ESSAYS ON HEALTH ECONOMICS AND INNOVATION

BY

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ABSTRACT

This dissertation consists of three chapters. In chapter 1, we studied the impact of competition on incremental innovation in the pharmaceutical context. Research and development is not a linear process that ends when a patent is granted. Instead, pioneer innovators continue innovating after their product has been patented. We study how competition affects post-patent innovation incentives for pharmaceutical firms that introduce first-in-class drugs. We find that "me-too" competition reduces R&D directed towards finding alternative uses for a safe drug. Our estimates suggest that the entry of a me-too drug reduces the number of post-approval clinical trials by 8.9 percent. In chapter 2, we ask that Does the market punish physicians' misconducts? We answer this question in the context of California physicians. We assemble a novel dataset that includes a history of disciplinary actions, detailing payments, Medicare information, and physicians' referral network. About 4.3 percent of physicians in California have at least one prior disciplinary action (DA). For those physicians who remain active after receiving a DA, we show that prior DAs have a negative impact on detailing payments. Physicians with prior DAs receive a less severe punishment from firms that have invested more in them. In chapter 3, we study innovation incentives in the presence of "product hopping," whereby the incumbent patents a minor modification of a drug (e.g., a new delivery method) and invests in marketing to switch demand towards the minor modification. In our setting, firms compete

sequentially to discover two innovative drugs. The winner of the first R&D race (the incumbent) can alter the market structure that follows the second R&D race through product hopping. This can increase investments during the second R&D race when product hopping softens competition or when the incumbent benefits from becoming a multi-product monopolist. The change in expected continuation values can increase or decrease investments during the first R&D race. Thus, the welfare effect of product hopping is ambiguous. We discuss our results in the context of the current policy debate on product hopping, welfare, and antitrust.

To my parents, Dudu Gök and Mustafa Özkul

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TABLE OF CONTENTS

CHAPTER 1

INCREMENTAL INNOVATION AND ME-TOO DRUGS

Innovation in the pharmaceutical industry is characterized by ex-ante uncertainty and significant development costs so firms rely heavily on patents to recoup (ex-post) their investments. Patented pharmaceutical products, however, do not guarantee profits. The rents that patent owners capture from exercising their exclusion right depend critically on their ability to commercialize the underlying invention. To sell a drug in a market, firms must provide evidence to the Food and Drug Administration (FDA) showing that the drug is safe and effective. If the FDA reviews and approves the drug based on this evidence for commercialization, the firm can start selling it.[1]

When studying innovation incentives, the literature has mostly focused on patents as the outcome of interest. Less research has been devoted to understanding how research that may expand the market for a patented product unfolds, despite the fact that pharmaceutical firms allocate a substantial amount of resources to this endeavor (incremental innovation).[2] In this paper, we empirically study the impact of market competition on post-approval innovation.

Our analysis focuses on new molecular entities ("NMEs") which are products containing parts that have not been previously approved by FDA. To use NMEs in

[1]Approval by the FDA does not hinge on whether the drug is protected by a patent.

[2]DiMasi, Hansen and Grabowski (2003) predict that post-approval R&D is about 25% of total out-pocket R&D cost. Frank (2003) estimates that around 30% of the R&D spending of the industry is dedicated to new or modified uses of existing drugs.

humans, FDA must approve evidence submitted by the firm showing the safety and effectiveness of the NME for a particular population (e.g., males 40 and older) and medical condition (the original or primary indication). After the FDA approves specific uses for a NME, the pharmaceutical firm will typically continue investigating the potential uses of the NME in other populations or diseases. If the evidence supports alternative uses of a NME, the FDA may grant the firm additional indications for the product. This is beneficial for the firm because it expands the drug market and increases the firm's profits. Post-approval innovations include improved formulations, combination therapies, new delivery methods, and reduced adverse effects. Products that result from these research efforts are called *incremental innovations*, and they are classified as non-NME by the FDA.

The scope of a patent (what is protected by it) is generally ambiguous. However, it is better defined for chemical molecules than for other inventions: a patent protects a specific molecule and slight variations fall outside its scope.[3] For this reason, pharmaceutical firms can use their patents to exclude firms producing an identical product (generic drug manufacturers). However, they cannot use patents to exclude competitors selling differentiated products ("me-too" competition).

For a given therapeutic class, we identify the pioneer innovator as the firm that brings to the market the first-in-class drug. For example, Novartis created "Gleevec," a drug used to treat chronic myelogenous leukemia (a rare type of blood cancer). This drug, which is considered a game-changer in the battle against cancer, was patented in 1993 and approved by the FDA in 2001. Post-patent research has lead to Gleevec also approved several types of gastrointestinal tumors. During the period

[3]Active-ingredient patents cover the formula of the drug and apply to any form (e.g., pill, capsule, or gel). This type of patent is strong and effective at preventing generic entry. Formulation or method-of-use patents protect the reformulation of a chemical molecule or combination of ingredients. Their validity is debatable, and they are considered weaker than active-ingredient patents.

of patent protection for these pioneer inventions, there was an entry by firms that have developed other NME, called addition-to-class drugs that are also approved by the FDA, which do not infringe the incumbent's existing patents ("me-too" drugs). For example, in 2006, the FDA approved "Sprycel" sold by Bristol-Myers Squibb, which belongs to the same therapeutic class as Gleevec.

This means that for any therapeutic class, it is possible that many NME coexists at any given point in time. Even if these NME are chemically different, i.e., they do not infringe on each other's technology, their effects (or biological pathways) may be similar, so physicians consider them substitutes. The change in market structure whenever there is an entry of me-too drugs impacts the post-approval incentive to innovate by pioneering firms.

Multiple NME in any given therapeutic class has ambiguous welfare effects. On the one hand, more variety has a positive impact on consumers because it increases the overall quality of drugs in a given class, and the competitive pressure between the firms can reduce prices. On the other hand, firms might spend more in detailing activities (marketing) to steer demand towards them. Ex-post competition can also reduce ex-ante innovation incentives. In this paper, we identify a novel welfare-reducing impact of more NME: a reduction in post-innovation efforts by pioneering firms. In other words, competition from me-too NME could reduce pioneer firms' effort to find new uses of an already safe and effective molecule.

We analyze the effect of product competition by me-too drugs on research activities of first-in-class drugs. In particular, how does a second entrant in a given class impact the pioneer innovator's research? Does the second entrant make the incumbent focus on "radical" or "incremental" innovation? How are public and industry R&D on first-in-class drugs affected by entry to an established class?

We exploit the pharmacological classifications of NMEs for each drug approved

between 1997-2018. This classification is crucial and novel since these drugs' chemical composition and physiological effects are similar, but they are different at the molecular level (i.e., non-infringing technologies). Within the same pharmacological class, the drugs are close substitutes from the perspective of prescribers and patients, yet they are different enough, so their marketing requires FDA approval. We create a rich panel data set that includes, for each NME, their pharmacological class, approval dates, generic-entry dates, exclusivity dates, patent information, and the history of clinical trials conducted by the inventor for each drug.

We use a difference-in-differences research design to evaluate the effect of second entry on incremental R&D investments by the incumbent. Under the assumption that FDA approval process is uncertain for product launches in a pharmacological class, we show that drugs that experienced second entry in their pharmacological class have the same pre-entry trend in clinical trials than drugs without entry.[4] Additionally, we use two econometric methodologies to check the robustness of our result: generalized synthetic control and matrix completion. We show that the increased competition within class caused by the entry of a me-too drug reduces the number of clinical trials initiated by the pioneer inventor by 8.9 percent. In a heterogeneous analysis, we classify the type of entrant into two categories: (1) "addition" drugs (minor therapeutic benefit over existing drug) and (2) "advance" drugs (superior products compared to existing drugs). Our results indicate that when the competition comes from "addition" drugs, the incumbent decreases its incremental innovation by 15 percent.

Me-too drugs are controversial. Some experts claim that they do not significantly

[4]To get approval for a new drug application (NDA), pharmaceuticals need to show that a drug successfully completed clinical trials phases I, II, and III. Mullard (2016), using the same data that we use, finds that the probability of NDA approval from Phase III is 49%, and the overall success rate (from Phase I to approval) is 9.6% between 2005 and 2016.

benefit consumers and they reduce the market reward of pioneering drugs, which decreases the *ex-ante* incentive to innovate. Me-too drugs also compete against generic drugs and increase market prices because, even when their benefit is small relative to a generic, firms spend resources in marketing to switch the demand towards me-too drugs (e.g., pharmaceutical detailing). Lichtenberg and Philipson (2002) report that the reduction of the innovator's return in the between-patent competition is as large as competition within-patent competition, where between-patent competition refers to competition from other drugs enters to the class and within-patent competition refers to the entry of generics. Lu and Comanor (1998) show that me-too drugs are typically introduced at the same price as the incumbent. DiMasi and Paquette (2004) suggests that me-too drugs can increase welfare by lowering side effects, alternative delivery systems, and increasing the market size. Hollis (2005) argues that the introduction of me-too drugs is a misallocation of the R&D resources and reduces the incentives for innovation in pioneering drugs without adding therapeutic value. Angell (2000) argue that me-too drugs need to show efficacy level not only against placebo but also against the incumbent's drug. Arcidiacono et al. (2013) studies anti-ulcer drugs and shows that me-too drugs increase pharmaceutical spending. Gilchrist (2016) shows that entrants to the pharmacological classes with fewer benefits are mainly driven by imitative incentives.

Thus, me-too drugs: (1) decrease the incumbent's market share, which decreases ex-ante innovation incentives without reducing prices; (2) result in R&D misallocation due to doubling the effects for approval (an entrant needs to complete all the phases as the incumbent for approval); (3) increase the detailing efforts rather than R&D efforts. Given that two close substitute drugs compete for the market share, it is expected to compete in terms of R&D. Different from the literature, we analyze the effect of me-too drugs on the incumbent's *ex-post* innovation activities by using

post-approval clinical trials as a proxy for ex-post R&D. We show that second entry to pharmacologic class decreases ex-post incremental innovation incentives for the incumbent. This effect is larger when the me-too drug has no additional therapeutic advantage over the existing drug. This decreases the incumbent's incentive to improve its existing drug. As a result, "me-too" drugs decrease not only ex-ante innovation incentives proposed by the literature but also ex-post. We also measure the impact of me-too drugs on science, which arguably should not be affected by profits motives, by measuring the number of academic publications that mention the pioneer drug.

The idea of competition and innovation activities is not new. There exist some studies that support the relationship between competition and R&D investments of pharmaceuticals. Branstetter, Chatterjee and Higgins (2014) studies the effect of generic entry on R&D investments and shows that generic entry decreases and changes the direction of the early stage of R&D investments. Rao (2020) shows that pharmaceuticals decrease the early-stage investments when competitors within a market receive FDA approval. To our best knowledge, no existing research has analyzed the effect of me-too drugs on incremental innovation for the existing drug.

1.1 Industry and Data

Following Lanthier, Kerr and Miller (2019), we classify all NMEs approved by FDA in the U.S. between 1987 and 2018 with their pharmacological information. This list provides information about drugs, pharmacological classes, and entry orders for each class based on NME drugs. Using this list, we use several databases. We obtain "application numbers" defined by FDA and "Biomed drug ID" information to collect our data.

Using the databases of FDA's Orange Book, FDA's Drugs@FDA database, Lex Machina, BiomedTracker, and PubMed databases, we construct our rich panel data. The final dataset is a panel in which an observation is a drug in a given year. Below, we briefly describe the data source and how we collect the data from several databases.

Number of patents: Using the application numbers, we obtain patent numbers associated with these application numbers on a historical basis from the FDA's Orange Book.

Number of substance patents: we identify the number of patents and patent numbers associated with drug molecules by using FDA's Orange Book.

Number of extended patents: Each NDA innovator can extend only one patent for each approved product under Patent term extension (PTE) act. The main objective of PTE is restoring the patent term lost during approval. Using the patent numbers from Orange book, we identify the patents which are extended by the pharmaceuticals by the PTE act.

Number of court cases: After identifying patent numbers associated with the drugs, we count the number of litigation cases associated with these patent numbers using Lex Machina database over the years.

Number of court cases for substance patents: This shows the number of litigation cases associated with substance patents for each drug over the years from Lex Machina data.

Number of court cases for extended patents: This shows the number of litigation cases associated with extended patents under PTE law for each drug over the years from Lex Machina data.

Exclusivity dates: For each drug, by using the application number, we obtain the maximum exclusivity dates for each drug for each year from Orange book database.

Generic entry dates For each drug, by using the application number, we identify whether there is an approved generic product for each application number. If there is, we get the approval date of the earliest generic application number from Drugs@FDA database.

Clinical trials: we use the BiomedTracker database, we collected information on clinical trials for each NMEs initiated by the incumbent after it was approved. To decide a clinical trial is initiated by the incumbent or not, we use the incumbent company name or subsidiary company names of the incumbent or partnered company names with the incumbent for each drug after the drug approval date. For each year, if a clinical trial is sponsored by the incumbent, subsidiary or partner company, we assume that this clinical trial is initiated by the incumbent. We complement initiation dates and ending dates of clinical trials by using the information on clinicaltrial.gov database. We use the 'NTC' number that identifies each clinical trial in both BiomedTracker and clinicaltrial.gov databases.

Pubmed publications: We search for each brand name of the drug and the molecule name on the PubMed website and scrape all information about published papers.

For the 1997 to 2018 period, we identified 134 drugs introduced as both new molecule entry (NME) and first-in-class drug (FIC) in their pharmacological class. Out of these drugs, 42 experienced entry by a drug in their pharmacologic class. Our dataset extends the data and uses similar pharmacological classifications in Gilchrist (2016)[5]. This classification is crucial and novel for our analysis since these drugs are similar in chemical composition and physiological effect. However, they are differentiated at the molecular level. Gilchrist (2016) states that this classification of the drugs enables to identify drugs very close in the eyes of prescribers and patients

[5]Gilchrist (2016) uses different categorization of FIC from FDA, which he defines as Effective FIC depending on entry year and type. We just use FIC as defined by FDA in our analysis.

such that they substitute each other. On the other hand, they are different at the molecular level means that each drug requires its own costly clinical trials for approval and does not infringe the patent right of the first inventor.

We present summary statistics for our panel data in Table 1.1. Panel A reports statistics for all first-in-class drugs and Panel B only for first-in-class drugs that experience entry during their period of patent protection. The table suggests that first-in-class drugs that experience entry are more valuable: incumbent firms conduct more clinical trials, issue more patents, and litigate more for these drugs relative to the overall population. Thus, although entry is likely not exogenous because entrants choose more profitable markets to enter, entry timing is somewhat random because firms need to get approval from the FDA. In our analysis, we exploit the timing of entry of me-too drugs.

1.2 Empirical Results

We use a difference-in-differences research design that compares the number of clinical trials initiated after the approval for the classes with entry to classes with no entry, before and after. In addition to time-variant variables to capture the changes over time in the market, we use time-invariant characteristics of each market which leads companies to target specific markets for entry.

Let i denote the pharmacological class since we are only including first-in-class drugs, we can use drug, market, and class interchangeably. We estimate several specifications of the following model:

$$log(Y_{it}) = \alpha + \beta SecondEntry_{i,t} + \gamma' X_{i,t} + \mu_t + \theta_i + \epsilon_{i,j} \tag{1.1}$$

where Y_{jt} is the outcome variable of interest for pharmacological class i in year t. $SecondEntry_{i,t}$ is a dummy variable that takes the value 0 before the second entry in pharmacological class i occurs and 1 afterward. $X_{i,t}$ is a vector of time-variant controls for pharmacological class i that includes number of patents registered at the orange book, court cases. We further include number of drug substance (DS) patents defined in orange book, DS patents' court cases, number of patents extended by PTE (AI), PTE patents' court cases, generic entry dates of the first-in-class drug, and length of patent exclusivity term for each drug using the information from orange book. μ_t is a year fixed effect and θ_i is pharmacological class fixed effect.

There is an important factor that can affect the interpretation of the coefficients in this analysis. A pharmacological class can have multiple entries (in some classes, the entry can be up to 11 drugs). Our estimates are based on the first entry so that the effect of any additional entry during the observed time frame is captured by our estimates. As a result, we should not interpret the coefficients as the effect of a single entry, but it should be interpreted as the total effect of the initial entry over the time frame we use in the analysis.

Table 1.2 (Column 1) reports the estimated coefficients when the outcome variable of interest is $ClinicalTtrials_{it}$, which corresponds to the number of clinical initiated (plus one) for first-in-class drug by firm i at year t. Our result indicates that the incumbent initiates fewer clinical trials related to that drug by 8.9 percent. The competition between the incumbent and the entrant decreases the additional potential profits by innovation. In other words, the ex-post innovation incentive of the incumbent decreases with entry due to a decrease in expected rents from the incremental innovation.

Next, we further classify the second entrant's type of products into two categories: 1) addition to class, which is defined as almost identical products and provides no

additional benefit comparing to first in class drug, 2) advance to the class, which represents the drugs that is more advance than the existing drug. The classification is based on "priority review" designation given by FDA. Dranove, Garthwaite and Hermosilla (2014) uses these designations as 'socially valuable products' in their analysis. They state that even though products with priority review designation target the conditions with existing treatments, these products represent meaningful improvements in efficacy.

The result at (Column 2) in Table 1.2 shows that when an additional drug enters the market with no additional benefit comparing to the existing first-in-class drug, the incumbent initiates fewer clinical trials for its drug. It means that introduction of relatively less differentiated products decreases the incentive for the incumbent's incremental innovation incentives due to reduction in expected rents from conducting additional R&D. This result aligns with Lichtenberg and Philipson (2002) which shows that rents decrease with additional products in the drug market. In the leader and follower perspective, the result is consistent with Aghion et al. (2005) that the market leaders, first-in-class drug companies in our framework, respond to the increased competition with less R&D incentives given that there is competition. In a different setting, Rao (2020) shows that pharmaceuticals reduce the investments when competitors received FDA approval in the product market. On the other hand, when the second entry drug is more therapeutically advance than the existing drug, the incumbent's reaction is less in terms of magnitude even though imprecisely estimated according to Column (2). This can be explained by the fact that "advance" type of entries socially innovative products so that they could increase the market share of the class. In this case, the incumbent's potential market expansion by the additional innovation is increased by the entrance of the advanced drug. The results at Column 3 and 4 in Table 1.2, we use disease fixed effects instead of class fixed

effects, and the results do not change significantly than Columns 1 and 2, respectively. In appendix A, we show that results are robust under Poisson and negative binomial regression specifications.

We use difference-in-differences approach under the assumption that FDA approval process is uncertain for product launches in a pharmacologic class. Having multiple treatments with multiple treatment periods, we test the main identifying assumption that similar trends between drugs experienced second entry and single drugs in the market before as Autor (2003). We allow leads and lags of the entry times to test the assumption by using the model;

$$log(ClinicalTrials_{it}) = \alpha + \sum_{j=-m}^{q} \beta_j D_{it}(t = k + j) + \gamma' X_{it} + \mu_t + \theta_i + \epsilon_{ij} \qquad (1.2)$$

where m and q defined as lead and lag to the entry time, respectively. k denotes the entry time. We expect that $\beta_j = 0$ for all $j < 0$ i.e. coefficients for leads should be zero. We show the coefficients on Figure 1.1 and all lead coefficients are statistically zero.

Next, we use the number of patients registered to a clinical trial as a proxy for initial R&D expenditure of ideas for each class. The result in column (1) in Table 1.3 shows that experiencing an "addition" entry in the product market decreases the number of patients used in the clinical trials by the incumbent. This result is consistent with the finding of Thakor and Lo (2015), competition reduces R&D expenditures of the incumbent. In overall, our finding in Table 1.3 is consistent with findings from Table 1.2. The incumbent reduces the number of patients registered in clinical trials by 50 percent when the entrant enters with a close substitute.

Table 1.3 (Column 2) reports the estimated coefficients when the outcome vari-

able of interest is "mean patients registered per trial". The result shows that the incumbent decreases the average number of patients per trial, which indicates that the incumbent does not initiate clinical trials that lead to direct approval (Phase III trials need a high number of patients for showing efficacy) after an addition entry in the product market. This might imply that the incumbent reduces the number of clinical trials that lead to direct approval such as Phase III trials.

Table 1.3 column (3) shows the result of "active clinical trials" as the outcome variable. In general, clinical trials take several years to complete depending on the endpoint of trials. Instead of using the clinical trials initiation date, we scrape the ending date of clinical trials from ClinicalTrial.gov and match those with the Biomed dataset based on the clinical trial number. Next, based on the initiation and ending date of clinical trials, we calculate "active clinical trials" funded by the incumbent for a given year. For instance, Company A initiated a clinical trial in 2005, and it was concluded in 2007. Assume that the same company initiated another clinical trial in 2006. As a result, we calculate that company A had two active clinical trials in 2006. Our result indicates that the incumbent decreases number of active clinical trials when there is an addition entry to the class. The outcome variable "active clinical trials" is a proxy for continuous R&D expenditure for first-in-class drugs rather than lump sump expenditure for the ideas. The result shows that the incumbent decreases continuous R&D expenditures by 25 percent after an addition entry due to a decrease in expected rents from incremental innovation.

We use PubMed publications related to the drug as the outcome variable in Table 1.3 column (5) to investigate the effect of second entry to an established drug market on public research. For each incumbent drug ingredient, we search the molecule name and scrape all the records from PubMed. We strict the results only on academic publications and collected information over time. We show that public research about

the existing drug increases by the advanced second entry. When there is a therapeutically advance entry occurs, this provides an opportunity for academic publishing due to comparison with the incumbent drug, head-to-head clinical trials. As a result, without profit incentives, the advance entry in product markets stimulates R&D activities in academic publications as well as generic drugs entry suggested by column 5.

As we mentioned earlier, pharmaceuticals might conduct additional trials after the approval to show the original drug works with new indications and many other reasons. We show that the effect of competition within class decreases incentives for incremental innovation for the incumbent. In terms of new indications, lack of incentives for incremental innovation causes off-label prescriptions. The term means that drugs usage by the doctors and the patients for a condition that is not approved by FDA. Off-label prescriptions are legal, and one out of five prescriptions are off-label usage shown by Radley, Finkelstein and Stafford (2006). There is a vast literature about this, and the scholars discuss that off-label is a result of lack of incentives. Additional patent terms and market exclusivity periods provided by FDA could protect incentives from generic entry but not from "me-too" competition. To test this, we identify the original indication of each drug in our data. Next, we identify the clinical trials initiated by the incumbent with a new indication as the endpoint for each trial. By doing this, we eliminate the studies for product-line extensions such as new delivery methods, new population, different dosages. Table 1.4 (Column 1) shows that the second entry decreases incremental innovation by the incumbent by around 9 percent. As a result, we can argue that the competition within class contributes to off-label uses.

Concerns about off-label uses are recent and get attention recently by scholars. One of the solutions proposed to overcome off-label uses is government-sponsored

studies for the drugs and National Institutes of Health (NIH) focuses on new uses of drugs. We use outcome variable as clinical trials initiated by NIH agencies (without any partners). Table 1.4 (Column 2) shows that when there is an entry, NIH initiates fewer clinical trials associated with the drug. The response is more precisely estimated with advance entry to the class. This result shows that it might be the case that advance entry drugs become standard care of the class. However, this leaves the first-in-class drugs understudied and underused, even with government-sponsored clinical trials.

1.2.1 Robustness Check: Generalized Synthetic Control and Matrix completion

We convert the dataset quarterly for entry dates and date of initiation of the clinical trials with a motivation: 1) expecting more precise estimates by increasing the number of observations 2) robustness check for the control group in the main analysis.

In addition to difference-in-differences method, we use Generalized Synthetic Control (GSC) and Matrix completion method (MC) for the estimation with quarterly data. (1) GSC uses observed time-varying confounders semi-parametrically, such as interactive fixed effects (IFE), to evaluate unit-specific intercepts interacted with time-varying coefficients. Xu (2017) connects these two approaches by estimating an IFE model on control data. Next, the method obtains a fixed number of latent factors such that putting pre-treatment treated outcomes onto space spanned by these factors to get factor loadings for the treated group. As a final step, the method generates a prediction for the post-treatment treated outcomes based on these estimated factors and factor loadings. (2) MC is described in Athey et al. (2020). This method is an extension of the GSC method by increasing the number of factors like

the number of units as well as an increase in the time period. Instead of estimating the factors and their loadings, the method minimizes the distance between the estimated matrix and the 'incomplete' matrix (the outcome of post-estimation treated units are defined as missing and those are estimated by the model). Athey et al. (2020) shows via simulation that the matrix completion method outperforms several synthetic control methods such as Synthetic Control and GSC. Table 1.5 shows the estimation results. Column 1 uses differences and differences. Column 2 and 3 show Generalized synthetic control and matrix completion methods for estimation, respectively.

1.2.2 Robustness Check: Instrument variable estimation

As an alternative to our identification, we use instrument variable(IV) approach for the analysis to check how the results change under IV estimation in this section. There are two main identifying assumptions we need. First, the instrument variable is independent from the unobservables i.e. assume z_i is the IV variable, we need to have $Cov(z_i, \epsilon_{i,t}) = 0$ for equation 1.1. Unfortunately, testing this assumption is not possible, but we discuss this assumption below. Second assumption is $Cov(z_i, SecondEntry_{i,t}) \neq 0$ and we show this as first stage in the results below.

As an instrument, we calculate the gap between when the patents are first established and filled on the molecule and the beginning of the development of the entrant drugs in terms of years, $z_i = t_{DevStart} - t_{PatentFilling}$, which is proposed by Gilchrist (2016). There are two reasons that this could be a valid instrument to our analysis; (1) This year gap is correlated with the timing of the entry for the entrant and correlated to the number of clinical trials initiated by the incumbent only through the effect on the second entry (2) Gilchrist (2016) shows that this instrument is unlikely

to pick up any class-specific unobservables such as sales and high correlation with class. As a result, this gap could be a valid instrument for our analysis.

There are several issues with IV estimation. First, the variable we take into consideration as IV is time-variant. Thus, we are not able to use "drug" fixed effects in this part of the analysis. Instead of this, we use disease-fixed effects. This might hinder the power of eliminating time-invariant class unobservables for identification. Second, we instrument entry timing with the delay variable, given that the class has an entry. This means that we do not account for the entry of the classes. Lastly, we do not have complete data for all the drugs, so we estimate the baseline model with this subset of the data.

We present the results in Table 1.6 that subset of the main data. Column (1) shows the main specification with the subset of the data as equation 1.1 with drug fixed effects. Column (2) shows the estimates with using "disease" fixed effects. Lastly, Column (3) shows the estimates with the instrument for the timing of the entry using the difference between the patent filing date and the starting date of clinical trials for the entrant. The results show that our estimates are strong, negative, and statistically significant for the effect of entry on incremental innovation of the incumbent in all the cases. Overall, the competition within class leads to 14-17 percent decrease in the initiated clinical trials by the incumbent.

1.3 Discussion

We control class and time-specific effects in the main model, which captures entry times and time-invariant class characteristics. We try to control market time-variant variables by using the number of patents submitted by the incumbent, number of litigation cases associated with these patents. However, endogeneity concerns arise

from two sources (1) incremental innovation activities are equilibrium responses, (2) omitted time-variant variables.

Concerns related to (1) cannot be mitigated with the reduced-form analysis that we studied in this analysis. There is well-defined literature in empirical IO literature following the papers of Bresnahan and Reiss (1991) and Berry (1992). These papers study oligopolistic markets and endogenous market structures. They discuss the important features of a determinant of entry decisions and the nature of the competition. From this literature, two studies are closely related to our analysis in terms of the research question; (1) Goettler and Gordon (2011) who estimates a structural estimation that endogenizes innovation for the counterfactual that whether Intel as an incumbent would innovate by incremental innovation when there is no AMD in a two-company model. They found that the quality of the products, by incremental innovation, would be 4.2 percent higher without AMD present. (2) Rao (2020) estimates a dynamic investment model with Phase 3 clinical trials before drug approvals, which is different from our analysis. She studies the effect of competition due to new-product launches on R&D activities of firms pre-approval periods for many markets but fifteen firms. She found that approval within the class by the rival, pharmaceuticals decrease the number of clinical trials in that class.

Concerns related to (2), such as market-time specific events that can lead to bias, might not be captured by the time-variant variables we use in the analysis. Concern related to this variable should lead us to underestimate the effect of competition on incremental innovation. To see this, a market-time-specific event, such as a scientific discovery that makes the clinical trials easier for the class for all pharmaceutical companies. In this case, we see more clinical trials conducted by the incumbent and this specific class experiences quicker second entry (and more entry) overall. In this case, the magnitude should be more negative than the one that we estimated

in the previous section. Similar intuition hold for the more profitable markets. In the descriptive statistics in Table 1.1, we argue that entrants choose more profitable markets to enter. These markets have more clinical trials by the incumbent and attract more entrants, which both are positively related. As a result, if profitability is the omitted time-variant variable that causes bias, we found the lower bound of the effect of competition on incremental innovation in our analysis. Lastly, Another omitted variable can result from previous clinical trials, such as a scientific discovery that shows the incumbent product cannot be improved anymore (bad news) and shows a potential for entrant's molecule. In this case, the incumbent will not invest in clinical trials anymore but the entry becomes easier for the entrant. If this is the case, we overestimate the effect of competition within the class on incremental innovation.

1.4 Conclusion

The literature discusses that having "me-too" drugs, that is close substitutes to existing drugs, can have ambiguous effects on welfare. They provide more variety and options to prescribes and patients. On the other hand, they lead to more detailing activities by pharmaceuticals by competition, decrease ex-ante innovation incentives, cause double-spending of R&D resources on the class that has a treatment, decrease the effect of generic entry on prices due to detailing, are a result of imitation rather than innovation.

In this paper, we show a novel welfare-reducing impact of "me-too" drug competition within a class. We show that the competition within the class by entry decreases the incremental innovation activities by the incumbent by 8.9 percent. When the entrant's drug has no additional benefit compared to the first-in-class drug, the orig-

inal inventor decreases the number of clinical trials initiated after the approval by 14 percent. We argue that expected rents from additional innovation after approval decreases by the competition. We use different outcome variables and several different empirical strategies to check the robustness of our results.

We argue that the competition within class might be the reason for off-label usage. Since first-in-class drugs are defined as "novel" that offers to treat conditions never treated before, competition within class caused by the entrant leaves these novel products understudied and underused. We discuss that lower incentives to innovate for new indications might cause a high ratio of off-label usage and it could worsen by with me-too drug competition. In other words, competition from me-too NME could reduce pioneer firms' effort to find new uses of an already safe and effective molecule. We show that the original innovator decreases initiated clinical trial with a new indication endpoint by 9 percent after observing an approval of a drug that is a close substitute. One of the solutions suggested by the literature for the off-label usage problem is conducting clinical trials sponsored by NIH agencies and focus on new indications in those trials. We show that this is not the case, clinical trials sponsored by NIH for first-in-class drugs decrease by 31 percent after a new drug approved in the same class.

We argue that when a drug seeks approval in a class that has already drug exists, the drug should show efficacy not only against placebo but also against first-in-class drugs. This might decrease the negative impact of competition within the class on innovation.

1.5 Figures and Tables

Table 1.1: Summary statistics of the data

	N	Mean	Median	St. Dev.	Max
Panel A. First in class drugs					
Number of incumbent clinical trials	134	4.10	1	6.07	28
Number of court cases	134	3.81	0	7.73	51
Number of patents	134	31.25	25	31.40	191
Number of drug substance patents	134	9.33	6.5	11.27	65
Drug substance patents court cases	134	1.62	0	4.99	41
Exclusivity (years)	134	6.66	6.80	3.86	13.30
Number of Extended patents	134	5.02	4.50	5.49	16
Extended patents court cases	134	1.31	0	3.70	22
Panel B. First in class drugs, with entry					
Number of incumbent clinical trials	42	6.17	3.5	7.47	28
Number of court cases	42	5.02	0	9.259	51
Number of patents	42	43.95	39.50	34.33	191
Number of drug substance patents	42	15.59	15	13.37	65
Drug substance patents court cases	42	3.05	0	7.34	41
Exclusivity (years)	42	8.05	8.65	3.71	13.30
Number of Extended patents	42	6.738	6	6.22	15
Extended patents court cases	42	1.095	0	2.68	14

Notes: Panel A shows the descriptive statistics for all small molecule first-in-class drugs approved between 1997 and 2008. Panel B shows the descriptive statistics for drugs from panel A with at least an entry to their class.

Table 1.2: Effect of competition on R&D

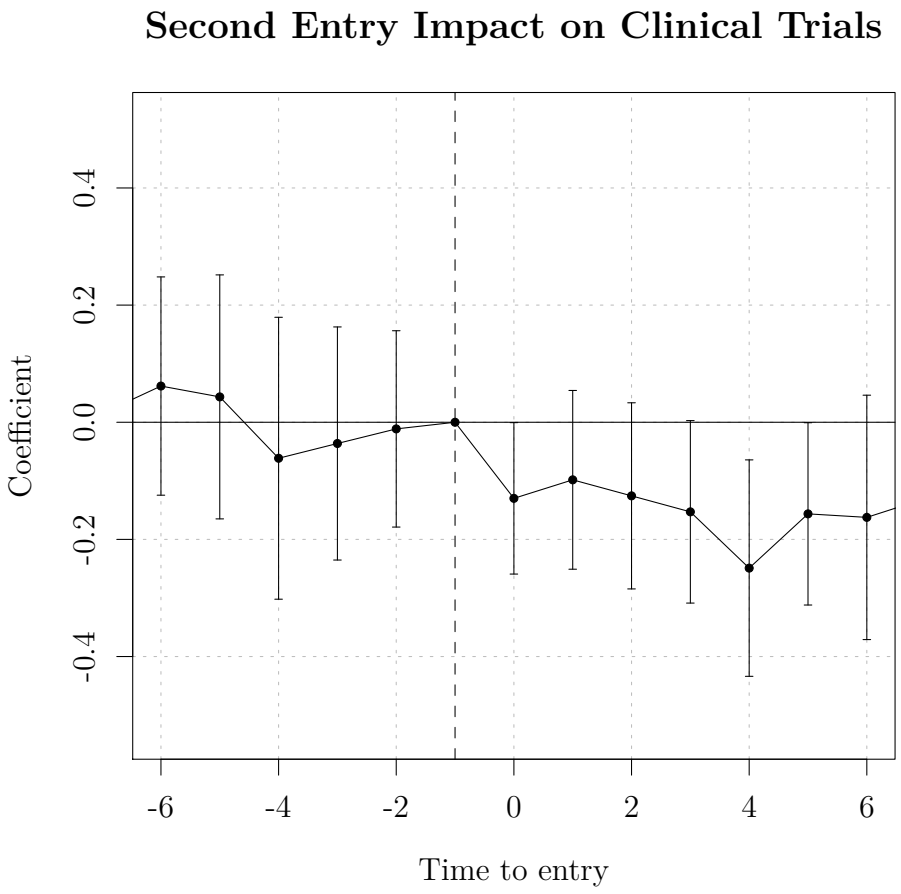
Dependent Variable:	ln(*Incumbenttrials*)			
Model:	(1)	(2)	(3)	(4)
Variables				
Second entry	-0.0890*		-0.0855*	
	(0.0505)		(0.0452)	
Second entry (Addition)		-0.1448**		-0.1242**
		(0.0632)		(0.0501)
Second entry (Advance)		-0.0249		-0.0535
		(0.0739)		(0.0639)
# of patent	-0.0081	-0.0090	-0.0122*	-0.0123*
	(0.0084)	(0.0083)	(0.0073)	(0.0072)
# of court cases	-0.0113	-0.0105	-0.0180**	-0.0177**
	(0.0075)	(0.0079)	(0.0077)	(0.0076)
Generic entry	0.0370	0.0387	-0.1638***	-0.1633***
	(0.0437)	(0.0430)	(0.0351)	(0.0352)
# of DS patent	-0.0372*	-0.0378*	0.0406**	0.0400**
	(0.0212)	(0.0212)	(0.0163)	(0.0167)
# of DS court case	0.0071	0.0069	0.0075	0.0081
	(0.0127)	(0.0128)	(0.0152)	(0.0149)
# of AI patent	-0.0385	-0.0416	-0.1252***	-0.1272***
	(0.0392)	(0.0384)	(0.0408)	(0.0418)
# of AI court cases	0.0026	0.0022	0.0165	0.0160
	(0.0148)	(0.0149)	(0.0184)	(0.0182)
Exclusivity Date	0.0068**	0.0074**	0.0133***	0.0137***
	(0.0033)	(0.0033)	(0.0040)	(0.0040)
Fixed-effects				
Class	Yes	Yes		
Year	Yes	Yes	Yes	Yes
Disease			Yes	Yes
Fit statistics				
Observations	1,413	1,413	1,413	1,413
R^2	0.52379	0.52485	0.18251	0.18386

Table 1.3: Different outcome variables with specification of equation 1.1

Dependent Variables:	# of patients per trial	Mean patients per trial	Active trials	Pubmed Publications
Model:	(1)	(2)	(3)	(4)
Variables				
Second entry (Addition)	-0.5665*	-0.4307*	-0.2519**	-0.1354
	(0.3000)	(0.2335)	(0.1045)	(0.3844)
Second entry (Advance)	-0.2078	-0.2010	0.0561	0.6301***
	(0.4278)	(0.3984)	(0.1068)	(0.2168)
# of patent	-0.0242	-0.0131	-0.0091	0.0615*
	(0.0417)	(0.0387)	(0.0096)	(0.0344)
# of court cases	-0.0596	-0.0590	0.0025	0.0306*
	(0.0501)	(0.0470)	(0.0097)	(0.0178)
Generic entry	0.1365	0.0746	-0.0003	0.4258*
	(0.2256)	(0.2113)	(0.0698)	(0.2336)
# of DS patent	-0.1762	-0.1445	0.0036	0.1290**
	(0.1132)	(0.1064)	(0.0246)	(0.0565)
# of DS court case	0.0718	0.0778	0.0068	0.0071
	(0.0989)	(0.0979)	(0.0177)	(0.0172)
# of AI patent	-0.4388**	-0.4442**	0.0225	-0.0911
	(0.2021)	(0.1856)	(0.0532)	(0.1323)
# of AI court cases	0.0389	0.0462	0.0069	0.0129
	(0.1353)	(0.1334)	(0.0173)	(0.0208)
Exclusivity Date	0.0397**	0.0365**	0.0151***	-0.0062
	(0.0182)	(0.0170)	(0.0054)	(0.0119)
Fixed-effects				
Class	Yes	Yes	Yes	Yes
year	Yes	Yes	Yes	Yes
Fit statistics				
Observations	1,413	1,413	1,413	1,413
R^2	0.47021	0.44434	0.86722	0.85379
*Signif. Codes: ***: 0.01, **: 0.05, *: 0.1*				

Notes: Column 1 is as result of number of patients registered to incumbent's trials. Similarly, we use average number of registered patients per trial yearly, number of active clinical trial given year, and pubmed publications as an outcome variable,respectively.

Figure 1.1: Point estimate of coefficients at 95% confidence intervals



Notes: The figure uses specification at equation 1.2 with m=6 and q=6. The omitted time period is the year prior to the entry. We show more general of this graph in Appendix A

Table 1.4: The effect of competition on new indication clinical trials and government-funded trials

Dependent Variable:	log(NewIndicationTrials)	log(NIHtrials)
Model:	(1)	(2)
Variables		
Second entry (Addition)	-0.0931*	-0.1348
	(0.0548)	(0.1141)
Second entry (Advance)	-0.0085	-0.3124*
	(0.0599)	(0.1788)
Fixed-effects		
Class	Yes	Yes
year	Yes	Yes
Fit statistics		
Observations	1,413	1,413
R^2	0.51915	0.71061

One-way (Class) standard-errors in parentheses
*Signif. Codes: ***: 0.01, **: 0.05, *: 0.1*

Notes: Table uses the the same specification with the main results. Outcome variables are number of clinical trials initiated by the incumbent with a new indication, and number of clinical trials initiated by NIH.

Table 1.5: Comparison of estimation methods with quarterly data

	Dependent variable:log(incumbent trials)		
	DiD	GSC	MC
Second entry (addition)	-0.047^{**}	-0.135^{**}	-0.132^{*}
	(0.022)	(0.052)	(0.040)
Second entry (advance)	-0.038	-0.107^{*}	-0.108^{*}
	(0.03)	(0.059)	(0.051)

Notes: Column 1 uses differences and differences. Column 2 and 3 show Generalized synthetic control and matrix completion methods for estimation, respectively.

Table 1.6: Instrumental variable estimation and its comparison

Dependent Variable:	$\ln(Incumbenttrials)$		
Model:	(1)	(2)	(3)
Second entry	-0.1398*	-0.1649**	-0.1768***
	(0.0832)	(0.0647)	(0.0672)
Estimates from first stage:			
Patent filling to clinical trials (years)	-	-	-0.0414***
			(0.0089)
F-Statistics	-	-	21.57
Drug FE	Yes	No	No
year FE	Yes	Yes	Yes
Disease FE	No	Yes	Yes
Control variables	Yes	Yes	Yes
Observations	1,049	1,049	1,049
R^2	0.47257	0.17431	0.17497

One-way (Drug) standard-errors in parentheses
*Signif. Codes: ***: 0.01, **: 0.05, *: 0.1*

Notes: Column 1 uses the main specification with subset data. Column 2 uses "disease" fixed effects rather than "drug" fixed effect. Column 3 shows the IV estimation results.

CHAPTER 2

PHYSICIAN MISCONDUCT AND MARKET PUNISHMENT

Physicians are highly educated professionals who are essential for the economy. These professionals must adhere to both medical-care and professional-conduct standards. In recent years, however, public confidence about the integrity of physicians has been shattered by reports of serious misconduct including overprescription of opioids and sexual abuse.[1] Besides these highly publicized cases, physicians are subject to accusations regarding a number of professional misconduct practices including patient discrimination (e.g., denying care to someone because of race, color or ethnicity), substance abuse (e.g., use of alcohol or narcotics), and mishandling of medical records.

If physicians are alleged to have engaged in misconduct in the United States, they are typically handled by state medical boards which investigate the allegations and further decide on whether to discipline physicians. In light of highly publicized recent cases, however, there are three questions regarding the effectiveness of this system. First, does this system discipline all physicians with misconduct at the appropriate level? Second, to what extent do state medical boards' disciplinary actions punish physicians with misconduct? Third, do disciplinary actions prevent future misconduct?

[0]Jointly with Seung-Hyun Hong and Jorge Lemus

[1]For an example of opioid cases, see www.justice.gov/usao-ndca/pr/san-jose-physician-charged-unlawfully-distributing-hydrocodone-and-oxycodone. For an example of sexual abuse cases, see www.bmj.com/content/372/bmj.n869

These questions are important, but difficult to answer directly. In this paper, we indirectly explore these questions by examining market consequences of disciplinary actions issued by state medical boards. Given that physicians interact with different market participants such as other physicians, patients, or drug firms, how these market participants respond to physicians with disciplinary actions can provide useful information on the effectiveness of the system.

For example, market participants may be indifferent to physicians with or without disciplinary actions, which implies underlying problems as follows: market participants may be unaware of physicians' disciplinary records, because disciplinary information may not be readily available to them or may be suppressed; or they may not think disciplinary actions matter, possibly because they presume that most wrongdoings are not disciplined. Alternatively, market participants may further punish physicians with disciplinary actions by reducing or discontinuing their interactions with those disciplined, in which case aforementioned problems are unlikely to be present in the system.

Therefore, understanding to what extent the market punishes those disciplined by state medical boards can shed light on the effectiveness of the disciplinary system of state medical boards. To this end, we construct a novel database of physicians registered in California, a state that publicly provides historical records of physicians' accusations and disciplinary actions.[2] We complement the database with data from Open payments. Using this data, we examine physician-firm interactions, which we then use to quantify the 'market punishment' experienced by physicians with disciplinary actions.

The Medical Board of California (MBC) is responsible to determine whether a

[2]There are over one million physicians in the US, and California is the state with the largest number of physicians and specialists. See www.kff.org/other/state-indicator/total-active-physicians.

physician accused of misconduct deserves a disciplinary action. There is a number of conducts that are considered unprofessional including excessive prescribing, sexual abuse or misconduct, gross negligence, and failure to maintain adequate and accurate hospital records, among others. Offenses related to the qualifications, functions, or duties of a physician (e.g., driving under the influence, shoplifting, drug offenses) are also considered professional misconduct. In our data, we identify over 100,000 physician with a California license between 2014 and 2018. Out of these physicians, 4.29 percent have received at least one disciplinary action by the MBC and 2.62 percent of physicians receives multiple disciplinary actions.

We find that the market punishes physicians with disciplinary actions, even after we exclude those who lost licenses. Our results on physician-firm interactions reveal that drug firms are less likely to detail physicians who have received any disciplinary action. A priori, this result is not self-evident: drug firms could be targeting sanctioned doctors because they may be more willing to receive payments in exchange for changing his/her prescription behavior. In fact, several reports have suggested a problematic relationship between firms and disciplined physicians, and some of them are discussed in Appendix B.2. In contrast to these reports, our study is a large-scale investigation of the impact of misconducts on physician-firms relationships.

There are two reasons for why firm do not want to be associated with these physicians. First, firms may have reputation concerns and may want to avoid being associated with physicians who committed misconduct. Second, firms choose to target physicians who deliver a high return to investment. As we shown before, physicians who are sanctioned with a disciplinary action receive fewer patient visits, so their ability to prescribe certain drugs may be jeopardized.

Compared to our results on disciplinary actions, we find similar but weaker results for physicians who receive an accusation but are not disciplined by the CA

medical board. This latter finding suggests that some physicians may be paying a reputation penalty from an accusation even if they are not proven to be guilty. This finding uncovers a tradeoff between transparency and reputation: publicly disclosing accusations may cause long-term harm for physicians that are not guilty.

2.1 Related Literature

Our paper contributes to the recent and growing literature that explores the impact of professional misconduct on market outcomes. This literature has examined this question in industries such as financial advisers, bank brokers, law enforcement, and academia. We contribute by exploring the impact of misconducts experienced by physicians in California.

Egan, Matvos and Seru (2019) study misconduct of financial advisers, documenting that about seven percent of advisers have misconduct records, and that one-third of advisers with misconduct are repeat offenders. They find that some firms are more prone to hire financial advisers with past misconduct. Also related to the financial advisers industry, Dimmock, Gerken and Graham (2018) show when a firm that employs financial advisers with misconducts merge, the probability of misconduct increases for worker of the merging party.

In the banking industry, Griffin, Kruger and Maturana (2019) explore whether bankers who signed fraudulent residential mortgage-backed securities receive a reputation penalty. They find that these bankers did not experienced adverse internal or external labor market outcomes.

Policing is another industry where misconducts have been prominent. Weitzer (2002) find that incidents of police misconduct have an unfavorable impact on public attitudes toward the police. Kane and White (2012) examine conditions under which

police officers engage in misconduct. They show that organizational policy and practices can facilitate misconduct. In terms of the 'market' impact of a misconduct, Grunwald and Rappaport (2019) focus on police misconduct and study where officers fired from the police force find employment.

Gibson et al. (2020) conducts laboratory experiments to evaluate how the perception of CEO's honesty impact investment decisions. They find that CEOs perceived as more honest by investors result in higher investment. In another experiment, Annan (2020) study the impact of two-sided anti-misconduct information programs on markets. The paper finds that market activities are underprovided due to misconduct and difficulty in building reputation.

In academia, several articles explore the impact of retractions, which could be due to an unintentional mistake or could reflect misconduct by the scientists. Lacetera and Zirulia (2011) present a model of academic misconduct explaining why scientists commit fraud and how fraud can be detected and prevented. Lu et al. (2013) measure the impact of the retraction of an academic paper. They show that citations fall by an average of 6.9 percent per year for each publication prior to the retraction. Stern et al. (2014) find that papers retracted due to misconduct accounted for approximately 1 percent of the NIH budget over this period, a mean of $392,582 in direct costs. Further, researchers experienced a median 91.8 percent decrease in publication output and large declines in funding after censure by the Office of Research Integrity. Azoulay et al. (2015) find that articles citing a retracted article experience a decline in citations, and this penalty is more severe when the retracted article involves fraud or misconduct rather than honest mistakes.

Lastly, our paper contributes to literature that explores physician-pharmaceutical interaction. Recent articles have found that detailing changes physicians' prescription behavior. Specifically, some articles have identified the elasticity between detailing

and prescription, finding that physicians who are detailed prescribe more frequently brand-name drugs. Grennan et al. (2018) study pharmaceutical firms' payments to physicians, and find that the average payment increases prescribing of the focal drug by 73 percent. Carey, Lieber and Miller (2020) show that physicians increase prescribing of drugs for which they receive payments in the months just after payment receipt. Liu et al. (2016) develop a structural model of pharmaceutical firms competition for physician detailing. Using the estimated parameters, they find that imposing a ceiling on detailing frequency could significantly reduce detailing of all firms in the market, and would soften competition between firms and enhance their profits. Harris and Byhoff (2017) there is variation in the annual rate of medical board physician disciplinary action by state. Different from the literature, we investigate the impact of misconducts on detailing payments in the perspective of physician-pharmaceutical interaction.

2.2 Data and Descriptive Statistics

In this section, we first describe our datasets. We then present the key patterns in disciplinary actions of physicians.

2.2.1 Data Description

We obtain our data from two main sources. The first is a novel dataset on physician disciplinary actions that we construct from the Medical Board of California (MBC) website. Specifically, we rely on two sources in the MBC website. One is "Disciplinary Actions/License Alerts" published since 2005, which contains various disciplinary actions issued by the MBC. The other is "Online License Search" that provides

a physician's record, including disciplinary actions issued by the MBC and other states, as well as court decisions.[3] Though the Online License Search can include the records before 2005, it removes some records (e.g. public reprimand, accusation) if they become confidential. Hence, we use both sources of data to construct our dataset.

We focus on California for two reasons. First, the MBC keeps public records of disciplinary actions issued to California physicians, while similar information is not readily available in most other states. Second, California has the largest population of physicians in the United States, and the findings from California physicians can shed light on physician disciplinary actions in other states.

The second main source of our data is the Open Payments database, from which we obtain information on physician-firm interactions between California physicians and pharmaceutical companies. This dataset contains detailed information on each drug firm's visit to each physician, including the payment amount, the purpose of the visit (e.g. food, consulting, etc.), and the date of the visit. Open Payments started to release its data from the second half of 2013. We use the data from 2014 to 2018.

Physicians in the MBC website are identified by their California licenses, whereas those in Open Payments are identified by their names, addresses, and taxonomy codes. To match the same physician across different datasets, we use the National Plan and Provider Enumeration System (NPPES) to obtain National Provider Identifiers (NPI) – unique identification numbers for covered health care providers used in administrative and financial transactions – and California license numbers for over 100,000 physicians. Using these datasets, we create a panel of all California

[3]Annual "Disciplinary Actions/License Alerts" can be downloaded from the MBC website. To obtain physicians' records, we scrape the MBC website for "Online License Search". In addition, we complement the data with textual information from public newsletters published by the MBC.

physicians including their name, NPI, licenses (self-reported), city location, gender, address, and taxonomy. Matching these datasets is not straightforward. We discuss more details on our matching procedures in Appendices B.1.

2.2.2 Disciplinary Actions

We consider all disciplinary actions reported in the Medical Board of California website. They can be grouped into three categories based on who issued disciplinary actions. The first category accounts for the majority of disciplinary actions in our data, and they are issued by the MBC (e.g. revocation, probation). The second includes court decisions such as malpractice and felony. The court system does not specifically target physicians, but it also handles some misconduct of physicians, and some of them are reported in the MBC website. Court decisions can play a similar role as disciplinary actions by the MBC, and so we also examine them. The third category is disciplinary actions by other systems, including disciplinary actions by the Medical Boards in other states or restrictions issued by hospitals.

Table 2.1 presents summary statistics on disciplinary actions in our data that includes all physicians registered in California between 2014 and 2018. In Panel A, we consider the flow of new disciplinary action (DA), where DA is equal to 1 if a physician received any disciplinary action in a given year. The table shows that 0.6% of physicians received at least one type of DA in each year. Some types of DA such as probation or suspension are more severe than other types such as public reprimand. In particular, the most severe disciplinary action by the Medical Board is revocation of a license, which means that the physician can no longer practice with that license. To continue practicing, the physician must obtain a new license. The table shows that 0.14% of physician licenses are revoked between 2014 and 2018.

In Panel B, we consider the stock of prior DA, where prior DA is equal to 1 for a physician in a given year, if the physician received any DA in any previous years. The table shows that 4.29% of physicians in 2014-2018 had received at least one type of DA in any prior years. Among them, the majority belong to DAs by the MBC – 0.83% for revocation and 2.74% for all other DAs by the MBC. The remaining are prior DAs by courts (1.28%) or prior DAs by other systems (0.81%).

The table also reports the percentage of physicians with prior accusations. However, we do not treat accusations as DA. Though an accusation may lead to a disciplinary action, it does not indicate any disciplinary action on its own.[4] Panel A shows that 0.34% of physicians have accusations each year, while Panel B reports that 1.76% of physicians received accusations previously. However, only 0.26% have prior accusations without any prior DA, and the majority of those with prior accusations also have prior DA. This suggests that many accusations are likely to result in some types of DA, and so it may be difficult to isolate the effect of accusations in our data.

In Table 2.2, we further examine variations in DAs over time. Column 1 presents the percentage of physicians with any prior DA before 2014 among physicians in 2014, whereas columns 2-6 report the percentage of the flow of DA in each year. As of 2014, 4.01% of physicians had received any type of DAs in any previous years. From 2014 on, DAs were newly issued to about 0.6% of physicians in each year. This suggests that DAs are likely to have been repeatedly issued to some physicians over time, given that 4.29% of physicians had previously received any type of DAs in 2014-2018. The table also reports that some physicians received multiple DAs in the

[4]We consider accusations because they are also reported in "Disciplinary Actions/License Alerts" published by the MBC, and they may also affect physicians' reputation. However, our measure of accusation is imperfect, because the MBC does not report if it is confidential or cleared.

same year. For example, 0.15% of physicians' licenses were revoked in 2014, while 0.48% of physicians in 2014 received all other types of DAs, excluding revocation. The sum of these two percentages is less than the percentage of physicians with any DA in 2014.

The table shows that most types of DAs have been issued at similar rates over time, though this does not applied to all types of DAs. For example, the percentage of probation is 0.07 in 2014, but it doubles in 2017. The percentage of public reprimand is 0.07 in 2014, but it almost doubles in 2018. In contrast, the percentage of other types of DAs issued by the MBC (excluding revocation, probation, suspension, and public reprimand) is 0.16, but it is reduced to 0.06 in 2018. Since different types of DAs entail different levels of punishment, the effect of DAs may not remain the same over time, though its variation over time may not necessarily be significant.

One seemingly puzzling observation in both Tables 1-2 is that physicians whose licenses were revoked previously are still observed in the data. However, this is likely to happen if updating in license information is delayed in the NPPES, or licenses are reinstated. For three reasons, our analysis excludes physicians whose licenses are revoked or have been revoked previously in California. First, excluding them addresses the aforementioned error in the NPPES.[5] Second, those who lost licenses cannot receive physicians' benefits including detailing payment by drug firms. Hence, the effect of prior revocation on detailing payment is obvious for them. Third, some physicians whose California licenses were revoked could obtain medical licenses from other states and move there. Though we do not consider them directly, we examine similar physicians, because our sample includes physicians who received DAs from other states, thereby including those whose licenses were revoked in other states but

[5]Of course, we may also exclude physicians whose licenses are indeed reinstated. By excluding them, our estimates on the effect of prior DA could be underestimated.

have obtained California licenses.

In addition to dropping those with current or previous revocation, we exclude physicians in a given year if they do not have an active NPI or are under probation in that year, or if their licenses are suspended in that year. These physicians are unlikely to be active in that year. It is not surprising that when physicians are temporarily or permanently inactive, many of them do not receive any payment from drug firms. To the extent that their current inactivity is correlated with their prior DA, including these inactive physicians is likely to overestimate the negative effect of prior DA, particularly on detailing payment. Therefore, our subsequent analysis excludes these observations, and focuses on physicians who are more likely active.

2.2.3 Who Receives Disciplinary Actions?

As discussed in the previous section, we exclude those who are unlikely active in a given year. Using the sample of these "active" physicians, we recompute the percentage of physicians with DA and prior DA, which is presented in Column 1 of Table 2.3. The percentage of current DA is 0.28, which is less than a half of that in Table 2.1. In contrast, 3.08% of active physicians have prior DA, and this percentage is about three quarters of that in Table 2.1. This is expected, because we exclude relatively more observations with current DAs that render physicians inactive.

Column 2 shows 2.62% of physicians who have received a prior disciplinary action receive a new disciplinary action. Thus, the rate of disciplinary actions within the population of physicians with prior disciplinary actions is about 10 times larger than the rate for all physicians, which is 0.28%. This evidence is consistent with repeated-

offenders, which has also been documented in other industries (see Egan, Matvos and Seru (2019)).

Column 3 reports that among female physicians, 0.15% of them have DA in a given year, and 1.38% received disciplinary actions in previous years. Therefore, female physicians are less likely to receive DA or prior DA than male physicians. In Column 4, we restrict the sample to physicians who have been visited by drug firms at least once during our sample period. The percentage of DA or prior DA in Column 4 is slightly higher than that in Column 1. This suggests that physicians with detailing visits are a bit more likely to receive DA or prior DA, or that drug firms may be slightly more likely to visit physicians with DA or prior DA than those without. However, this difference seems to be small, and it may only indicate a simple correlation. The next section explores the relationship between prior DA and detailing in more detail.

2.3 Disciplinary Actions and Market Punishment

Physicians with misconduct are directly punished by the Medical Board or other systems such as courts and hospitals that issue disciplinary actions to these physicians once their misconduct is verified and appropriate disciplinary actions are determined. The consequences of some of DAs appear to be evident. For instance, revocation of a license permanently removes all benefits associated with physicians at least in principle, while suspension temporarily does so, and other types of DAs such as restrictions could partially remove those benefits.

Nevertheless, DAs may not necessarily punish physicians with misconduct, because physicians may be able to circumvent direct punishment from their DAs. For example, some physicians with their licenses revoked can even regain their full benefits by

obtaining licenses from other states. On the other hand, punishment from DAs may not necessarily be confined to warnings or restrictions on medical practice. Note that physicians typically interact with multiple market participants such as other physicians, patients, or drug firms. Therefore, these other parties can provide additional punishment, if they change their interactions with physicians who received DAs.

Three market outcomes may result from DAs. First, market participants may avoid interacting with physicians with DAs. For example, drug firms may stop paying physicians who received DAs, or patients may stop visiting those physicians. In this case, DAs can lead to market punishment. Second, market participants may not respond differently to DAs, in which case the effective punishment of DAs may be significantly constrained, thus resulting in market indifference. Third, some parties with corrupt intent may interact more with physicians with DAs, in which case DAs result in market reward. These market consequences of DAs have different implications, and so it is important to understand the extent of different market outcomes from DAs, as well as underlying mechanisms that lead to more or less market punishment.

Before we examine the effect of DAs on market outcomes in the following sections, this section briefly explores the patterns in the data regarding the difference between physicians with any prior DAs and those without, in terms of their interactions with drug firms. We examine these interactions because they reflect market punishment (or indifference or reward) for physicians to whom DAs have been issued.

In Table 2.4, we consider detailing payments and visits by drug firms, using the Open Payments dataset matched with our data on DAs in the MBC. In this table, we use only physicians who are observed in Open Payments, that is, those who received at least one visit by a drug firm in a given year. These physician-year observations account for about 45% of active physicians in California between 2014 and 2018,

which is consistent with Marshall et al. (2020), who show that 52 percent of eligible physicians receives at least one payment in 2014, and this percentage declines to 45 percent in 2018. Thus, the proportion of physicians that receive payments in California is similar to the proportion of physicians that receive payments overall in the US.

The table reports the mean and median of payment amount (Panel A.1) and the number of visits (Panel A.2) between those with prior DA and those without. We consider three types of detailing: all types that combine all different purposes of visits; food-related visits; payments for consulting or speaking. Comparing those with prior DA and those without, we do not find any strong pattern on whether drug firms interact more or less with physicians who previously received DAs. For example, physicians with prior DAs receive \$2,925 (or \$15,134) on average for all types (or speaking/consulting), which is much less than \$5,363 (or \$22,760) received by those without prior DAs. In contrast, the average food payment or the average number of visits for all types or food is higher for those with prior DAs than those without. Moreover, this pattern does not seem to be fully consistent with the pattern from the medians.

For two reasons, however, we cannot use the patterns in Table 2.4 to infer any effect of prior DAs on market punishment. First, one main channel for market participants to punish physicians with prior DAs is to discontinue their interactions. This means that drug firms do not visit or pay those physicians, but such punishment cannot be observed in Table 2.4 which uses only physicians with positive detailing payments. Second, physicians are considerably heterogeneous, and so any positive or negative (or no) correlations between prior DAs and detailing payments may simply reflect unobserved physician heterogeneity. The next section provides further discussion on these two issues and our empirical strategy.

2.4 Empirical Strategy

To estimate the effect of prior disciplinary actions on market consequences, our basic empirical strategy is to compare physicians with prior DAs and comparable physicians without any prior DAs. We focus on the effect of prior DAs, as opposed to the flow of current DAs, for three reasons. First, market participants are more likely to respond to DAs after they were issued rather than before they are issued. Second, we cannot observe exactly when each market participant becomes aware of a physician's DA. Some market participants such as other physicians may know even the upcoming DAs of their colleagues in advance, but many of them may not learn about DAs until long after DAs were issued. Third, DAs may have a long-term effect because market participants may take into account not only recent DAs but also past DAs.

If we can assume that each market participant's responses are observed for all physicians and they are determined exogenously to the factors that led to prior DAs, we can use the following regression to estimate the effect of prior DAs:

$$y_{ijt} = \beta \mathsf{Prior\ DA}_{it} + X_{ijt}\gamma + \epsilon_{ijt}, \tag{2.1}$$

where y_{ijt} is physician i's market outcome determined by market participant j in period t, $\mathsf{prior\ DA}_{it}$ is the dummy variable for whether physician i has received any disciplinary action before period t, X_{ijt} is a vector of control variables, including physician i's characteristics, and ϵ_{ijt} is the idiosyncratic error term. The coefficient β measures the average effect of prior DAs.

However, the assumptions behind (2.1) may not hold due to the following two identification issues. The first issue is that we may not observe all market par-

ticipants' responses. For physician-firm interactions, the Open Payments dataset includes detailing information only if a physician receives a drug firm's visit. For other interactions, we only observe aggregated outcomes for each physician (e.g., the number of patients instead of each patient's response). Of course, we can also assume that if market participant j's response is not observed in our data, y_{ijt} is simply zero. However, not all zero responses are the same. Drug firms may not interact with physician i, either because they respond to physician i's prior DA by discontinuing their interactions or because they never consider interacting with physician i. Hence, we need to set $y_{ijt} = 0$ only for physician i that drug firm j considers for detailing.

The second issue is that the factors that led to prior DAs may not be exogenous to y_{ijt}. There are two concerns. First, prior DAs may be caused by future market outcomes. This may occur if physicians intentionally commit misconduct to receive better market outcomes in the future. Though this is not normally plausible, one likely cause is that physicians may overprescribe to receive more detailing payments, which also increases the chance to receive DAs. This case will be a concern if both DA and detailing are determined simultaneously, but in our setting, prior DAs always precede y_{ijt}.

Second, prior DAs may result from unobserved heterogeneity in physicians and market participants. For example, some physicians with unobserved high skills will attract more patients as well as more visits from drug firms that target such physicians. However, these physicians' frequent interactions with diverse patients are likely to lead to more complaints and thus more DAs. This example suggests that unobserved physician heterogeneity can also explain why some physicians may be repeated offenders and why some physicians with prior DAs may receive more or less detailing payments.

To address these issues, we use the following approaches. The first issue above

would be resolved if we observed drug firm j's "consideration set" of physicians whom it considers for detailing. Some physicians with prior DAs may not receive any visit and payment simply because drug firms never consider them for detailing, regardless of DAs. We can easily rule out such cases by using only observations of physicians within each firm's consideration set. Since we do not directly observe such consideration sets, our approach is to approximate firm j's consideration set by using only physicians whom firm j has visited in any year during our sample period. Because firm j's consideration set for food detailing may be different from its consideration set for speaking/consulting detailing, we construct firm j's consideration set separately for different detailing types.

To address the second identification issue, we need to control for unobserved heterogeneity in physicians and drug firms. To the extent that such unobserved heterogeneity does not change over time for most physicians and firms, we can account for this issue by using physician-firm specific fixed effects. Specifically, we use the following regression:

$$y_{ijt} = \beta \mathsf{Prior\ DA}_{it} + \delta_{ij} + \eta_t + \epsilon_{ijt}, \tag{2.2}$$

where δ_{ij} is physician-firm fixed effects, and η_t is time fixed effects.

Nevertheless, physician-firm fixed effects may not fully address two potential concerns as follows. One is that unobserved heterogeneity may be time-varying. Given our current data, we cannot account for this concern, but we do not expect this concern to be critical since our sample period is rather short. The other concern is that even after controlling for physician-firm fixed effects, physicians with prior DAs may still not be comparable to those without. Ideally, we would like the "treatment group" to be similar to the "control group" at least before the "treatment" of prior

DA, which is similar to a difference-in-differences setting. However, DAs can be issued to physicians in any period, and prior DAs include not only DAs issued last year, but also those issued in any previous years. Nevertheless, we can modify our data to resemble the difference-in-differences setting as follows.

We first use physicians whose prior $\text{DA}_{it} = 1$ only in 2017-2018. Thus, these physicians did not receive any DA until 2016 or 2017. We consider their prior DA as the "treatment", and these physicians belong to our "treatment group". For the "control group", we use physicians who never receive any DA in any year. Without physician-firm fixed effects, it is not surprising that our treatment group is not comparable to our control group. The question is whether they can become comparable once we include physician-firm fixed effects. This question is explored in Table 2.5.

Panel A of the table reports the coefficient estimates on the interaction terms between year dummies and the dummy for the treatment group. Note that the default year is 2013 in this table, because we additionally use 6 months in 2013, the earliest released data from Open Payments, so that we can examine one more year before the treatment in 2017-2018. The table shows that the coefficient estimates are small and statistically indistinguishable from zero for the period before the treatment. This result suggests that the treatment group is comparable to the control group before the treatment. Therefore, our estimates on prior DAs reported in Panel B are likely to reflect the causal effect of prior DAs on market outcomes. Though an ideal difference-in-differences setting does not directly apply to our full data, the results in Table 2.5 suggest that our estimates on prior DAs presented in the next section can still be interpreted similarly as difference-in-differences estimates.

2.5 Market Consequences of Disciplinary Actions

2.5.1 The Extent of Market Punishment

Table 2.6 reports the coefficient β in (2.1) for different measures of interactions between physicians and pharmaceutical firms. Panel A uses our main sample that includes only active physicians with active NPIs and excludes those if they are currently under probation, or their licenses are suspended or revoked in a given year. In Panel A (Column 1), the dependent variable (denoted 'Visit') is a dummy that takes the value 1 if firm j visited physician i. The coefficient indicates that physicians are 2.87 percent less likely to be visited by a pharmaceutical representative when they have prior disciplinary actions. In Panel A (Column 2), the dependent variable (denoted 'Payment') is $\log(\text{Payment}_{ijt} + 1)$, where Payment_{ijt} is the total amount that firm j pays to physician i in year t. The table shows that physicians are less likely to be visited by a pharmaceutical representative when they have prior disciplinary actions. The coefficient implies that payments to physicians with prior disciplinary actions are 9.66 percent lower than payments to physicians without prior disciplinary actions. In Panel A for Columns 1 and 2, we create firm-specific consideration sets. We assume that any physician who receives a payment from firm j at any point in our sample is a valid target to receive payments from firm j at any year t. In Panel A (Column 3), the dependent variable is also 'Payment' but we consider only physicians who received positive payments, which is informative to understand whether the payment reduction reported in Column 2 is due to a smaller positive payment or no payment at all. We find no significant effect of prior disciplinary actions on payments, conditional on receiving payment. In other words, the result in Column 2 reflects that the impact of prior disciplinary actions is to prevent payments to some

physicians rather than reduce the amount paid. In comparison, Panel B uses the sample that excludes those currently under probation but includes those suspended or revoked in a given year or in the past. The results in panel B suggest that the estimated coefficients are bigger when we include physicians with suspended and revoked disciplinary actions.

2.5.2 Heterogeneous Punishment and Potential Mechanisms

We decompose our results into a number of dimensions to provide a heterogeneity analysis. For all our results, we drop inactive physicians. The reason is that inactive physicians cannot practice, so they are technically not physicians anymore.

Table 2.7 decomposes the impact of prior disciplinary actions by the type of payment. Food payments occur when a representative of a pharmaceutical firm meets with physicians to talk about the firms' drugs. Speaking/consulting payments occur when a physician receives compensation for services on behalf of the firm (e.g., promoting a drug during a conference). On average, food payments are smaller, more frequent, and given to more physicians than consulting/speaking payments. In Table 2.7, columns 1 to 3 (columns 4 to 6) report the impact of prior disciplinary action on food (speaking/consulting) payments on active physicians. The estimates suggest that pharmaceutical firms are less likely to approach physicians with prior disciplinary actions in terms of food payments. The coefficient implies that food payments (visit related to food payments) to physicians with prior disciplinary actions are 11.92 (3.33) percent lower than food payments(visit related to food payments) to physicians without prior disciplinary actions. One of the explanations is that food payments are informative about drugs and related to prescription behavior of the physicians suggested by Carey, Lieber and Miller (2020). Thus, a physician with

prior disciplinary actions might become less 'active' in terms of practice so that less responsive to food payments as an 'investment' in the eyes of pharmaceuticals. Furthermore, Column 5 shows that the coefficient is statistically zero; there is no difference between physicians with or without disciplinary actions for the pharmaceuticals when the relationship is defined by speaking/consulting perspective. The estimates in Column 6 suggest that pharmaceuticals reduce speaking/consulting payments to physicians with at least one prior disciplinary action by 58 percent.

Table 2.8 decomposes these results by the issuer of the disciplinary action. Some disciplinary actions are triggered by court decisions (e.g., criminal conduct), and some are triggered by decisions by peers at the medical board (e.g., professional negligence). The table shows that the impact of a court decision on food payments is much severe than a decision by the medical board. On the other hand, the impact of court decisions on speaking/consulting payments is less precisely estimated. This suggests that pharmaceutical companies do not respond to disciplinary actions in terms of payments, so the relationship between pharmaceuticals and physicians is established stronger with speaking/consulting payments than food payments regardless of the issuer of the disciplinary action.

Table 2.9 decomposes these results by the number of prior disciplinary actions. The estimates in Columns 1 and 2 show that the main impact in terms of food payment is driven by prior disciplinary action rather than first disciplinary action. In other words, the estimate shows that first and multiple offenders have been punished more or less the same for food payments but a lot less for speaking/consulting payments. One explanation is that the relationship between physicians and firms is closer when speaking/consulting payments are involved, and breaking this relationship is costly. Therefore, the firm is willing to overlook a first disciplinary action compared.

Table 2.10 reports the impact of an accusation that has not yet been granted disci-

plinary action. Accusations have almost no impact on food payments, but they have a big impact on speaking/consulting payments. The estimates for speaking/consulting payments suggest that accusation towards a physician leads pharmaceuticals to reduce the payments by 86 percent even without DA.

Table 2.11 reports the impact of disciplinary action and gender on pharmaceutical payments. The table shows that female physicians receiving speaking/consulting payments are punished slightly more than males. In terms of visits, the coefficient implies that gender has no impact statistically on physicians with prior disciplinary actions.

Table 2.12 reports the impact of disciplinary action on pharmaceutical payments according to whether a physician is registered to Medicare. The coefficient implies that food payments (visit related to food payments) to physicians not registered on Medicare with prior disciplinary actions are 12 (3.29) percent lower than food payments (visit related to food payments) to physicians without prior disciplinary actions. Column 4-6 suggests that Physicians not registered on Medicare are not punished by a prior disciplinary action when receiving speaking/consulting payments. Physicians registered in Medicare part D who have prior disciplinary actions receive similar food payments with physicians not registered on Medicare part D but lower speaking/consulting payments.

Table 2.13 reports the impact of disciplinary action on pharmaceutical payments distinguishing between firms that sell only medical devices. The table shows that these firms do not punish prior disciplinary actions regardless of the payment type. This implies that the interaction between pharmaceuticals and physicians different through medical devices.

Table 2.14 reports the impact of DA on pharmaceutical payments for physicians who receive payment from firms that sell opioids. Physicians with prior disciplinary

actions who are also receiving food payments are punished more severely by firms selling opioids. In contrast, Table 2.15 reports the impact of DA on pharmaceutical payments for physicians who receive payment from firms that are registered in the DEA list. This table suggests that physicians with prior disciplinary actions who are also receiving food payments are punished less severely by firms registered in the DEA list.

2.6 Conclusion

In this paper, we study the impact of disciplinary actions on detailing payments to investigate pharmaceutical-physician interaction. Detailing payments could provide useful information about a pharmaceutical company's product but also nudge physicians to push them to less cost-efficient drugs. We construct a rich panel data by using several databases between 2014 and 2018 for California doctors, which is a good representative of all US in terms of detailing payments. Our data indicates that each year, on average, 0.6 percent of physicians (around 625 physicians) receive disciplinary action by the Medical Board of California.

We show that physicians with prior disciplinary action are 2.87 percent less likely to be visited by a pharmaceutical representative. Payments to physicians are 9.66 percent lower when they have a prior disciplinary action. We argue that pharmaceuticals less likely to interact with a physician received at least a disciplinary action as a "market punishment". By decomposing the type of the payments from pharmaceuticals, we show that the physicians are 3.33 percent less likely to be visited related to food payment when they received disciplinary actions while there is no impact of disciplinary actions in terms of speaking/consulting visits. We explain the results by arguing that pharmaceuticals develop stronger and costly relationships with physi-

cians through speaking/consulting payments. This interaction by food payments is more fragile and located in the center of "investment-return" for pharmaceuticals. We discuss that by "market punishment", physicians receive fewer patients in general due to disciplinary actions. These results could be evidence that pharmaceuticals use detailing payments to promote their products instead of providing information about drugs to physicians. Carey, Lieber and Miller (2020) supports our argument and shows that pharmaceuticals target physicians based on prescription rates.

2.7 Figures and Tables

Table 2.1: Disciplinary Actions for Physicians in California

Variable	Percentage
A. Flow of Disciplinary Action (DA)	
Disciplinary Action (DA)	0.60
Revoked	0.14
DA by CA Medical Board, excluding revoked	0.35
DA by court	0.04
DA by other systems	0.17
Accusation	0.34
B. Stock of Disciplinary Action (DA)	
Prior DA	4.29
Prior revoked	0.83
Prior DA by CA Medical Board, excluding prior revoked	2.74
Prior DA by court	1.28
Prior DA by other systems	0.81
Prior accusation	1.76
Prior accusation w/o prior DA	0.26
Observations	519,197

Notes: An observation is a physician-year combination. Panel A reports the average percentage (by year) for the years 2014 to 2018. Panel B reports the percentages for the pooled data over five years.

Table 2.2: Percentage of Physicians with Disciplinary Actions Over Time

	Cumulative DA	Flow of DA in				
	up to 2013	2014	2015	2016	2017	2018
	(1)	(2)	(3)	(4)	(5)	(6)
DA	4.01	0.58	0.56	0.62	0.65	0.58
Revoked	0.64	0.15	0.09	0.15	0.17	0.13
DA, excluding revoked	3.77	0.48	0.50	0.52	0.54	0.50
Probation (newly issued)	1.22	0.07	0.13	0.12	0.15	0.12
Suspended	0.22	0.04	0.02	0.04	0.01	0.04
Reprimand	0.88	0.07	0.08	0.10	0.10	0.13
Other DA by MB	0.59	0.16	0.12	0.12	0.11	0.06
DA by court	1.29	0.04	0.04	0.04	0.04	0.02
DA by other systems	0.64	0.16	0.14	0.17	0.18	0.18
Currently under probation		0.32	0.38	0.42	0.49	0.53

Notes: The table reports the percentage of physicians with disciplinary actions (DA) among all California physicians in the NPPES. Column 1 is the percentage of physicians with any prior DA before 2014 among all CA physicians in 2014, whereas columns 2-6 report the percentage among all CA physicians in each year. Currently under probation is the percentage of physicians who are identified to be still under probation in a given year, based on their probation periods, even if probation was issued to them in the past. Other DA by MB include all other disciplinary actions issued by CA medical board, thus excluding revocation, probation, suspension, and reprimand. DA by court include malpractice and felony, while DA by other systems include restrictions by hospitals as well as disciplinary actions issued by Medical Boards in other states.

Table 2.3: Disciplinary Actions among Different Physician Groups

	All	Prior DA	Female	Detailing
	(1)	(2)	(3)	(4)
DA	0.28	2.62	0.15	0.33
prior DA	3.08	100.00	1.38	3.33
Observations	512,070	15,753	177,977	231,860

Notes: An observation is a physician-year combination. The data is pooled over the years 2014 to 2018. We only keep physicians that are active, i.e., they have an active NPI and their license allows them to practice. The sample thus excludes physicians who are currently under probation or whose licenses are suspended or revoked in a given year. In addition, all physicians whose licenses were revoked in the past are also excluded. Each row reports the percentage of physicians with either current DA or prior DA. Column 1 includes all active physicians. Column 2 uses only physicians with prior DA. In column 3, we use only female physicians. In column 4, we include only physicians who have received at least one pharmaceutical payment during our sample period.

Table 2.4: Summary Statistics for Physicians Registered in California

	Disciplined Before			Never Disciplined		
	Mean	Median	Obs.	Mean	Median	Obs.
	A. Physician-Firm Interactions					
	A.1. Payments					
All Types ($)	2925	248	7730	5363	211	224130
Food ($)	613	217	7513	513	182	217018
Speaking/Consulting ($)	15134	3000	745	22760	4231	26914
	A.2. Number of Visits					
All Types	26	6	7730	21	5	224130
Food	25	6	7513	19	5	217018
Speaking/Consulting	6	2	745	8	2	26914

Notes: The unit of observation is physician-year. We include only active physicians with active NPIs and exclude physicians if they are currently under probation, or their licenses are suspended or revoked in a given year, or their licenses were revoked in the past. In addition, we use only physicians who received at least one visit by pharmaceutical representatives each year.

Table 2.5: "Difference-in-Differences" Estimates of the First-Time Prior DA in 2017-18

	Physician-Firm		
	Visit dummy	ln(Payment)	ln(Payment)—Visit = 1
	(1)	(2)	(3)
	A. Pre-trend (2014-2016) before "treatments" in 2017-2018		
"Treatment" group × 1{year = 2014}	0.0073	0.0561	0.0419
	(0.0105)	(0.0442)	(0.0465)
"Treatment" group × 1{year = 2015}	0.0130	0.0435	-0.0181
	(0.0129)	(0.0523)	(0.0542)
"Treatment" group × 1{year = 2016}	0.0040	-0.0084	-0.0591
	(0.0138)	(0.0560)	(0.0543)
"Treatment" group × 1{year = 2017}	-0.0299*	-0.1058+	-0.0132
	(0.0138)	(0.0558)	(0.0748)
"Treatment" group × 1{year = 2018}	-0.0346*	-0.1105+	0.0268
	(0.0167)	(0.0661)	(0.0738)
	B. "Difference-in-Differences" Estimates		
Prior DA	-0.0298**	-0.0998*	0.0093
	(0.0106)	(0.0451)	(0.0482)
Year FE	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes
Observations	3457483	3457483	891255
R^2	0.290	0.399	0.745

Notes: The sample excludes physicians whose prior DA is 1 in any year before 2017. The "treatment" group consists of physicians whose prior DA is 0 before 2017 and becomes 1 only in 2017-2018. Panel A presents the coefficient estimates on the interaction terms between year dummies and the dummy for the treatment group. To include one more period before the treatment, we additionally use 6 months in 2013, the earliest released data from Open Payment. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.6: Effect of Prior Disciplinary Actions on Physicians' Interactions

	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)
	Panel A		
prior DA	-0.0287**	-0.0966**	0.0205
	(0.0078)	(0.0328)	(0.0312)
Observations	3008225	3008225	799245
R^2	0.316	0.431	0.759
	Panel B		
prior DA	-0.0855**	-0.3268**	0.0282
	(0.0077)	(0.0323)	(0.0295)
Observations	3021180	3021180	801360
R^2	0.315	0.430	0.759
Year FE	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes

Notes: Panel A uses our main sample that includes only active physicians with active NPIs and excludes those if they are currently under probation, or their licenses are suspended or revoked in a given year, or their licenses were revoked in the past. All subsequent tables also use this main sample of active physicians. In comparison, Panel B uses the sample that excludes those currently under probation, but includes those suspended or revoked in a given year or in the past. In Column 1, Visit is the dummy for whether firm j visited physician i in a given year. In Column 2, ln(Payment) is $\ln(\text{Payment}_{ijt}+1)$, where Payment_{ijt} is the total amount that firm j pays to physician i in year t. Columns 1-2 use all the physicians who are paid by firm j at any point in time in our sample period. In Column 3, the sample includes the observation of physician-firm-year only if the firm visits the physician in that year. Standard errors (in parenthesis) are cluster at the firm level in columns 1 to 3. $^{+}$ $p<0.10$, * $p<0.05$, ** $p<0.01$.

Table 2.7: Effect of Prior Disciplinary Actions on Pharmaceutical Payments

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0333**	-0.1192**	-0.0139	-0.0307	-0.1811	-0.5845+
	(0.0080)	(0.0314)	(0.0326)	(0.0335)	(0.2654)	(0.3487)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,893,529	2,893,529	790,428	145,552	145,552	66,620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes:Columns 1-2 (or 4-5) use all the physicians who are paid by firm j for food (or speaking/consulting) at any point in time in our sample period. Column 3 (or 6) considers the set of physicians who receive a positive food (or speaking/consulting) payment. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.8: Effect of Prior Disciplinary Actions by Issuer

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA, Medical Board	-0.0284**	-0.0994**	0.0306	-0.0000	0.0374	-0.3238
	(0.0094)	(0.0367)	(0.0343)	(0.0407)	(0.3314)	(0.4708)
Prior DA, Court	-0.1178**	-0.4858**	-0.2980	-0.0441	-0.6855	-0.7768
	(0.0231)	(0.1020)	(0.1878)	(0.1319)	(1.1309)	(1.6564)
Prior DA, Other	0.0089	0.0366	-0.0706	-0.0678	-0.3708	-0.5303
	(0.0110)	(0.0435)	(0.0570)	(0.0632)	(0.4633)	(0.7117)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,893,529	2,893,529	790,428	145,552	145,552	66,620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.9: Impact of prior disciplinary actions on pharmaceutical payments: Repeated offenders

	Food Payments			Speaking/Consulting Payments		
	Visits	Payments	Payment—Visit	Visits	Payments	Payment—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0317**	-0.1191**	-0.0135	-0.0731^{+}	-0.5780^{+}	-0.6246
	(0.0102)	(0.0399)	(0.0386)	(0.0430)	(0.3308)	(0.4340)
First DA	-0.0020	0.0036	0.0043	0.0834*	0.7385**	0.0298
	(0.0089)	(0.0358)	(0.0340)	(0.0376)	(0.2803)	(0.4222)
Repeated DA	-0.0096	-0.0398	-0.0820^{+}	-0.0520	-0.1411	0.8853
	(0.0127)	(0.0481)	(0.0485)	(0.0580)	(0.3787)	(0.8471)
N	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: In columns 1 and 4, 'Visit' takes the value 1 if firm j visited physician i and 0 otherwise. In columns 2 and 5, 'Payment' is $\log(\text{Payment}_{ijt} + 1)$, where Payment_{ijt} is the total amount that firm j pays to physician i in year t. Columns 3 and 6 consider the set of physicians who receive a positive payment. All columns include physician-firm and year fixed effects. The sample excludes physicians that are inactive in a given year. Standard errors (in parenthesis) are cluster at the physician-firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$

Table 2.10: Effect of Accusations on Pharmaceutical Payments

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0320**	-0.1200**	-0.0306	-0.0470	-0.3665	-0.8576*
	(0.0091)	(0.0353)	(0.0352)	(0.0357)	(0.2775)	(0.3640)
Accused, no DA yet	0.0045	-0.0028	-0.0573+	-0.0568	-0.6479*	-0.8606+
	(0.0097)	(0.0368)	(0.0325)	(0.0391)	(0.3020)	(0.4805)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.11: Effect of Prior Disciplinary Actions by Gender

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0358**	-0.1259**	-0.0128	-0.0294	-0.1506	-0.5483
	(0.0090)	(0.0346)	(0.0338)	(0.0362)	(0.2867)	(0.3937)
Prior DA×Female	0.0165	0.0436	-0.0096	-0.0223	-0.5274	-0.5369
	(0.0206)	(0.0819)	(0.0874)	(0.1221)	(1.0435)	(2.0347)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.12: Effect of Prior Disciplinary Actions for Medicare Part D Physicians

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0329*	-0.1203*	0.0172	0.1211+	0.8290	1.1919
	(0.0134)	(0.0556)	(0.0906)	(0.0698)	(0.5173)	(0.9248)
Prior DA×Medicare	-0.0001	0.0024	-0.0315	-0.1598**	-1.0628*	-1.8009*
	(0.0118)	(0.0478)	(0.0812)	(0.0612)	(0.4497)	(0.8882)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,893,529	2,893,529	790,428	145,552	145,552	66,620
R^2	0.315	0.408	0.630	0.305	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.13: Effect of Prior DA for Physicians Who Receive Payments from Device Firms

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0449**	-0.1611**	-0.0132	-0.0758+	-0.4495	-0.6668
	(0.0111)	(0.0415)	(0.0343)	(0.0393)	(0.2890)	(0.4318)
Prior DA×Device	0.0472+	0.1693	-0.0040	0.1320+	0.7871	0.2386
	(0.0281)	(0.1165)	(0.1004)	(0.0777)	(0.6345)	(0.7175)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.14: Effect of Prior DA for Physicians Paid by Opioid-selling Firms

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0232*	-0.0849*	-0.0139	-0.0418	-0.2577	-0.6097^{+}
	(0.0100)	(0.0395)	(0.0388)	(0.0350)	(0.2724)	(0.3606)
Prior DA×Opioid	-0.0564	-0.1920	-0.0002	0.1123	0.7804	0.2514
	(0.0370)	(0.1460)	(0.0726)	(0.1161)	(1.0349)	(1.2332)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

Table 2.15: Effect of DA for Physicians Paid by Firms Registered in the DEA

	Food Payments			Speaking/Consulting Payments		
	Visit	ln(Payment)	ln(Payment)—Visit	Visit	ln(Payment)	ln(Payment)—Visit
	(1)	(2)	(3)	(4)	(5)	(6)
Prior DA	-0.0406**	-0.1520**	-0.0204	-0.0319	-0.2311	-0.5959
	(0.0115)	(0.0444)	(0.0375)	(0.0369)	(0.2950)	(0.3913)
Prior DA×DEA	0.0438	0.1952	0.0359	0.0094	0.4128	0.0963
	(0.0550)	(0.1881)	(0.1243)	(0.0951)	(0.5732)	(0.5577)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Physician-Firm FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2893529	2893529	790428	145552	145552	66620
R^2	0.315	0.407	0.630	0.304	0.410	0.535

Notes: See Table 2.7 for the definition of the dependent variables in the table. Standard errors (in parenthesis) are cluster at the firm level. $^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$.

CHAPTER 3

PRODUCT HOPPING AND INNOVATION INCENTIVES

Pharmaceutical firms rely on patents to recoup R&D investments.[1] A simplistic view of pharmaceutical innovation is the following: an inventor (a "brand" firm) patents a new drug and gets monopoly profits until the patent expires, which is when generic competitors can enter. In reality, the pharmaceutical industry is embedded in a complex regulatory landscape that firms navigate using creative business strategies, some of which have prompted antitrust scrutiny.[2] In particular, "product hopping" is a strategy that consists on switching consumers from one drug to an almost-identical one. In this strategy, a brand firm patents a minor modification of an original drug (e.g., a new delivery method). Then, it invests in marketing to divert demand from the original drug to the minor modification, shortly before the patent of the original drug expires. Finally, when the patent of the original drug expires and generics are allowed to enter the market, demand has switched from the original drug to the minor modification. This paper presents a framework to study the effect of product hopping on R&D investments and on competition, and we assess the welfare consequences of this practice.

Product hopping grants large rewards to marginal improvements, in contrast to

[0] Jointly with Jorge Lemus

[1] DiMasi, Grabowski and Hansen (2016) estimates the cost of developing a drug to be above $2 billion.

[2] Strategies include pay-for-delay settlements (e.g., FTC v. Actavis, 2012), or transferring patents to an American Indian tribe to get sovereign immunity (Dyer, 2017). See Jones et al. (2016).

the premise that innovators should be rewarded according to the social value of their innovation (e.g, O'donoghue, Scotchmer and Thisse, 1998; Hopenhayn, Llobet and Mitchell, 2006). This is enabled by two distinct features of the prescription drug market: the limited discretion of consumers and the generic-substitution laws. First, when buying prescription drugs, consumers rely on a doctor's prescription (Carrier and Shadowen, 2016); doctors, who do not pay for the drugs, are routinely "detailed" by pharmaceutical companies to prescribe their drugs.[3] Second, generic-substitution laws may prevent competition between two almost-identical products. If drug B is a minor modification of drug A, generic-substitution laws do not permit to substitute drug B by a generic version of drug A (Song and Barthold, 2018). Exploiting these frictions, a brand firm can divert demand from drug A (patent soon to expire) to drug B (recently patented) by coaxing physicians through marketing, even when drugs A and B are almost identical.

An example of product hopping is the case of Prilosec and Nexium, two drugs sold by AstraZeneca and used to treat severe stomach-acid-related conditions.[4] In 2001, a few months before Prilosec's patent expired, AstraZeneca introduced Nexium. After intense marketing efforts, a large fraction of Prilosec patients switched to Nexium. AstraZeneca was accused of exclusionary conduct by "introducing Nexium, a drug virtually identical to and no more effective than Prilosec," and by "switching the market from Prilosec, which now has generic competition, to a virtually identical drug, Nexium, which does not [have generic competition.]."[5] U.S. courts argue this was not an antitrust offense—they argued that generics are free to compete with the

[3]"Detailing" is a marketing effort to persuade physicians by sending company representatives to their offices, giving them free samples, meals, travels, or consultancy fees. On average, pharmaceutical companies expend over $20,000 annually per physician (Datta and Dave, 2017).

[4]For more details, see, e.g., Feldman and Frondorf (2016) or Jain and Conley (2014) (Chapter 8).

[5]Walgreen Co. vs Astrazeneca Pharmaceuticals L.P. 534 F. Supp. 2d 146 (D.D.C. 2008)

off-patent product (Prilosec) and it was not an antitrust offense to advertise a new product—whereas the European Union fined AstraZeneca for abusing its dominant position (Vandenborre, York and Frese, 2014). Additionally, recent product hopping cases include Abbott reformulating TriCor (a drug used to lower triglyceride) from capsules to tablets;[6] Reckitt switching Suboxone (a drug to treat opiod addiction) from a sublingual tablet to a sublingual film;[7] Warner Chilcott switching Doryx (an acne medication) from tablets to capsules;[8] Actavis and Forest Laboratories switching Nameda (an Alzheimer's drug) from an immediate release to an extended release formulation.[9]

Despite the prominence of the product hopping, the antitrust and welfare implications of this practice remain unclear. Product hopping is troublesome for at least three reasons. First, it may point innovation efforts towards marginal improvements rather than radical innovation. Second, consumers end up paying high prices for a drug almost identical to an old version now off-patent.[10] Third, firms waste resources persuading doctors to prescribe less cost-effective drugs—in 2013, the 10 biggest pharmaceutical companies spent 98.4 billion in marketing and only 65.8 billion in R&D.[11] On the other hand, pharmaceutical firms argue that minor modifications, such as switching from a pill to a capsule, are valuable for consumers.[12]

[6]Abbott Laboratories v. Teva Pharmaceuticals, 432 F. Supp. 2d 408 (D. Del. 2006).

[7]In Re: Suboxone Antitrust Litigation (201., 64 F. Supp. 3d 665, 681-83 (E.D. Pa. 2014)

[8]Mylan Pharmaceuticals v. Warner Chilcott, No. 12-3824 (E.D. Pa. June 13, 2013).

[9]New York ex rel. Schneiderman v. Actavis PLC (Namenda), 787 F.3d 638 (2d Cir. 2015)

[10]Arcidiacono et al. (2013) show that removing minor modifications reduces insurance payments by over $7 billion annually, and brand firm profits by more than $4 billion. See also Angell (2004).

[11]"Big pharmaceutical companies are spending far more on marketing than research," by Ana Swanson, published by the Washington Post on 2/11/2015, available at: `https://wapo.st/2RWkAkY` (Visited on 10/18/2018). See also Lexchin (2018). Additionally, switching is persistent: around 15 percent of consumers switched from drug A to drug B switch back to drug A when a generic becomes available. See https://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/.

[12]Bokhari and Fournier (2013) show that for AHDH drugs minor modifications could benefit

We present a model to shed light on the welfare effects of product hopping. We show that conditions under which product hopping *increases* equilibrium R&D investments, by increasing the value of incumbency at the expense of an ex post consumer-welfare loss. Similar to Segal and Whinston (2007), we show that policies favoring an incumbent may have ambiguous effects on the rate of innovation. In our model, product hopping allows the incumbent to suppresses generic competition and it affects the entrant's innovation incentives, i.e., product hopping works as form of strategic entry deterrence (Gilbert and Newbery, 1982).[13]

We assume that only the incumbent can engage in product hopping. There are a number of reasons why incumbents have an advantage to introduce minor modifications. First, developing and patenting a minor modification may be more costly for an entrant because of the lack of experience. Second, the incumbent would likely sue for patent infringement an entrant selling a minor modification before the expiration of the first product's patent (Gans and Stern, 2000). This litigation risk may also force the entrant to begin the marketing of the minor modification only *after* the patent for the original drug has expired. At this point, it may be hard to switch consumers from a generic version of the original drug to the minor modification.[14] In contrast, when the incumbent develops the minor modification it benefits from previous experience, no litigation threats, and the freedom to introduce the minor modification before the expiration of the patent of the original product. Thus, product hopping creates an asymmetry between the incumbent and the entrant.

consumers.

[13]In Gilbert and Newbery (1982), a monopolist that is threatened by an entrant with a new technology has incentives to preempt it by developing the new technology itself, as long as the efficiency industry condition holds—the monopoly profit when the monopolists sells the old and the new product is higher than total industry profits when the entrant sells the new product.

[14]Incumbents usually switch demand *before* the original drug's patent expires by increasing the price of the original drug (or taking it off the market), apart from investing in marketing.

Our setting captures some of the salient features of product hopping. At $t = 1$, several firms compete to discover and patent product $\mathcal{O}$. The winner of this R&D competition becomes the incumbent (the brand firm) and obtains monopoly profits until $\mathcal{O}$'s patent expires. By paying a cost $K \geq 0$, the incumbent can engage in product hopping whereby (1) develops and patent product $\mathcal{H}$; and (2) persuade physicians and consumers through marketing to buy product $\mathcal{H}$ instead of $\mathcal{O}$ or any of $\mathcal{O}$'s generic versions. At $t = 2$, there is a new R&D race between the incumbent and an entrant to develop and patent product $\mathcal{I}$, which is a radical innovation relative to product $\mathcal{O}$ (or product $\mathcal{H}$). Figure 3.1 summarizes the timing of our model.

Product hopping changes the competition landscape at $t = 2$ by putting product $\mathcal{H}$ in the market and removing product $\mathcal{O}$ and its generic versions. This change in competition landscape affects R&D incentives at period 2. Without product hopping, the winner of the R&D race will face competition from product $\mathcal{O}$ and $\mathcal{O}$'s generic versions, sold at marginal cost. With product hopping there are two scenarios, depending on the identity of the winner of the second innovation race. If the incumbent is the winner, it becomes a multi-product firm that can sell both $\mathcal{H}$ and $\mathcal{I}$. If the entrant is the winner, then the incumbent offers $\mathcal{H}$ and the entrant offers $\mathcal{I}$. Depending of the strength of competition (substitution) between $\mathcal{I}$ and $\mathcal{H}$ the entrant's (incumbent's) incentives to invest in R&D may increase/decrease relative to the case of no product hopping. Proposition 2 characterizes the conditions under which product hopping increases for total R&D investments at $t = 2$.

The option of product hopping will be exerted by the incumbent when the introduction of product $\mathcal{H}$ gives it a sufficient advantage in the second R&D race. This is, the expected payoff of the incumbent under product hopping must increase by more than cost K of exerting this option. Whether or not the incumbent engages in product hopping will affect the expected continuation value of winning the first

R&D race. We show that equilibrium R&D investments can increase or decrease at $t = 1$. In Proposition 4, we characterizes the conditions under which product hopping increases total R&D investments at $t = 1$.

The main message from our results is that banning product hopping without further intervention may reduce welfare. There are several elements to consider when studying the effect of product hopping on consumer welfare. One important aspect is whether product $\mathcal{H}$ offers any therapeutic benefit over product $\mathcal{O}$. If not, there are at least two clear negative aspects of product hopping: (1) the wasteful marketing spending to persuade physician to switch consumers to a less cost-efficient drug; (2) the reduction in consumer surplus from buying a less cost-efficient drug. The only positive aspect of product hopping in this case is the potential boost on equilibrium R&D investments. If this is the only reason why product hopping should be allowed, it is a bad reason. There are other mechanisms more efficient than product hopping to encourage innovation. The literature on the optimal patent length and breadth advocates for a heterogeneous reward system—based on the innovation's incremental social value.[15] Product hopping bypasses the uniformity of the patent system by enabling an endogenous reward to incumbents. A system where product hopping is banned and firms receive subsidies or patent extensions for pioneer drugs, or drugs that sufficiently improve the current state of the art, for example, can mimic the effect of product hopping on innovation incentives but avoids wasteful marketing investments and reduction of consumer surplus in the second period.

Various policies could effectively ban of product hopping. One alternative is to tighten patentability standards, to make minor modifications ineligible for patent protection. For instance, India modified its patent law in 2005 and required firms

[15] E.g., Gilbert and Shapiro (1990); Denicolo (1996); O'donoghue, Scotchmer and Thisse (1998); Denicolo (1999); Hopenhayn, Llobet and Mitchell (2006).

to provide clinical evidence of an increase in efficacy of the new drug relative to the current available ones.[16] A second alternative is to monitor and limit firms' marketing efforts. The U.S. already monitors financial relationships between the pharmaceutical companies drug and physicians (and hospitals), so a policy could cap marketing spending. A third alternative is to broaden the definition of "generic equivalents," so pharmacists can substitute a minor modification by a generic version of the original drug.[17] Finally, insurers could only reimburse minor modifications with a clear benefit for consumers.

Related Literature. Most of the legal antitrust literature discusses product hopping from an ex post welfare perspective, ignoring ex ante R&D investments. Carlton, Flyer and Shefi (2016) suggest that product hopping is a regulatory problem associated to the Hatch-Waxman Act and should not be remedied by antitrust laws. Miller (2016) concludes that product hopping is not anticompetitive under the current U.S. antitrust laws, and argues that banning it would deter innovative reformulations. Noah (2015) argues that antitrust laws did not apply to the product hopping case of OxyContin/OxiContin-OP. In contrast, Carrier and Shadowen (2016) propose an antitrust analysis of product hopping under price disconnection—doctors who prescribe drugs are not paying for them, and consumers who pay for them are not choosing them. Shadowen, Leffler and Lukens (2009) evaluate the extent of product hopping empirically finding that some reformulations are not used to block generic entry. Burke (2018) claims that the anti-competitive harm of product hopping outweighs the minor benefit of a reformulation. Fielding (2016) discusses

[16]Novartis' patent application for the cancer drug Glivec was rejected under this law (Liu, 2015).

[17]In the U.S. a pharmacist can only substitute "AB-rated" generic versions of the brand drug, i.e., the generic drug must be bio-equivalent (i.e., absorbed into the body at the same rate) and therapeutically equivalent (i.e., it has the same active ingredient, form, dosage, strength, and safety and efficacy profile) to the original brand drug (Carrier and Shadowen, 2016).

the court's finding of anticompetitive conduct in the product hopping case Nameda-IR/Nameda-XR. Iyengar (2015) also examines this case and proposes a framework to evaluate under what conditions product hopping should be subject to antitrust liability.

Product hopping, and more broadly "evergreenning" practices, have been studied empirically. Huskamp et al. (2008) show that marketing efforts shift sharply from an original drug to a reformulation, for a class of antidepressants. Other articles exploring the effect on marketing on prescription of drugs include Grennan et al. (2018), Shapiro (2018), Chernew et al. (2018), Feldman (2018), Castanheira et al. (2019), Carey, Lieber and Miller (2020), among others. Daidoji, Yasukawa and Kano (2013) find that an incumbent's effective patent length after considering reformulation patents is beyond the 20 years, especially for oral formulations. Hemphill and Sampat (2012) show that patent validity challenges are more common for higher sales drugs, and for low quality patents for minor modifications. Huckfeldt and Knittel (2011) documents the substitution between a drug and its reformulations after generic entry.

Advertising as barrier to entry has been examined by Salop (1979), Schmalensee (1983), and Fudenberg and Tirole (1984), among others. More recently, and focusing on the pharmaceutical industry, Morton (2000) shows that advertising is not a barrier to entry for generics. Using a different methodology, Ellison and Ellison (2011) do not find strong evidence of entry deterrence. Dave (2013) studies the effect of advertising to consumers versus advertising to physicians and finds that advertising to physicians increases the demand for the brand, but it does not strongly deter entry. Empirical work should define products carefully, because the endogenous demand shift from the original drug to the minor modification, as a consequence of product hopping, could misrepresent the level of advertising on different products.

3.1 Model

There are two innovators and generic drug manufacturers. There are two stages. At stage $t = 1$, the two innovators are symmetric and compete by invest in R&D to be the first to patent drug $\mathcal{O}$. The winner of this R&D race becomes the incumbent (the brand firm) and obtains monopoly profits π^m until the patent of product $\mathcal{O}$ expires at $t = 2$.[18] Anticipating the expiration of product $\mathcal{O}$'s patent, the incumbent can engage in *product hopping*, whereby the incumbent commit resources ($K \geq 0$) to develop, patent, and promote product $\mathcal{H}$, which is a minor modification of product $\mathcal{O}$. Only the incumbent can develop and promote this marginal improvement. This advantage over the entrant can be justified from learning-by-doing, no-infringement risk, and it is also often the case empirically. When the incumbent engages in product hopping, product $\mathcal{H}$ takes over product $\mathcal{O}$'s market, effectively foreclosing the entry of generic versions of $\mathcal{O}$. Regulatory frictions—marketing, efforts to persuade physicians to prescribe $\mathcal{H}$ rather than $\mathcal{O}$ or one of $\mathcal{O}$'s generic versions, generic substitution laws, and patentability standards—allow the incumbent to engage in product hopping and to divert the demand from product $\mathcal{O}$ and its generics towards product $\mathcal{H}$.

At stage $t = 2$, when the patent of the original product $\mathcal{O}$ expires, free entry of generic drug manufacturers drive the profit of product $\mathcal{O}$ to zero. At this point, the incumbent and the entrant compete in a new innovation race to develop and patent product $\mathcal{I}$, which is *radical innovation* relative to product $\mathcal{O}$. The market structure at $t = 2$ depends on whether the incumbent engaged in product hopping right before the expiration of product $\mathcal{O}$'s patent. If the incumbent does not engage in product hopping, then the market consist of product $\mathcal{I}$, sold by the winner of the second R&D race, and product $\mathcal{O}$ and its generics. We denote by π_I^0 the equilibrium profit

[18] For the sake of exposition, we assume the patents are ironclad.

of a firm that offers product $\mathcal{I}$. If the incumbent engaged in product hopping, then product $\mathcal{O}$ and its generics are excluded from the market. There are two different scenarios. First, if the incumbent wins the innovation race at $t = 2$, then it becomes a multi-product firm offering both products $\mathcal{H}$ and $\mathcal{I}$. Let π be the incumbent's profit when it offers both $\mathcal{H}$ and $\mathcal{I}$, which internalizes the price externalities from offering both products. Second, if the entrant wins the innovation race at $t = 2$, then the incumbent offers $\mathcal{H}$ and competes with the entrant that offers $\mathcal{I}$. Let π_H and π_I be the profit of selling product $\mathcal{H}$ and product $\mathcal{I}$, respectively, when $\mathcal{I}$ is offered by the entrant and $\mathcal{H}$ is offered by the incumbent. As in Gilbert and Newbery (1982), we assume that a multi-product monopolist generates higher profits than competing firms, i.e., $\pi \geq \pi_I + \pi_H$. Figure 3.1 illustrates the timing of the model, showing how the market structure is affected by the decision of the incumbent to engage in product hopping before the second R&D race.

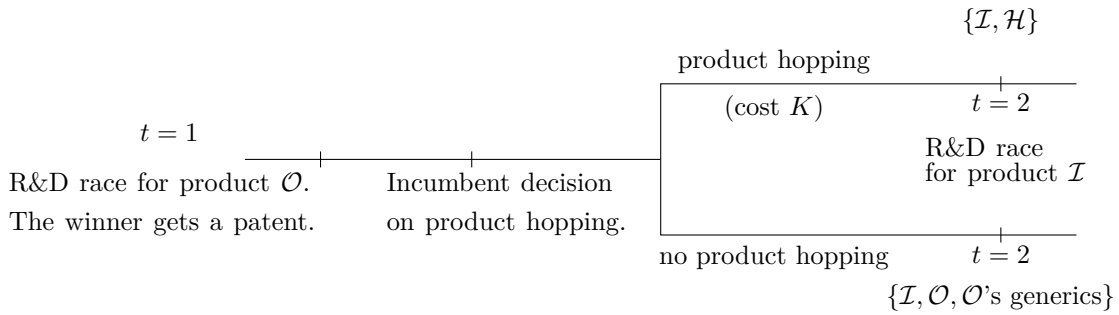


Figure 3.1: Timing of the events in the model.

Product hopping not only affects the market structure at period 2, but also the incentives to invest in R&D in the competition for product $\mathcal{I}$. Without product hopping, the second innovation race is symmetric, i.e., the incumbent's and the entrant's incentives to invest in R&D are the same. Under product hopping, however, incentives to invest in R&D are asymmetric: product $\mathcal{H}$ is the outside option of

the incumbent. Additionally, product hopping distort the incentives of the entrant, because now it will compete against product $\mathcal{H}$ sold at a positive price, rather than product $\mathcal{O}$ an its generics sold at price of zero.

Note that $\pi_I^0 \leq \pi$ because the incumbent can do better when it sells both $\mathcal{H}$ and $\mathcal{I}$ rather when it sells $\mathcal{I}$ in competition with $\mathcal{O}$ (sold at a price of zero). The comparison between π_I and π_I^0 is ambiguous and depends on the additional therapeutic value of $\mathcal{H}$ relative to $\mathcal{O}$. We have $\pi_I^0 < \pi_I$ when the consumers value products $\mathcal{H}$ and $\mathcal{O}$ equally. In this case, competition between product $\mathcal{I}$ and $\mathcal{O}$ (and $\mathcal{O}$'s generic versions) is stronger than competition between $\mathcal{I}$ and $\mathcal{H}$. We have $\pi_I^0 \geq \pi^I$ when product $\mathcal{H}$ offers higher therapeutic value to consumers than product $\mathcal{O}$, and therefore competition between $\mathcal{H}$ and $\mathcal{I}$ may be stronger than the competition between $\mathcal{I}$ and $\mathcal{O}$ (and $\mathcal{O}$'s generic versions).

We solve the model by backward induction starting from the R&D race at stage $t = 2$, conditional on the incumbent having engaged in product hopping or not. We then determine whether it is optimal for the incumbent to engage in product hopping. Finally, we study the R&D race at stage $t = 1$.

3.1.1 Stage 2: R&D Race for Product $\mathcal{I}$ (Radical Innovation)

We first consider the case where the incumbent engaged in product hopping. In this case, the demand for product $\mathcal{O}$ and $\mathcal{O}$'s generics is diverted to product $\mathcal{H}$. The incumbent chooses its R&D investment to solve

$$\max_{x \geq 0} \frac{x}{x+y}\pi + \frac{y}{x+y}\pi_H - x, \tag{3.1}$$

where y is the R&D investment of the entrant. Similarly, the the entrant solves

$$\max_{y \geq 0} \frac{y}{x+y} \pi_I - y. \tag{3.2}$$

In Equation 3.1, the incumbent obtains π from winning the R&D race, which happens with probability $\frac{x}{x+y}$, and π_H from losing it. In Equation 3.2 the entrant gets π_I from winning the innovation race and zero from losing it.

Lemma 1. *The equilibrium level of R&D for the incumbent (x^*) and the entrant (y^*) in the R&D race at $t = 2$ is given by*

$$x^* = \frac{\pi_I}{(1+\gamma)^2}, \quad \textit{and} \quad y^* = \gamma x^*, \quad \textit{where} \quad \gamma = \left(\frac{\pi_I}{\pi - \pi_H} \right).$$

Proof. The first order conditions imply $\dfrac{(\pi - \pi_H) y^*}{(x^* + y^*)^2} = 1$ and $\dfrac{\pi_I x^*}{(x^* + y^*)^2} = 1$. Solving these equations we obtain the result. □

Note that $\gamma \leq 1$ because of the industry efficiency assumption (Gilbert and Newbery, 1982). This implies that the incumbent invests more than the entrant, so the incumbent is more likely to win the second R&D race.

Next, consider the case where the incumbent does not engage in product hopping. Then, the incumbent does not develop product $\mathcal{H}$, and therefore does not have an advantage over the entrant in the R&D race at $t = 2$. Thus, incumbent and the entrant have symmetric incentives to invest in R&D and each firm solve

$$\max_{\hat{x}_i \geq 0} \frac{\hat{x}_i}{\hat{x}_i + \hat{x}_{-i}} \pi_I^0 - \hat{x}_i. \tag{3.3}$$

It is easy to see that the equilibrium level of R&D of both firms is identical and equal

to

$$\hat{x}^* = \frac{\pi_I^0}{4}. \tag{3.4}$$

We now study how equilibrium R&D investments at $t = 2$ are affected by product hopping, when product $\mathcal{H}$ eliminates the market for product $\mathcal{O}$ and $\mathcal{O}$'s generic versions. Comparing the incumbent's equilibrium R&D investments x^* and $\hat{x}^*$ we have

$$x^* \geq \hat{x}^* \iff \frac{4\pi_I}{(1+\gamma)^2} \geq \pi_I^0 \tag{3.5}$$

Proposition 1. *Product hopping increases the incumbent's R&D investment for the radical innovation (product $\mathcal{I}$) at stage $t = 2$ when*

$$\bar{\pi}_I^{\text{inc}} \equiv \frac{4\pi_I}{(1+\gamma)^2} \geq \pi_I^0.$$

Furthermore, we have that $\bar{\pi}_I^{\text{inc}} \in [\pi_I, \pi]$.

Proof. When condition (3.5) holds product hopping increases the incumbent's R&D at $t = 2$. Note that $(1+\gamma)^2 \leq 4$ for any $\gamma \in [0,1]$, so $\frac{4\pi_I}{(1+\gamma)^2} \geq \pi_I$. Next, let $D = \pi - \pi^H$ so we have

$$\frac{4\pi_I}{(1+\gamma)^2} \leq \pi \Leftrightarrow 4D^2\pi^I \leq (D+\pi^I)^2\pi \Leftrightarrow -4D\pi^I\pi^H \leq (D-\pi^I)^2\pi.$$

The left-hand side is negative and the right-hand side is positive, so the inequality holds. □

Proposition 1 shows that the whether product hopping increases or reduces the incumbent's R&D investment at $t = 2$ depends on how different is π_I^0 from π. In other words, it depends on the size of the increase in profits for a monopolist that can offer both products $\mathcal{I}$ and $\mathcal{H}$, relative to a firm that offers product $\mathcal{I}$ in competition

with $\mathcal{O}$ and $\mathcal{O}$'s generic versions. The reason is that the the incentive to innovate depends on the difference between winning and losing the R&D race. That difference is $\pi - \pi_H$ under product hopping and $\pi_I^0 - 0$ without product hopping. When $\pi_I^0 \geq \bar{\pi}^{\text{inc}}$ the incentive to innovate is larger without product hopping, because the incremental profit from winning the R&D race is larger. Product $\mathcal{H}$ is the incumbent's outside option and creates a replacement effect that decreases the incumbent's incentive to innovate. When $\pi_I^0 < \bar{\pi}^{\text{inc}}$ product hopping increases the incentive to innovate because it softens market competition: the profits of the firm selling product $\mathcal{I}$ are larger when $\mathcal{I}$ competes against $\mathcal{H}$ rather than $\mathcal{O}$ and its generic versions. Without product hopping, the winner of the race competes against $\mathcal{O}$ and its generic versions, and this competition effect can be intense.

We now study whether product hopping increases or decreases the *total* investment in R&D for product $\mathcal{I}$ at stage $t = 2$. When the incumbent engages in product hopping the total R&D investment at the second innovation race is

$$x^* + y^* = x^* + \gamma x^* = (1 + \gamma)x^* = \frac{\pi_I}{1 + \gamma}.$$

When the incumbent does not engage in product hopping is

$$2\hat{x}^* = \frac{\pi_I^0}{2}.$$

Thus, comparing total R&D investments at the second innovation race we have

$$x^* + y^* \geq 2\hat{x}^* \iff \frac{2\pi_I}{1 + \gamma} \geq \pi_I^0. \tag{3.6}$$

Proposition 2. *Product hopping increases the total R&D investment for product* $\mathcal{I}$

at $t = 2$ *when*

$$\bar{\pi}_I^{\text{tot}} \equiv \frac{2\pi_I}{1+\gamma} \geq \pi_I^0.$$

Furthermore, we have that $\bar{\pi}_I^{\text{tot}} \in [\pi_I, \pi]$ *and* $\bar{\pi}_I^{\text{tot}} \leq \bar{\pi}_I^{\text{inc}}$.

Proof. When condition (3.5) holds product hopping increases total R&D at $t = 2$. Note that $1 + \gamma \leq 2$ for any $\gamma \in [0, 1]$, so $\frac{2\pi_I}{(1+\gamma)^2} \geq \pi_I$. Next, let $D = \pi - \pi^H$ so we have

$$\frac{2\pi_I}{1+\gamma} \leq \pi \Leftrightarrow 2\pi^I D \leq (D + \pi^I)\pi \Leftrightarrow D\pi^I \leq D(\pi - \pi^I) + \pi^\pi \Leftrightarrow \pi^H - \pi^I \leq \pi,$$

which always holds. $\bar{\pi}_I^{tot} \leq \bar{\pi}_I^{inc}$ is direct from the definition of these variables. □

Proposition 2 shows that the total R&D investment for the radical innovation at stage $t = 2$ (product $\mathcal{I}$) decreases when there is a high degree of cannibalization of the profits of product $\mathcal{H}$ by product $\mathcal{I}$. The intuition is similar to that of Proposition 1: the incumbent has less incentives to invest in R&D with an outside option, which reduces the innovation incentives of the entrant; but, the incumbent would like to soften competition and introduce product $\mathcal{H}$ if, under its absence, competition between $\mathcal{I}$ and $\mathcal{O}$ and $\mathcal{O}$'s generics is intense.

Figure 3.2 illustrate the different regions as a function of the parameters. It shows that R&D incentives increase when π_I^0 is relatively low. This occurs, for instance, when product $\mathcal{H}$ has no therapeutic benefit for consumers relative to $\mathcal{O}$. This case is problematic from a consumer-welfare perspective, because the introduction of product $\mathcal{H}$ and the foreclosure of the market for $\mathcal{O}$ and its generic versions precludes consumers from accessing more cost-efficient drugs. However, as Figure 3.2 shows, product hopping *increases* total R&D investment at $t = 2$ in this case. The reason is that it softens competition for the innovative product $\mathcal{I}$, and therefore encourages

the entrant to invest more in innovation, which raises total equilibrium R&D.

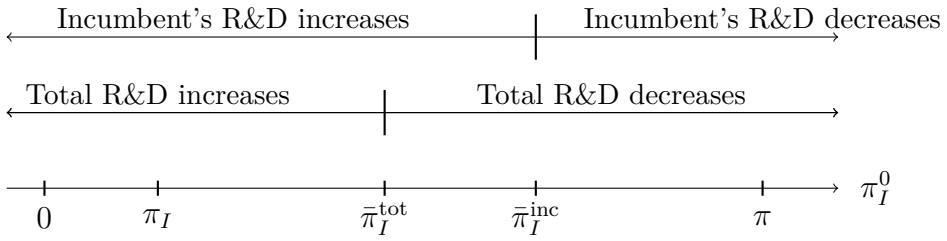


Figure 3.2: Effect of product hopping on R&D investments at the second innovation race.

Equilibrium continuation value:

The continuation values for the incumbent and the entrant, V^I and V^E, respectively, depend on whether or not the incumbent engaged in product hopping right before the expiration of product $\mathcal{O}$'s patent. When the incumbent engages in product hopping it expects a continuation value of

$$V^I = \frac{\pi + \gamma\pi_H}{1+\gamma} - \frac{\pi_I}{(1+\gamma)^2} = \frac{(\pi + \gamma\pi_H)(1+\gamma) - \pi_I}{(1+\gamma)^2}, \tag{3.7}$$

The expected continuation value for the entrant under product hopping is

$$V^E = \frac{\gamma}{1+\gamma}\pi_I - \gamma\frac{\pi_I}{(1+\gamma)^2} = \frac{\pi_I\gamma^2}{(1+\gamma)^2}. \tag{3.8}$$

If the incumbent does not engage in product hopping, then winning the first innovation race does not create an advantage for the incumbent during the second innovation race. Thus, in this case, the continuation value for the incumbent and the entrant are the same and equal to

$$V_0^I = V_0^E = \pi_I^0/4. \tag{3.9}$$

Engaging in product hopping has a fixed cost $K \geq 0$ for the incumbent. The incumbent decides whether to engage in product hopping comparing this cost to the marginal benefit of entering period 2 with an advantage. Thus, the incumbent engages in product hopping when $V^I - K \geq V_0^I$.

Proposition 3. *The incumbent engages in product hopping when*

$$\pi_H + \frac{\pi_I}{\gamma(1+\gamma)^2} - \pi_I^0/4 \geq K, \tag{3.10}$$

which holds for any $K \in [0, \bar{K}]$ *when* $\pi^0 \leq \bar{\pi}_I^{inc}$.

Proof. Using the definition of γ, we obtain that $V^I - K \geq V_0^I$ is equivalent to condition (3.10). When $\pi_I^0 \leq \bar{\pi}_I^{\text{inc}}$, the right-hand side of this condition is strictly positive, because $\gamma \leq 1$. Thus, there exists some strictly positive cutoff $\bar{K}$ such that condition(3.10) holds for any $K \leq \bar{K}$. □

Proposition 3 shows that a sufficient condition for the incumbent to engage in product hopping is that K is small and that $\pi_I^0 \leq \bar{\pi}_I^{\text{inc}}$. This implies that the incumbent will invest more than the entrant in the race for product $\mathcal{I}$, but total R&D in this race may increase or decrease as a consequence of product hopping. Specifically, when $\pi_I^0 \in [\bar{\pi}_I^{\text{tot}}, \bar{\pi}_I^{\text{inc}}]$ the incumbent wants to engage in product hopping, but the total R&D investment at $t = 2$ decreases; whereas when $\pi_I^0 < \bar{\pi}_I^{\text{tot}}$ the incumbent engages in product hopping and the total R&D investment at $t = 2$ increases. When $\pi_I^0 > \bar{\pi}_I^{\text{inc}}$ the condition in Proposition 3 may hold, but the total R&D investment at $t = 2$ unequivocally goes down.

3.1.2 Stage 1: R&D Race for Product $\mathcal{O}$

In the first period, the two innovators race to bring product $\mathcal{O}$ to the market. At this point, the two innovators are symmetric. The winner of the first R&D race obtains a patent, and the monopoly profits π^m associated to selling product $\mathcal{O}$ under patent protection until period 2. Additionally, the winner of the first R&D race becomes the incumbent, which creates the option value of engaging in product hopping at cost $K \geq 0$. We assume that firms do not discount future payoffs.

The incentive to innovate in the first period is driven by the difference between the payoff of winning and the payoff of losing the R&D race for product $\mathcal{O}$. Winning the R&D race guarantees profits π^m from product $\mathcal{O}$'s patent. The continuation value, however, depends on the equilibrium decision of invest in product hopping or not, and on the equilibrium R&D investment in the second period. When it is optimal for the incumbent to engage in product hopping, the difference in the payoff of winning and losing the first R&D race is $\pi^m + V^I - K - V^E$. Given that the firms are symmetric in period 1, it is easy to show that the equilibrium level of investment is

$$x^* = \frac{\pi^m + V^I - K - V^E}{4}.$$

Recall that without product hopping $V_0^I = V_0^E$. Thus, product hopping increases innovation incentives at $t = 1$ if it makes incumbency valuable, i.e., when under product hopping $V^I > V^E + K$. Subtracting Equation 3.7 and Equation 3.8, and using the definition of γ, we have that product hopping increases equilibrium R&D investments at $t = 1$ if

$$K^* \equiv \pi_H + \frac{\pi_I(1-\gamma^3)}{\gamma(1+\gamma)^2} \geq K. \tag{3.11}$$

Note that the condition (3.11) holds for K sufficiently small, specifically, $K \leq K^*$.

Therefore, we have the following result:

Proposition 4. *If the condition in Proposition 3 and $K \leq K^*$, the incumbent engages in product hopping and the total equilibrium R&D investment at $t = 1$ increases. A sufficient (but not necessary) condition for R&D to increase is $\pi_I^0 \geq \pi^I$.*

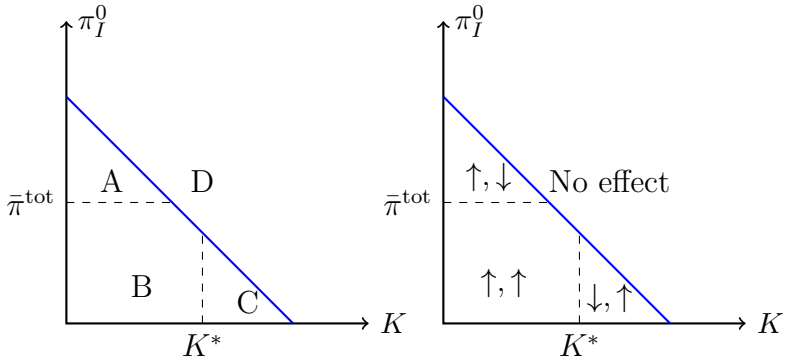
Proof. If the condition in Proposition 3 and Equation 3.11 hold, by definition, the incumbent engages in product hopping and the total equilibrium R&D investment at $t = 1$ increases. For the sufficient condition, note that

$$\pi_H + \frac{\pi_I(1-\gamma^3)}{\gamma(1+\gamma)^2} - K \geq \frac{\pi_I^0}{4} - \frac{\pi_I\gamma^2}{(1+\gamma)^2} \geq \frac{\pi_I^0 - \pi_I}{4},$$

where the last inequality holds because $\frac{\gamma^2}{(1+\gamma)^2} \leq \frac{1}{4}$ for all $\gamma \leq 1$. □

Proposition 4 shows that banning product hopping may have negative welfare consequences by reducing the R&D investment at $t = 1$. This would only happen when π_I^0 is sufficiently lower than π_I. When $\pi_I^0 > \pi_I$ and it is optimal for the incumbent to engage in product hopping, we have that R&D at $t = 1$ increases. The reason for why R&D decreases at $t = 1$ is because product hopping raises both the incumbent and the entrant's payoff at $t = 2$, but the entrant's payoff increases by more than the incumbent's payoff. To see this, suppose the incumbent engages in product hopping, i.e., $V_I - K > V_I^0$, and R&D investments at $t = 1$ decrease, i.e., $V_I - K - V^E < V_I^0 - V_E^0$. It is easy to see that these two conditions imply $0 < V_I - K - V_I^0 < V^E - V_E^0$. Thus, when product hopping reduces R&D investments at $t = 1$ it increases the entrant's payoff by more than the incumbent's payoff.

Figure 3.3 (Panel a) shows the four different cases in the model. In region D, the incumbent does not engage in product hopping. In all the remaining regions the incumbent engages in product hopping. In regions A and B, the total R&D's



(a) Different Regions (b) R&D under product hopping

Figure 3.3: Panel (a) shows for regions. In region D, the incumbent does not engage of product hopping. In regions A, B, C the incumbent engages in product hopping. Panel (b) shows an arrow pointing upwards (downwards) when product hopping increases (decreases) R&D in a each period.

equilibrium level in period 1 increases, whereas in region C it decreases, relative to the case of no product hopping.[19] In regions B and C, product hopping increases total R&D's equilibrium level in period 2, whereas in region A it decreases it, relative to the case of no product hopping. Figure 3.3 (Panel b) indicates whether product hopping increases or reduces the total equilibrium R&D investment in the first and in the second period.

3.1.3 Welfare

Our results, summarized in Figure 3.3, show that product hopping has ambiguous effect on R&D, depending on the cost for the incumbent of creating an advantage in period 2 (how K compares to K^*) and whether the profit of an innovator that

[19]The maximum K for which the incumbent engages in hopping is $K_{\max} = K^* + \frac{\gamma^2 \pi_I}{(1+\gamma)^2} > K^*$, and the maximum π_I^0 for for which the incumbent engages in hopping is $\pi_{I,\max}^0 = 4\pi_H + \bar{\pi}^{\text{inc}} > \bar{\pi}^{\text{tot}}$.

competes with $\mathcal{O}$ and its generic versions is relatively large (how π_I^0 compares to $\bar{\pi}^{\text{tot}}$).

Apart from affecting equilibrium R&D levels, product hopping has other welfare consequences. For instance, when the therapeutic benefit of product $\mathcal{H}$, relative to product $\mathcal{O}$ is small, by engaging in the product hopping cost K the incumbent steers consumers to a less cost-effective drug. Additionally, in this case the incumbent's spending of K is wasteful. It is also plausible that even minor modifications may create value for consumers.

To evaluate the consumer welfare trade-offs that arise from banning product hopping, we consider a consumer-welfare function that increases when innovative products arrive quickly. The speed of arrival of products is determined by the total R&D investment. We assume that firms can start investing in the second product only after the patent of the first product expires.[20] We interpret the contest success function in the R&D contests as the probability that a firm's discovery arrives first. Suppose the incumbent invests x and the entrant y in an R&D race. Let τ_x be the time of arrival of the incumbent's invention, which we assume is distributed according to an exponential distribution of parameter x; let τ_y time of arrival of the entrant's invention, which we assume is distributed according to an exponential distribution of parameter y. Thus, the probability that the incumbent discovers first (and therefore wins the R&D race) is $\frac{x}{x+y}$. Suppose that the social planner discount the future at rate $r > 0$. Then, the expected discount rate for the first product is $E[\exp(-r\tau)]$ where $\tau = \min\{\tau_x, \tau_y\}$. Denote by X_t^* the total equilibrium effort in the period t.

[20]This is a simplification to avoid solving a fully dynamic model, where the flow profit of the incumbent can be interrupted by the arrival of the next product.

Then, the expected consumer surplus is

$$ECS = A_1(X_1)\left[CS_1 + A_2(X_2)CS_2\right]\delta(T,r). \tag{3.12}$$

In the definition above, CS_t is the consumer surplus in period t, $A_1(X_1) = \frac{X_1}{r+X_1}$ is the expected discounted rate for the first invention and $A_1(X_2) = \frac{e^{-rT}X_2}{r+X_2}$ is the expected discounted rate for the second invention and $\delta(T,r) = \frac{1-\exp(-rT)}{r}$ is the discount rate for a period of length T. Note that $A_t(X_t)$ is increasing in X_t. We denote by X_t and $\hat{X}_t$ the total equilibrium R&D investment in period t with and without product hopping, respectively.

When the incumbent engages in product hopping, $CS_2 = CS^H \equiv \frac{1}{1+\gamma}CS^{I,m} + \frac{\gamma}{1+\gamma}CS^{I,E}$. The term $CS^{I,m}$ is the consumer surplus when the incumbent wins the second innovation race (and, therefore, it is a multi-product monopolist offering $\mathcal{H}$ and $\mathcal{I}$); the term $CS^{I,E}$ is the consumer surplus when the entrant wins the second innovation race and, therefore, products $\mathcal{H}$ and $\mathcal{I}$ are sold under competition. Given that the second R&D race is asymmetric when the incumbent has developed product $\mathcal{H}$ as an outside option, the incumbent wins the R&D with probability $\frac{1}{1+\gamma} > \frac{1}{2}$. When the incumbent does not engage in product hopping, we have $CS_2 = CS^I$, the consumer surplus when $\mathcal{I}$ is offered on the market in competition with $\mathcal{O}$ and $\mathcal{O}$'s generic versions. Finally, CS_1 is the consumer surplus when product $\mathcal{O}$ is sold by the winner of the first R&D race, and product $\mathcal{O}$ is the only product in the market.

When product $\mathcal{H}$ is almost identical to product $\mathcal{O}$, consumers are better off when $\mathcal{O}$ and $\mathcal{O}$'s generic versions are offered at zero price rather than $\mathcal{H}$, i.e., $\max\{CS^{I,m}, CS^{I,E}\} \leq CS^I$ which implies $CS^H \leq CS^I$. In this case, $\pi_I^0 \leq \pi^I$, so product hopping increases total R&D investments in the second period. Suppose that K is small, so in the first period R&D investments also increases. The effect

of product hopping on welfare is ambiguous: welfare increases when the incumbent engages in product hopping if $W(x_1, x_2) \geq W(\hat{x}_1, \hat{x}_2)$ or

$$\underbrace{[A_1(X_1) - A_1(\hat{X}_1)]CS^m}_{A} + \underbrace{A_1(X_1)A_2(X_2)CS^H - A_1(\hat{X}_1)A_2(\hat{X}_2)CS^I}_{B} > 0.$$

The first term, A, is positive and correspond to a gain in consumer surplus from a speedier introduction of product $\mathcal{O}$. Product hopping increases the value of incumbency, which pushes firms to compete more fiercely in the first R&D race. The sign of the second term, B, is ambiguous. First, $A(X_1)A(X_2)$ is larger than $A(\hat{X}_1)A(\hat{X}_2)$ when product hopping accelerates the arrival of both product $\mathcal{O}$ and product $\mathcal{I}$. But product hopping reduces consumer surplus at $t = 2$ relative to the case of no product hopping, $CS^H < CS^I$, and therefore the term B could be negative. This is case is the best-case scenario for supporting product hopping. In any other case, when the incumbent engages in product hopping, there will be a reduction of R&D either in the first or in the second period.

3.1.4 Banning Product Hopping

Consumers may benefit from product hopping from two channels: (1) product $\mathcal{H}$ is more valuable for consumers than product $\mathcal{O}$; (2) higher R&D investments accelerate the arrival of new products. When products $\mathcal{H}$ and $\mathcal{O}$ are similar, consumers benefit from product hopping only from its potential to increase R&D investments. Thus, a simple consumer-welfare-improving alternative to product hopping is one that deters the incumbent from engaging in product hopping but provides firms with higher innovation incentives.[21] One such mechanism could reward firms that develop the

[21] In the Introduction we discuss a number of regulatory changes that would ban product hopping.

first drug for a given disease (a pioneer drug) or those that dramatically improve the existing drugs. Such a mechanism would generate a payoff of $\pi^m + R + \pi_I^0/4$ for the winner of the first R&D race. Thus, for an appropriate reward R this mechanism mimics the good feature of product hopping, in terms ex ante innovation incentives, and it avoids the negative aspects of product hopping including wasteful marketing investments K as well as higher prices in the second period. Another alternative would be to award longer patents to pioneer drugs, so as to increase π^m, which increases the ex ante innovation investments but decreases consumer welfare (longer length of a monopoly). Finally, another alternative is to give subsidies to firms, which in our model is equivalent to increase the prize in the R&D competition.

In the next section, we present an example with differentiated products to further explain our results.

3.2 Differentiated Products Example

There is a continuum of consumer uniformly distributed along the interval $[0, 1]$. Product $\mathcal{O}$ and any of its generic versions give consumers a utility of v, and they are located at $x = 0$. In period 1, product $\mathcal{O}$ is the only product in the market and it sells at monopoly price p_O. In period 2, product $\mathcal{O}$ and its generic versions sell at price of zero. Product $\mathcal{H}$ gives consumers a utility of v_H, is located at $x = 0$ and it is sold at price p_H. Product $\mathcal{I}$ gives consumers a utility of v_I, is located at $x = 1$, and it is sold at price p_I. The products in the market at $t = 2$ depends on whether the incumbent engaged in product hopping. Without product hopping, the products in the market at $t = 2$ are $\mathcal{O}$, $\mathcal{O}$'s generic versions, and $\mathcal{I}$, whereas with product hopping the products in the market are $\mathcal{H}$ and $\mathcal{I}$. This change in market structure is the friction introduced by product hopping. We assume that the marginal cost of

each product is zero and that $v \leq v_H < v_I$. Consumers pay a linear transportation cost κ. Figure 3.4 describes the location of different products in the market at time t, depending on whether the incumbent engages in product hopping.

	$x=0$ ⊢———	———⊣ $x=1$
$t=1$	$\mathcal{O}$	None
$t=2$, no hopping	$\mathcal{O}$, $\mathcal{O}$'s generics	$\mathcal{I}$
$t=2$, hopping	$\mathcal{H}$	$\mathcal{I}$

Figure 3.4: Products in the market with and without product hopping.

We assume that the market is fully covered and the solutions are interior.

Assumption 1. *$v_I + v_H \geq 3\kappa$, $v_I - v_H \leq 2\kappa$, and $v_I - v \leq 2\kappa$.*

3.2.1 Market Equilibrium at $t = 2$

Product Hopping. In this case there are two scenarios depending on which firm wins the R&D race at $t = 2$.

Competition: First, suppose the entrant wins the R&D race at $t = 2$. Product $\mathcal{I}$ is offered by the entrant and product $\mathcal{H}$ by the incumbent.

Lemma 2. *The equilibrium profits under competition for products $\mathcal{H}$ and $\mathcal{I}$ are, respectively,*

$$\pi_H = \frac{(3\kappa - \Delta v)^2}{18\kappa}, \quad \pi_I = \frac{(3\kappa + \Delta v)^2}{18\kappa},$$

where $\Delta v = v_I - v_H > 0$. The consumer surplus is

$$CS^{I,E} = \frac{(v_I - v_H)^2 + 18\kappa(v_I + v_H) - 45\kappa^2}{36\kappa}.$$

Multiproduct monopolist: Second, consider the case where the incumbent wins the R&D at $t = 2$. In this case, the incumbent can sell both products $\mathcal{H}$ and $\mathcal{I}$ at prices

p_H and p_I. Under Assumption 1, the multi-product monopolist that does not exclude any consumer.

Lemma 3. *The equilibrium profit for the multi-product monopolist is*

$$\pi = \frac{(v_I - v_H)^2 + 4\kappa(v_I + v_H) - 4\kappa^2}{8\kappa}.$$

The consumer surplus in multi-product monopolist case is

$$CS^{I,m} = \frac{(v_I - v_H)^2 + 4\kappa^2}{16\kappa}.$$

No Product Hopping. In this case, the innovator, which is either the incumbent or the entrant, competes with product $\mathcal{O}$ and its generic versions located at $x = 0$ and sold at price equal to zero (marginal cost).

Lemma 4. *If the incumbent does not engage in product hopping, the innovator's profit is* $\pi_I^0 = \frac{(\kappa + v_I - v)^2}{8\kappa}$, *and the consumer surplus is*

$$CS^I = \frac{(v_I - v)^2 + 2\kappa(v_I + v) + 12\kappa v - 7\kappa^2}{16\kappa}.$$

3.2.2 Market Equilibrium at $t = 1$

In period 1, the winner of the R&D race sells product $\mathcal{O}$ under no competition until the patent of product $\mathcal{O}$ expires.

Lemma 5. *The winner of the first R&D race receives a profit of* $\pi_m = \frac{v^2}{4\kappa}$ *during the first period. The consumer surplus in this period is* $CS^m = \frac{3v^2}{8\kappa}$.

Expected Consumer Surplus. We use Equation 3.12 to compute the expected consumer surplus with and without product hopping for different parameters. Table 3.1 show for different cases to illustrate how product hopping affects R&D incentives, competition, and welfare. We set $v_I = 4$, $v = 2$, $\kappa = 1$. With these parameters, we have $\pi_I^0 = 1.13$ and $\pi_m = 1$. The equilibrium investment without product hopping in the first and in the second stage are, respectively, $\hat{X}_1 = 0.5$ and $\hat{X}_2 = 0.56$.

v_H	K	r	π_H	π_I	π	$\bar{\pi}_I^{tot}$	K^*	X_1	X_2	ECS_H	ECS_{NH}
3.5	0	0.1	0.35	0.68	3.28	1.10	2.26	1.63	0.55	1.82	2.46
3.5	0	0.4	0.35	0.68	3.28	1.10	2.26	1.63	0.55	1.17	1.06
2.0	0	0.1	0.06	1.39	3.00	1.89	1.27	1.14	0.94	1.98	2.45
2.0	1.3	0.1	0.06	1.39	3.00	1.89	1.27	0.49	0.94	1.79	2.45

Table 3.1: Value of profits under different market structures and other relevant parameters.

In the first row of Table 3.1, product $\mathcal{H}$ is more valuable than product $\mathcal{O}$, but less valuable than product $\mathcal{I}$. These parameter values imply that we are in Region A in Figure 3.3. Product hopping changes the market structure that follows the second R&D race. The direct effect encourages the incumbent it is invest more ($\pi - \pi^H > \pi_I^0$) and the entrant to invest less ($\pi_I < \pi_I^0$). But because the entrant invests less, the strategic effect of the incumbent is to reduce its investment. The overall effect is a reduction in total R&D at stage 2 ($X_2 < \hat{X}_2$). Product hopping increases the value of incumbency and it is costless ($K = 0$), which boosts R&D investments in the first period ($X_1 > \hat{X}_1$). Consumers pay higher prices in the second period, but they get higher value from product $\mathcal{H}$ relative to product $\mathcal{O}$. The price effect dominates and consumer surplus decreases in the second period. All these effects combined imply that product hopping reduces the expected consumer surplus overall ($ECS_H < ECS_{NH}$).

The second row in Table 3.1 is identical to the first row except for the value of r,

which measures how much consumers value a quick arrival of new products. A larger value of r implies that consumers are more impatient, and therefore the value more faster arrival of new products. When $r = 0.4$ instead of $r = 0.1$, product hopping increases expected consumer surplus because product hopping increases R&D at the stage 1, accelerating product arrivals.

In the third row of Table 3.1, consumers value products $\mathcal{H}$ and $\mathcal{O}$ the same (i.e., $v_H = v = 2$). Product $\mathcal{H}$ prevents consumers to access $\mathcal{O}$ or $\mathcal{O}$'s generics, located at zero and sold at marginal cost, so it softens competition in the stage 2. The direct effect for both the incumbent and the entrant encourages R&D in the second period $\pi_I > \pi_I^0$ and $\pi - \pi^H > \pi_I^0$. This direct effect is larger than the strategic effect or R&D competition which increase total R&D in the second period. The increase in value for the incumbent (and the entrant) imply that R&D also increases in the first period. In other words, this case correspond to a point in Region B in Figure 3.3. Expected consumer welfare decrease because consumers care more about paying lower prices than having access to new products sooner ($r = 0.1$).

The third row of Table 3.1 is identical to the third row except that $K > 0$. Increasing K decreases the value of incumbency, but it is sub-game perfect to engage in product hopping. Thus, R&D investments decrease in the first period under product hopping, i.e., we are in Region C in Figure 3.3.

3.3 Discussion and Concluding Remarks

Pharmaceutical firms often patent minor modifications of a pioneer drug and invest in marketing to switch consumers from the original drug to the minor modification. This switch often happens just before the patent of the pioneer drug expires. This strategy, called product hopping, reduces consumer welfare by preempting the entry

of generic drugs, which would have lowered the price of the original drug after patent expiration. We show that product hopping may increase the value of incumbency and, therefore, increase ex-ante innovation incentives. In some cases, product hopping unambiguously reduces ex-post welfare, i.e. it reduces both consumer welfare and innovation incentives for follow-on (radical) innovation. We characterize conditions under which product hopping increases or decreases consumer welfare, as a function of the cost of engaging in product hopping, and the degree of competition between a follow-on innovative product and the original drug sold at marginal cost.

Product hopping affects firms' incentives in two ways. First, it changes the competition landscape in the second period: without product hopping, product $\mathcal{O}$, generic versions of $\mathcal{O}$, and product $\mathcal{I}$ are offered in the market; with product hopping products $\mathcal{H}$ and $\mathcal{I}$ are offered in the market. Thus, product hopping prevents generic manufacturers to enter the market and reduce the price of product $\mathcal{O}$. This change in the competition landscape is the main complaint raised by generic manufacturers in antitrust lawsuits they have filed against incumbents that have engaged in product hopping.[22] The second effect of product hopping is to change innovation incentives. Under product hopping, in the second period, the incumbent's incentive to innovate is driven by the difference of profits of a multi-product firm (offering both products $\mathcal{H}$ and $\mathcal{I}$) and the profits of offering product $\mathcal{H}$ in competition with product $\mathcal{I}$. The entrants incentive to innovate is driven by the profit of selling product $\mathcal{I}$ in competition with product $\mathcal{H}$. Without product hopping, firm's incentives to invest in R&D are symmetric and driven by the profit of selling product $\mathcal{I}$ in competition with $\mathcal{O}$ and $\mathcal{O}$'s generic versions. Proposition 2 analyzes how these trade-off resolve, and it characterizes when total R&D in the second stage increases. The incumbent will engage in product hopping only when the increase expected profits in the second

[22]See examples in footnotes 5 to 9.

period are larger than the cost of engaging in product hopping. Product hopping changes equilibrium continuation values and, therefore, affect ex-ante innovation incentives. Ex-ante R&D incentives can increase or decrease under product hopping. Proposition 4 characterizes when product hopping increases R&D investments in the first period.

The main policy implication from our analysis is that simply banning product hopping may be detrimental for innovation and consumer welfare. A situation of particular interest is one where product $\mathcal{H}$ is identical to product $\mathcal{O}$, i.e., product $\mathcal{H}$ does not offer any therapeutic benefit over product $\mathcal{O}$. In this case, the only positive aspect of product hopping is that it can increase R&D investments. Thus, an argument in favor of product hopping is that it encourages innovation. However, providing innovation incentives via product hopping is inefficient. A more efficient mechanism would mimics the positive effects of product hopping on innovation incentives, but it would avoid wasteful marketing investments and reduction in competition in the second period. Such a policy must assure that firms cannot engage in product hopping, which would require regulatory changes in the current system such as tightening patentability standards, capping marketing investments, or modifying generic substitution laws. Alternative mechanisms to encourage innovation include prizes or subsides for pioneer drugs.

At the core of the problem of product hopping is the fact that the current patent system is not optimally crafted. Such a system would reward innovators differentially depending on the incremental contribution of their inventions (e.g, O'donoghue, Scotchmer and Thisse, 1998; Hopenhayn, Llobet and Mitchell, 2006). Product hopping arises from giving large rewards to marginal improvements, which counteract other defects of the system like rewarding too little pioneer drugs. Our results suggest that, taken the current patent system as given, we can improve welfare by regulating

product hopping to preserve its positive aspects (enhanced innovation incentives) and to remove negative ones (e.g., wasteful marketing spending to steer demand to less cost-efficient drugs).

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APPENDIX A

ADDITIONAL TABLES FOR CHAPTER 1

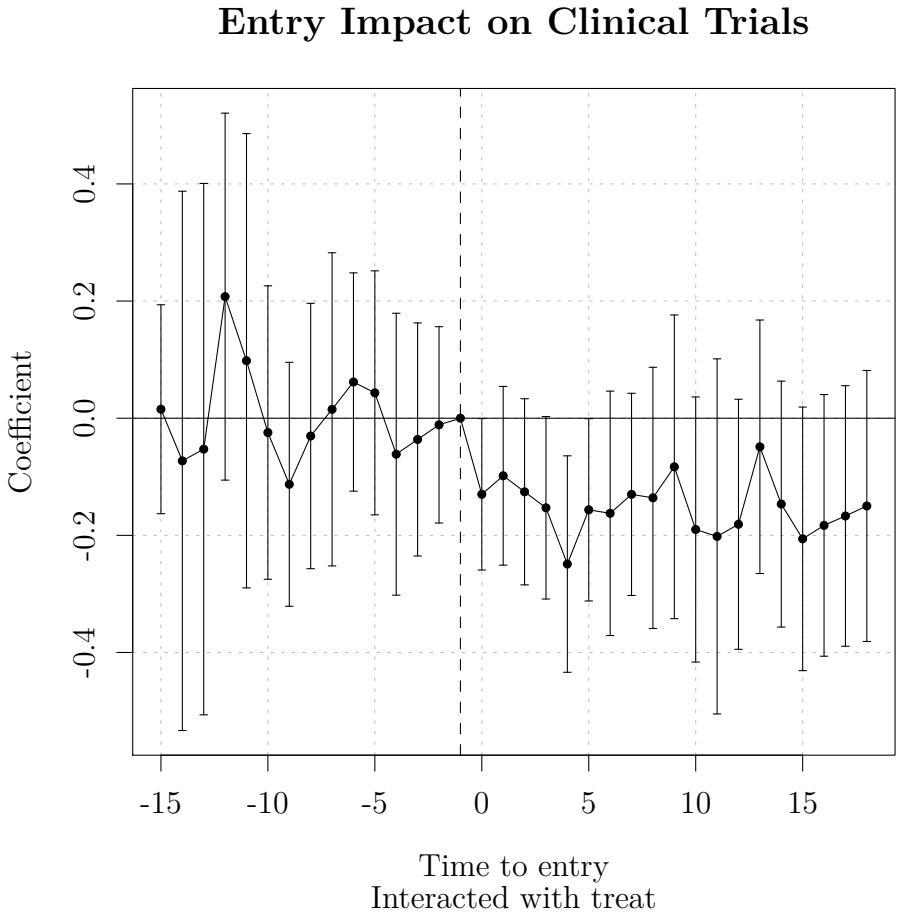

Figure A.1: Point estimate of coefficients for 95% confidence intervals from the estimation. The omitted time period is the year prior to the entry.

Dependent Variable:	own_trials_biomed			
Model:	(1)	(2)	(3)	(4)
	Neg. Bin.	Neg. Bin.	Poisson	Poisson
Variables				
Second entry	-0.4842**			-0.4515**
	(0.2389)			(0.2251)
Second entry (Addition)		-0.7037***	-0.7083***	
		(0.2294)	(0.2244)	
Second entry (Advance)		-0.2632	-0.2121	
		(0.3426)	(0.3128)	
# of patent	0.0106	0.0059	0.0011	0.0059
	(0.0462)	(0.0460)	(0.0444)	(0.0449)
# of court cases	-0.0275	-0.0268	-0.0249	-0.0254
	(0.0441)	(0.0440)	(0.0432)	(0.0433)
Generic entry	-0.3546	-0.3493	-0.3695	-0.3775
	(0.6213)	(0.6251)	(0.6246)	(0.6192)
# of DS patent	-0.0282	-0.0331	-0.0325	-0.0260
	(0.0867)	(0.0854)	(0.0842)	(0.0861)
# of DS court case	0.0186	0.0185	0.0139	0.0133
	(0.0676)	(0.0665)	(0.0670)	(0.0692)
# of AI patent	-0.1009	-0.1232	-0.1232	-0.1021
	(0.2252)	(0.2178)	(0.2198)	(0.2280)
# of AI court cases	-0.0221	-0.0195	-0.0260	-0.0301
	(0.0872)	(0.0856)	(0.0896)	(0.0931)
Exclusivity Date	0.0341**	0.0356**	0.0373**	0.0362**
	(0.0170)	(0.0167)	(0.0162)	(0.0165)
Fixed-effects				
Class	Yes	Yes	Yes	Yes
year	Yes	Yes	Yes	Yes

One-way (Class) standard-errors in parentheses
*Signif. Codes: ***: 0.01, **: 0.05, *: 0.1*

Table A.1: Negative binomial and poisson model regression results for Table 1.2

APPENDIX B

CHAPTER 2

B.1 Matching Disciplinary Actions and Open Payments Data

We identify 9094 unique licenses that have received disciplinary actions between 1940 and 12/31/2018 by scraping public records of the Medical Board of California and from files containing a list of disciplinary actions.[1] Several public actions do not raise to the level of a disciplinary action including malpractice payments, a public letter of reprimand. These public records, however, contain useful information such as the name of the physician, medical school, graduation year, and address.

Unfortunately, the Medical Board of California does not provide the NPI for physicians who have engaged in misconduct. Having NPI numbers is important for our analysis for at least two reasons. First, NPI numbers are unique and with them we can match physician information from other sources. Second, NPI numbers are mandatory for physicians when their patients use any kind of insurance (private or public), whereas if the patient pays out of pocket, state licenses are enough for practice.

We use several datasets to match California licenses with NPI numbers:

[1] We downloaded files from www.mbc.ca.gov/Publications/Disciplinary_Actions/ and scrapped information from search.dca.ca.gov.

- **Profile of enrolled Medi-Cal providers (only current date)**: It includes both NPI and license numbers for physicians who are registered in Medi-Cal.[2]
- **Suspended and ineligible provider list of Medi-Cal**: It includes both NPI and license number of a provider who is excluded from Medi-Cal.[3]
- **NPPES data from NBER between 11-2007 and 10-2019:** It is an official NPI database and license numbers, but it could be outdated or there could be typos in physician licenses.
- **Physician compare 2014-2018:** It includes physicians who are active in Medicare. The records consist of NPI number, medical school, and graduation year from medical school.
- **Docinfo.com**: It contains information for all US physicians including medical school, graduation year, any location during physician's career, disciplinary actions, any active license currently from any medical board in the US.

B.1.1 Matching Procedure for Licenses and NPI Numbers

We utilize the databases described in the previous section to identify physician NPI numbers for those physicians who receive disciplinary action or have a public report issued by the Medical Board of California. We follow a sequential procedure.

1. **Medi-Cal Providers and Medi-Cal Suspended List:** Medi-Cal databases are administrative and include license numbers and NPI for each doctor who participates Medi-Cal program in California. We use last name and license

[2]data.chhs.ca.gov/dataset/profile-of-enrolled-medi-cal-fee-for-service-ffs-providers/resource/d7cd2c98-3454-46c5-810b-b5436b54de3a

[3]files.medi-cal.ca.gov/pubsdoco/SandILanding.asp

number to match physicians as a first step and first name and license number as a second step. We matched 3,706 physicians out of 9,094.

2. **NPPES data between 2007-2019:** NPPES is available since 2006. It is mandatory for any healthcare provider who accepts any type of insurance in the US to register in this database. Physicians enter their information into the system manually. This creates two potential concern with these data: (1) the information could be outdated; and (2) there are typos. Another difficulty is that licenses are not written in a standardized way. So the first step was to standardize all the license numbers in NPPES and match them with license numbers from the California Medical Board. We also use first and last names to improve the quality of the match. For instance, JOHN HARPER with a license number A12345, might enter his license number as 20A12345, A012345, A1234560, 12345, and 012345 to the system. In any case, we capture this doctor by standardizing license numbers. We match 2011 of license numbers with NPI number with this method out of 5048 licenses that remaining from the first match. All these matches are one-to-one i.e. one licenses matched with one NPI number. Overall, we are able to match 5,410 out of the 9,094 licenses. When we remove the matches from first stage, we identify 2237 new licenses' NPIs with this method.

3. **Physician Compare:** Physician compare data include information about the doctors who participate in the Medicare system. We use last name, first name, medical school, graduation year, and location information to match licenses. There are 409 one-to-one matches out of the 3,151 licenses left over from the previous step, leaving 2,948 licenses to match.

4. **DocInfo.com:** Docinfo is maintained by the Federation of State Medical Boards (FSMD), which collects information from all the medical boards in the US. Any physician holding a license from any medical board in the US is typically in the Docinfo database. Here, we are able to match 459 licenses out of the 2,742 licenses left over from the previous step, leaving 2,267 licenses to match.

5. **Manual Search:** Manual matching tries to captures license numbers that cannot be captured by other matching IDs. We can match 66 license numbers with NPI with this method. These are the ones that have very recent disciplinary actions (such as 2018) or very recent graduation date (i.e. 2017) or the doctor changed her/his name. We checked around 750 license numbers manually (graduation year is starting from 1980).

Table B.1 summarizes the outcome of each matching step.

Table B.1: Summary of matching following our sequential procedure[a]

Database	Licenses to Match	Total Matched	Remaining Licenses to Match
1. Medi-Cal Provider and Suspension	**9,094**	3,706	5,388
2. NPPES 2007-2019	5,388	2,237	3,151
3. Physician Compare 2014-2018	3,151	409	2,742
4. Docinfo.com	2,742	459	2,267
5. Manual Checking	2,267	66	**2,201**
	9,094	6,866	2,201

[a]Out of 9,904 licenses we are able to match 6,866 licenses with NPI numbers. We are unable to match 2,201 licenses with NPI numbers. Among 6,866 NPI numbers we matched with a disciplined licenses, 178 of the NPI numbers deactivated before 2014.

From the public records of the Medical Board of California, we identified 9,904

unique license numbers associated to public actions. Disciplinary actions are reported as far back as 1940', although those very old records are likely incomplete and not relevant for our analysis (most physicians with disciplinary actions before 1970 will be retired or deceased). Table B.2 reports the the number of licenses that receive their first disciplinary action in a given period.

Table B.2: Total Licenses with DA[a]

Years	Total Licenses	Unmatched (no NPI)
1940-1979	169	158
1980-1989	594	487
1990-1999	1848	1002
2000-2006	2153	755
2007-2013	2482	186
2014-2018	1848	73

[a]The table reports the number of licenses that received their first disciplinary action in a given period.

We do not know the reason for why we cannot match certain physicians. It could be that they stop practicing medicine, or they never got their NPI number perhaps because they were towards the end of their careers when NPIs became mandatory. Physicians begin their careers at around 30 years old—4 years of college plus 4 years of medical school plus at least 3 years of internships—and retire, on average, at age 65. Thus, the average length of a physician's career is 35 years. This can explain why our matching performs much better for recent years.

We divide disciplinary actions into two categories:

- Disciplinary Action: License cancellation, probation, public reprimand, hospital disciplinary actions.
- Non-disciplinary actions: Malpractice actions, arbitration award, accusations

without disciplinary actions yet.

Table B.3: Matching Licenses[a]

Type of Public Record	Total License	NPI found	Open Payment Profile
Disciplinary Action	7,429	5,267	3,267
Non-disciplinary actions	1,665	1,599	1,458
Total	9,094	6,866	4,725

[a]Matching between licenses associated to public actions by the Medical Board of California and physicians receiving payments according to the Open Payments database.

B.2 Reports on Firms and Disciplined Physicians

In 2010, a small-scale study by ProPublica found that seven drug companies paid $7.1 million to 292 doctors who faced disciplinary action or other regulatory sanctions[4].

For the promotion of Subsys, the highest marketing payment made by Insys in 2013 was to a doctor who was under investigation by the Texas Medical Board. A New York Times article reports that: "five of the 20 physicians who received the most money from Insys recently faced legal or disciplinary action, including three who were said to have inappropriately prescribed painkillers"[5].

In 2015, Stryker Corp., a medical device maker, paid $14,000 in consulting fees and travel expenses to an orthopedic surgeon, who had been fined and placed on three years' probation for improperly prescribing pain medications by the New York's Board for Professional Medical Conduct[6].

[4]www.propublica.org/article/pharma-payments-to-doctors-with-sanctions

[5]www.nytimes.com/2014/11/28/business/drug-maker-gave-large-payments-to-doctors-with-troubled-track-records.html

[6]www.npr.org/sections/health-shots/2016/08/23/490675125

An investigation by Milwaukee Journal Sentinel and MedPage Today found that "at least 216 doctors remained on Medicare rolls in 2015 despite surrendering a license, having one revoked, or being excluded from state-paid health care rolls in the previous five years. In all, these doctors were paid $25.8 million by taxpayers in 2015 alone"[7].

[7] www.jsonline.com/story/news/investigations/2018/05/17/609534002/

APPENDIX C

ADDITIONAL PROOFS FOR CHAPTER 3

Proof of Lemma 2

Proof. A consumer located at $x \in [0,1]$ is indifferent between product $\mathcal{I}$ and product $\mathcal{H}$ iff

$$v_H - xt - p_H = v_I - (1-x)t - p_I \Rightarrow x = \frac{1}{2} + \frac{p_I - p_H}{2t} - \frac{\Delta v}{2t},$$

where $\Delta v = v_I - v_H > 0$. The equilibrium prices are $p_H^* = t - \frac{\Delta v}{3}, \quad p_I^* = t + \frac{\Delta v}{3}$. The equilibrium profits are $\pi_H = \frac{(3t - \Delta v)^2}{18t}, \quad \pi_I = \frac{(3t + \Delta v)^2}{18t}$.

We require $v_H - x^* t - p_H^* \geq 0$, equivalently, $v_I + v_H \geq 3t$, for the market to be fully covered and $\Delta v \leq 3t$ for prices to be positive. The consumer surplus is given by

$$CS^{I,E} = \int_0^{x^*} (v - p_H^* - ty)dy + \int_{x^*}^1 (v_I - p_I^* - t(1-y))dy = \frac{(v_I - v_H)^2 + 18t(v_I + v_H) - 45t^2}{36t}$$

□

Proof of Lemma 3

Proof. The monopolist will extract the entire surplus from the indifferent consumer, located at x. Then, it must be the case that $v_H - p_H - tx = v_I - p_I - t(1-x) = 0$,

which implies $p_H = v_H - tx$ and $p_I = v_I - (1-t)x$. Thus, the problem is to choose the location of the indifferent consumer

$$\max_{0\leq x\leq 1}(v_H - tx)x + (v_I - t(1-x))(1-x).$$

The objective function is concave, so the first order condition results in

$$x^* = \frac{2t - \Delta v}{4t}.$$

Note that x^* is always less than 1 and $x^* \geq 0$ if $\Delta v \leq 2t$. The equilibrium prices are

$$p_H^* = \frac{v_I + 3v_H - 2t}{4}, \quad p_I^* = \frac{3v_I + v_H - 2t}{4}$$

which are positive then $3v_H + v_I \geq 2t$. The equilibrium profit for the multi-product monopolist is

$$\pi = \frac{(v_I - v_H)^2 + 4t(v_I + v_H) - 4t^2}{8t}$$

The consumer surplus in multi-product monopolist case is $CS^{I,m} = \frac{(v_I - v_H)^2 + 4t^2}{16t}$. □

Proof of Lemma 4

Proof. The consumer that is indifferent between these products is located at

$$x = \frac{1}{2} + \frac{p_I}{2t} - \frac{v_I - v}{2t}.$$

Thus, the optimal price of product $\mathcal{I}$ is $p_I^* = \frac{t + v_I - v}{2}$, which implies the indifferent consumer locates at $x^* = \frac{3}{4} - \frac{v_I - v}{4t}$ which is always less than 1 and positive when

$v_I - v \leq 3t$. The innovator's profit is

$$\pi_I^0 = \frac{(t + v_I - v)^2}{8t}.$$

The consumer surplus when the incumbent does not engage in product hopping is

$$CS^I = \frac{(v_I - v)^2 + 2t(v_I + v) + 12tv - 7t^2}{16t}$$

□

Proof of Lemma 5

Proof. By charging price p_O, the incumbent makes the consumer located at x indifferent between buying $\mathcal{O}$ or not buying it, so $p_O = v - tx$. The monopolist solves

$$\max_{0 \leq x \leq 1} (v - tx)x$$

The solution is $x^* = \frac{v}{2t}$, which is always positive and less than 1 for $v \leq 2t$. The equilibrium price and profit of the monopolist at t=1 are, respectively, $p_O^* = \frac{v}{2}$ and $\pi_m = \frac{v^2}{4t}$. In this case, consumer surplus is $CS^m = \frac{3v^2}{8t}$. □