal cannibalization costs and external benefits of capturing market share from rivals. As competitive threats increase—whether through new firm entry, pricing pressures from rivals, or technological advancements—the expected profitability of a firm's existing products decreases. This alleviates the cannibalization concern and encourages firms to launch pipeline products to stay competitive.

In this paper, we empirically examine whether firms' new product introduction decisions respond to competitive shocks that lower cannibalization costs. Our focus is on the pharmaceutical industry, where cannibalization is a common challenge during the commercialization stage. Given the high risk and uncertainty of drug development, firms often build pipelines with multiple product lines targeting related diseases to improve success rates. However, this approach can lead to some products becoming (partial) substitutes for one another. While some drugs achieve blockbuster status with high value creation, others, despite being approved, are less valuable due to lower standalone profits or higher cannibalization costs, making their launch decision a strategic consideration.[2]

The introduction decision for drug products represents a classical capital budgeting problem, shaped by the balance between upfront launch costs and expected future cash flows. Since drugs are experience goods—where quality can only be assessed after use—pharmaceutical firms often make substantial investments in marketing activities, such as sales detailing, direct-to-consumer advertising, and free-sample distribution, to address information asymmetry and support new product adoption.[3] A nuance in this process is that initial marketing costs are spread out over time, rather than being incurred

[2] Between 1996 and 2015, 62% (23%) of drug launches averaged less than $100 million ($10 million) in annual sales during the initial five years, while only 3% achieved blockbuster status, generating over $1 billion annual sales during the same period. (Source: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/lifetime-trends-in-biopharmaceutical-innovation-recent-evidence-and-implications)

[3] The aggregate marketing and administrative expenditures of the twelve largest pharmaceutical companies reached $120 billion in 2015, surpassing their research and development spending of $80 billion (National Academies of Sciences, Engineering, and Medicine, 2018).

as a single expense. The resource allocation toward marketing is guided by the expected value of specific products, which ultimately influences how quickly a new drug can generate meaningful sales—a milestone commonly referred to as the "market launch". When competitors threaten an existing product, incumbents are incentivized to accelerate the market launch of related pipeline products. This is because reduced concerns about cannibalization enhance the expected value of the new product, making it more attractive investment project.

To test this hypothesis, we study Paragraph IV certifications, which are filed by generic firms (entrants) to signal intent to enter a brand-name (incumbent) product market before patent expiration.[4,5] Generic drugs, at the molecular level, pose major competitive threats to brand-name products. Paragraph IV events reduce the expected revenue of an existing brand-name product, thereby lowering the cannibalization costs of incumbent's pipeline launches. On the other hand, they pose limited threats to the stand-alone profit potential of pipeline products, which tend to offer more advanced therapeutic effectiveness and minimized side effects.[6] Since the timing of these events is generally unpredictable (Conti, Ortega, and Sung, 2025), they provide a natural setting to study incumbents' responses to entry threats.[7] Furthermore, when faced with a Paragraph IV challenge, brand-name producers typically file patent lawsuits against generic entrants, delaying their potential entry by several years until litigation is resolved. This creates a unique opportunity for researchers to study how incumbents' own pipelines affect the sales of threatened products in the absence of actual external competition.

We first construct a control group comprising drugs with a similar ex-ante likelihood of facing Paragraph IV challenges, based on factors such as commercial potential, regulatory feasibility of patent challenges, likelihood of litigation success, and trends in year and therapeutic area. For each challenged drug between 2010 and 2019, we identify three drugs from different firms with the closest ex-ante likelihood of challenge but no prior Paragraph IV events. Using the stacked matching sample, we analyze the quarterly likelihood of new product launches, defined as the point when a new product

[4] Brand-name drugs are developed through extensive research and clinical trials, while generic drugs are bioequivalent copies with an abbreviated approval process, as their active ingredient's safety and efficacy are already established.

[5] Generic manufacturers can file a Paragraph III application after a brand-name drug's patents expire or a Paragraph IV application before expiration, claiming the patents are invalid or not infringed. Paragraph IV challenges, enabled by the Hatch-Waxman Act (1984), account for 55% of initial generic entry actions (Source: FDA's research report of "marketing of first generic drugs approved by U.S. FDA from January 2010 to June 2017" https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives)

[6] We elaborate in Section 2.2 that while increased competition in current product markets does spill over to the pipeline products, the effect is relatively minor, since it is optimal for the incumbent firm to shift outputs and sales toward the new market, which has higher base demand and greater profit potential in equilibrium.

[7] Conti, Ortega, and Sung (2025) provide substantial evidence supporting the unpredictability of Paragraph IV filings, which is discussed in our Section 2.1. However, we cannot entirely rule out the possibility that some brand-name firms may acquire private information about impending Paragraph IV events. Nonetheless, we later discuss why this possibility does not undermine our core argument that cannibalization concerns drive pipeline launch decisions.

begins generating meaningful sales.[8] This timing is captured by the first sales appearance in the IQVIA MIDAS database, which provides a third-party validated record of initial drug sales.[9]

We find that Paragraph IV events significantly increase the likelihood of new product launches by the challenged firms. These incremental launches occur within six months of the event and are preceded by parallel trends in pre-event launch activities between treated and control firms. The economic impact is substantial: after Paragraph IV events, challenged firms are 2.9 percentage points more likely per quarter to launch new products—representing a 40.8 percent increase over the unconditional launch rate of 7.1%. Notably, these additional launches are primarily concentrated in the same therapeutic categories as the challenged products, indicating potential demand substitution. Additionally, the effect is particularly pronounced for products featuring new active ingredients, rather than those with minor extensions. This suggests that the entry threats encourage incumbents to prioritize the launch of genuinely innovative therapies – pipeline products with the potential to render current offerings obsolete and incur substantial cannibalization costs, but whose standalone value remains largely unaffected by intensified competition within the current product space.

Furthermore, we examine the sales of challenged products during the period surrounding Paragraph IV events but prior to actual entry by generic competitors. In this interim phase, the sales of the challenged drug remain unaffected by external generic competition but can be influenced by the incumbent's pipeline products. Our findings reveal a significant decline in both sales volume and quantity of the challenged drug following Paragraph IV events, but only when the incumbent launches new products in the same therapeutic categories. This effect is absent when no such launches occur. These results remain robust even after excluding samples where other brand-name competitors introduce new branded products in the same therapeutic area during the post-event window. These highlight our central argument: pipeline products can exert substantial competitive pressure on current products, making cannibalization concern a critical factor in product introduction decisions.

A key assumption in our identification strategy is the ability to isolate shocks to cannibalization costs from variations in the market demand for pipeline products. If Paragraph IV filings coincide with positive demand shocks in the therapeutic area, the observed increase in pipeline launches could be driven by higher stand-alone revenue prospects for the new products. To address this concern, we examine the correlation between total sales of each therapeutic category and the occurrence of Paragraph IV events and find no significant associations. This suggests that there is no systematic association between generic entry intentions and segment demand, indicating that our findings are unlikely to be driven by shifts in market demand.

[8] We do not use the timing of initial marketing cost expenditures to identify product launch time, as this timing is neither transparent nor universally comparable across pharmaceutical products.

[9] IQVIA is a comprehensive database that tracks the commercial performance of therapeutic products, covering over 90% of sales channels in the U.S.

Additionally, we leverage a regulatory feature of the Hatch-Waxman Act that FDA grants 180-day exclusivity to the first generic filer to enter the market, creating strong incentives for Paragraph IV filings to occur as early as permitted—typically the 16th quarter after brand-name drug approval. These "early" filings are less likely to reflect contemporaneous demand conditions. Importantly, we find that our baseline results are even stronger within this subset, reinforcing the conclusion that unobserved demand shocks cannot explain our findings.[10]

We also rule out several alternative explanations. First, we address the possibility of reverse causality—where new product launches might distract incumbents from defending patents, potentially attracting more challenges from generic firms. Our analysis finds no evidence for this: treated and control firms in the matched sample had comparable numbers of ready-to-launch products prior to Paragraph IV events, and generic firms' success rates in patent litigation are statistically similar regardless of whether incumbents launched new products or not. Second, we examine whether new launches in response to entry threats are intended to deter entry. The evidence suggests otherwise: Paragraph IV events followed by incremental launches are actually associated with a higher likelihood of generic entry within five years, indicating no clear entry-deterrence effects in equilibrium.

We cannot completely rule out the argument that incumbent brand-name companies receive private information regarding the impending Paragraph IV events and ramp up their commercialization efforts before these events occur. However, our finding that the incremental launch of pipeline products occurs shortly after, rather than before, the Paragraph IV events suggests one of two possibilities: either firms are unable to predict the precise timing of the event and therefore do not act until it occurs, or their private knowledge arrives only shortly before the event, leaving insufficient time to accelerate and complete the marketing process for pipeline products. In either case, the alleviation of cannibalization concerns remains a valid explanation for our findings.

Our findings further imply that firms anticipate the *long-term* likelihood of generic entry and develop pipeline products in advance, though the launch of these products could be postponed until generic entry threats intensify. We next examine whether the entry threats influence the pipelines' timing of FDA *approvals*, which mark the completion of drug development and the earliest point at which firms can legally sell therapeutic products. However, we find that Paragraph IV events do not affect the quarterly likelihood for obtaining new product approvals, indicating that approval timing is largely beyond firms' control.

Combining this with our baseline findings, we infer that there could exist a delay between when a product is approved for sale and when it starts generating meaningful sales in the absence of competitive threats. Consistently, in our sample of all brand-name products approved and launched between 2010 and 2019, the mean (median) post-approval delay is 1.46 (1) years. Additionally, we

[10] Patent challenges occurring in the 16th quarter after FDA approval remain unlikely to be predictable, as only 31.5% of drugs with their initial molecule patents expiring by the end of the fourth year receive Paragraph IV challenges.

predict that the length of the post-approval delay till launch could be reduced by a firm's marketing preparedness and its intensity of marketing efforts, both shaped by cannibalization concerns and competitive pressures. Using duration regressions, we find that the delay is longer when a firm's current products in the same therapeutic area generate higher sales but is significantly shortened following a generic challenge to these products. These findings reinforce our argument that firms accelerate the launch of products with lower cannibalization costs.

Finally, we examine the heterogeneities in firms' responses to Paragraph IV events. Our baseline findings are more pronounced for firms with concentrated product portfolios, which are more likely to have pipeline products overlapping with their existing offerings. Additionally, the effects are amplified for Paragraph IV challenges targeting drugs that contribute a larger share of the incumbent's revenue, indicating higher cannibalization concerns. Last, the effects are stronger for new products with longer patent protection, reflecting a lower opportunity cost of delaying and strategically timing their market launch.

Overall, our findings suggest that cannibalization concerns can slow the pace at which novel products reach the market, creating a gap between innovation and the realization of consumer welfare. Competition, however, drives creative destruction by mitigating these concerns. This phenomenon is not limited to the pharmaceutical industry but applies to any industry where accumulated knowledge gives incumbent innovators a technological edge in developing follow-up products.[11] Our research highlights that fostering competition, including from imitators, can unleash the value of innovation.

Our work speaks to the literature on competition, innovation, and growth—examined both theoretically (e.g., Aghion, Harris, Howitt, and Vickers, 2001; Aghion, Bloom, Blundell, Griffith, and Howitt, 2005) and empirically within the pharmaceutical sector (e.g., Higgins and Graham, 2009; Garfinkel and Hammoudeh, 2024; Branstetter, Chatterjee, and Higgins, 2022; Thakor and Lo, 2022; Li, Lo, and Thakor, 2024). While prior research has focused on how competition shapes innovation incentives—often assuming a direct path to commercialization—less attention has been given to the strategies and frictions that arise during the commercialization stage. These decisions are critical, as they determine both the financial returns on innovation and the speed at which innovations reach consumers. By examining firms' product launch decisions, our analysis highlights an underexplored channel through which competition affects the innovation-growth relationship.

[11] 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.

One key issue in this literature is understanding what incentivizes incumbents to pursue creative destruction. Despite Arrow's replacement effect, Garcia-Macia, Hsieh, and Klenow (2019) find that most growth comes from existing product improvements, with incumbent-led innovation larger than new entrant disruption. However, given that cannibalization could stifle such incumbent-led improvements, the question of what incentivises incumbents to launch improved products is of crucial importance. The work of Aghion et al. (2001) suggest that competition drives incumbents to innovate, particularly when they compete "neck-to-neck" with rivals; moreover, a moderate level of imitation can enhance growth by fostering more frequent neck-to-neck competition. Our findings align with this theoretical perspective, showing that imitator entry threats positively influence incumbents' new product launches. By leveraging a unique institutional setting separating threats from actual entry, we provide direct evidence on cannibalization costs and their influence on multiproduct firms' product launch strategies.

Finally, our paper contributes to the growing healthcare finance literature on pharmaceutical companies' innovation, investment, competition, and pricing (e.g., Cunningham, Ederer, and Ma, 2021; Krieger, Li, and Papanikolaou, 2022; Krieger, Li, and Thakor, 2022; Li, Liu, and Taylor, 2023; Bonaime and Wang, 2024; Aghamolla, Karaca-Mandic, Li, and Thakor, 2024; Garfinkel and Hammoudeh, 2024). Recent studies have highlighted inefficiencies in pharmaceutical innovation, such as how collusion may dampen innovation incentives (Li, Lo, and Thakor, 2025) and the persistence of delayed projects due to managerial sunk-cost bias (Guenzel and Liu, 2025). Building on these insights, we focus on the critical but underexplored commercialization stage of the product lifecycle. Frictions and strategies at this stage can have broader implications for earlier stages of research and development and overall welfare.

2. Conceptual Framework

2.1 Institutional Background

This section introduces the competitive dynamics, regulatory requirements, product definitions, and firms' product lifecycle management strategies in the pharmaceutical industry.

First, developing therapeutic products requires significant investment and lengthy research and development processes. Once approved by the FDA, the brand-name drug companies gain monopolistic market power through administrative market exclusivity (granted by the FDA) and intellectual property (patent) protections. Under the Hatch-Waxman Act of 1984, generic drug manufacturers can pursue market entry by demonstrating that their product is bioequivalent—meaning it delivers the same active ingredient into the systemic circulation at the same rate and to the same extent as the reference branded product. Generic entry can occur after all patents of the reference product expire through a Paragraph III certification, or before patent expiration via a Paragraph IV certification. Filing a Paragraph IV certification indicates a more aggressive entry strategy by challenging the validity or applicability of existing patents. Although actual entry typically occurs years later—pending litigation outcomes—

these filings signal a clear intent to compete. According to FDA research conducted in 2017, 55% of the initial generic entry actions occurred through Paragraph IV filings, which is the focus of our study.

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 (granted by the FDA) is about to expire. 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, while other three types of exclusivities have different restriction periods.[12] This rule leads to a clustering of Paragraph IV filings immediately after four years have passed since the brand-name drug's approval, consistent with the findings in the literature (e.g., Grabowski, Brain, Taub, and Guha, 2015),

The timing of Paragraph IV challenges is difficult to predict due to the complex interplay of manufacturing challenges, regulatory hurdles, legal environments, patenting strategies, market dynamics, and competitive forces. Conti, Ortega, and Sung (2025) provide substantial evidence highlighting this unpredictability. They find that while many filings occur in the fourth year post-approval, over 75% happen either earlier or later. Their interviews with Gregory Glass, a pharmaceutical expert with over 25 years of experience and the creator of the *Paragraph IV Report*, further emphasize this variability. Glass notes that some brands receive Paragraph IV certifications within months of FDA approval, while others wait years (Glass, 2021; paragraphfour.com). Additionally, Conti et al. show that these filings are rarely aligned with the expiration of molecule patents, as identified using the methodology of Gupta (2024). The uncertainty is further exacerbated by challenges related to production costs and replication methods (Morton, 1999; Voet, 2020; Wang, Li, and Anupindi, 2023).

Next, we discuss the definition of drug products. In the pharmaceutical industry, product details are highly standardized and transparent to researchers. To bring therapeutic products to market, FDA approval is mandatory and requires disclosure of key product characteristics to ensure safety and efficacy. We define a **drug product** as a distinct combination of the following attributes: active

[12] 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 (https://www.fda.gov/media/92548/download). 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.

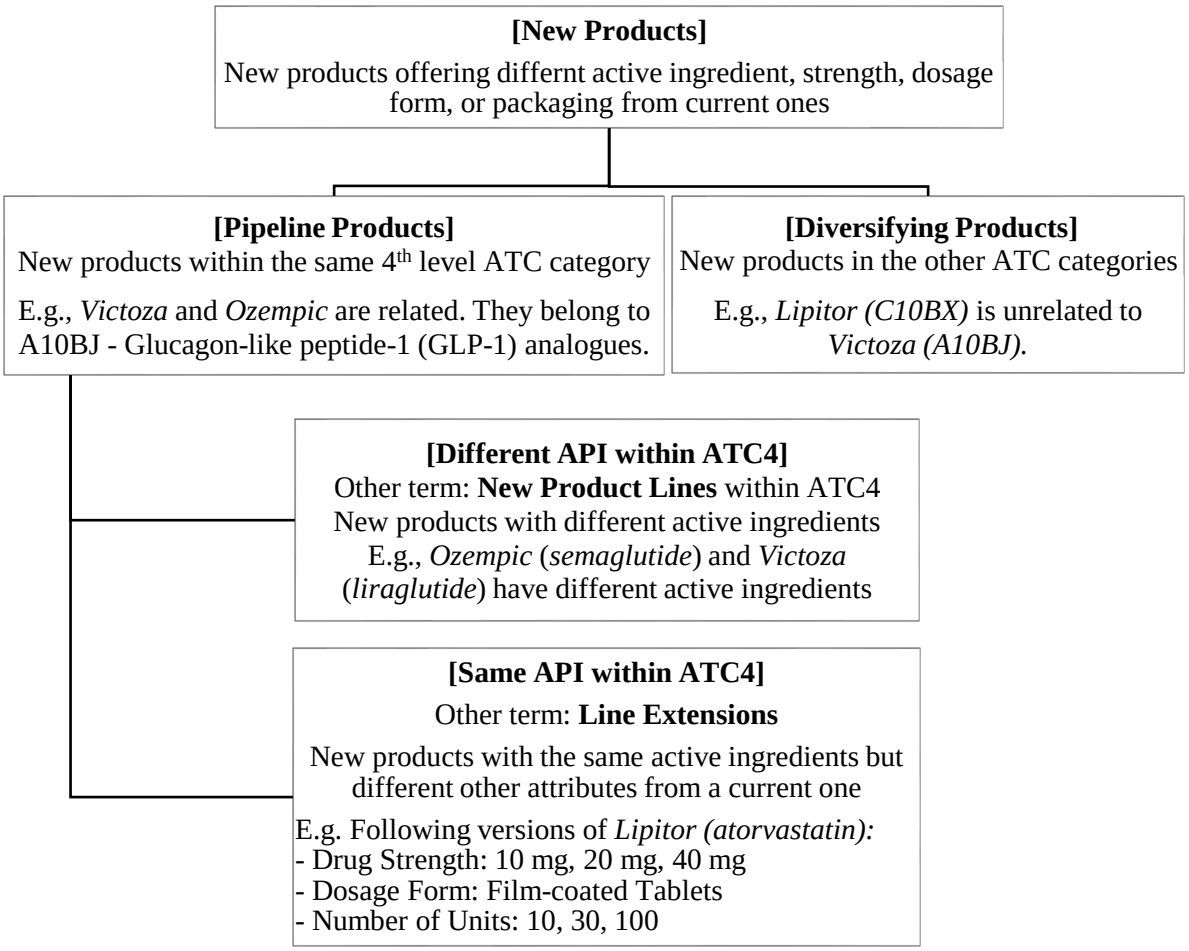
pharmaceutical ingredients (i.e., the molecule producing the intended the therapeutic effect), route of administration (e.g., oral, topical, injection), dosage form (e.g., capsule, tablet, inhaler), strength (e.g., 50 mg or 100 mg per tablet), and packaging configuration (e.g., number of units per package). Our definition is consistent with the FDA's use of the National Drug Code (NDC) system, which assigns a unique code to each drug product based on a combination of the labeller (the company that manufactures or distributes the product), product code (denoting active ingredients, strength, form, and formulation), and the code for each drug product (representing its size and type).[13]

Drug products can be grouped into **product lines** according to the active pharmaceutical ingredients (API). More broadly, product lines can also be grouped according to their anatomical, therapeutic, and chemical similarities, as measured by **Anatomical Therapeutic Chemical (ATC) Classification**.[14] Brand-name companies carefully manage their **pipeline products** by expanding their portfolios with "**line extension products**," which share the same API as current products, and "**new product lines**" in the same or related therapeutic categories. An illustrative chart for terminologies is provided below.

Pharmaceutical firms pursue several strategies to maximize the commercial lifespan of products, including both the staggered development of pipeline products and sustained commercial viability of existing marketed drugs. These stragegies are known as **product lifecycle management (PLM)**. Two PLM tactics, in particular, are highly controversial due to their potential anticompetitive effects. The first is "**patent evergreening**," where companies secure additional patents as the initial substance patents and market exclusivity near expiration. These patents often cover formulations, manufacturing processes, polymorphs, dosage forms, or new uses, increasing legal complexity and raising entry barriers for generic manufacturers (see Congressional Research Service, 2021; Gupta, 2024; Conti, Ortega, and Sung, 2025). The second is "**product hopping**," where brand-name companies shift users to reformulated versions of existing drugs by altering dosage forms or release mechanisms. Since generics of the original branded versions are not bioequivalent to the reformulated ones, these "superior"

[13] This definition has been widely adopted in studies analysing drug sales and pricing, as it reflects the detailed variations that influence market dynamics and consumer behavior (e.g., Bonaime and Wang, 2024). However, it extends beyond the scope of the FDA's New Drug Application (NDA) requirements, which mandate separate approval for changes in active ingredients, dosage forms, or strengths. By incorporating unit counts per drug product into our definition, we account for a granular level of product differentiation that aligns more closely with how drug companies design and market their products.

[14] The Anatomical Therapeutic Chemical (ATC) classification system is a hierarchical method used to categorize drugs based on their anatomical and therapeutic properties. The first level indicates the anatomical main group. The second level denotes the therapeutic subgroup. The third level specifies pharmacological subgroup, and the fourth-level details chemical subgroup. For example, the third-level "A10B" represents Blood glucose lowring drugs excluding insulins, while the fourth-level "A10BA" represents Biguanides.



reformulations create additional challenges for generic manufacturers.[15] Critics argue that product hopping hinders generic competition and prolongs monopoly pricing, while proponents claim it fosters innovation and improves therapeutic options (e.g., Shadowen, Leffler, and Lukens, 2009; Carrier, 2010; Field, 2023; Carlton, Flyer, and Shefi, 2016; Shapiro, 2016). Notably, the debates and previous literature on both "patent evergreening" and "product hopping" primarily focus on line extensions, where the therapeutic benefits are sometimes unclear. However, our empirical analysis extends beyond line extensions, offering new insights that will be discussed in later sections.

2.2 New Product NPV in Market Equilibrium

We illustrate the net present value (NPV) of pipeline product introductions based on a standard Cournot framework. First, we consider the current product market (market 1), where the demand function is:

[15] Under state Drug Product Selection (DPS) laws, generic products can only be automatically substituted for branded products if they are deemed bioequivalent. When reformulations are perceived by consumers as more advanced therapeutics, the generic versions of the original products face a significant competitive disadvantage. To qualify as bioequivalent to the reformulated drug, generic manufacturers must obtain new FDA approvals, incurring additional costs and delays.

$$p_1 = a - (q_{11+}q_{12}) \quad (1)$$

Here, q_{11} represents the output sold by the incumbent (firm 1) and q_{12} the output sold by a rival (firm 2) in product market 1. If the rival is not in the market, q_{12} equals zero.

We assume that the marginal cost of production is zero. It is straightforward to show that, in the absence of rival entry ($q_{12} = 0$), the incumbent's monopoly profit in market 1 is $\Pi_{11}^{m} = \frac{a^2}{4}$. However, when the rival enters the market ($q_{12} > 0$), the incumbent and rival firms earn a symmetric duopoly profit of $\Pi_{11}^{e} = \Pi_{12}^{e} = \frac{a^2}{9}$.

Now we consider a pipeline product in market 2, which is accessable to the incumbent (brand-name firm) but not the rival (generic firm). We attempt to capture the following features of the pipeline products: (i) The pipeline products in market 2 are partial substitutes for the current products in market 1, thereby capturing some customers from market 1; (ii) Moreover, these pipeline products offer advanced features that also attract new customers who were previously unaware of— or underserved by— market 1.

Accordingly, we assume that when the incumbent offers pipeline products in market 2, the demand in market 1 is given by:

$$p_1 = \frac{a}{2} - bq_{21} - (q_{11+}q_{12}) \quad (2)$$

Here, the demand intercept drops from a to $a/2$, reflecting the reduced "base" demand or maximum willingness to pay in market 1 due to the availability of alternative products in market 2. Additionally, q_{21} represents the output sold by the incumbent (firm 1) in market 2, and the parameter b ($0 < b < 1$) captures the degree of substitution between the two markets.

Similarly, the demand function in market 2 is given by:

$$p_2 = a - q_{21} - b(q_{11+}q_{12}) \quad (3)$$

Here, the cross-market demand substitution also applies, as the sales of products in market 1 partially influence demand in market 2 through parameter b.

We derive the optimal quantities and corresponding profits for the incumbent after introducing the pipeline product in market 2 under two scenarios: (1) without the rival entering market 1 ($q_{12} = 0$) and (2) with the rival entering market 1 ($q_{12} > 0$).

In the first scenario, where the rival does not enter market 1, the incumbent operates as a monopolistic in both markets. The incumbent's profits in market 1 and market 2 are $\Pi_{11}^{m,L} = \frac{a^2(1-2b)}{16(1-b^2)}$ and $\Pi_{21}^{m,L} = \frac{a^2(2-b)}{8(1-b^2)}$ correspondingly.

In the second scenario, where the rival enters market 1, the competition in market 1 becomes asymmetric because market 2 is more attractive to the incumbent than market 1. In this case, the

incumbent's profit in market 1 is $\Pi_{11}^{e,L} = \frac{a^2(2+b^2-6b)}{72(1-b^2)}$ and the rival's profit in this market $\Pi_{12}^{e,L} = \frac{a^2}{36}$. In market 2, the incumbent earns the profit of $\Pi_{21}^{e,L} = \frac{a^2(b^2-8b+12)}{48(1-b^2)}$.

To simplify the illustration, we summarize the profits of the incumbent and the rival in the table below using the following parameter values: (1) a = 1, (2) b = 0.25. The first number in each cell denotes the incumbent's profit in market 1, and the second number denotes the profit in market 2 The number in blue represent the rival's profit if it enters market 1. All numbers are multiplied by 100.

Incumbent (current + new product) \ Entrant	Entry	No Entry
New product launched (launch cost = $K not included)	0.8+22.36=$23.16\ $2.75	3.3+23.33=$26.63\ $0
No new product launch	11+0=$11\ $11	25+0=$25\ $0

We assume a fixed cost of $K to launch the new product in market 2. Launch costs for new products are common and often substantial. For example, in the pharmaceutical industry, the launch cost for new drug products can reach several hundred million dollars. According to a consulting company in the industry, the average commercial launch cost for a new drug has been $345.6 million in recent years.[16] To simplify the illustration, we assume the launch cost is incurred as a single expense. However, the intuition extends to the more complex scenario where the cost is distributed over time, and the time when initial sales is generated depends on the magnitude of $K.

Finally, we derive the NPV of launching the pipeline product in market 2 for the incumbent under two scenarios:

- Scenario 1: No Generic Entrant in Market 1

$$\text{NPV}^{\text{m}} = 23.33 + 3.3 - 25 - K = \$1.63 - K$$

In this monopolistic scenario, launching the new product is only value-enhancing if the launch cost is limited, i.e., $K < \$1.63$.

- Scenario 2: Generic Rival Enters Market 1

$$\text{NPV}^{\text{e}} = 22.36 + 0.8 - 11 - K = \$12.16 - K$$

Under competitive pressure in the current product market, launching new products in related markets becomes more attractive. In this case, the pipeline launch adds value as long as $K < \$12.16$. These suggest that new product launch is more appealing in presence of competitor entry to the current market.

To see how the reduction of cannibalization costs influences the new product's attractiveness, we decompose the NPVs into the stand-alone value of new product in market 2 and the impact of this new product on the current product in market 1 as follows.

[16] Source: https://www.eversana.com/insights/avoid-20-percent-investment-waste/

$$\text{NPV}^{\text{m}} = (23.33 - K) - (25 - 3.3) = (23.33 - K) - 21.7$$

$$\text{NPV}^{\text{e}} = (22.36 - K) - (11 - 0.8) = (22.36 - K) - 10.2$$

When the genric rival enters market 1, the cannibalization cost decreases substantially by \$11.5 (=\$21.7-\$10.2). This is primarily because the profits in market 1 before the new product launch are significantly reduced by the rival's entry. However, the stand-alone value of pipeline product dereases by only \$0.97 (=\$23.33-\$22.36). While increased competition in market 1 does spill over to market 2, the effect is relatively minor, since it is optimal for the incumbent to shift output and sales toward the new market, which has higher base demand and greater profit potential in equilibrium.

Key Takeaways: *Pipeline product launches become more appealing when current products are threatened by rival entrants, which significantly reduces the cannibalization costs while potentially having a minor impact on the stand-alone value of the pipeline product.*

2.3 Endogenous Generic Entry and Entry Deterrence

We now examine the generic rival's decision to enter the market, starting with the scenario without information asymmetry regarding the incumbent's readiness to launch the new product in market 2. We assume that rival firm faces a fixed cost of entry, which is uniformly distributed between \$0 and \$5.5. Only the rival can observe the realization of this cost. The rival observes its cost at t=0, and if it is optimal to enter, enters immediately. The incumbent can either launch the new product at t=0, or condition its launch decision on the entrant's entry decision at t=1.

Suppose the incumbent's launch cost is moderate, i.e., $\$1.63 < \text{K} < \$12.16$. In this case, if the incumbent waits until t=1, its optimal strategy is to launch the new product only if the rival enters the market but not launch in the absence of entry. Anticipating this response, the rival's optimal pure strategy is to enter the market if its fixed cost is below \$2.75, and not enter if the fixed cost exceeds this threshold. In summary, if the incumbent does not launch the new product at t=0, the new product will only be launched in the presence of entry in the current product market. Moreover, an early launch of the new product (unconditional on the rival's move) does not improve the incumbent's payoff, as it does not reduce the likelihood of entry in equilibrium.

We next consider the role of information asymmetry regarding the incumbent's readiness to launch a new product, which may incentivize early launch as an entry-deterrence strategy. Suppose the incumbent has a 50% chance of being "ready" (able to launch immediately) and a 50% chance of being "unready" (unable to launch). The entrant cannot observe the incumbent's type unless it is revealed through an early product launch at t=0.

Suppose the entrant believes that neither type of incumbent firm will launch any pipeline product at t=0. The entrant cannot distinguish between two types of incumbents and anticipates an expected gain of $0.5 \times \$2.75 + 0.5 \times \$11 = \$6.875$ from entering. Since the entrant's fixed cost is always below \$5.5, entry occurs with 100% probability, and the ready incumbent launches the new product subsequently, earning a profit of \$23.16 – K. However, this strategy is not optimal for the ready

incumbent, as it can achieve a higher expected gain by launching the pipeline new productat t=0 , thereby revealing its type. If the ready incumbent launches early, the entrant observes this signal, learns the incumbent's type, and only enters if its fixed cost is below $2.75, which happens with 50% probability. In this case, the ready incumbent's expected payoff becomes 0.5 × $23.16 + 0.5 × $26.63-K = $24.895 – K. By launching early, the ready incumbent reduces the likelihood of rival entry, making this strategy more profitable. Thus, under asymmetric information, in equilibrium, the ready incumbent will launch immediately, and the entrant will enter if and only if its fixed cost of entry is less than or equal to $2.75.

However, if the incumbent with a ready new product has an alternative way to credibly reveal its type—such as through a verifiable signal—it would prefer this approach over launching the product immediately. To see why, consider the scenario in which the entrant becomes aware of the incumbent's readiness. The entrant anticipates that the incumbent will launch the new product if entry occurs, yielding the latter an expected gain of $2.75. Thus, the entrant would choose to enter only if its fixed cost is below $2.75, which happens with 50% probability.

By revealing its readiness but delaying the actual launch, the incumbent earns an expected payoff of 0.5 × $(23.16 – K) + 0.5 × $25 = $24.08 – 0.5×K—the same as in the symmetric information case. This gives a higher payoff than the early launch to reveal type for any K > $1.63. This illustrates that a credible threat to launch can deter entry just as effectively as an actual launch.

As described in the institutional environment section, to get new drug products to the stage of "launch readiness", prior approval from the FDA is needed. This is a transparent process and it is common knowledge whether the incumbent is "ready" for pipeline launches. The new product is launched if and only if the entry becomes likely (or, generic entry cost is below $2.75 as argued before), and the launch occurs not to deter entry but because cannibalization costs are lower.

Key Takeaways: *Entry threats incentivize pipeline product launches primarily due to the reduction in cannibalization costs, rather than entry deterrence effects, since a credible threat to launch the pipeline can deter entry just as effectively as an actual launch.*

2.4 Further Discussions

Our stylized model assumes that uncertainty about the entry decision gets resolved at time t=1. In our empirical setting, however, the threat of entry (a Paragraph IV challenge) precedes actual entry, often by several years. This temporal separation is not a departure from the model's logic but rather what makes it testable. A Paragraph IV challenge signals that eventual entry is highly likely. Forward-looking incumbents immediately update their expectations, recognizing that the future monopoly profits of their existing product are now at high risk. Consequently, the expected cannibalization cost of introducing a pipeline substitute decreases, making the launch decision more attractive, just as our model predicts. The Paragraph IV filing thus acts as the trigger that shifts the firm's strategic calculation on the profitability of the launch decision.

Furthermore, this time lag provides a clean empirical window to observe the firm's strategies responses and associated revenue-substitutions. A market launch, empirically defined as the first appearance of meaningful sales, is not instantaneous, but rather stems from a lengthy and costly commercialization process including (1) marketing to physicians and patients; (2) persuading doctors to switch from the old drug to the new one through repeated visits and clinical data; (3) ramping up production and ensuring nationwide availability; and (4) negotiating favorable terms with insurers and PBMs to secure formulary placement. By accelerating the commercialization process, the incumbent can promptly launch pipeline products in response to the Paragraph IV threats, migrating its customer franchise to the new, patent-protected product before it is lost to a generic of the current product. Therefore, we anticipate to observe incremental pipeline launches during a window shortly after Paragraph IV challenges and most likely before the actual generic entries. These launches during the interim window allow us to isolate and measure the cannibalization effect—the sales decline of the threatened drug caused by the firm's own new product—before the market is confounded by the generic's actual presence.

3. Data

We construct a sample of therapeutic products marketed in the U.S. 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 on Paragraph IV events are also collected from the FDA's official website.

Second, we gather data on launch dates of drug products from IQVIA, which are the first appearance of sales in the database. We also collect information on the price and quarterly sales for each drug product from IQVIA. While IQVIA offers the drug price at various stages of the supply chain, we focus on the manufacturer selling price, which refers to the price at which a drug manufacturer sells its products to wholesalers or other intermediaries. Additionally, this database provides information on the Anatomical Therapeutic Chemical (ATC) Classification, allowing us to identify the products with potential substitution of consumer demand. 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 main 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 3,792 different brand-name drug products manufactured by 147 unique U.S. listed companies, among which 1,026 products (in 298 product lines) are challenged by generic applicants with Paragraph IV certifications from 2010 to 2019. Table 1 shows the distribution of drug lines and products in the level-one ATC category. The categories that exhibit the highest number of drug lines are nervous system, antineoplastic and immunomodulating agents, and alimentary tract and metabolism, collectively accounting for 44.4% of the overall sample. For the sample of brand-name drugs with Paragraph IV challenges from 2010 to 2019, these categories remain the dominant therapeutic areas.

[Insert Table 1 about Here.]

We construct several variables to facilitate our analysis of new product launches. *New product launch* is defined as a binary indicator representing the first sales appearance of a product with characteristics distinct from existing products, including differences in active ingredients, strength, form, or packaging. Our focus is on new products that have valid patents listed in the FDA's Orange Book at the time of market launch, which is the typical scenario for brand-name products.

Additionally, in our baseline analysis using Paragraph IV challenges, we further distinguish between the launch of new products within the same fourth-level ATC therapeutic category as the products in the matched sample (the construction of which to be described in Section 4) and those in other categories. New products in the same category have a higher potential to substitute demand from existing products.[17]

Lastly, among the new products within the same therapeutic category, we differentiate between "*line extensions*", which share the same active ingredients as the products in the matched sample, and "*new product lines*" that feature distinct active pharmaceutical ingredients (APIs). New product lines are more likely to offer superior therapeutic features, thereby attracting additional customers who were previously unaware of or unserved by the exisitng products. Internet Appendix B shows an example to illustrate the novel feature of new product lines within the same therapeutic category, as well as the potential of demand substitution.

Appendix A lists the definition of all the variables used for our analyses.

4. Empirical Specification

[17] Branstetter, Chatterjee, and Higgins (2016) provide evidence of demand substitutions between drug products within the second level ATC categories. By focusing on the more granular fourth-level ATC level, our approach ensures a high chance of capturing the related products involving demand substitution.

To examine how entry threats through Paragraph IV events affect new product launches, we adopt the stacked difference-in-difference (DID) approach following Gormley and Matsa (2011). This approach avoids the bias arising from heterogeneous treatment effects in staggered DID approaches, as summarized by Baker, Larcker, and Wang (2022). Specifically, we first construct a matched control sample of drugs with similar ex-ante likelihoods of being challenged that are estimated based on factors including the anticipated market potential, regulatory feasibility, litigation prospects, and technological barriers. The "already-treated" drugs are excluded from the control group. A difference-in-differences analysis is conducted within the matched sample to isolate the causal impact of Paragraph IV challenges on new product launch behavior.

First, we estimate a logit regression to predict the likelihood of being challenged through Paragraph IVs in the next quarter, using a panel data organized at product line-quarter level. The dependent variable takes the value of one if product line *i* experiences its initial Paragraph IV challenge in the next quarter *t+1* and zero otherwise.[18] The explanatory variables include: (1) a dummy indicator of a four-year gap between the quarter *t* and the first FDA approval date of products within the line, (2) a dummy variable indicating whether the average annual sales of the product line over the past three years is above 250 million USD,[19] (3) the number of unexpired patents covering the drugs in product line *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 first-level ATC category dummies.

The results of the logistic regressions are presented in Table 2. We find that a product line is more likely to be challenged in the next quarter if four years have just passed since the FDA approval, which is the earliest time allowed to file Paragraph IV certifications for most brand-name products by the FDA. Among all the predictors, the four-year indicator has the strongest explanatory power, as indicated by the pseudo-R^2.[20]

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

[18] Our attention is restricted to the sample of initial Paragraph IV filing within each product line following the literature (e.g., Hemphill and Sampat, 2011, 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.

[19] 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.

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

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 product line and a greater fraction of patents claiming the drug's substance are positively associated with the likelihood of patent challenges. This finding contradicts the common intuition that patent challenges are less likely when a brand-name product is associated with strong patent protection. Instead, it aligns with an equilibrium outcome where brand-name firms file a larger portfolio of patents for more innovative and valuable product lines, which, in turn, attract greater attention from generic entrants.

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.[21] On the other hand, launching new products might suggest that the brand-name manufacturer has less to lose from generic entry in the current market and, hence, is less likely to engage in costly litigation, which could encourage generic makers to file patent challenges. As a result, recent product launches have largely insignificant effects on the patent-challenging behavior of generic firms.

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. This finding is robust to alternative measurement of explaintary factors (untabulated) and aligns with the argument of Conti, Ortega, and Sung (2025) that timing of Paragraph IV timings is difficult to predict. The remaining variability in generic entry timing may be attributed to differences in manufacturing complexity and perceived uncertainty in the approval process, as highlighted by Wang, Li, and Anupindi (2023).

[Insert Table 2 about here.]

Based on the logit regression, we construct a matched sample to perform stacked difference-in-difference tests following Gormley and Matsa (2011). For each challenged product line, we identify three matches from the unchallenged product lines 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 products to be manufactured 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 product gets challenged during the post-event window, the observations since the quarter of the control product's challenge are excluded. The treated and control observations in each event cohort are required to have at least two quarters with non-missing data in

[21] In 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).

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 and 338 control product lines.[22]

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 observations in terms of their propensity score of being treated and the variables utilized in the logit regression during the quarter preceding Paragraph IV events. Figure IA1 demonstrates that the fitted densities of the estimated propensity scores for treated and control groups closely resemble each other.

Additionally, our matched sample reveals an insignificant difference in the number of ready-to-launch products—measured by the count of a sample firm's 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 group has an average of 1.047 ready-to-launch products within the same company, while control group has 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.

In our baseline analysis, we assess whether treated firms respond to patent challenges by launching new products. As the product launching decisions are made by the company, we change the data structure of the matched sample from "cohort-product line-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 Internet Appendix Table IA1. Our regression specification is outlined as follows.

$$y_{c,i,t} = \beta \times Treat_{c,i} \times Post_{c,t} + X_{c,i,t-1} + \delta_{c,i} + \eta_{c,t} + \varepsilon_{c,i} \qquad (4)$$

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, leverage ratio, and research and development expenses.

Our primary dependent variables are binary indicators of launching new drug products in the subsequent quarter. As shown in Panel B of Table 3, the average likelihood of new product launches for our sample firms is 7.1 percent per quarter. In addition, our sample firms launch new products within the same (different) fourth-level ATC category at a quarterly rate of 2.2% (5.1%). Finally, among the new products within the same ATC category, those from different (the same) product lines, having different (the same) APIs compared to the drugs in the matched sample, are launched at a quarterly rate of 0.7% (1.6%).

[22] A total of 298 product lines were challenged during our sample period from 2010 to 2019. The reduction in the number of events is attributed to the lack of similar control matches and missing sales information.

The coefficient of our main interest is β in Equation (4), which captures the incremental likelihood of new product launches due to intensified threat of entry from generic competitors. Since therapeutic categories are accounted for in the logistic regression propensity score estimation, 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 launches. Thus, β represents the treatment effect of Paragraph IV events.

[Insert Table 3 about here.]

5. Empirical Results

5.1 Baseline Results

Table 4 presents our baseline findings. In Column (1), we find that following the escalation of generic entry threats signalled by Paragraph IV challenges, there is a notable increase in the probability of new drug products launched by treated firms compared to control firms. Specifically, treated firms exhibit a 2.9% higher quarterly likelihood of launching new drug products. This effect is statistically significant at the 5 percent level and represents 40.8 percent of the unconditional launching rate of 7.1%.

More importantly, we find a more pronounced effect for new drug products within the same thereapeutic (fourth-level ATC) category as the products in the matched sample, where demand substitution is likely to occur. As shown in Column (2) of Table 4, the challenged firms are 2.3% more likely to launch new products within the same therapeutic category than the control firms after the Paragraph IV events, which corresponds to 105 percent of the unconditional launching rate of 2.2%. In contrast, as shown in Column (3), we do not find a significant increase in the likelihood of launching new products in different categories.

These findings support our argument that concerns about cannibalization, driven by demand substitution, may have prevented firms from launching 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 pressure in one therapeutic area does not directly impact the company's product launches in the unrelated market segments.

Furthermore, among the new drugs within the same therapeutic cateogry, we differentiate between those belonging to a different product line (i.e., featuring different active ingredients) and those within the same product line (i.e., sharing the same active ingredients) as the products in the matched sample. The regression results are reported in Columns (4) and (5), respectively. We find a significant and strong effect in Column (4), but not in (5), suggesting that treated firms respond to entry threats by launching new product lines within therapeutic area rather than within-line extensions.

This finding aligns with the theoretical predictions outlined in Section 2.2, which suggest that pipeline products with more advanced features and higher base demand are particularly sensitive to

cannibalization concerns and entry threats. In contrast, the launch of pipeline products that closely resemble existing ones (or include only minor modifications) is less likely to respond positively to entry threats. This is because generic entries diminish the standalone profitability of these similar products, making them less appealing as investment projects.[23]

Moreover, this result sets our findings apart from the existing literature on "patent evergreening" (e.g., Gupta, 2024) and "product hopping" (e.g., Shapiro, 2016), which primarily focus on line extension products that involve minor therapeutic modifications without altering active ingredients. One remaining concern is that the dependent variable in Column (4) of Table 4 might still capture minor modifications of challenged drugs, as the new active ingredients might be chemically similar to existing drugs, differing only in minor ways (e.g., esters or isomers). To address this issue, we manually reviewed all new product lines identified in our regression sample. Our analysis confirms that none of these products represent minor modifications lacking significant therapeutic advancements. Therefore, our findings highlight a distinct and underexplored product lifecycle management strategy, separate from the widely discussed tactics of patent evergreening and product hopping.

Next, we conduct two robustness analyses to address the limited number of new product line launches identified by the dependent variable in Column (4), Table 4. First, we broaden the definition of new product lines by considering differences not only in active ingredients but also in key product attributes, including routes of administration (e.g., oral, topical, or injection) and dosage forms (e.g., capsules, tablets, or inhalers). Internet Appendix B shows an example to illustrate the expanded definition of new product lines. As shown in Internet Appendix Table IA2, we continue to find a positive and statistically significant effect of Paragraph IV filings using this broader definition. Second, we extend the definition to include new product lines within a broader therapeutic category, measured at the third-level ATC. Again, we observe similar results to Column (4) of Table 4. These findings reinforce the robustness of our baseline results.

For the rest of our analyses, we mainly focus on new products, new products within the same therapeutic category, and products featuring different active ingredients within the same category—corresponding to the dependent variables in Columns (1), (2), and (4) of Table 4. Our results remain robust when using a matched sample at the "cohort-drug-quarter" level, as reported in Internet Appendix Table IA3.

[Insert Table 4 about here.]

Next, we examine the dynamic effects of the entry threats. We replace the indicator of $Post_{i,t}$ in the baseline regression with a group of cohort-year indicators relative to the event time. We focus on annual instead of quarter event-time intervals because per-quarter launch rate is small and noisy. The

[23] In section 2.2, if the demand intercept a in equation (3) is represented at $\lambda \cdot a$, the parameter λ would capture how differentiated the new product is from the existing product (higher values indicating more novelty or improved features within the same drug category). It is easy to check that lower values of λ reduce the NPV of the new launch.

omitted base period is the year before the Paragraph IV challenge, i.e., [*t-4, t-1*]. As shown in Table 5, the coefficients on the interaction of $Treat_{i,c}$ and the indicator of period [*t-8, t-5*] are insignificant throughout all dependent variables, suggesting that there is no diverging trend between the treated and control firms before the events. Similarly, in Figure 1, 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 1 suggest that new product launches begin to increase within a short window following Paragraph IV events. 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 1 about here.]

5.2 Cannibalization of Sales

We now explore whether and how the pipeline product launches in response to Paragraph IV events influence the sales of challenged products. 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 threatened market segment. 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.[24] We anticipate that sales of challenged drug products will decline following Paragraph IV challenges if pipeline products in the same therapeutic category are launched by the incumbent in response. Conversely, there should be no changes in the sales of challenged products if the Paragraph IV events are not accompanied by the launch of new products.

We test these predictions in similar stacked DID setting, differentiating between events followed by treated firm's pipeline launches and those that are not. The regression specification is outlined as follows.

$$y_{c,i,t} = \alpha_1 \times Treat_{c,i} \times Post_{c,t} \times Abn.D.NewProducts\_ATC4_c + \alpha_2 \times Treat_{c,i} \times Post_{c,t} + X_{c,i,t-1} + \delta_{c,i} + \eta_{c,t} + \varepsilon_{c,i} \dots\dots (5)$$

The dependent variables are the natural logarithm of quarterly sales, the number of units sold in a quarter, and the unit price for each version of a drug. Since IQVIA provides price and quarterly sales data for each drug product (defined as distinct combination of active ingredients, strength, form, and number of

[24] A product "launch," defined here as the first appearance of meaningful sales, stems from a lengthy and costly commercialization process that must start well before a competitor's actual entry (when the latter is deemed highly likely). As argued in Section 2.4, if the incumbent delays until a generic competitor hits the market, it will lose its patient base as pharmacists substitute the generic. To establish the new product as a viable alternative in time, the launch process must begin months or years earlier, triggered by a Paragraph IV challenge that signals the impending end of revenue from the old product. By launching before the actual generic entries, the incumbent can stabilize patients on the new drug, making doctors less likely to switch them back to cheaper generics of the old products.

units per package), we utlize the matched sample at cohort-product-quarter level and include cohort-product fixed effects and cohort-quarter fixed effects.

We introduce the binary variable, $Abn.D.NewProducts\_ATC4_c$, to classify Paragraph IV events into those followed by treated firm's pipeline launches and those that are not. For each event, we calculate the abnormal rate of launching new products in the same therapeutic category. This is defined as the average increase in the treated firm's quarterly launch rate after the Paragraph IV challenge (but before actual entry), minus the average increase in the corresponding rate for the control firms. Using the 75th percentile of this abnormal rate as a threshold, we partition the events into two groups, with the dummy variable of $Abn.D.NewProducts\_ATC4_c$. Similarly, we construct the measure of abnormal rate of launching new products with different active ingredients within the ATC category, denoted as $Abn.D.Diff\ API\_ATC4_c$, and interact it with the treated and post dummies.

We anticipate the coefficient α_1 in Equation (5) to be negative for sales or quantity of the challenged versions, reflecting demand substitution between these products and newly launched 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 before actual entry occurs.

Consistent with these predictions, we find in Columns (1) to (2) of Table 6, Panel A, that the triple difference involving $Abn.D.NewProducts\_ATC4_c$ 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 subsequent new product launches do not directly affect market demand. However, when pipeline products in the same therapeutic category are launched following these events, demand for the challenged drug is cannibalized.

Table 6 also shows that an F-test for the sum of coefficients on $Treat_{c,i} \times Post_{c,t} \times Abn.D.NewProducts\_ATC4_c$ and $Treat \times Post$ yields significant results. The point estimations indicate that dollar sales and unit sales of the challenged drug products decline by 32% and 43%, respectively, following the Paragraph IV events associated with an abnormal rate of launching new products within the therapeutic category by the treated firm.[25] These effects are economically sizable, given that the average quarterly sales of a branded drug are approximately 40 million U.S. dollars when the Paragraph IV challenge is filed.[26]

[25] The sum of two coefficients for *Log(Sales)* and *Log(Quantity)* is -0.385 and -0.570, respectively. We convert these log changes to percentage changes as follows: exp(-0.385) - 1 = -0.32; exp(-0.570) - 1 = -0.434.

[26] 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 Internet Appendix Figure IA2. 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.

In the regression of drug prices reported in Column (3) of Table 6, Panel A, the triple interaction term of $Treat_{c,i} \times Post_{c,t} \times Abn.D.NewProducts\_ATC4_c$ 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 new product launches. 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.

In Panel B of Table 6, we analyze the triple interaction term involving an abnormally high rate of launching products with different active ingredients in the same therapeutic category ($Abn.D.Diff\ API\_ATC4_c$) and find results consistent with those in Panel A. Taken together, new products within the therapeutic category, including those in different product lines, are likely to substite demand from current products, resulting in cannibalization concerns.

[Insert Table 6 about here.]

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 high rate of pipeline 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 IA3 in the Internet Appendix.

Our results in Figure IA3 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 new 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 incremental new product launches, with a brief delay, consistent with the time needed to shift demand from current to new products. In contrast, among the subsample of events without incremental new launches, sales, quantity, and price all remain stable at pre-event levels.

Lastly, we rule out the possibility that the observed cannibalization effect is driven by competing drugs from other branded producers. Internet Appendix Table IA4 reports the triple-difference regression following Equation (5) using the sample that excludes cohorts with competing branded products launched in the same ATC category. The triple interaction terms remain significantly negative for both sales and quantity. This confirms that the cannibalized sales, as indicated in Table 6,

are primarily driven by competition between the challenged drug and the firm's own new products, rather than by external competitors.

5.3 Alternative explanations

In this section, we rule out several alternative interpretations of baseline findings, including omitted variable bias, reverse causality, and entry deterrence.

5.3.1 Unobservable demand shocks

One major concern 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 launch more related products and the generic maker's decision to enter the market. We rule out this alternative explanation through two approaches.

First, 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 fourth-level ATC category. In Figure IA4 in the Internet Appendix, 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, especially around a short window, contradicting the presence of an unobserved positive demand shock coinciding with Paragraph IV.

We also investigate this pattern using panel regressions with all quarterly observations of category-level drug sales, as detailed in Table 7. In Column (1) of Panel A, we find that drug sales exhibit high stickiness, with sales from the previous quarter explaining approximately 90% of the variation in quarterly sales.[27] However, after controlling for the past sales, the indicator of Paragraph IV challenge during the current quarter does not show any significant impact on drug sales. This lack of significance persists after controlling for quarter fixed effects and drug fixed effects, as reported in Column (2). Additionally, the insignificance of the Paragraph IV effect remains over at least the subsequent four quarters, as shown in Columns (3) to (6).[28] These findings suggest that the generic makers' decisions to file Paragraph IVs are unlikely to coincide with unobservable 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 fourth-level ATC category offered by a given

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

[28] The insignificance of Paragraph IV events remains robust to alternative specifications that control for lagged sales of the category but not the fixed effects (untabulated).

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.]

Second, 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 IA5 in the Internet Appendix, 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 8, 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 8 about here.]

5.3.2 Reverse causality

We argue that reverse causality—where generic manufacturers file Paragraph IV challenges precisely when they expect incumbents to launch more new products—is not a plausible explanation. This is because pipeline products reduce the market demand for existing products. Since the market demand for a generic version largely depends on the demand for its corresponding brand-name product, a declining market demand for the brand-name product would likely reduce the profitability of the generic version, thereby discouraging its entry into the market.

If reverse causality were true, we would expect treated firms to be associated with a larger number of ready-to-launch products. However, as discussed in Section 4, the treated and control firms in our matched sample held a similar number of approved but unlaunched pipeline products prior to the patent challenges. This finding contradicts the notion that generic manufacturers specifically target brand-name drugs with imminent pipeline launches.

To further address the reverse causality, we collect data on the outcomes of patent litigation following Paragraph IV events in our sample from *ParagraphFour.com*. In these cases, generic manufacturers—acting as defendants in patent infringement lawsuits—are considered successful when the case is settled, ruled in their favor (defendant found innocent), or dismissed. As shown in Internet Appendix Table IA5, the success rates of generic firms in patent litigation are statistically

indistinguishable between cases involving incumbents with abnormally high pipeline product launches and those without. This finding provides no evidence to support the reverse causality argument.

5.3.3 Entry deterrence

Another alternative explanation is that launching pipeline products following escalated entry threats could discourage the eventual entry of generic entrants. However, as argued in Section 2.3, entry deterrence is unlikely to be the primary motivation for these launches. This is because credible threats of new product launches are 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.

In Internet Appendix Table IA6, we explore whether 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 had an abnormally high likelihood of launching pipeline products following the challenge but before entry. As shown in Panel A, among the challenges followed by abnormal launches, 71.7% of the treated drugs experienced eventual entry within five years, which is 49.5% higher than the likelihood of the matched control drugs. In contrast, among the cohort without abnormal pipeline launches, only 54.3% of the treated drugs faced generic entry within five years, exceeding the control group by 25.3%. These suggest that new launches following Paragraph IVs are NOT associated with a reduced chance of successful entry.

Moreover, Panel B reveals that, among those challenges with eventual entry occurring during our sample period, abnormal pipeline launches following Paragraph IVs 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.

5.3.4 Anticipation of Paragraph IV challenges

Although the Paragraph IV events in our sample are generally unpredictable, we cannot entirely rule out the possibility that some brand-name companies receive private information about impending patent challenges and respond by accelerating their pipeline launches. However, as shown in Table 5 and Figure 1, the incremental pipeline launches predominantly occur shortly after, rather than before, the Paragraph IV challenges. This timing pattern points to two plausible explanations. First, firms may lack the ability to predict the precise timing of upcoming challenges and thus delay new product launches until the uncertainty is resolved by the filing of a Paragraph IV. Second, any private information about entry threats may arrive only shortly before the event, leaving insufficient time to expedite and complete the marketing process for pipeline products. In either case, the primary motivation for these launches

remains the alleviation of cannibalization costs, whether the accelerated launches are driven by firms' private information or triggered directly by the Paragraph IV events.

5.4 Heterogeneity

We conduct several heterogeneity tests for our baseline results. First, we investigate whether firms' responses to Paragraph IV events differ based on the concentration of their product portfolios. To measure this, we calculate the Herfindahl-Hirschman Index (HHI) of firms' sales by category (at the fourth-level ATC) and construct a dummy variable, *D[HHI_ATC4_High]*, which equals one if the HHI exceeds the sample median in the year prior to the Paragraph IV event, and zero otherwise. Columns (1) to (3) of Table 9, Panel A, present the triple-difference regression results using this indicator. Again, we find that the triple interaction term *Treat*Post*D[HHI_ATC4_High]* is positive and significant, while the double interaction term *Treat*Post* is insignificant. This suggests that the treatment effects are driven by firms with concentrated product portfolios, which are more likely to have pipeline products that overlap with their existing offerings.

Second, we examine whether the effect is stronger for patent challenges targeting products that contribute a larger share of the incumbent company's sales. To capture this, we construct a dummy variable, *D[Treated Drug Sales High]*, which equals one if the sales of the challenged, as a percentage of the treated firm's total sales in the year prior to the Paragraph IV event, exceed the 75th percentile of our sample, and zero otherwise. Columns (4) to (6) of Table 9, Panel A, present the triple-difference regression results using this indicator. We find that the triple interaction term *Treat*Post*D[Treated Drug Sales High]* is positive and significant, while the double interaction term *Treat*Post* is insignificant. This indicates that pipeline launches are accelerated only when the challenged products are particularly important to the brand-name company, as these products create significant cannibalization concerns.

Finally, we study the patent protection period for the pipelines launched following Paragraph IV events. Strategic timing the market launches are costly as any postponement after FDA approval burns the market exclusivity. Therefore, we anticipate our baseline results to be weaker for the pipeline products with short remaining patent life span. To test this, we decompose the dependent variable of launch dummies into two: an indicator for launching a new product with patent life above sample mean and that below it. Panel B of Table 9 reports the baseline regressions with two dependent variables. We find that the baseline effect is only positive and significant for the pipeline products with long patent protection, which are associated with a higher flexibility in choosing the market launch time.

[Insert Table 9 about here.]

5.5 Extensions

5.5.1 FDA approval of pipeline products

Next, we examine whether Paragraph IV challenges influence the timing of FDA approval for pipeline products, which marks the completion of drug development and the earliest point at which firms can legally market therapeutic products. The increased incentive to commercialize pipeline products, driven by competitive pressure, may extend to a greater urgency in completing their development. To test this hypothesis, we replace the dependent variable of new product launch dummies with indicators for FDA approvals in Table 10. The specifications follow those in Table 4. However, we find no significant effect on the quarterly approval rate of new products following patent challenges. This suggests that FDA approval timing is largely beyond firms' control.

[Insert Table 10 about here.]

5.5.2 Post-approval delays in new product launch

Combining the baseline results in Table 4 with the findings in Table 10, we infer that, in the absence of competitive threats, there may be a delay between when a product is approved for sale and when it begins generating meaningful sales. To verify this, we analyze post-approval delays until market launch for all brand-name products approved and launched between 2010 and 2019. Panel A of Table 11 reveals that the mean (median) delay is 1.46 (1) years in this sample. In addition, the delay is longer for line extension products, with a mean (median) of 2.1 (2) years, compared to the initial launches of product lines, which have a mean (median) delay of 0.7 (1) year.

Next, we examine whether the post-approval delay is related to cannibalization concerns and entry threats. Using data on product lines approved and launched between 2010 and 2019, we estimate a proportional hazard model with a Weibull distribution as follows.

$$h\left(t\middle|X_{i,t}\right) = p \cdot \lambda^{p} \cdot t^{p-1} \cdot e^{\mathrm{X_{i,t}'}\beta} \ldots (6)$$

Here, t is time elapsed since FDA approval became "at risk" of launch, and the stop time corresponds to the initial launch of products within the line, i. $X_{i,t}$ is a set of time-varying covariates. The shape parameter p determines how the baseline hazard evolves over time, and β captures the percentage change in the conditional launch probability associated with a one-unit change in covariates.

Our key variables of interest are: (1) an indicator for whether the firm's sales in the same therapeutic category during the previous quarter exceeded the sample median, serving as a proxy for high cannibalization concerns; and (2) the presence of Paragraph IV challenges related to these drugs in the current or previous two quarters, which signals generic entry threats. We expect the former to have a negative coefficient, as higher cannibalization risk decreases the likelihood of a product launch. In contrast, the latter should have a positive coefficient, as entry threats reduce expected future sales and, in turn, alleviate cannibalization concerns.

We find consistent results in Panel B of Table 11. High sales from existing products are significantly associated with lower hazard rates and longer post-approval delays for the firm's launches of new product lines in the same therapeutic category. In contrast, the occurrence of Paragraph IV

challenges has the opposite effect. The magnitude of this impact is substantial. For example, as shown in Column (2), Paragraph IV events in the current quarter are associated with an estimated 46.2% reduction in expected launch delays, calculated as $1-\left(\frac{1}{2.981}\right)^{\frac{1}{1.76}}$. This response appears to be immediate, as Column (3) shows no significant effect when the Paragraph IV indicator is replaced with a lagged version that captures events from the prior two quarters. Furthermore, Column (4) confirms the robustness of this result when the binary indicator is replaced by the total sales of drugs challenged during the current quarter.

Additionally, Panel B of Table 11 reveals that post-approval delays are longer in crowded therapeutic areas, as indicated by high sales from existing branded products offered by other companies. However, other control variables, such as firm size, sales growth rate, and an indicator for products identified as urgently needed by the FDA, do not show a significant relationship with the delay of new product line launches.

5.5.3 Actual generic entries following Paragraph IVs

We now examine whether actual generic entry following Paragraph IV filings triggers another wave of pipeline launches. After a Paragraph IV filing, brand-name companies typically sue the generic manufacturer for patent infringement, delaying market entry until the dispute is resolved or a settlement permits entry. Among Paragraph IV filings from 2010 to 2014, 60% lead to generic entry within five years, with entry occurring on average 15 quarters after the filing. (Events from 2015 to 2019 are excluded due to insufficient post-event data.) As shown in Figure IA6, most entries occur between 10 and 24 quarters after the filing.

To study the effects of actual entries, we extend the sample to include two years before the Paragraph IV filing and five years after, focusing on filings from 2010 to 2014. The post-event period is divided into two phases: (1) post-filing but pre-entry, and (2) post-entry (if occurring within five years). In Internet Appendix Table IA7, baseline regressions with interaction terms for both phases are estimated. We find that the effects of Paragraph IV filings remain largely robust after controlling for actual entries. Additionally, actual entries have incremental effects on the launch of new product lines within the therapeutic area. These findings suggest that firms are likely to launch pipeline products when the likelihood of generic entry increases—initially after the filing of Paragraph IVs, and later when entry is confirmed.

6. Conclusion

In this paper, we examine how competition influences firms' decisions to introduce pipeline products. We argue that cannibalization costs represent a significant barrier to pipeline launches, but these costs are mitigated by competitive threats to the firm's existing product domain. Using comprehensive product data from the pharmaceutical industry, we find that entry threats to existing products accelerate

the launch of pipeline products. Furthermore, during the interim period between the escalation of competitive threats and actual market entry, the sales of challenged products are significantly reduced by the launch of pipeline products. Our findings highlight cannibalization as a critical obstacle to creative destruction and demonstrate how competition from imitators helps alleviate this barrier.

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Figure 1. Dynamic Effects of Paragraph IVs on New Product Launches

The figures represent the dynamic effects of new product launches following Paragraph IV challenges. Specifically, we regress the dummy indicator 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 (t in the horizontal axis refers to quarters), with the year before the event excluded as the benchmark period (to keep consistent with Table 5). Each graph shows the coefficients on the interaction terms, including point estimates and 95% confidence intervals. In Graph (1), the dependent variable is a dummy indicator of new therapeutic products launched per firm semi-annual. In Graph (2), the dependent variable is a dummy indicator of new products that are in the same fourth-level ATC category as the challenged/control drug. In the Graph (3), the dependent variable is a dummy indicator of new products featuring different active ingredients from the challenged/control drugs within the same fourth-level ATC.

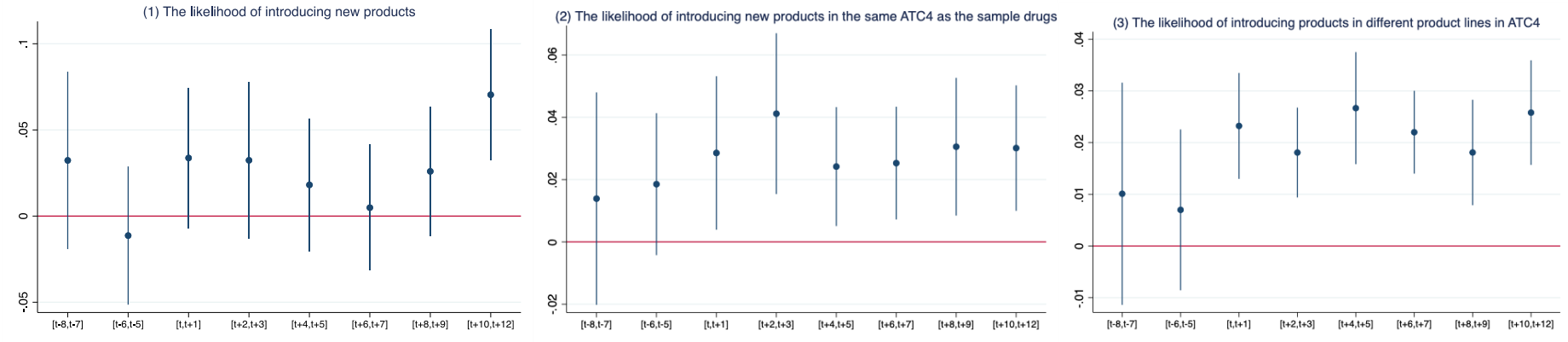


Table 1. Summary Statistics

This table reports the distribution of product lines (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 first-level ATC category. Columns (1) to (3) show the statistics among the overall sample, which includes all products challenged through Paragraph IV from 2010 to 2019 and those that have not been challenged by 2019. Columns (4) to (6) show the statistics among the subset of drug products 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]		
	First-Level ATC Categories	#Lines	#Products	#Firms	# Lines	#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	846	3,792	147	298	1,026	82

Table 2. Occurrence of 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 *t* and the drug's approval date, (2) a dummy indicator of whether the average annual sales in the past three years is above 250 million USD, (3) the number of unexpired patents covering the product line 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 new product lines and line extenstions launched per firm-quarter from *t-7* to *t*. The sample is a panel data organized by product line (defined by distinct active ingredients) and quarter. The dependent variable takes the value of one if a product line experiences its first Paragraph IV challenged in quarter *t+1* and zero otherwise. We include the year dummies and first-level 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)
			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 T-test results on the matched sample (at the "cohort-product line-quarter" level) based on the logit regression in Column (6) of Table 2. Matching details are in Section 4. We calculate the mean values of the propensity score and matching variables for treated drugs and control drugs during the quarter before Paragraph IV events. 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
# Product Lines	129	338		

Panel B. Summary Statistics for the Regression Sample

	Mean	Median	S.D.
1. Dependent variables:			
D[New launches]	0.071	0	0.257
D[New launches within ATC4]	0.022	0	0.147
D[New launches in diff. ATC4]	0.051	0	0.219
D[Diff API within ATC4 (new product line)]	0.007	0	0.082
D[Same API within ATC4 (line extension)]	0.016	0	0.126
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	0.240
R&D	0.024	0.018	0.034
# Firms	Treat = 129	Control = 324	
# Observations	Treat = 2,634	Control = 6,488	

Table 4. Baseline Result: the Likelihood of Launching 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 product lines 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 column (1), dependent variable is the dummy indicator of new therapeutic products launched per firm-quarter. In columns (2) and (3), we distinguish new products which are in the same fourth-level ATC category as the products in the matched sample from other new products in different ATC categories. In columns (4) and (5), we further decompose the new products in the same ATC category into those involving different active ingredients from products in the matched sample (referred to as "new lines"), from new products within the product line, i.e., those sharing the same active ingredients as the challenged (or control) drugs (referred to as "line extension"). We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and research and development (R&D) expenses. 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)
	New launches	*New launches within ATC4*	*New launches in diff. ATC4*	*New launches within ATC4*	
				Diff API (new line)	*Same API (line extension)*
*Treat * Post*	0.029**	0.023**	0.008	0.019***	0.004
	(2.096)	(2.565)	(0.697)	(3.615)	(0.510)
l. Firm Size	0.040***	0.014**	0.027**	0.009**	0.006
	(3.444)	(2.158)	(2.585)	(2.359)	(1.180)
l. M/B	0.004	0.003	0.001	0.003	0.001
	(0.996)	(1.132)	(0.193)	(1.568)	(0.510)
l. ROA	-0.067	-0.028	-0.045	-0.027	-0.007
	(-0.988)	(-0.638)	(-0.823)	(-0.839)	(-0.212)
l. Cash Holding	0.000	0.000	-0.000**	0.000**	-0.000
	(0.359)	(1.576)	(-2.272)	(2.293)	(-0.879)
l. Leverage Ratio	-0.094***	-0.020	-0.081***	-0.016	-0.009
	(-3.911)	(-1.223)	(-4.354)	(-1.493)	(-0.672)
l. R&D	-0.190	-0.248**	-0.019	-0.173**	-0.072
	(-1.219)	(-2.311)	(-0.140)	(-2.012)	(-0.947)
Cohort-Firm FE	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.050	0.050	0.043	0.028	0.062

Table 5. Dynamics of Treatment Effects

This table presents pre-treatment effects and post-treatment effects of Paragraph IV challenges on the launch of new therapeutic products. For each Paragraph IV, the event window spans from eight quarters before to twelve quarters after each event. In column (1), the dependent variable is a dummy indicator of new therapeutic products launched per firm-quarter. In column (2), the dependent variable is a dummy indicator of launching new products that are in the same fourth-level ATC category as the products in the matched sample. In column (3), the dependent variable is a dummy indicator of launching new products with different active ingredients from the products in the matched sample within the same fourth-level ATC category. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and R&D expenses. 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) *New launches*	(2) *New launches within ATC4*	(3) *Diff API within ATC4 (new product line)*
Treat[t-8,t-5]*	0.009	0.016	0.008
	(0.418)	(1.201)	(0.984)
Treat[t,t+4]*	0.025	0.032***	0.021***
	(1.268)	(2.743)	(4.228)
Treat[t+5,t+8]*	0.019	0.027***	0.024***
	(1.009)	(2.624)	(4.631)
Treat[t+9,t+12]*	0.060***	0.031**	0.023***
	(2.909)	(2.583)	(3.786)
l. Firm Size	0.039***	0.014**	0.009**
	(3.410)	(2.158)	(2.361)
l. M/B	0.004	0.003	0.003
	(1.047)	(1.135)	(1.594)
l. ROA	-0.068	-0.027	-0.027
	(-1.016)	(-0.630)	(-0.835)
l. Cash Holding	0.000	0.000	0.000**
	(0.369)	(1.536)	(2.269)
l. Leverage Ratio	-0.095***	-0.021	-0.016
	(-3.943)	(-1.268)	(-1.538)
l. R&D	-0.192	-0.247**	-0.171**
	(-1.239)	(-2.311)	(-1.995)
Cohort-Firm FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	8,290	8,290	8,290
Adjusted R^2	0.051	0.050	0.028

Table 6. Sales Cannibalization of Challenged Drug Products

In this table, we examine whether launching pipeline products is associated with changes in the quarterly sales (*Log(Sales)*), the number of units sold (*Log(Qty.)*), and the unit price (*Log(Price)*) of the challenged product. 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. In Panel A (B), we identify the Paragraph IV event associated with an abnormally high likelihood of launching new products (or product lines) within the same fourth-level ATC category as the challenged drug by the treated firm. Lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and R&D expenses, are controlled for but not reported. 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 the triple interaction and *Treat * Post* sum up to zero. We show the sum of these coefficients, F statistics, and the p-value.

Panel A: New Products within the Same Fourth-level ATC

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.D.NewProducts_ATC4*	-0.512**	-0.611**	0.084***
	(-2.050)	(-2.530)	(2.868)
*Treat * Post*	0.068	0.040	0.007
	(0.449)	(0.277)	(0.376)
Control Variables	YES	YES	YES
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	12,252	12,252	12,252
Adjusted R^2	0.910	0.930	0.999
Sum of first two Coefficients	-0.385**	-0.570***	0.092***
F statistics	4.89	8.67	17.83
P-value	0.027	0.003	0.000

Panel B: New Product Line within the Same Fourth-level ATC

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.D.Diff API_ATC4*	-0.436*	-0.528**	0.074***
	(-1.721)	(-2.178)	(2.610)
*Treat * Post*	0.088	0.067	0.003
	(0.564)	(0.442)	(0.151)
Control Variables	YES	YES	YES
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	12,252	12,252	12,252
Adjusted R^2	0.910	0.930	0.999
Sum of first two Coefficients	-0.349*	-0.461**	0.077***
F statistics	3.02	5.91	16.08
P-value	0.083	0.015	0.000

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 fourth-level ATC category. The 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 fourth-level ATC category. The independent variable is an indicator of whether any of the company's drugs in the category have faced Paragraph IV challenges. Fixed effects are controlled for Columns (2) to (6), as indicated at the bottom of the table. T-statistics are reported in parentheses, with robust standard errors in Column (1) and clustersed standard errors at the year level in Columns (2) to (6). ***, **, and * denote statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Sales at the ATC4-Quarter Level

	(1)	(2)	(3)	(4)	(5)	(6)
		Segment (ATC4) Sales at quarter:				
	[t]	*[t]*	*[t+1]*	*[t+2]*	*[t+3]*	*[t+4]*
PIV [t]	0.002	0.022	0.024	0.019	0.024	0.025
	(0.216)	(1.312)	(1.378)	(1.112)	(1.327)	(1.384)
Segment (ATC4) Sales [t-1]	0.874***					
	(33.240)					
Year FE	NO	YES	YES	YES	YES	YES
ATC4 FE	NO	YES	YES	YES	YES	YES
Observations	7,371	7,604	7,371	7,138	6,903	6,673
Adjusted R^2	0.901	0.574	0.609	0.613	0.619	0.625

Panel B: Sales at Firm-ATC4-Quarter Level

	(1)	(2)	(3)	(4)	(5)	(6)
		Firm-Segment (ATC4) Sales at quarter:				
	[t]	*[t]*	*[t+1]*	*[t+2]*	*[t+3]*	*[t+4]*
PIV [t]	0.002	0.001	0.002	0.001	0.002	-0.000
	(0.627)	(0.086)	(0.335)	(0.101)	(0.359)	(-0.050)
Firm-Segment Sales [t-1]	0.882***					
	(43.651)					
Year FE	NO	YES	YES	YES	YES	YES
Firm FE	NO	YES	YES	YES	YES	YES
ATC4 FE	NO	YES	YES	YES	YES	YES
Observations	20,230	20,969	20,230	19,491	18,755	18,026
Adjusted R^2	0.902	0.242	0.254	0.258	0.262	0.265

Table 8. 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 Columns (1) to (3), and Columns (4) to (6), respectively. In Columns (1) and (4), the dependent variable is a dummy indicator for new therapeutic products launched per firm-quarter. In Columns (2) and (5), the dependent variable is a dummy indicator of launching new products that are in the same fourth-level ATC category as the products in the matched sample. In Columns (3) and (6), the dependent variable is a dummy indicator of launching new products with different active ingredients from the products in the matched sample within the same fourth-level ATC category. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and R&D expenses. The control variables are included but not reported in the following panels. 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) *New launches*	(2) *New launches within ATC4*	(3) *Diff API within ATC4 (new line)*	(4) *New launches*	(5) *New launches within ATC4*	(6) *Diff API within ATC4 (new line)*
Sample:	*PIVs in the 16th quarter since approval*			*PIVs during other times*		
*Treat * Post*	0.080***	0.046***	0.025**	0.008	0.014	0.016***
	(2.945)	(2.944)	(2.530)	(0.504)	(1.369)	(2.711)
l. Firm Size	0.060**	0.012	0.007	0.028**	0.012*	0.008**
	(2.432)	(1.021)	(0.858)	(2.171)	(1.673)	(2.009)
l. M/B	0.011	0.008*	0.008**	0.001	0.001	0.002
	(1.312)	(1.881)	(2.302)	(0.311)	(0.425)	(0.742)
l. ROA	-0.179	-0.035	-0.038	-0.022	-0.019	-0.023
	(-1.131)	(-0.300)	(-0.313)	(-0.291)	(-0.415)	(-0.823)
l. Cash	-0.000	0.000	0.000	0.000	0.000	0.000**
	(-1.339)	(0.112)	(0.026)	(0.581)	(1.570)	(2.359)
l. Leverage	-0.144**	-0.052	-0.061**	-0.076***	-0.012	-0.006
	(-2.530)	(-1.453)	(-2.050)	(-2.926)	(-0.659)	(-0.573)
l. R&D	-0.529	-0.426	-0.472*	-0.093	-0.208*	-0.109
	(-1.577)	(-1.530)	(-1.827)	(-0.536)	(-1.876)	(-1.512)
Cohort-Firm	YES	YES	YES	YES	YES	YES
Cohort-Time	YES	YES	YES	YES	YES	YES
Observations	1,916	1,916	1,916	6,374	6,374	6,374
Adjusted R^2	0.011	0.068	-0.080	0.060	0.044	0.058

Table 9. Heterogeneity

This table presents heterogeneity tests for baseline regressions. In Panel A, *D[HHI_ATC4 High]* is a dummy indicating whether the firm's sales concentration (measured by the HHI across fourth-level ATC fields) in the year prior to Paragraph IV events exceeds the sample median. *D[Treated Drug Sales High]* indicates whether the percentage of the challenged drug's sales in total sales during the year prior to Paragraph IV events exceeds the 75th percentile. Panel B splits the dependent variables from the baseline specification into two categories: the launch of new products with remaining patent protection periods above or below the sample mean. We controlled for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and R&D expenses. All specifications include cohort-firm and cohort-quarter fixed effects, with standard errors clustered at both levels. ***, **, and * denote statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Triple Interactions

	(1) *New launches*	(2) *New launches within ATC4*	(3) *Diff API within ATC4 (new line)*	(4) *New launches*	(5) *New launches within ATC4*	(6) *Diff API within ATC4 (new line)*
*Treat *Post * D[HHI_ATC4 High]*	0.072***	0.033*	0.022**			
	(2.693)	(1.808)	(2.063)			
*Treat * Post * D[Treated Drug Sales High]*				0.030	0.040*	0.023*
				(0.861)	(1.726)	(1.724)
*Treat * Post*	-0.004	0.008	0.006	0.011	-0.006	-0.000
	(-0.233)	(0.720)	(0.920)	(0.333)	(-0.294)	(-0.031)
Control Variables	YES	YES	YES	YES	YES	YES
Cohort-Product FE	YES	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES	YES
Observations	7,198	7,198	7,198	6,842	6,842	6,842
Adjusted R^2	0.041	0.041	-0.010	0.036	0.041	-0.015
Sum of first two Coefficients	0.067***	0.041***	0.028***	0.041***	0.034***	0.023***
F statistics	13.27	7.82	11.46	6.977	10.523	14.045
P-value	0.000	0.005	0.001	0.009	0.001	0.000

Panel B: Dependent Variable Splits

	(1) *New launches*	(2) *New launches within ATC4*	(3) *Diff API within ATC4 (new line)*	(4) *New launches*	(5) *New launches within ATC4*	(6) *Diff API within ATC4 (new line)*
	With Patent Life>Mean			*With Patent Life<=Mean*		
*Treat * Post*	0.036*	0.029**	0.013*	-0.005	-0.005	-0.018**
	(1.823)	(2.170)	(1.808)	(-0.256)	(-0.319)	(-2.011)
l. Firm Size	-0.003	-0.005	0.007	0.070***	0.016	0.022***
	(-0.216)	(-0.558)	(1.184)	(4.210)	(1.159)	(3.894)
l. M/B	-0.000	0.001	0.002	0.000	0.007**	0.002
	(-0.085)	(0.340)	(0.896)	(0.066)	(2.175)	(1.528)
l. ROA	-0.244***	-0.240***	-0.127***	0.037	-0.025	0.028
	(-2.886)	(-3.557)	(-3.323)	(0.476)	(-0.463)	(1.300)
l. Cash Holding	-0.000	0.000	0.000***	-0.000*	-0.000*	-0.000***
	(-0.058)	(1.079)	(3.186)	(-1.762)	(-1.791)	(-2.785)
l. Leverage Ratio	0.003	0.019	0.013	0.082**	0.024	-0.023*
	(0.084)	(0.940)	(1.074)	(2.163)	(1.005)	(-1.828)
l. R&D	-0.347*	-0.473***	-0.237***	0.360*	-0.125	0.117**
	(-1.796)	(-3.460)	(-3.029)	(1.788)	(-1.114)	(2.334)
Cohort-Product 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	0.148	0.030	0.008	0.238	0.122	0.091

Table 10. FDA Approval of New Products

This table reports the OLS regression results using the same matched sample as the baseline. In column (1), dependent variable is the dummy indicator new therapeutic products approved by the FDA per firm quarter. In columns (2) and (3), we distinguish new products which are in the same fourth-level ATC category as the products in the matched sample from other new products in different ATC categories. In columns (4) and (5), we further decompose the new products in the same fourth-level ATC category into two types: those involving different active ingredients from the products in the matched sample, and those within the product line, i.e., sharing the same active ingredients as the challenged (or control) drugs. We control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and research and development (R&D) expenses. 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)
	New approval	*New approval within ATC4*	*New approval in diff. ATC4*	*New approval within ATC4*	
				Diff API (new line)	*Same API (line extension)*
*Treat * Post*	-0.020	0.003	-0.025	0.004	0.000
	(-1.271)	(0.661)	(-1.639)	(1.446)	(0.088)
l. Firm Size	0.031**	0.005	0.025**	0.004**	0.002
	(2.392)	(1.414)	(2.058)	(2.124)	(0.606)
l. M/B	-0.005	0.000	-0.006*	0.001	-0.000
	(-1.457)	(0.119)	(-1.845)	(1.129)	(-0.072)
l. ROA	-0.047	-0.021	-0.025	-0.016	-0.002
	(-0.827)	(-0.799)	(-0.478)	(-0.646)	(-0.201)
l. Cash Holding	-0.000	0.000	-0.000*	0.000	-0.000
	(-1.301)	(1.040)	(-1.663)	(0.571)	(-0.271)
l. Leverage Ratio	-0.078***	-0.003	-0.078***	-0.004	-0.001
	(-2.693)	(-0.430)	(-2.891)	(-0.689)	(-0.138)
l. R&D	-0.036	-0.209**	0.176	-0.182**	-0.060
	(-0.257)	(-2.379)	(1.569)	(-2.281)	(-1.157)
Cohort-Firm FE	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES
Observations	8,290	8,290	8,290	8,290	8,290
Adjusted R^2	0.052	-0.040	0.058	-0.031	-0.036

Table 11. Post-Approval Delay until Market Launch

Panel A summarizes the time gap (in years) between FDA approval and market launch for drug products approved and launched between 2010 and 2019. Panel B explores how this time gap varies with drug and market characteristics, focusing on first launches (excluding line extensions) of new product lines in the same period. The time gap is measured in quarters from FDA approval to the first launch. Key variables include *l.D[HighOwnSales_ATC4]*, a dummy indicating whether the firm's drug sales in the same fourth-level ATC category in the previous quarter exceeded the sample median; *D[PIV]_current*, an indicator for Paragraph IV challenges targeting the firm's drugs in the same fourth-level ATC category during the current quarter; *D[PIV]_half year*, an indicator for challenges in the previous two quarters; *Sales_PIV*, the sales of challenged drug products in the current quarter; *D[Priority Review]*, an indicator for new molecular entities under FDA priority review; *l.Firm Size* and *l.Sales Growth*, the firm's logged total assets and sales growth rate of the previous quarter; and *l.D[HighOtherFirmSales _ATC4]*, a dummy for whether branded drug sales in the same fourth-level ATC category by other firms exceeded the sample median in the previous quarter. All specifications include year dummies and first-level ATC category dummies, with standard errors clustered at the fourth-level ATC category. *lnP* represents the log of the Weibull shape parameter. We report the Z statistics in the brackets. ***, **, and * denote statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Summary Statistics

	N	Mean	SD	Min	P25	Med	P75	Max
All Drug Products	409	1.460	1.498	0	1	1	2	7
First Launches	188	0.702	0.668	0	0	1	1	5
Line Extensions	221	2.104	1.696	0	1	2	3	7

Panel B: Weibull Duration Regression

		(1)	(2)	(3)	(4)
l.D[HighOwnSales_ATC4]	Coefficient	-0.972***	-0.881**	-0.965***	-1.006***
	Z-stat	(-2.706)	(-2.341)	(-2.671)	(-2.709)
	Hazard Rate	0.378	0.415	0.381	0.366
D[PIV]_current	Coefficient		1.092***		
	Z-stat		(3.038)		
	Hazard Rate		2.981		
D[PIV]_half year	Coefficient			-0.430	
	Z-stat			(-0.911)	
	Hazard Rate			0.651	
Sales_PIV	Coefficient				0.066***
	Z-stat				(2.747)
	Hazard Rate				1.068
D[Priority Review]	Coefficient	-0.940	-1.109	-0.909	-1.016
	Z-stat	(-0.374)	(-0.413)	(-0.368)	(-0.369)
	Hazard Rate	0.391	0.330	0.403	0.362
l.Firm Size	Coefficient	0.028	0.016	0.026	0.033
	Z-stat	(0.324)	(0.177)	(0.308)	(0.374)
	Hazard Rate	1.028	1.016	1.026	1.034
l.Sales Growth	Coefficient	0.038	0.042	0.040	0.039
	Z-stat	(0.208)	(0.225)	(0.208)	(0.198)
	Hazard Rate	1.039	1.043	1.041	1.039
l.D[HighOtherFirmSales_ATC4]	Coefficient	-0.659*	-0.612*	-0.651*	-0.564
	Z-stat	(-1.850)	(-1.668)	(-1.822)	(-1.557)
	Hazard Rate	0.517	0.542	0.521	0.569
Ln(p)	Coefficient	0.572***	0.566***	0.573***	0.571***
	Z-stat	(4.955)	(4.979)	(4.939)	(4.919)
Year dummies		YES	YES	YES	YES
ATC1 dummies		YES	YES	YES	YES
Log Likelihood		-373.680	-367.986	-373.230	-370.132
Number of Obs.		994	994	994	994

Appendix A: Variable Definitions

1. Dependent Variables

- ***D[Paragraph IV] (t+1):*** A dummy variable which equals one if there is a Paragraph IV challenge for the brand-name drug *j* in the next quarter *t+1*, and zero otherwise.
- ***New launches****:* A dummy variable that equals one if firm *i* launches new drug products in quarter *t*, and zero otherwise.
- ***New launches within ATC4****:* A dummy variable that equals one if firm *i* launches new drug products within the same fourth-level ATC category as the products in the matched sample in quarter t, and zero otherwise.
- ***New launches in diff. ATC4****:* A dummy variable that takes the value of 1 if firm *i* launches new drug products outside the fourth-level ATC category of the products in the matched sample in quarter *t*, and zero otherwise.
- ***New launches within ATC4_Different API (new line)****:* A dummy variable that equals one if firm *i* launches new product lines in quarter *t*, and zero otherwise. These new product lines are in the same fourth-level ATC category as the products in the matched sample but have different active pharmaceutical ingredients (APIs).
- ***New launches within ATC4_Same API (line extension)****:* A dummy variable that takes the value of 1 if firm *i* launches new drug products within the same product line in quarter *t*, and zero otherwise. These new products are in the same fourth-level ATC category and have the same active ingredients (APIs) as the products in the matched sample.
- ***Log(Sales)****:* Natural logarithm of product *j*'s sales (in USD) for firm *i* in quarter *t*.
- ***Log(Qty)****:* Natural logarithm of the number of units sold for product *j* by firm *i* in quarter *t*.
- ***Log(Price)****:* Natural logarithm of the price of product *j* by firm *i* in quarter *t*.
- ***Segment (ATC4) Sales****:* The sum of sales (in billion USD) for all drug products within each fourth-level ATC therapeutic category in each quarter.
- ***Firm-Segment (ATC4) Sales****:* The sum of sales (in billion USD) for all drug products within each firm and fourth-level ATC therapeutic category in each quarter.
- ***New approval****:* A dummy variable that takes the value of 1 if firm *i* has new drug products being approved by the FDA in quarter *t*, and 0 otherwise.
- ***New approval within ATC4****:* A dummy variable that takes the value of 1 if firm *i* has new drug products within the same fourth-level ATC category as the products in the matched sample being approved by the FDA in quarter *t*, and 0 otherwise.
- ***New approval in diff. ATC4****:* A dummy variable that takes the value of 1 if firm *i* has new drug products outside the fourth-level ATC category of the products in the matche sample being approved by the FDA in quarter *t*, and 0 otherwise.
- ***New approval within ATC4_Different API (new line)****:* A dummy variable that takes the value of 1 if firm *i* has new product lines being approved by the FDA in quarter *t*, and 0 otherwise. These

new product lines are in the same fourth-level ATC category as the products in the matched sample but have different active pharmaceutical ingredients (APIs).

- ***New approval within ATC4_Same API (line extension)****:* A dummy variable that takes the value of 1 if firm *i* has new drug products within product lines being approved by the FDA in quarter *t*, and 0 otherwise. These new products are in the same fourth-level ATC category and have the same active pharmaceutical ingredients as the products in the matched sample.

2. Explanatory Variables

- ***D[4 years after approval]:*** A dummy indicator of a four-year gap between the current quarter *t* and the initial approval date of the products.
- ***D[annual sales > 250m]:*** A dummy indicator of whether the average annual sales of drug *j* in the past three years is above 250 million USD.
- ***#[valid patents]:*** The number of unexpired patents covering drug *j* in quarter *t*.
- ***%[substance patents]:*** The proportion of patents claiming drug *j*'s substance among all the unexpired patents linked to drug *j* in quarter *t*.
- ***Log(Total Assets):*** The natural logarithm of 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.
- ***l.Firm Size***: Natural logarithm of firm *i*'s total assets in the previous quarter *t-1*.
- ***l.M/B*****:** Market value of assets of firm *i* in quarter *t-1*, divided by its book value of assets, i.e., $Market\text{-}to\text{-}Book_{i,t-1} = (csho_{i,t-1} * prcc\_f_{i,t-1} + at_{i,t-1} - ceq_{i,t-1} - txdb_{i,t-1}) / at_{i,t-1}$.
- ***l.ROA*****:** Firm *i*'s operating income before depreciation in quarter *t-1*, divided by its total assets in quarter *t-2*, i.e., $ROA_{i,t-1} = oibdp_{i,t-1} / at_{i,t-2}$.
- ***l.Cash Holding*****:** Firm *i*'s cash and short-term investments in quarter *t-1*, divided by tangible assets in quarter *t-2*, i.e., $Cash\ Holding_{i,t-1} = che_{i,t-1} / ppent_{i,t-2}$.
- ***l.Leverage Ratio*****:** The sum of firm *i*'s total current liabilities and long-term debt, divided by total assets in quarter *t-1*, i.e., $Leverage\ Ratio_{i,t-1} = (dlc_{i,t-1} + dltt_{i,t-1}) / at_{i,t-1}$.
- ***l.R&D*****:** Firm *i*'s research and development expenses, divided by total assets in quarter *t-1*, i.e., $R\&D_{i,t-1} = rd_{i,t-1} / at_{i,t-1}$.
- ***Abn.D.NewProducts_ATC4****:* A dummy indicator of whether the Paragraph IV challenge is associated with an abnormally high likelihood of launching new products in the same fourth-level ATC category as the sample drugs by the treated firm. The abnormal likelihood of new product launches is calculated using a difference-in-difference approach, defined as the change in the average probability of launching new products for treated firms before and after the Paragraph IV event, relative to the corresponding change for control firms. *Abn.D.NewProducts_ATC4* is a dummy indicator of whether the abnormal likelihood for a specific cohort exceeds the 75th percentile of the distribution across all cohorts.
- ***Abn.D.Diff API_ATC4****:* A dummy indicator of whether the Paragraph IV challenge is associated with an abnormally high likelihood of launching new products that have different active

pharmaceutical ingredients compared to the sample drugs and in the same fourth-level ATC category as the sample drugs by the treated firm. This abnormal likelihood of new product launches is calculated using a difference-in-difference approach, defined as the change in the average probability of launching new products for treated firms before and after the Paragraph IV event, relative to the corresponding change for control firms. *Abn.D.Diff API_ATC4* is a dummy indicator of whether the abnormal likelihood for a specific cohort exceeds the 75th percentile of the distribution across all cohorts.

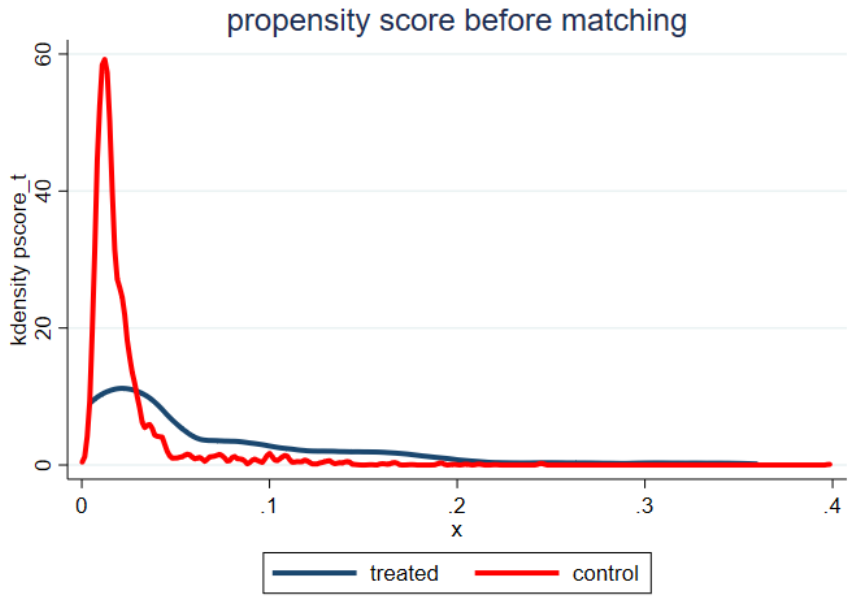
- ***PIV***: A dummy indicator of whether there are Paragraph IV events within a fourth-level ATC therapeutic category (within firm) in quarter *t*.
- ***D[HHI_ATC4 High]:*** A dummy indicator of whether the firm's sales concentration (measured by the HHI across four-digit ATC categories) in the year prior to the Paragraph IV event exceeds the sample median.
- ***D[Treated Drug Sales High]:*** A dummy indicator of whether the percentage of the treated drug's sales in total sales in the year prior to the Paragraph IV event exceeds the 75th percentile.
- ***l.D[HighOwnSales_ATC4]:*** A dummy indicator of whether the firm's drug sales in the same fourth-level ATC category in the previous quarter exceeded the sample median;
- ***D[PIV]_current:*** A dummy indicator for Paragraph IV challenges targeting the firm's drugs in the same fourth-level ATC category during the current quarter *t*.
- ***D[PIV]_half year:*** A dummy indicator for Paragraph IV challenges in previous two quarters.
- ***Sales_PIV:*** The sales of challenged drug products in the current quarter.
- ***D[Priority Review]:*** An indicator for new molecular entities under FDA priority review.
- ***l.Sales Growth:*** The firm's revenue growth rate of the previous quarter.
- ***l.D[HighOtherFirmSales _ATC4]:*** A dummy for whether branded drug sales in the same ATC category by other firms exceeded the sample median in the previous quarter.

Internet Appendix for

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

Internet Appendix A: Supplementary Evidence

Figure IA1. 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.



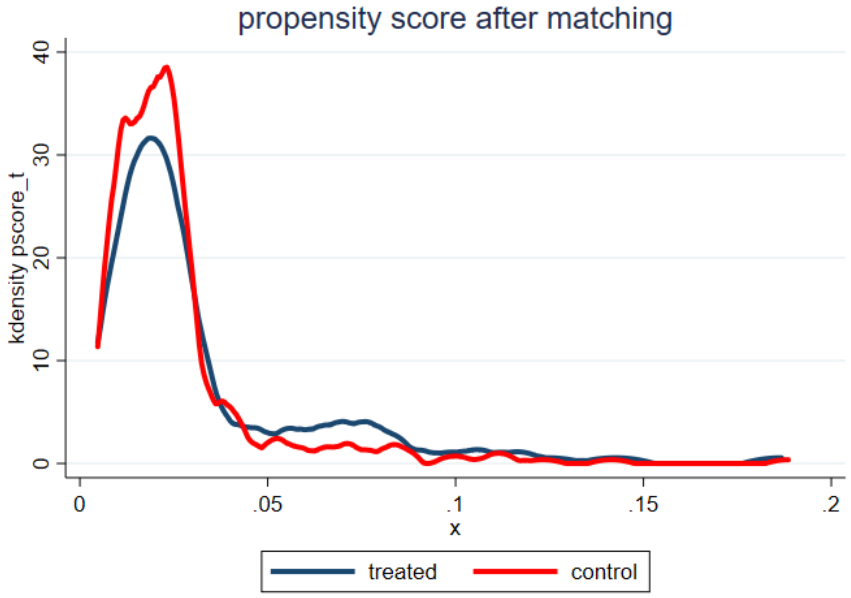
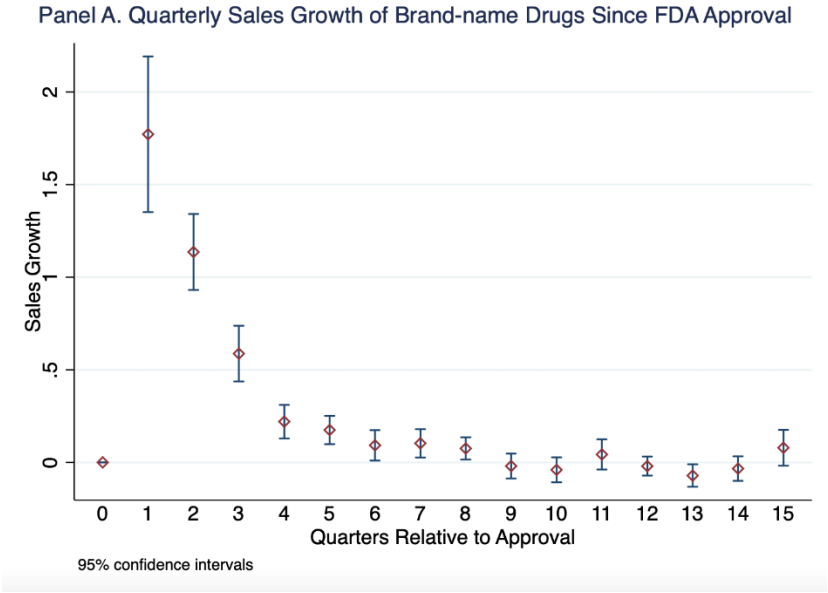


Figure IA2. Life-cycle of Brand-name Drugs for the First Four Years after Approval
For each brand-name drug in our sample, we calculate the total quarterly sales of all versions within the drug line, grouped by active ingredients. Panel A (B) plots the growth rate of drug sales (dollar sales) per quarter 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.



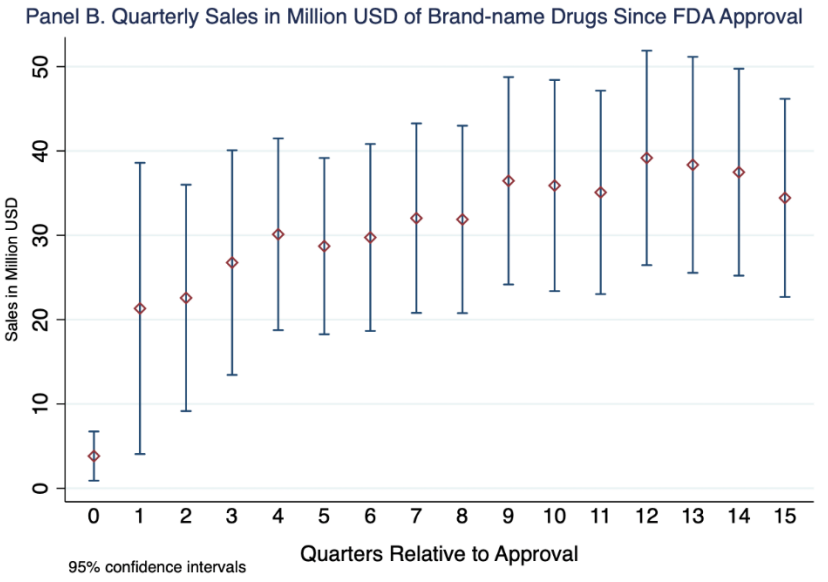
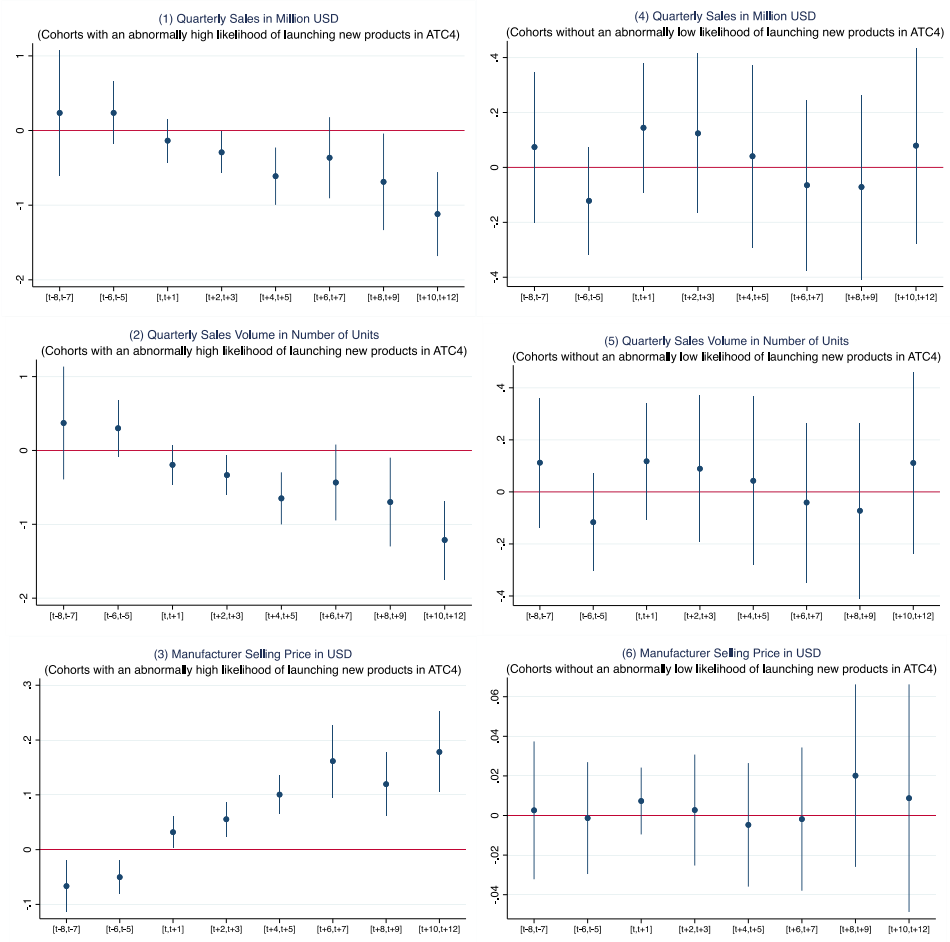


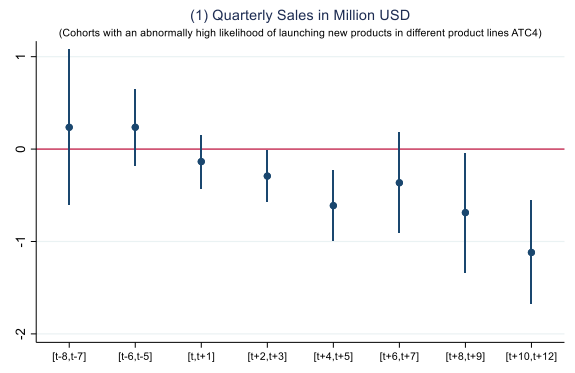
Figure IA3. Dynamics of the Cannibalization Effects

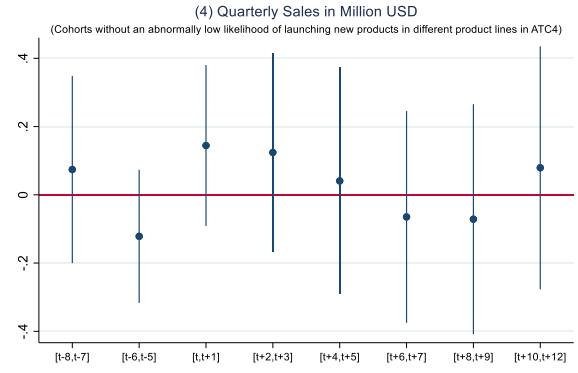
The figures illustrate the dynamics of the cannibalization effects resulting from the launches of pipeline products by the challenged firms. In Panel A, we divide the sample into two subsamples: one where the challenged firm has an abnormally high likelihood of launching new products within the same therapeutic category 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 Panel B, we divide the sample according to whether the challenged firm has an abnormally high likelihood of launching new product lines (with different API) within the same therapeutic category from the products in the matched sample. 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 (to keep consistent with Table 7). 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 had an abnormally high likelihood of launching new products, while the right column, i.e., graphs (4), (5), and (6), shows results for the subsample without such launches.

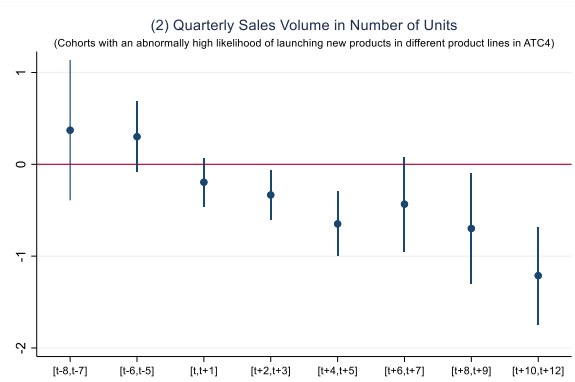
Panel A: Subsample: High vs. Low Launches of New Products in ATC4

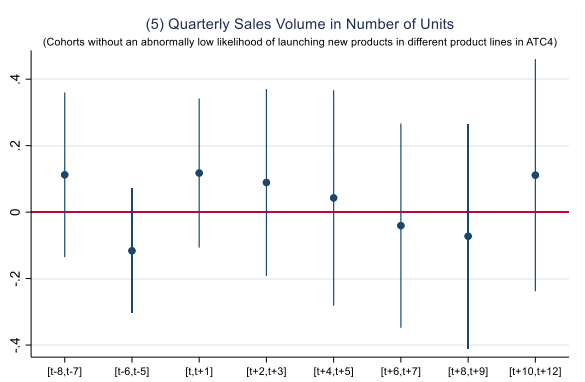


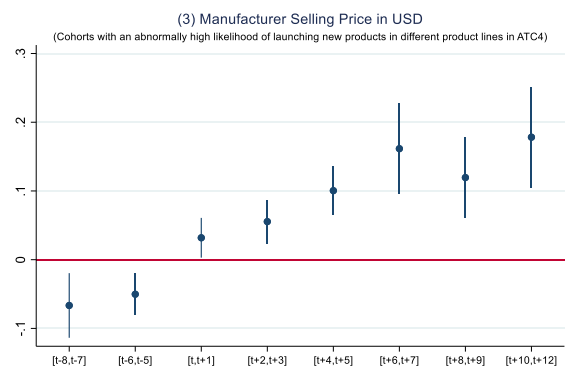
Panel B: Subsample: High vs. Low Launches of New Product Lines in ATC4











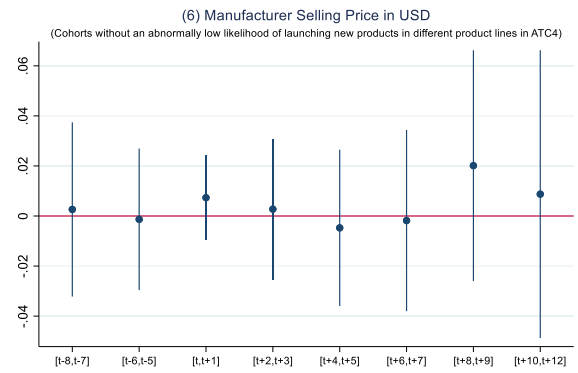
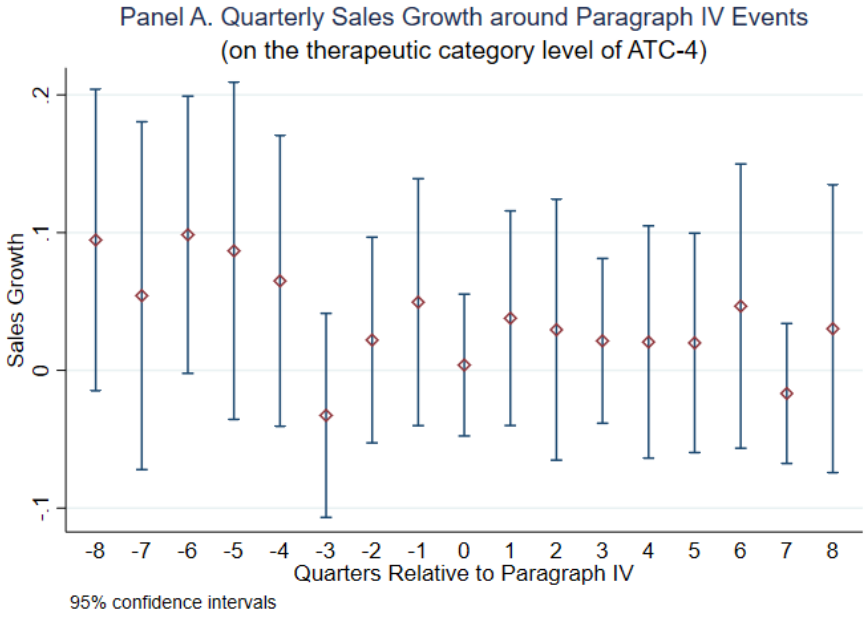


Figure IA4. Drug Sales Surrounding Paragraph IV Events
This figure presents the quarterly sales growth (Panel A) and the dollar amount of sales (Panel B) for each fourth-level ATC category over a four-year window surrounding the occurrence of Paragraph IV events within the category. The dots represent the sample mean values, while the bars indicate the 95 percent confidence intervals.



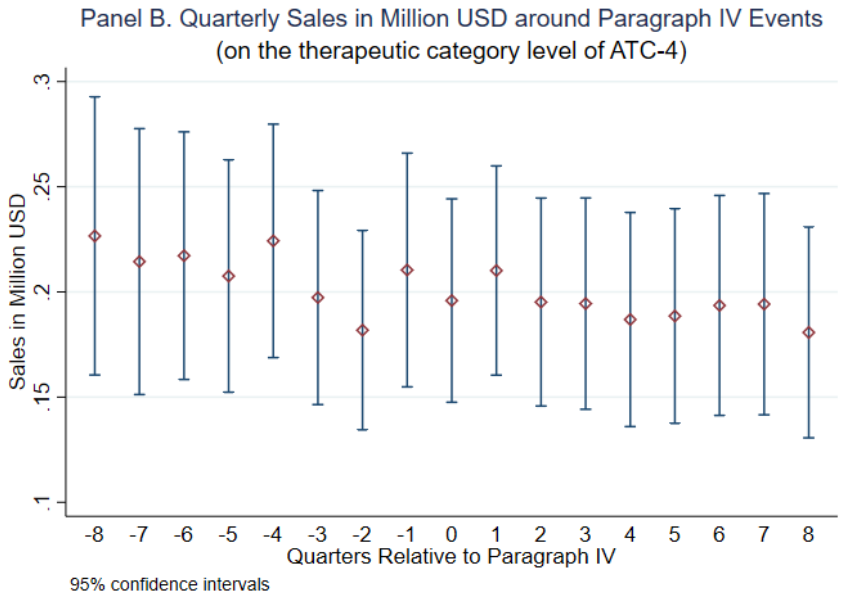


Figure IA5. Timing of Paragraph IV Challenge Relative to the FDA Approval Dates
In this figure, we show the distribution of the time gap, measured in quarters, between the FDA approval date of a challenged drug (at product line level) and the date when the Paragraph IV challenge occurs. The quarter of approval is referred to as the 0^{th} quarter in the horizontal axis.

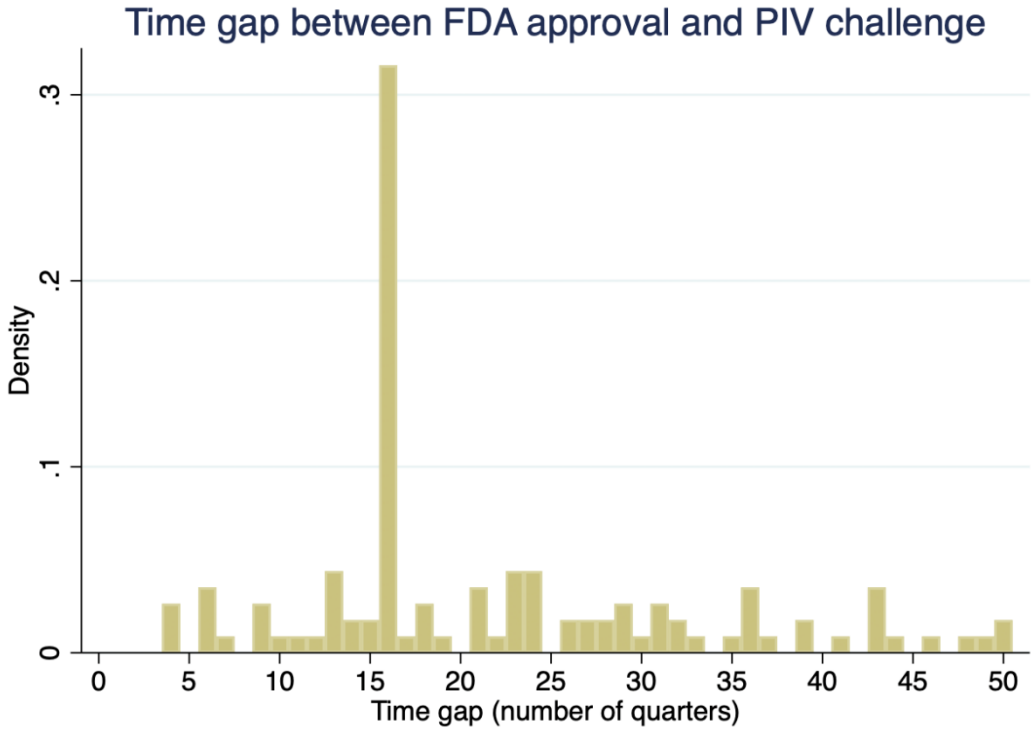


Figure IA6. Timing of Actual Entry Relative to Paragraph IV filings
In this figure, we show the distribution of the time gap, measured in quarters, between the Paragraph IV filing date of a challenged drug and the date when the generic maker eventually enters the market. The quarter of Paragraph IV filing 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.

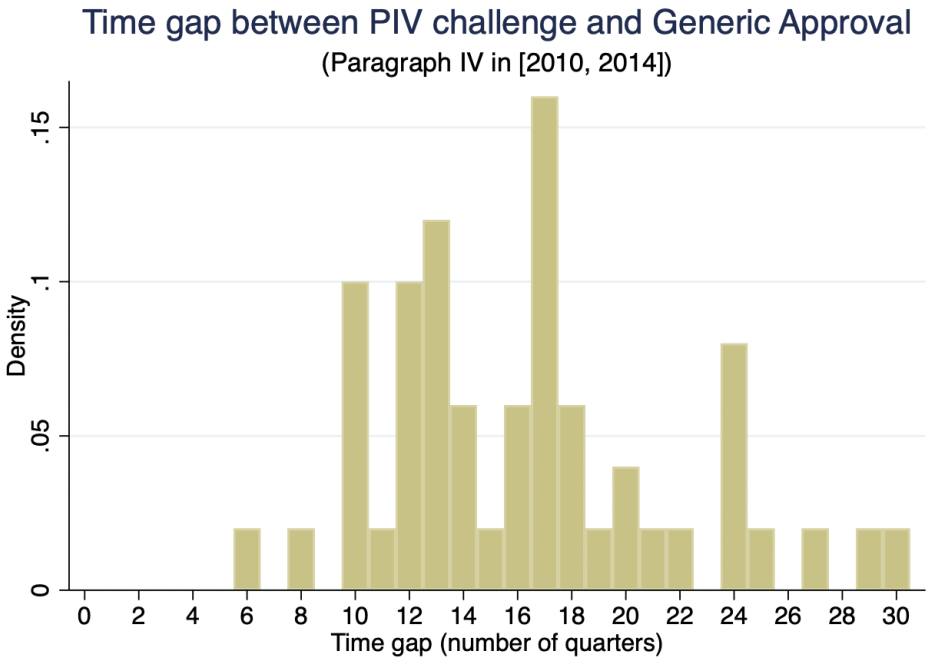


Table IA1. Balance Test for the Regression Sample

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 3. The construction details are described in Section 5. 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 IA2: Robustness: Alternative Definition of New Product Lines

This table presents a robustness test for the Column (4) of Table 4. Specifically, the dependent variable in Column (1) is the dummy variable of new products in the same level-four 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 (2) is the dummy variable of new products with different active pharmaceutical ingredients (API) in the same *level-three* ATC category as the sample drugs. The regression sample and specification follow the same approach as in Table 4.

	(1) *New Products within ATC4 with different API, routes of administration, or dosage form from current ones*	(3) *Different API within ATC3*
*Treat * Post*	0.020***	0.017***
	(3.306)	(2.803)
l. Firm Size	0.009*	0.010***
	(1.872)	(2.668)
l. M/B	0.004*	0.003*
	(1.859)	(1.711)
l. ROA	-0.019	-0.022
	(-0.559)	(-0.653)
l. Cash Holding	0.000**	0.000**
	(2.213)	(2.221)
l. Leverage Ratio	-0.017	-0.017
	(-1.241)	(-1.549)
l. R&D	-0.148	-0.184**
	(-1.643)	(-2.099)
Cohort-Firm FE	YES	YES
Cohort-Time FE	YES	YES
Observations	8,290	8,290
Adjusted R^2	0.018	0.038

Table IA3: 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 4. 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)
	New launches	*New launches within ATC4*	*New launches in diff. ATC4*	*New launches within ATC4*	
				Diff API (new line)	*Same API (line extension)*
*Treat * Post*	0.027**	0.024***	0.011	0.019***	0.002
	(1.967)	(2.641)	(0.950)	(3.605)	(0.287)
l. Firm Size	0.037***	0.014**	0.026**	0.009**	0.006
	(3.185)	(2.205)	(2.387)	(2.391)	(1.154)
l. M/B	0.003	0.003	-0.000	0.003	0.001
	(0.780)	(1.095)	(-0.007)	(1.560)	(0.456)
l. ROA	-0.074	-0.024	-0.045	-0.026	-0.008
	(-1.092)	(-0.543)	(-0.820)	(-0.811)	(-0.253)
l. Cash Holding	0.000	0.000	-0.000**	0.000**	-0.000
	(0.289)	(1.597)	(-2.182)	(2.286)	(-0.950)
l. Leverage Ratio	-0.093***	-0.021	-0.080***	-0.016	-0.009
	(-3.831)	(-1.243)	(-4.242)	(-1.508)	(-0.653)
l. R&D	-0.193	-0.235**	0.005	-0.172**	-0.077
	(-1.225)	(-2.161)	(0.037)	(-2.002)	(-1.026)
Cohort-Firm FE	YES	YES	YES	YES	YES
Cohort-Time FE	YES	YES	YES	YES	YES
Observations	8,577	8,577	8,577	8,577	8,577
Adjusted R^2	0.080	0.107	0.081	0.087	0.052

Table IA4. Robustness for Demand Cannibalization Test

This table shows the robustness test for the demand cannibalization effect documented in Table 6. Specifically, we exclude the cohorts where new branded products in the same fourth-level ATC category are launched by other brand-name companies during the post-event period. The specifications follow from Table 6. Control variables are included and not reported.

Panel A. New Products in the Same ATC4 as the Sample Drugs

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.D.NewProducts_ATC4*	-0.509*	-0.598**	0.107***
	(-1.750)	(-2.163)	(3.107)
*Treat * Post*	0.022	-0.013	-0.017
	(0.105)	(-0.065)	(-0.706)
Control Variables	YES	YES	YES
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	8,655	8,655	8,655
Adjusted R^2	0.900	0.920	0.999
Sum of first two Coefficients	-0.487**	-0.611***	0.089***
F statistics	5.70	9.76	15.83
P-value	0.017	0.002	0.000

Panel B. New Products in the Same ATC4 with Different Active Ingredients

	(1)	(2)	(3)
	Log(Sales)	*Log(Qty.)*	*Log(Price)*
*Treat * Post * Abn.D.Diff API_ATC4*	-0.492	-0.597**	0.115***
	(-1.603)	(-2.066)	(3.387)
*Treat * Post*	0.066	0.047	-0.032
	(0.303)	(0.230)	(-1.225)
Cohort-Product FE	YES	YES	YES
Cohort-Product FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	8,655	8,655	8,655
Adjusted R^2	0.900	0.920	0.999
Sum of first two Coefficients	-0.594*	-0.549***	0.083***
F statistics	3.85	7.31	15.92
P-value	0.051	0.007	0.000

Table IA5. Generic Success Rates in Patent Lawsuits following Paragraph IV

In this table, we examine whether the success rate of generic firms in patent litigation is statistically indistinguishable between cases involving incumbents that launched new products and those that did not. To calculate the success rate, we obtain the outcome of patent litigation following Paragraph IV events from our sample at pargraphfour.com and classify the events into five categories: (1) Brand-name firm wins, (2) Generic firm wins, (3) Settle, (4) Dismiss, (5) Other cases. First, the success rate is defined as the fraction of categories (2) and (3), as settlements may indicate a favorable outcome for the generic firm. Second, we further incorporate category (4), as case dismissal can signal an advantageous outcome for the generic firm, particularly when it occurs without prejudice or as part of a voluntary agreement. In Panel A, we partition the sample based on the *Abn.D.NewProduct_ATC4*, a dummy indicator for Paragraph IV challenges associated with an abnormally high likelihood of launching new products in the same fourth-level ATC category by the treated drug. In Panel B, we partition the sample based on the *Abn.D.Diff API_ATC4*, a dummy indicator for Paragraph IV challenges associated with an abnormally high likelihood of treated firms launching new products that have different active pharmaceutical ingredients but in the same fourth-level ATC category as the sample drugs. ***, **, and * indicate significance at the 1%, 5%, and 10% levels, respectively.

Panel A. Abnormal product launches in the same ATC4 category by the treated firm

	(1)	(2)	(3)	(4)
	Abn.D.NewProducts_ATC4		Diff.	T-stat
Case Outcomes:	= 0	= 1		
Generic wins + Settle	0.531	0.636	-0.105	-1.045
Generic wins + Settle + Dismiss	0.729	0.758	-0.028	-0.317

Panel B. Abnormal product-line launches in the same ATC4 category by the treated firm

	(1)	(2)	(3)	(4)
	Abn.D.Diff API_ATC4		Diff.	T-stat
Case Outcomes:	= 0	= 1		
Generic wins + Settle	0.563	0.545	0.017	0.169
Generic wins + Settle + Dismiss	0.740	0.727	0.012	0.137

Table IA6. 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 high likelihood of launching new product (or product lines) within the same therapeutic category 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. 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.D.NewProducts_ATC4 = 1	0.717	0.222	0.495***	7.642
Abn.D.NewProducts_ATC4 = 0	0.543	0.290	0.253***	5.257

	(1) Treated	(2) Control	(3) Difference-in-Likelihood	(4) T statistic
Abn.D.Diff API_ATC4 = 1	0.625	0.185	0.440***	6.156
Abn.D.Diff API_ATC4 = 0	0.594	0.294	0.300***	6.511

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.D.NewProducts_ATC4 = 1	3.818	5.082	-1.264***	-4.125
Abn.D.NewProducts_ATC4 = 0	3.880	4.231	-0.351	-1.111

	(1) Treated	(2) Control	(3) Difference-in-Time Span	(4) T statistic
Abn.D.Diff API_ATC4 = 1	3.774	5.490	-1.716***	-3.893
Abn.D.Diff API_ATC4 = 0	3.886	4.185	-0.298	-1.082

Table IA7. New Product Launches 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 of new therapeutic products launched per firm-quarter, (2) a dummy indicator of new therapeutic products that are in the same fourth-level ATC category as the products in the matched sample, and (3) a dummy indicator of new products with different active ingredients from the products in the matched sample within the same fourth-level ATC category. In each column, we control for lagged firm characteristics, including firm size, market-to-book ratio (M/B), ROA, cash holdings, leverage ratio, and R&D expenses. 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) *New launches*	(2) *New launches within ATC4*	(3) *Diff API within ATC4*
*Treat * PostPIV*	0.014	0.024**	0.021***
	(0.755)	(1.998)	(3.924)
*Treat * PostEntry*	0.026	0.020	0.026***
	(0.936)	(1.425)	(3.282)
l. Firm Size	0.005	0.005	-0.001
	(0.527)	(0.975)	(-0.617)
l. M/B	-0.001	-0.002	-0.002
	(-0.290)	(-0.730)	(-0.914)
l. ROA	-0.023	-0.024	-0.049*
	(-0.229)	(-0.500)	(-1.679)
l. Cash Holding	-0.000	-0.000	0.000
	(-0.536)	(-0.401)	(0.527)
l. Leverage Ratio	-0.084***	-0.023	-0.005
	(-3.797)	(-1.581)	(-0.707)
l. R&D	-0.181	-0.154	0.065
	(-0.625)	(-1.015)	(0.832)
Cohort-Firm FE	YES	YES	YES
Cohort-Time FE	YES	YES	YES
Observations	6,662	6,662	6,662
Adjusted R^2	0.063	0.077	0.071

Internet Appendix B: Examples of new therapeutic products

Example 1: New Product Lines within Therapeutic Category.

Victoza and Ozempic are both medications manufactured by Novo Nordisk, but they come from different product lines and differ significantly in their active pharmaceutical ingredients, pharmacokinetics, and clinical applications. Both drugs fall under the same fourth-level ATC category A10BJ which includes GLP-1 receptor agonists used in diabetes treatment, resulting in overlapping customer demands. However, their chemical structures and pharmacological distinctions lead to notable differences in their efficacy, dosing regimens, and therapeutic profiles.

Victoza, approved by the FDA in 2010, is primarily indicated for the management of type 2 diabetes and weight loss. Liraglutide, the active pharmaceutical ingredient in Victoza, is a synthetic GLP-1 analog that works by stimulating insulin secretion in response to meals, inhibiting glucagon release, slowing gastric emptying, and promoting satiety. These actions help improve blood glucose control and promote weight loss in obese patients. Victoza is typically administered once daily through a subcutaneous injection.

Ozempic, approved by the FDA in 2017, represents a significant improvement over Victoza due to its modified molecular structure and enhanced clinical profile. The active pharmaceutical ingredient, Semaglutide, enhances GLP-1 receptor affinity, resulting in greater efficacy in lowering HbA1c and promoting weight loss. Additionally, it demonstrates notable cardiovascular benefits, with the SUSTAIN-6 trial showing a 26% reduction in major adverse cardiovascular events (MACE) in high-risk patients with type 2 diabetes. The drug's extended half-life of approximately one week facilitates once-weekly dosing, offering a significant advantage in terms of patient adherence when compared to daily injections. Further broadening treatment options, semaglutide is also available in an oral formulation, making it the first oral GLP-1 agonist. Additionally, its higher-dose version (2.4 mg) has been FDA-approved for chronic weight management, surpassing liraglutide's obesity treatment in clinical trials. These innovations establish Ozempic as a more potent, versatile, and patient-friendly treatment compared to Victoza.

Example 2: Line Extensions

Zyprexa Zydis (ORAL SLD ODT) 15 mg and Zyprexa Relprevv (Dry RT Vial) 300 mg are two products under the same product line Zyprexa, manufactured by Eli Lilly. They have the same active ingredient, olanzapine, and belong to the same level-four ATC category N05AH (Antipsychotics). Both products are used to manage symptoms of schizophrenia and bipolar disorder. However, they are different in formulation and administration routes. Zyprexa Zydis, launched in 2001, is an orally disintegrating tablet (ODT), while Zyprexa Relprevv 300 mg, introduced in 2015, is a long-acting injectable formulation, offering rapid relief during acute episodes through extended-release dosing. These two products are potential substitutes, as they 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. However, the degree of advancement and overall welfare improvement for patients is likely lower for Zyprexa Relprevv than the products with new active ingredients shown in Example 1.

In our baseline analysis, which defines product lines based on active ingredients, Zyprexa Relprevv is considered as within the same product line or line extensions. In Internet Appendix Table IA2, we use a granular definition of product lines and consider the products with new forms or routes of administration (such as Zyprexa Relprevv) as representing new product lines.