Patent Breadth versus Length: 
An Examination of the Pharmaceutical Industry*

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Abstract

This paper empirically assesses the trade-off between patent breadth and patent length, a topic that has attracted significant theoretical but little empirical attention. I estimate a model of pharmaceutical demand and supply that incorporates insurance and advertising for the antidepressant market. Using these estimates, I consider the potential welfare effects of giving some of the most important product innovations broader but shorter patents, which increases the market power that these innovators have in the short-run but also allows for more rapid entry by generics. My results indicate that in this setting broader patents could increase total welfare by more than 9%, mostly through savings in insurer expenditures. These results are robust to endogenizing the entry of other branded drugs.

I Introduction

Innovation is a primary source of growth for social welfare. Often, innovation is spurred by patents, which confer market exclusivity to innovators. The aim of patent policy is to maximize social welfare by balancing the two competing forces that correspond to this exclusivity: the increasing incentive to innovators and the increasing social cost from market distortions. The standard levers of these policies are patent breadth (the scope of protection), which restricts competitive imitation, and patent length, which specifies the amount of time the protection can be enforced. While the theoretical literature provides some guidance on what combination of these levers might

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be optimal, there has been relatively little work using data to measure the possible gains to alternative breadth-length designs. In this paper, I use data from the pharmaceutical industry to provide the first empirical assessment of the trade-off between patent breadth and patent length.

The U.S. pharmaceutical industry is a particularly relevant setting in which to examine modifications to patent policy. Pharmaceutical companies rely heavily on patents to safeguard innovator profits and there has been an on-going debate over the possible need for innovation-related policy reform.\(^1\) The debate revolves around the idea that there are two types of pharmaceutical product innovations: those that involve groundbreaking new therapies and major improvements over existing products and much more incremental innovations that provide little, if any, added therapeutic benefit.\(^2\) Despite this difference, both types of innovations require substantial investment to develop (DiMasi et al., 2003). Critics of the current policy argue that this latter group of innovations, often referred to as “me-too” products, provide insufficient social benefits to warrant these substantial costs and contribute to the rising costs of health care.\(^3\) My work directly informs this debate by asking the following question: What is the impact on the market of giving some of the most important product innovations broader but shorter patents, which limit the profitability of “me-too” products but allow for more rapid entry of generics?

To estimate the welfare implications of modifying patent breadth and length, I employ a structural approach. While historically there have been a number of patent policy modifications significant to the pharmaceutical industry, none of these occurred in recent decades. Taking a structural approach allows me to identify how changing patent breadth and length would impact social welfare. Existing theoretical work points out that product substitutability and market competitiveness affect the optimal balance of patent breadth and patent length. I begin by estimating a model of demand and supply with differentiated products. My framework accounts for the effect that health insurance has on consumers’ prescription drug prices. For pharmaceutical products, insured patients pay only a fraction (the copay) of the full retail price. Therefore, ignoring this feature runs the risk of underestimating consumers’ price sensitivities and distorting the results of any subsequent analyses that build on these estimates. Using the model estimates, I then examine the implication of the modified policies on welfare through counterfactual simulations.

For a patent policy to be feasible, the measure of patent breadth must be defined in such a way that it is known to the market and independent of any decisions made by the firms. Hence, in a practical setting, there are only a limited number of available levels that can be used for breadth. I consider a specific set of modifications that are available for the pharmaceutical market. Given

\(^{1}\)This debate is primarily targeted to innovation of small-molecule drugs, as opposed to biologics, which differ in how innovation and patenting are conducted. For this reason, this paper focuses exclusively on small-molecule drug markets.

\(^{2}\)This distinction is also recognized by other countries, including Canada (Lexchin, 2006).

that patent breadth in the pharmaceutical industry is already specified in the narrowest feasible terms, the basic counterfactual expands the breadth of a groundbreaking (high-value) drug’s market exclusivity by temporarily blocking from the market subsequent drugs that provide little, if any, added value (“me-too”s). This expansion, which leads to increased profits for the high-value innovator, is balanced by a reduction in patent life in order to make her indifferent between the two policy settings. Once the patent for the high-value drug has expired, the “me-too” drugs as well as the generic versions of the high value drug are allowed to enter the market. Effectively, this counterfactual delays market entry of “me-too” drug innovations and advances generic entry on the high-value drug. In this way, I propose to shift incentives, and consequently R&D investment, away from “me-too” innovations to those that are greater in value. I then examine the net impact on drug producers (innovators and manufacturers), consumers, insurers, and overall social welfare.

My analysis focuses on the market for antidepressants. Antidepressants constitute one of the best selling pharmaceutical markets of the past two decades and are exclusively comprised of prescription drugs. I use data containing monthly U.S. pharmaceutical prices and quantities for retail prescription sales as well as national advertising expenditures, for the period 1991 to 2010. These data capture the evolution of the dominant therapeutic drug class, from the pioneer molecule to the entry of subsequent molecules and the eventual generic entry on nearly all of the top selling molecules.

I estimate own-price elasticities, based on consumer copays, in the range between -1.6 and -3.2. As expected, I find much higher cross-price elasticities among drugs that are similar in the way they function versus those that are not. This suggests that if the modified policy is targeted to a specific grouping, it will have limited impact on products outside of that grouping.

Using estimates from the static models of demand and supply, I consider two policy experiments. The first modifies the patent of the first-in-class groundbreaking drug to address the debate in the pharmaceutical policy literature about the value of limiting the development of “me-too” drugs. Specifically, I expand the patent breadth and limit the patent length of the groundbreaking antidepressant, Prozac, in order to temporarily restrict the subsequent “me-too” products in the same therapeutic class from entering the market. I find that the patent life of Prozac is shortened by nearly six years (70 months). Additionally, the $3.8 billion in lost profits (64%) suffered by “me-too” innovators is overshadowed by the $10.2 billion in savings (14.4%) realized by insurers. Finally, consumers experience a welfare gain of $312 million (1.6%) under the modified framework. The total social impact of this modified policy is a gain of more than $10.6 billion (9.4%).

The second counterfactual extends the first, by allowing the “me-too” innovators to anticipate the impact of the modified policy and reoptimize their entry decisions during their respective drug

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4In this paper, I assume that all products that enter after the first-in-class are “me-too”s. At the end of the paper, I discuss on-going work in which this assumption is relaxed and these subsequent entrants can be recognized as high value products.
development processes. Those innovators that abandoned their drugs save their remaining investment expenditures. I find that while Zoloft would always proceed through Phase III clinical trials and onto the market, Paxil and Celexa would do so with probabilities of only 48.5% and 88%, respectively. The net effect on producers is a slight gain ($178 million or 1.1%) due to the expenditures saved by entry re-optimization. In cases where the products do not enter the market, consumers lose the value of their entry as well as the generics that would have followed on each molecule. However, this loss is still overshadowed by the gain of earlier generic entry on Prozac’s molecule, fluoxetine ($194 million or 1%). Insurers realize even greater gains ($10.9 billion or 15.4%) as consumers who would have otherwise purchased Paxil and Celexa, turn to generic fluoxetine instead. The net social welfare effect sums to $11.4 billion (10.1%). These results indicate the potential for meaningful social gains from exploring modified patent policies.

While this is the first empirical study of the tradeoff between patent breadth and length, some aspects of the problem are not addressed. For example, this paper does not try to address the question of whether initial innovators should be rewarded more generous patents; instead, like most of the theory literature, it considers how to give the initial innovator a fixed reward. Additionally, the analysis includes only a limited range of dynamics. While “me-too” innovators are allowed to reoptimize their entry decisions, the decisions of other market participants are assumed to be exogenous and held fixed. Finally, all follow-on products that enter prior to Prozac’s patent expiration are assumed to be “me-too”s. At the end of the paper, I discuss ongoing work that seeks to address this last limitation.

I proceed in the paper by first presenting the related literature, which is comprised of the theoretical work on optimal patent design as well as the empirical work aimed at quantifying the effects of competition and social welfare in the pharmaceutical industry. In Section III, I then describe the salient features of the pharmaceutical industry, the data sets, and the market for antidepressants. I present the static models of demand and supply in Section IV and the estimation procedure in Section V. In Section VI, I describe the results and their implications for the counterfactual simulations. Finally, I implement the counterfactual simulations to measure the welfare implications on consumers, insurers, and producers (innovators and manufacturers) in Section VII.

II Related Literature

This section reviews the relevant literature and contrasts it with the policy simulations in this paper. The theoretical literature has provided important insights on the underlying determinants of optimal patent policy, particularly with regard to the combination of patent breadth and patent length. Despite the theoretical foundation, relatively little applied work has considered this trade-off.
II.1 Theory of Optimal Patent Design

Substantial theoretical work has been done to examine incentives to innovation and the social value of patents. The segment of the literature relevant to my work analyzed how the balance between patent breadth and patent length influences social cost for a given stand-alone product innovation. These papers employed stylized models to highlight the importance of the market structure and the shape of the demand curve in determining optimal patent policy. The market structure is broadly defined to include whether products are differentiated, the number of potential innovators, and the nature of innovation and production costs. For a given innovation, the shape of the demand curve reflects consumers’ product substitution behavior. The greater this substitutability, the more sensitive consumers will be to a product’s price increases and thus, the lower the price that will maximize the innovator’s profit. In this way, the shape of the demand curve defines how much profit the patentholder can extract under a given policy.

Many of the relevant papers in this literature share two common features in their approach to optimal patent policy. First, they examined the optimal combination of patent breadth and length that guarantees an innovator a given reward, rather than determine what that award should be. Thus, in a given market, the optimality of a patent policy lies in its ability to minimize social costs while providing sufficient incentive to the innovator. The second key feature is the assumption that demand is independent of patent policy. This means that consumers are expected to purchase and consume products as needed and do not substitute across time.

I focus on a differentiated product market with multiple potential innovators and imitators, along with insurers and two types of social costs, deadweight loss and entry cost (cost of innovation or imitation). Using a differentiated product market with heterogeneous consumers, Klemperer (1990) showed that if consumers all have the same transportation costs, social cost primarily stems from deadweight loss, making narrow patents with long lengths optimal. Alternatively, if consumers all have the same valuation of products, then social cost primarily stems from substitutability.

For a comprehensive review of this literature, see Rockett (2010).

Stand-alone innovation refers to the final market product being composed of one innovation. Other segments of the literature have considered products that are comprised of a combination of different innovations (Scotchmer, 1991; Green and Scotchmer, 1995; O’Donoghue et al., 1998; Bessen and Maskin, 2009) and optimal patent policy with different combinations of policy levers, including patent length alone (Nordhaus, 1969; Scherer, 1972; Nordhaus, 1972), patent length with compulsory licensing (Tandon, 1982), patent renewals (Cornelli and Schankerman, 1999), and menus of patents (Cornelli and Schankerman, 1999; Hoppenhayn and Mitchell, 2001).

The literature has considered various settings, including: one innovator and many potential imitators in homogeneous products markets (Gilbert and Shapiro, 1990; Gallini, 1992); multiple innovators that develop differentiated products (Klemperer, 1990; Wright, 1999); and costly innovation or imitation (Gallini, 1992; Wright, 1999).

This implies that the total profit earned by the innovator under patent protection is necessary to induce the given level of innovation. The patentholder’s net present discounted profit $V$ earned under patent protection is therefore set to be nondecreasing. The significance of this restriction, which amounts to a form of Ramsey pricing, lies in its implicit assumption that the long-run innovation flow is not reduced regardless of the policy chosen (Ayres and Klemperer, 1999).

If consumers could substitute across time, the roles of patent breadth and length would be more similar (Klemperer, 1990).
tion to less preferred products, and broad patents with short lengths are optimal. Drawing on these insights, I start by estimating the demand parameters to determine the substitutability of products to others on the market as well as to the outside good.

The impact of high entry cost was also considered by the literature. Gallini (1992) considered a market in which imitators pay an entry cost and produce perfect substitutes that don’t infringe on the innovator’s patent. If patent breadth increases imitators’ entry cost, then the optimal patent policy was shown to consist of broad patents with short lengths. Allowing these entry costs to differ among the imitators, Wright (1999) found that the optimal patents could have narrow breadths and long lengths if deadweight loss is monotonically decreasing in the number of imitators. Otherwise, if deadweight loss were nondecreasing in the number of imitators, broad patents with short lengths would be optimal. To account for the presence of high entry cost and its potential effect on the modified patent policy, I compare innovators’ discounted profits to their innovation costs. Cases in which the cost exceeds the profit indicate that the innovators would be better off not entering the market.

II.2 Empirical Literature

The empirical literature relevant to the search for optimal patent policy includes reduced form and structural papers aimed at quantifying the effects of competition and social welfare in the pharmaceutical industry. The first strand of this literature examined natural experiments stemming from changes to patent policy in the U.S. and other countries in order to better understand the potential welfare implications of policy changes. The most notable of the U.S. policy changes is the adoption of the Hatch-Waxman Act (1984). In streamlining the process and reducing the costs of generic entry, this law not only ensured that firms with profitable products would face generic competition after patent expiration, but also reduced the average time for generic entry after patent expiration from three years to only three weeks (or less) (CBO, 1998; Schacht and Thomas, 2005; Grabowski and Kyle, 2007). In some cases, challenges under Paragraph IV of the Hatch-Waxman Act allow generic firms to enter the market prior to the patent expiration date originally claimed by the innovator. Branstetter et al. (2011) estimated that paragraph IV challenges led to a substantial net social gain in the hypertension market over the last decade. Grabowski and Kyle (2007) examined the decrease in the average amount of time brand name pharmaceuticals enjoy on the market before generic competition and found that this shift is even more pronounced in larger markets with blockbuster drugs.

10In this subsection, I provide a brief overview of the relevant empirical literature. For a more comprehensive review, see Cohen (2010) and Hall and Harhoff (2012).

11One concern discussed in the literature is that this type of reduction in market exclusivity for patented products has decreased the incentives for future innovators. For more details, see Grabowski and Kyle (2007), Higgins and Graham (2009), and Panattoni (2011).
examined the impact of the 1988 patent reforms in Japan on the country’s innovative effort. The authors found little evidence that the uniform expansion of patent scope led to greater R&D effort by domestic innovators.

The other strand of relevant literature utilized structural frameworks to implement counterfactual simulations. A few papers have estimated the value consumers place on having follow-on products and/or generics in the market. Using data for the ADHD drug market, Bokhari and Fournier (2012) found that generic entry led to a significantly larger welfare increase than entry by follow-on products. Arcidiacono et al. (2013) found that “me-too” anti-ulcer drugs increase insurer spending by billions of dollars each year. Next, Chaudhuri et al. (2006) and Dutta (2011) applied a structural framework to estimate the effect that the Trade-Related Intellectual Property Rights (TRIPS) would have on pharmaceutical industry in India. These papers found that the new patent rules will lead to substantial loss to consumer welfare and a relatively small gain to foreign patent holders. However, these results reflect short-term estimates, couched in the presumption that domestic firms will not engage in any significant innovative activity. Incorporating consumer learning into the analysis, Ching (2010b) found that shortening the time between patent expiration and generic entry leads to a very small welfare gain for consumers. Finally, the closest work to this paper was provided by Yin (2013), who estimated the welfare effects of granting additional periods of exclusivity to original innovators who make incremental improvements to their own existing products (e.g. new drug formulations, new indications, or improved efficacy and safety). Using the market for antidepressants, Yin (2013) found that while the value of the incremental innovations in aggregate is greater than the corresponding costs, some products netted a social loss.

This paper differs from and contributes to the empirical literature in two ways. First, I look specifically at the tradeoff between patent breadth and length that has been the focus of the theoretical literature. In this way, I attempt to limit the impact of any patent modification on long-run innovation flow. Second, I explicitly consider different ways of handling how a modified policy would impact the entry of later drugs.

12 These papers examined demand through a variety of discrete choice models, including nested-logit (Stern, 1996b; Mortimer, 1998; Azoulay, 2002; Currie and Park, 2002; Dutta, 2011), principles of differentiation generalized extreme value (Arcidiacono et al., 2013), random coefficients (mixed) logit (Cleanthous, 2002; Dickstein, 2011; Yin, 2013) and the almost ideal demand system (Ellison et al., 1997; Chaudhuri et al., 2006; Bokhari and Fournier, 2012). Several papers also incorporate physician/patient learning into their frameworks (Ching, 2010a,b; Dickstein, 2011).

13 The estimation framework used by Yin (2013) is very similar to the one proposed by Dunn (2012), which found that the quality-adjusted price in the anti-cholesterol drug market decreases with the introduction of new product innovations.
III Background and Data

In this section, I provide background information relevant to the market structure and briefly detail the multiple datasets that allow me to implement the counterfactual simulations. First, I describe the key features of the U.S. Pharmaceutical industry and explain why it is particularly suitable for an examination of a modified patent policy. I then present information on the antidepressant market, which serves as a good application for my analysis, given that the data captures the evolution of the dominant therapeutic drug class.

III.1 The U.S. Pharmaceutical Industry

The U.S. pharmaceutical industry differs from most other industries in several important ways. First, new products in this industry are expensive to develop and cheap to produce, which implies that the industry is highly dependent on patents to safeguard innovators’ profits and that it may be more socially efficient to limit development of all but the most valued innovations. As part of the development process, innovators must prove that their products are sufficiently safe and effective in order to enter the market. However, innovators (pioneers and followers) only need to compare the efficacy of their products to either long-established quality minimums or placebo control groups. Thus, products following the pioneer can enter the market with equivalent, or even inferior, quality. As depicted in Figure 1, the drug development process can take more than a decade, and require thousands of patients, to complete. DiMasi et al. (2003) estimated that the average out-of-pocket cost of this process for successfully developed and approved products amounted to
several hundreds of millions of dollars, after accounting for risk of failure. On the other hand, marginal manufacturing costs per dose tend to be less than one or two dollars, if not just a few cents. Moreover, given that product development predominantly occurs after the innovation has been patented, a product generally has between eight and 14 years of patent protection remaining once it reaches the market (this period is commonly referred to as the effective patent life).

Second, each pharmaceutical product innovation is generally distinct in molecular structure from other product innovations, even though they may be used for the exact same purpose and be very similar in quality. Under the current policy, each pharmaceutical patent protects the active component of the molecule and allows the innovator to generalize on the weak or inert components that may be combined to it. While technically a patent can be further narrowed in scope to all complete molecules, this would amount to a substantial burden on innovators, since the innovation tends to be fully embodied in the active component and the rest represents little more than filler. In this way, pharmaceutical patents represent as narrow a scope for patent protection as is feasible (henceforth, I refer to this measure of patent breadth as the molecule level).

The next key feature of this industry is that pharmaceutical product innovations are patented before their value is known, normally at the beginning of the development process (Mossinghoff, 1999; Grabowski, 2002). Usually, by the end of Phase II, innovators have gained their first significant evidence of efficacy and safety (DiMasi et al., 1991; Mossinghoff, 1999). This means that innovators might wait as long as seven or eight years after applying for the patent before they know the value of their product, an another four to five years before they can enter the market (see Figure 1). The temporal disconnect between these events means that a “me-too” innovation will be patented before it is known to be a “me-too”. For this reason, the conventional framework of patent policy needs to be adapted to focus on which products may enter the market, rather than strictly specifying the products that are owned by a given innovator. The need to exclude the ownership requirement stems from the molecular differences between the groundbreaking and “me-too” innovations, which are described above. In practice, greater patent breadth on high-value innovations would mean that innovators of “me-too” products would still retain their patents, but be restricted from entering the market.

A fourth key feature is that products belong to therapeutic classes, which are categorized according to the mechanism or chemistry that the products target in the body and, typically, more than one therapeutic class is used for a specified treatment. In this way, there is a limit to the degree to which two products in the same therapeutic class can be differentiated. Given that this classification is independent of any decisions made by the firms, it provides a clear level to which breadth could be expanded from the current molecule level. The only other potentially feasible

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14Exceptions to this include the type of incremental improvements innovators make to their own products in order to get additional periods of exclusivity. This paper focuses on small molecule (non-biologic) patents that identify the chemical structure and activity of a new compound.
level that breadth could take in this context would be to encompass the full antidepressant market, but still allow prior market entrants to remain.\footnote{While I ignore the possibility that a drug may be used for multiple completely different markets (treatments), it is a simple matter to focus the entry restriction to only a specified market and still allow access in other markets. For example, the popular hair treatment Rogaine (minoxidil) is also used to treat high blood pressure (under the trade name Loniten). Even if it had temporarily been blocked as a high blood pressure medication, as the first hair growth drug approved by the FDA, it would be free to enter this second market.}

Next, entry in this industry by generic drug competitors once the patent has expired provides substantial cost savings to consumers. Indeed, generic entry has been observed to reduce a molecule’s average price by as much as 80% within 18 months after expiration (Jena et al., 2009). Competitive pressure stems not only from the number of generic entrants, but also from state laws that permit or require pharmacists to dispense an available generic version, unless expressly prohibited by the prescribing physician. Therefore, as long as developers of high-value drugs have sufficient incentive to innovate, enabling earlier generic entry on these drugs to occur will allow consumers to enjoy these gains that much sooner.

The final key feature of the pharmaceutical industry is that most consumers generally pay only a small fraction of a product’s full price, called the copayment or copay, while their prescription insurer pays the rest. For this benefit, consumers (or their employers) regularly pay a premium to their insurer. With the market power that results from covering many consumers, insurers are then able to negotiate reduced prices with the drug manufacturers, often in the form of a rebate. I discuss the available data below.

\section*{III.2 Data}

To analyze this market, I combine several data sets. I acquired the first from SDI Health (hereafter, “SDI”).\footnote{Shortly after this data was purchased, SDI Health was acquired by IMS Health.} This data contains monthly, national-level revenue and quantities for prescription drug sales by retail vendors, over the period 1991 to 2010. Observations are broken down by individual drug, identified by either its brand name or as a generic, its formulation (i.e. capsule, tablet, etc.), the dose size, and the manufacturer that produced it. While this data takes into account discounts, it does not include rebates.\footnote{As previously discussed, rebates are direct payments from drug manufacturers to health care providers and they represent another dimension in which patented molecules can compete for sales. Unlike discounts, which are observed by the entire market, rebates are generally kept confidential between the two entities in the agreement.} For this reason, retail prices may not represent the effective product prices, but they are the best data available to the public.\footnote{While rebate data are not publicly available, some inference can be made on their bounds and volatility. Under the Medicaid Drug Rebate Program, branded drug manufacturers must give the U.S. government either 15.1\% off of their average price or their best rebated price, if it is lower. Hence, it is likely that manufacturers only rarely exceeded this threshold prior to generic entry on the drug (Arcidiacono et al., 2013). Additionally, it is likely that rebate agreements between manufacturers and insurers are generally negotiated on an annual or semiannual basis, which limits their impact on volatility in the national average price per drug.} Additionally, the SDI data does not include sales through hospitals or prescriptions provided to consumers directly from third party...
institutions, such as psychiatric institutions and the military.\textsuperscript{19}

A drawback of the SDI data is that it reflects information reported by retailers, rather than by manufacturers. Hence, the data does not consistently capture changes in ownership among manufacturers and also includes sales attributed to firms that merely package or distribute the pharmaceuticals, rather than the true manufacturers. To remedy the issue with changes in ownership, I conducted an extensive search through public filings and company websites to identify mergers and acquisitions among the relevant firms. To address the second issue, I use the FDA’s National Drug Code Directory (NDC) database to determine firm affiliations according to two key identifiers, NDC Number and Application Number. Given the sparsity of the historical data available on the FDA’s website, I obtained a more comprehensive dataset through a Freedom of Information Act (FOIA) request.\textsuperscript{20}

I acquired the second data set that I use from Encuity, Inc. This data includes monthly, national-level advertising to physicians, nurse practitioners, and physician assistants (also known as “detailing”). It is generally understood that marketing strategies for branded drugs include a great deal of detailing expenditures, while generic manufacturers rarely engage in this practice. It should be noted that generics are not necessarily considered perfect substitutes by consumers for many reasons, including brand loyalty and preferences for formulation, flavor, and even color.\textsuperscript{21} However, their efficacy and side effect profiles should be very similar, if not identical, to their branded counterparts, for any given molecule. Due to some data limitations, I do not include advertising that directly target patients. However, the effect if this is likely mitigated by the fact that patients and doctors generally make the product decisions together and I include advertising to physicians.

Finally, I use the MarketScan Commercial Claims and Encounters (CCAE) Database, obtained through the National Bureau of Economic Research, which consists of a nation-wide sample of healthcare insurance claims provided by large employers and health plans. This data set is comprised of patient-level prescription drug purchases between 1996 and 2009. It includes patient copay expenditures per prescription as well as some corresponding insurance plan information. However, the consumer premiums paid to insurers are not available.


\textsuperscript{20}Additional information on the historical data available through the FDA’s website can be found at www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.

\textsuperscript{21}Ching (2010b) and Ching (2010a) provide some support that consumers perceive this difference between a brand product and its generic versions. These papers argue that consumers are initially uncertain about the quality of generics and that the rate of generic diffusion is explained by consumers learning from others’ use.
III.3 The Antidepressant Market

Major depression or lower-level chronic depression affects 9.1% of adults in the United States.\textsuperscript{22} However, according to The National Ambulatory Medical Care Survey, the number of people receiving treatment for depression tripled between 1987 and 1997. In studying this trend, Olfson et al. (2002) noted that this substantial increase “coincided with the advent of better-tolerated antidepressants, increased penetration of managed care, and the development of rapid and efficient procedures for diagnosing depression in clinical practice.” These concurrent events imply that the new drugs to the market were of higher quality, and consumer costs were reduced by the increase in insurance coverage and the improved diagnostics. Figure 2 shows that drug sales in this market increased substantially over time. Antidepressants are generally categorized by into four main therapeutic classes. Each class targets a different mechanism in the body in order to elicit the desired effect.

The first two of these classes are generally considered by the medical literature to be first-generation antidepressants. In the early 1950’s, monoamine oxidase inhibitors (MAOIs) were found to reduce the symptoms of depression and were introduced as a treatment. However, MAOIs were temporarily taken off the U.S. market when it was discovered that under specific conditions, the drug could cause death. The promise of MAOIs led to continued research on treatments for mental illness. By the 1970’s, tetracyclics (TCAs) had been shown to increase the brain’s supply of norepinephrine and serotonin and were introduced as the second therapeutic class. While not as likely to cause death, TCAs offered little added benefit in efficacy and contributed to a host of other side effects that range from mild to severe.

The second-generation antidepressants include the last two classes. The most prominent antidepressant class consists of selective serotonin reuptake inhibitors (SSRIs), which elevate only serotonin in the brain. While SSRIs did not offer significant benefit in efficacy over MAOIs or TCAs, their side effects were not nearly as frequent or severe. Little more is known about the true way that these chemicals influence depression. The last class is also the least well understood. This class is often referred to as Other Antidepressants or as New Generation Antidepressants (NGAs). NGAs appear to allow for increased levels of norepinephrine and dopamine in the brain. Nearly all of the products sold under patent during the date range of the SDI data belong to either the NGAs or SSRIs.

Figures 2 and 3 provide monthly totals of daily-dose sales by therapeutic class and molecule, respectively. While the TCAs are the dominant drug class at the start of my time period, they

\textsuperscript{22}See the Centers for Disease Control and Prevention (CDC) revised estimates for more details (www.cdc.gov/features/dsdepression). Prevalence rates identified in other papers vary. Dickstein (2011) cites a prevalence of 6.5% for adults affected by major depression, Berndt et al. (1996) note survey evidence that indicates a 9% prevalence rate for major and lower-level chronic depression among the employed labor force, Greenberg et al. (2003) use the Epidemiologic Catchment Area survey to support a 10.1% rate, and Kessler et al. (2005) find a rate of 8.2% across all adults.
experienced a steady decline thereafter. Conversely, the NGAs drew a sizable share of the market during the same time period with the introduction of several new molecules. However, the SSRIs clearly became the dominant class of antidepressants. MAOI sales are included in Figure 2, but are too small to see. Figure 3 illustrates how quickly sales for branded molecules can be overtaken by their generic counterparts after patent expiration. Prozac’s patent expired in mid-2001 and within a few months, most of fluoxetine hcl sales were made by generics. Similar switching can be observed for Zoloft and Celexa.

The SSRIs began in 1988 with the market introduction of Prozac, which immediately became the dominant product in the market with annual sales of over $1 billion. Figure 4 shows weighted average prices for SSRI products, presented at the daily-dose level in 2010 dollars. Following on Prozac’s success, Zoloft was released in early 1992 and competed with a price that trended downward, falling below Prozac’s price by the end of 1995. Then Paxil, in the beginning of 1993, and Celexa, in the second half of 1998, were each released with prices significantly higher than either Zoloft or Prozac. The remaining SSRIIs entered the market after Prozac’s patent expiration. It is important to note that generic prices on each of the first four SSRIs (denoted by the dashed lines) begin close to their brand counterparts and then quickly drop thereafter. Specifically, average daily-dose price for generic variations of Prozac (fluoxetine) starts at a high of $3.07 and falls to $0.76 within 18 months.
As previously mentioned, advertising is an important component of competition in the pharmaceutical industry. Firms spent an average of $8.5 million per month to advertise Prozac, Zoloft, and Paxil to physicians during the molecules’ patent protected period. However, there were small increases in advertising for Zoloft and Paxil around the time of Prozac’s patent expiration. This suggests that firms that correspond to these drugs were attempting to limit consumer switching from their respective products to generic variations of fluoxetine. Advertising expenditure was nearly double the average amount for Lexapro. For each brand name, advertising quickly tapered off after its patent expired. Interestingly, this tapering off of brand advertising provides a countervailing effect that balances with the lower generic pricing. This likely explains why total quantity sales on many molecules remain stable in the years around a brand’s patent expiration. Generic manufacturing firms might advertise only if they are the first to enter on a given molecule and then stop once other generics enter the market.

The comparison between the prescription-level retail prices and the copays paid by patients is presented in Table 1 for a selected sample of the top selling NGA and SSRI drugs. The average retail price for a prescription of brand drugs tends to be over $100, while an insured patient’s expense ranges between $15 and $30. This means that insurers pay the vast majority of the cost of these prescription drugs. The retail prices of generics tend to be about half the price of the branded drugs, if not less. For generics, insured patients pay around $10. Also included in the table are
the dates that the molecules first launched onto the market and their first patent expiration dates.\footnote{As previously mentioned, innovators occasionally patent new formulations of their products in an effort to extend their market exclusivity.} Next, are the number of generic producers that compete under a given molecule. Note that while generic manufacturers do provide a great deal of price competition, these products may still be differentiated by formulation and manufacturer.

The antidepressant market provides a particularly useful example in examining modified patent policy for a few reasons. First, the market consists almost entirely of prescription drugs, which implies that sales are more likely to be captured in the data. Second, sales in the antidepressant market over the period 1991 to 2010 were dominated by SSRI manufacturers, which mostly consisted of large pharmaceutical firms that relied on patent protection to prohibit generic competition. Finally, the data captures the competitive evolution of the dominant therapeutic drug class. While the entry of the pioneer molecule in the SSRI class is not observed, the data does capture the entry of all subsequent products. I examine the impact of broadening Prozac’s patent’s breadth while simultaneously shortening its patent length in order to reduce incentives for the some of the subsequent SSRI entrants, which I assume to be “me-too” products. Once these profits are earned, the modified patent would expire and allow both generic competitors and the available “me-too” products to enter.
IV The Model

In this section, I present a static model of differentiated-product demand and supply which will be used to determine the shape of the demand curve and recover the implied marginal costs. Building off of Berry (1994) and Cardell (1997), I estimate demand using a three-level nested-logit model, which adequately provides the flexibility of substitution patterns that will be applied to the counterfactual simulations. I then apply these estimates to a supply model and equilibrium conditions similar to those proposed in Nevo (2000a). This approach allows me to implement the modified policies by simply removing products from the market and then reoptimizing price to equilibrium.

IV.1 Product Price and Consumer Copay

As presented in the previous section, the copay paid by insured consumers for product \( j \) at time \( t \), given by \( c_{jt} \), tends to be substantially lower than the price the set by manufacturers, \( p_{jt} \). Insurers generally assign drugs to three copay tiers, based on their relative prices. High priced brand drugs tend to be assigned to the top tier (non-formulary), which may have a copay around $50 per prescription, while more moderately priced brands are assigned in the second tier (formulary) may have a copay of $30 per prescription. The final tier is for generic drugs, which tend to have a copay of $10 per prescription (see Table 1). Since these assignment decisions are likely independent of any specific drug or class of drugs, I treat them as given. Moreover, I assume that insurers play a passive role, limited to their payment expenditures on consumer purchases.

I model the relationship between copay and price as a power function with a power value less than one (Arcidiacono et al., 2013). In particular, I assume the form

\[
    c_{jt} = p_{jt}^{\phi} \cdot e^{\gamma_0 + \gamma_1 X_{jt} + \nu_{jt}},
\]

where \( X_{jt} \) are observed product characteristics, \( \nu_{jt} \) is an error term, and \( \{\phi, \gamma_0, \gamma_1\} \) is the set of parameters to be estimated.

IV.2 The Demand Side

Suppose consumers choose from an assortment of products which belong to two levels of nests (or groups). Let \( g \) index the nests in the upper level and \( m_g \) index the groups in the lower level, the subnest. While consumers consider all of the products in their choice set, products within a nest (or subnest) are more similar in value than those across nests (or subnests). Within this three-level nested logit framework, a consumer is assumed to first choose a nest \( g \) (a therapeutic class), then a

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24The power function dampens high prices, which matches the trends observed in the data.
subnest \( m \) (a molecule) from those available in \( g \), and finally a product \( j \) from those within subnest \( m \).

The indirect utility that consumer \( i \) gets from product \( j \) at time \( t \) is given by

\[
    u_{ijt} = \delta_{jt} + \psi_{ijt}
\]  

(2)

where

\[
    \delta_{jt} = X_{jt} \beta + \alpha c_{jt} + \gamma \ln(a_{mg}) + \xi_{jt}
\]  

(3)

and

\[
    \psi_{ijt} = \zeta_{ig} + (1 - \sigma_g) \zeta_{igm} + (1 - \sigma_g)(1 - \sigma_m) \varepsilon_{ijt}.
\]  

(4)

The first term in equation (2) is the mean utility level of product \( j \), which is a function of observed product characteristics \( (X_{jt}) \) and those characteristics which are observed by consumers but not by the econometrician \( (\xi_{jt}) \). The mean utility also includes the consumer’s copay, \( c_{jt} \), and the natural log of the advertising, \( a_{mg} \), for product \( j \).\(^{26}\) Since firms may offer multiple products within the same subnest \( m \), I assume that a firm simultaneously advertises this collection of products and index advertising accordingly.

The other term in equation (2) is the heteroskedastic error, which captures the effects of the random taste parameters and reflects the form of the nesting structure. For consumer \( i \), \( \zeta_{ig} \) and \( \zeta_{igm} \) capture the unobserved variation common to all products indexed by \( g \) and \( m \), respectively. Within the bounds of \( [0,1) \), \( \sigma_g \) and \( \sigma_{mg} \) measure the importance of the structure that defines each nest (subnest) as being distinct from the rest of the sample. As \( \sigma \) approaches one, the products in the same nest (subnest) can be considered stronger substitutes, than products across nests (subnests). If \( \sigma \) is zero, preferences for the products within the nest (subnest) are not correlated in any way distinct from the rest of the products and the model simplifies to either the nested logit (if \( \sigma \) for only one of the levels is zero) or the standard logit model (if both).

Finally, \( \varepsilon_{ijt} \) represents the distribution of consumer preferences around the mean valuation \( \xi_{jt} \) and is assumed to be an identically and independently distributed (i.i.d) extreme value. Cardell (1997) shows that \( \zeta_1 \) and \( \zeta_2 \) have unique distributions, such that if \( \varepsilon \) is an extreme value random variable, then so is \( \zeta_1 + (1 - \sigma_1) \zeta_2 + (1 - \sigma_1)(1 - \sigma_2) \varepsilon \). Berry (1994) and Nevo (2000b) note that an important implication of the i.i.d assumption for \( \varepsilon_{ijt} \) across customers and choices is that products in the same nest are solely differentiated by the mean utility levels, \( \delta_{jt} \). Hence, market shares and elasticities are solely determined by \( \delta_{jt} \). However, when some products are more sim-

\(^{25}\)In order to avoid the complexity of decision-making and consumption involved in this setting, I assume that the “consumer” includes both the prescribing doctor and the patient who uses the medication, and that patients are fully compliant in using all of the prescribed medication they purchase. Dickstein (2011) employed a dynamic learning model that relaxes both of these assumptions. Additionally, I assume that a “producer” includes the drug manufacturer as well as the pharmacies that sell its product to consumers. Both of these assumptions are common in the literature.

\(^{26}\)Allowing advertising to enter the utility function in this way captures the persuasive role it has on consumer choices. However, given the possibility that consumers may be uncertain about the quality of new drugs, advertising might also play an important informative role (Ching and Ishihara, 2010, 2012). In Section V.1, I discuss the use of fixed effects to incorporate consumer learning into the estimation.
ilar than others, this dependence on just $\delta_{jt}$ for consumer choices will result in estimated product substitution patterns that do not match the true patterns. The advantage of the nested-logit model over the standard logit model is to lessen this restriction on substitution patterns by grouping products known to be more comparable into nests. Despite its reliance on the a priori assumption on how the market is segmented into nests, this framework provides sufficient flexibility on the substitution patterns for my needs.  

Another feature of logit models is the S-shaped nature it imposes on demand. Whether firms price in the convex or concave regions is determined by the parameter estimates and costs.

Following the three-level nested logit analog of Berry (1994) and defining $\eta = [1 - (1 - \sigma_g)(1 - \sigma_{mg})] \in [0, 1)$, the demand equation can be restated as

$$
\ln(s_{jt}) - \ln(s_{0t}) = X_{jt}\beta + \alpha c_{jt} + \gamma \ln(a_{mg}) + \sigma_g \ln(s_{mg}) + \eta \ln(s_{jt/mg}) + \xi_{jt}.
$$

The first term on the left-hand side is the log of the market share of product $j$ at time $t$, while the second term is the log of the share of the outside good in the same period. Finally, at time $t$, $s_{jt/mg}$ is product $j$’s share of sales by all products in subnest $m$ and $s_{mg}$ is subnest $m$’s share of sales by all products in nest $g$. The derivation of this form of the demand equation is provided in Appendix A.

IV.3 The Supply Side

Suppose there are $F$ firms, each of which produces some subset, $J_{ft}$, of the $j = 1, \ldots, J_t$ different products available at time $t = 1, \ldots, T$. The profit of firm $f$ at time $t$ is

$$
\Pi_{ft} = \sum_{m \in J_{ft}} \sum_{j \in m} [(p_{jt} - mc_{jt})M_ts_j(p_t)] - a_{mt} - C_{ft}
$$

where $s_j(p_t)$ is the market share of product $j$ and is a function of the prices of all products at time $t$. Note that I hold advertising fixed and do not attempt to solve for new advertising trajectories when performing counterfactuals. The market size at time $t$ is denoted by $M_t$, $mc_{jt}$ is the marginal cost of production, and $C_{ft}$ is the fixed cost of production.

In line with the literature, I assume that there’s a unique Bertrand-Nash pricing equilibrium, with prices that satisfy these first-order conditions.  

A key feature of this assumption is that it

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27The market I focus on experienced a great deal of product entry during my sample period. Given that the Almost Ideal Demand System (AIDS) approach does not have a good way of dealing with a varying number of products, I chose not to use it (Chaudhuri et al., 2006).

28The validity of this assumption is supported by conversations with pharmaceutical industry experts and ample evidence in the relevant literature, which indicate that firms compete by setting prices. In most markets, products are differentiated and firms are not capacity constrained. Additionally, Nevo (2001) found that the Bertrand-Nash equilibrium leads to more accurate predicted margins than other behavioral models. The assumption of a static game does
enables me to measure the impact of alternative policies on social welfare. For firm $f$ at time $t$, let $r$ index the individual products in $J_{ft}$. The price, $p_{jt}$, and the marginal cost, $\hat{mc}_{jt}$, for product $j$ must then satisfy the following first-order condition (FOC):

$$s_j(p_t) + \sum_{r \in J_{ft}} (p_{rt} - \hat{mc}_{rt}) \frac{\partial s_r(p_t)}{\partial p_{jt}} = 0. \quad (7)$$

The $J_{ft}$ equations in (7) can be used to calculate the price-cost margins for each product. I define

$$\omega_{jr}^{pre}(p_t) = \begin{cases} -\partial s_r(p_t)/\partial p_{jt} & \text{if } \exists f : r, j \in J_{ft} \\ 0 & \text{otherwise} \end{cases} \quad (8)$$

and substitute it into the vector form of the FOC to get

$$s(p_t) - \omega^{pre}(p_t)(p_t - \hat{mc}_t) = 0.$$  

This equation can then be rearranged and used to solve for the markups and the implied marginal costs

$$p_t - \hat{mc}_t = \omega^{pre}(p_t)^{-1}s(p_t) \quad \Rightarrow \quad \hat{mc}_t = p_t - \omega^{pre}(p_t)^{-1}s(p_t). \quad (9)$$

Assuming marginal costs are not observed, equation (9) allows these values to be calculated using the demand system estimates. This equation can also be used to simulate the equilibrium prices under the modified policy by returning to the previous Bertrand-Nash equilibrium assumption.

### V The Estimation

I estimate the parameters of the model presented in the previous section using the data discussed in Section III. I consider each therapeutic class to be a different top-level nest and each molecule to be a bottom-level nest. Thus, the consumer first chooses one of these classes or the outside good, then a molecule from that nest, and finally, a specific product of the molecule.

Observed characteristics include whether the product is a brand or generic, the form of the drug, who produces it, the months in which it was purchased, and how long the molecule has been on the market. However, it is important to note that marginal cost estimates rely on the use of consistent demand system estimates. Inconsistent estimates may result in implied marginal costs that appear to jump erratically over time. Additionally, non-negative marginal cost estimates rely on the model correctly capturing firms’ profit maximizing behavior.

29 However, it is important to note that marginal cost estimates rely on the use of consistent demand system estimates. Inconsistent estimates may result in implied marginal costs that appear to jump erratically over time. Additionally, non-negative marginal cost estimates rely on the model correctly capturing firms’ profit maximizing behavior.
V.1 Market Size and the Outside Good

To form my sample, I take the following steps. First, I assign molecules in the SDI database to their corresponding therapeutic classes according to the Anatomical Therapeutic Chemical (ATC) Classification System.\textsuperscript{30} Next, I follow the established path of defining daily dose as a common basis of comparison to allow for the estimation of substitutability between products (Stern, 1996b; Berndt et al., 1996; Currie and Park, 2002). I use the Physicians’ Desk Reference for various years to establish each molecule’s daily maintenance dose levels and divide dose sizes by these corresponding values. These results are then multiplied by the monthly unit sales and divided by the number of days in that month. Third, I calculate the antidepressant market size by multiplying the prevalence rate of depression by both the U.S. Census Bureau’s monthly estimates for the civilian population and by the proportion of people that are at least 18 years of age.\textsuperscript{31} Fourth, prices are inflated to December 2010 dollars using the Consumer Price Index from the Bureau of Labor Statistics.\textsuperscript{32} Finally, for ease of computation, I aggregate the data in two ways. First, I aggregate doses for each brand, manufacturer, and form in a given month. While resulting in a substantial reduction, this step still leaves over 700 brand-manufacturer-form combinations per month. As discussed in Section III.2, I then combine firms that are affiliated through production chains or mergers and end up with 364 products. This last step is particularly relevant to generic drug manufacturers, many of which had merged with or acquired other generic manufacturers. However, the data still includes multiple distinct generic products for each molecule not under patent.

To estimate the relationship between copay and price, I use the MarketScan CCAE Database merged by drug and month with prices from the SDI database. Copay values are taken from the insurer listings that correspond to each patient transaction. I exclude observations in which the corresponding insurer plan requires patients to pay anything other than a copay.\textsuperscript{33} The parameters in equation (1) are estimated on patients’ transaction-level data with prescription-level prices, and weighted by the number of enrollees in each plan. These estimates are then converted to the daily-dose level and incorporated into the demand estimation.

In estimating the demand, I account for both time-varying and time-invariant effects. A number of time-varying product characteristics, \((c_{jt}, X_{jt}, a_{mt})\), enter the consumer’s utility. Among the \(X_{jt}\) characteristics, I first include patent expiration dummies for each molecule to capture any changes that occur.

\textsuperscript{30}Established by the World Health Organization Collaborating Centre for Drug Statistics Methodology in 1982, the ATC classifications provide a clear system by which innovating firms can determine to which drug class their innovation corresponds. Moreover, since firms generally sell their pharmaceutical drugs to multiple countries, this international classification system is appropriate.

\textsuperscript{31}Both the SDI database and the U.S. Census Bureau estimates exclude people who are in the military or are in institutional facilities. (http://www.census.gov/popest/).

\textsuperscript{32}The Consumer Price Index can be found at http://www.bls.gov/cpi/.

\textsuperscript{33}In the MarketScan CCAE database, some patients are observed to pay other costs, such as co-insurance and a deductible. However, a majority of the observed plans require patients to only pay a copay.
in how a product is perceived by consumers. Next, I include time dummies, alone and interacted with a therapeutic class identifier, to capture news that enters the market and affect consumer perceptions. Additionally, I incorporate months-on-market dummies for the first twelve months after a molecule enters the market in order to isolate trends in product availability or consumer awareness and/or learning. These dummies are allowed to vary by therapeutic class. Finally, I include copay at the product level and log advertising at the manufacturer-molecule-month level. This paper treats advertising as exogenous. Pharmaceutical firms typically lay out their advertising schedules far in advance and these expenditures do not appear sensitive to monthly demand shocks that are commonly absorbed into the error term. Furthermore, I do not attempt to solve for new advertising levels in the counterfactuals, but I do exclude advertising for products that have been removed from the market. The time-invariant characteristics are captured by molecule-level and manufacturer-form-level fixed effects. The distinction is necessary due to the nesting structure of the model.

Following Nevo (2003), I make two important assumptions relevant to the interpretation of the counterfactual results. First, I assume that the quality of the outside option (possibly, therapy or nothing) does not decrease over time. Second, I assume that any changes in consumers’ perceived value of a product’s unobserved characteristics primarily stem from changes of those characteristics that happen over time. Hence, $\xi_{jt}$ is allowed to vary over time in the welfare calculation.

V.2 Instruments

Following Stern (1996a,b), I instrument for product prices and the potential endogeneity of the within-nest shares using supply-side factors. These instruments are intended to be unrelated to the unobserved heterogeneity (possibly quality), but are systematically correlated with pricing decisions and the determinants that affect within-group share. The first set of instruments are those based on the amount of competition within a nest. For a given product, I count the total number of other products in the nest that are generics, the percentage of those other products that are generics, and the number of other firms that sell products in the nest. These three simple measures capture the degree of competition a given product faces, but should not be related to unobserved quality. Also, I can use the total sum of time since entry of other products in the nest as an instrument. The FDA imposes strict regulations on the drugs sold on market and all changes to an approved product must also be approved. Hence, controlling for a product’s own time on market, the aggregate time since entry of all other products will not be related to a given product’s unobserved quality.

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34 For robustness, I included longer periods of time and found no meaningful variation.

35 This assumption was included after conversations with several industry experts and medical practitioners.

36 One concern raised by Ellison et al. (1997) to the use of the number of firms as an instrument is that firms could be entering or exiting a market in response to changing demand characteristics. While this is a valid concern, I do not find a great deal of this type of movement by firms in the data. I observe a great deal of entry, but not as much exiting. Further, it is rare to see a product enter the market, leave, and then re-enter.
As noted by Stern (1996a,b), multi-product market power is also likely to influence prices, but not unobserved quality. To that end, the second set of instruments I employ are the numbers of other products sold by a given product firm in each nest. Since firms are assumed to maximize profits over their entire product portfolio, changes to the portfolio will affect the prices it sets, but not the unobserved quality of a given product.

VI Estimation Results

In this section, I review the estimates of the model and compare them to findings in other papers. I start with the copay-price relationship defined in equation (1), which is estimated by nonlinear least squares regression. As expected, Table 2 shows a positive relationship between copay and price. More specifically, a one percent increase in the price of product \( j \) results in roughly a 0.42% increase in the copay for that product.

The copay regression results allow me to estimate demand based on the costs that patients observe. Table 3 provides the key demand-side parameter estimates. The nest parameters imply that the therapeutic class designation is meaningful. That is, products in the same therapeutic class are considered better substitutes and so, consumers are less likely to switch to other product classes. Given that a molecule belongs to only one therapeutic class, the second parameter will be larger by construction. However, there is still some meaningful distinction between molecules.\(^{37} \) The estimated parameters on the fixed effects are also meaningful. The months-on-market parameters show that the SSRI class were slow to gain traction in the first couple of months, but resembled the other drugs on market soon after.

Own-price and cross-price elasticities provide additional insight into how a change to patent policy will affect a market.\(^{38} \) Using the demand estimates, I calculate the own-price elasticities to range between -1.6 and -3.2 for the two dominant therapeutic classes, shown in Table 4. The average cross-molecule elasticities for the SSRI class, which are presented in the last four rows of the last column, are quite large. These imply that blocking one of these products from the market will have a substantial positive impact on the market shares of the other SSRI products. Alternatively, the cross-class price elasticities in the first four rows of the last column are relatively small. This implies that if an SSRI product is blocked from the market, consumers are not very likely to switch to an NGA product. Additionally, any product blocked from the NGA class would have an even lower impact on the SSRI products. These results indicate that substitutability within a given drug class is quite high, which suggests that extending patent breadth from the molecule level to the therapeutic class may be welfare improving. Beyond that, the products are sufficiently

\(^{37}\)Omitting the class-level nests and estimating demand as a simple nested logit with molecule-level nests, yields an estimate of similar magnitude to the coefficient for \( \ln(s_{jt/m_g}) \).

\(^{38}\)I provide the derivation of these elasticities in Appendix B.
Figure 5
differentiated that extending breadth to the full market would most likely have a negative impact on both producers and consumers by comparison.

A few other papers have examined the antidepressant market with mixed results. Mortimer (1998) used three years of data from the early 1990’s to estimate own-price elasticities for branded drugs in this market range between -1.9 and -1.1, but with small cross-price elasticities. Alternatively, Cleanthous (2002) used annual data and found own-price elasticities between -0.54 and -0.02, and similarly small cross-price effects. Both Mortimer (1998) and Cleanthous (2002) rely on average retail prices rather than copays in their demand estimation which may explain why they found consumers to be less price sensitive. Finally, Dickstein (2011) employed a dynamic learning model on patient-level claims data and reported own-price elasticities that range between -0.9 to -0.24.

Figure 5 depicts two residual demand curves for January 1995 that are convex. The first, represented by the solid convex line, is the residual inverse-demand curve for Prozac, while the second is the residual inverse-demand curve for Prozac if it were the only SSRI product on the market. For completeness, I also include Prozac’s implied marginal cost from the supply-side estimation as well as the profit-maximizing price and resulting share level for each curve (red dots). Intuition from the theory states that the optimal patent policy with convex demand should consist of either infinitely broad patents with minimal lengths or minimal breadth patents that are long lived (Klemperer, 1990). Note that if deadweight loss were the only social cost, then the ratio of social cost to Prozac’s profit would be higher if Prozac were the only SSRI on market, which would be suboptimal. However, for sufficiently high innovation cost, the intuition from the theory

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39For robustness, I also estimated demand with a nonparametric specification of market shares on price, price-squared and product characteristics for Prozac alone. The estimates also implied that the residual demand curves are convex.
would suggest that broad patents with minimal lengths would be optimal.

VII Modified Policies

This section provides a framework that measures the welfare implications of modifying patent breadth and length, which is then applied to the pharmaceutical industry. As suggested by the theory, I utilize my estimates of consumers’ substitution behavior as well as features of the market to inform my analysis.

VII.1 Overview

An empirical assessment of the trade-offs between patent breadth and length is motivated by two key factors. The first is that this assessment would better inform the theory and provide additional insight to policymakers. While some of the prior applied literature has attempted to provide insights through indirect analysis, this paper is the first to directly examine this trade-off. The other key factor is the debate on the value of “me-too” drugs. This paper provides an approach that allows for a more reasonable comparison of the value of these products to the potential value of earlier generic entry on high-quality drugs. The approach is also extended to consider the incentives of “me-too” innovators to provide more accurate welfare calculation.

The abstract search for an optimal patent policy is limited to what is feasible for a given market. As previously mentioned, any analysis that searches for an optimal patent policy requires that the measure of patent breadth be defined in such a way that is known to the market and independent of any decisions made by the firms. For the pharmaceutical industry, there are three such feasible levels for breadth. The narrowest is the molecule level, which is the breadth specified under the existing policy. The other two are the therapeutic class level and the entire market. I expand breadth to the therapeutic class and then scale the patent length in order to make the high-value innovator indifferent between the two policies.40

For my policy experiments, I model patent breadth on the high-value innovation as the degree to which it can restrict “me-too” products from entering the market.41 Moreover, I allow those “me-too” innovators that are restricted from the market to keep their patents under the modified policy.42 The implication of this is that once the patent on the high-value product expires, the “me-too” products can then enter the market.

40 This follows the conceptual framework in much of the prior literature.
41 As discussed in Section III.1, the temporal disconnect between when an innovation is patented and when its value is known implies that the conventional framework of patent policy is not well suited for examining alternative levels of patent breadth and length.
42 This paper focuses on only one market. In footnote 15, I discuss how the framework can be adapted to allow for products that compete in multiple markets.
For the purpose of exposition, Figure 6a depicts the profit over time for both a high-value innovation, \(m_0\), and a subsequent “me-too” innovation, \(m_1\). Upon its entry, \(m_1\) negatively impacts the profit of \(m_0\). I propose a policy modification whereby \(m_0\)’s patent breadth is increased so as to exclude \(m_1\) from the market, while simultaneously limiting its patent life to ensure at least the same net present discounted profit earned under patent protection, \(V^f\). Figure 6b portrays this balance with the shaded regions, which are equivalent in present discounted value. In practice, \(m_0\)’s net present discounted profit under patent protection may be greater than \(V^f\) if time is treated as a discrete measure. As previously mentioned, the market exclusion restriction on \(m_1\) expires with \(m_0\)’s patent.

Figure 6

(a)

(b)

I focus my analysis on the market for antidepressants, in which Prozac was the first SSRI and was clearly a high-value innovation. Given that there is no formal definition or explicit quality thresholds that distinguish high-value and “me-too” innovations, I assume that the four SSRI products that enter the market after Prozac are “me-too”s. Note that this assumption is independent of how consumers may view these products.\(^{43}\) I extend Prozac’s patent breadth to the therapeutic

\(^{43}\)Ongoing work relaxes this assumption and allows for the consideration that these subsequent products may themselves be high-value innovations.
class level and temporarily exclude these “me-too” innovations. This restriction only applies to subsequent entrants in the SSRI class and therefore, innovations in other classes would not be directly affected.

Below, I present two counterfactuals. The first assumes that all “me-too” innovations that entered under the original policy also enter under the modified policy, once Prozac’s shortened patent length expires. For the second counterfactual, I provide a framework which allows “me-too” innovators to anticipate the impact of the modified policy and re-optimize their entry decision before entering Phase III clinical trials. Innovators that choose to forgo additional drug development and eventual market entry would save the associated investment costs.

VII.2 Counterfactual Pricing

Under the counterfactuals, equilibrium prices are determined for the set of products on the market in each period. To do so, the implied marginal costs under the current policy are assumed to remain the same under the counterfactual policy. I define the matrix $\Omega_{post}$ according to equation (8) under the modified policy. The predicted equilibrium price, $p^*_t$, under the modified policy solves

$$p^*_t = \hat{m}c_t + \Omega_{post}(p^*_t)^{-1}s(p^*_t)$$

where $\hat{m}c_t$ is the implied value calculated from equation (9). This equation entails a couple of nontrivial assumptions in addition to the Bertrand-Nash equilibrium. First, I assume that the cost structure between the two policies remains the same. Second, the matrices $\Omega_{pre}$ and $\Omega_{post}$ are assumed to rely on the same demand estimates. Hence, the alternate market structure and resulting price differences for the remaining products are assumed to capture all the differences between the two systems. This implies that firms do not change their strategies in any other dimensions that may affect demand.\(^{44}\)

VII.3 Exogenous Entry

VII.3.1 Social Welfare under Exogenous Entry

The net discounted social welfare impact of the modified policy is the sum of the discounted effects on consumers ($CV$), insurers ($\Pi_{ins}$), and producers ($\Pi_{diff}$).\(^{45}\) This is given by

$$SC = CV + \Pi_{ins} + \Pi_{diff}.$$  

\(^{44}\)As previously discussed, advertising is held fixed.

\(^{45}\)Producers include both innovators and manufacturers.
I assume that consumers and insurers have an annual discount rate of 5% while the producers’ discount rate is 11%, which accounts for the innovator’s risk of product failure during the product development process (DiMasi et al., 2003). The use of this higher producer discount rate means that, for a given amount of patent breadth, the innovator of the groundbreaking drug will require relatively less patent length in order to realize $V^f$. Under exogenous entry, consumers benefit from this shortened patent length due to the expedited entry of the generics on Prozac’s molecule.\footnote{In the case of endogenous entry, consumer welfare will depend on the choices made by the “me-too” innovators.}

The implications for the “me-too” innovators is less clear. While they are able to enter the market sooner under the higher discount rate, they also place greater value on the time they are restricted from the market. However, I find that the final results are not qualitatively different when I use a 5% discount rate for producers.

As previously noted, prescription drug costs comprise only a small fraction of household income. Thus, I use compensating variation to calculate the impact that switching to the modified patent policy will have on consumers. Interestingly, this impact can be fully captured by the difference in log shares of the outside good under the two policies, magnified by the size of the market and translated into dollars by the disutility of price (copay) (Arcidiacono and Miller, 2011). For all consumers at time $t$, this is given by

$$CV_t = -\frac{M_t}{\alpha} \left[ \ln(s^\text{ante}_{0t}) - \ln(s^\text{post}_{0t}) \right]$$

where $s^\text{ante}_{0t}$ and $s^\text{post}_{0t}$ denote the share of the outside good at time $t$ under the current and modified policies, respectively. The total discounted welfare change is then

$$CV = \sum_{t=1}^{T} CV_t \cdot (1 - d^c)^{t-1}$$

where $d^c$ is the rate at which consumers discount utility.

While consumers pay only a fraction of the full drug prices, the rest of the price is paid by insurers. Therefore, insurer savings from the switch to the modified policy is given by

$$\Pi^{\text{ins}} = \sum_{t=1}^{T} \left\{ \sum_{j=1}^{J} \left( (p^\text{ante}_{jt} - c^\text{ante}_{jt}) s^\text{ante}_{jt} - (p^\text{post}_{jt} - c^\text{post}_{jt}) s^\text{post}_{jt} \right) \cdot M_t \cdot (1 - d^c)^{t-1} \right\},$$

where the terms identified as $\text{ante}$ and $\text{post}$ correspond to the equilibrium prices and shares under the current and modified policies, respectively. Note that the insurers, like the consumers, are payers and so their expenditures are discounted by the consumer rate, $d^c$.

For the producers’ net total welfare effect (innovators and generic manufacturers), the difference of each producer’s profit under the current and modified policies is summed across all
producers and discounted to time $t = 1$. That is,

$$
\Pi_{diff} = \sum_{t=1}^{T} \left[ \sum_{f=1}^{F} \left( \Pi_{ft}^{post} - \Pi_{ft}^{ante} \right) \cdot (1 - d_f)^{t-1} \right],
$$

(15)

where $d_f$ is the rate at which producers discount profits, and $\Pi_{ft}^{ante}$ and $\Pi_{ft}^{post}$ are producer $f$'s profit (calculated according to equation (6)) under the current and modified policies, respectively.

For simplicity in implementing the simulations of the modified patent policies, I use the averages over time of both implied marginal cost, $mc_j$, and unobserved product heterogeneity, $\xi_j$, for each product $j$.

### VII.3.2 Results under Exogenous Entry

Prozac entered the antidepressant market in January 1988 and its patent expired in July 2001. This means that Prozac enjoyed an effective patent life of 13.5 years. During its patent-protected time on market, three other SSRI drugs entered the market: Zoloft, Paxil, and Celexa. I assume that these are “me-too” drugs, and restrict them from the market until Prozac’s patent expires under the modified policy. Under the original policy, I then calculate the present discounted profits generated by Prozac while under patent protection. This amount is then set as the minimum profit requirement under the modified policy. Given the restriction under the modified policy, I find that Prozac’s innovator, Eli Lilly, is able to earn at least the same present discounted profits with a patent that expires in September 1995.\(^{47}\) This is a difference of nearly six years (70 months) or a 43\% reduction in Prozac’s effective patent life.

The impact of the policy switch on the “me-too”s is shown in Table 5. The effective patent life for Zoloft and Paxil is shortened by 3.58 years and 2.67 year, respectively. This is roughly a 25\% reduction in the patent protected time on market for both drugs.\(^{48}\) On the other hand, Celexa entered the market in August 1998 and so its effective patent life is unaffected. Once on the market, the “me-too” drugs compete against both Prozac and its generic variants (fluoxetine). Discounted to January 1991, Zoloft experienced a $2.9 billion loss in profit (63\% reduction) due to its delayed entry and competition against generic fluoxetine. For Paxil, this loss was only $621 million, but this amounts to more than 75\% of its profit under the original policy. The impact on Celexa is exclusively from its competition with generic fluoxetine. The last row in Table 5 shows the impact of the generic versions of each of these “me-too” drugs, which are fairly insignificant, amounting to less than 1\% of their respective profits.

Table 6 provides the total effect for each segment of the market. Under the counterfactual

\(^{47}\)Note that time in my data is in increments of months.

\(^{48}\)While Paxil entered the market a several months after Zoloft, its patent expired nearly four years before Zoloft’s. See Table 1.
simulation, Prozac earned an additional $16 million, primarily due to the discreteness of time in setting the new patent length. The impact of the policy switch generated more than $4 billion in additional profits for producers of generic fluoxetine. Note that I assume that the number and relative timing of entry among the generic fluoxetine producers remains the same. The overall timing is simply advanced to the new patent expiration date for Prozac. Additionally, the generic products are differentiated products on the market and generally price above marginal cost. The total impact for “me-too” brands and generics are simply the totals of the figures in Table 5. As expected, the impact on the rest of the products in the market is nearly insignificant. Interestingly, the net impact across all producers is a gain of only $36 million. Allowing additional generic entry on fluoxetine would then reduce their super-normal profits and lead to a large and negative net impact across all producers. However, this potential negative impact on producers is overshadowed by the substantial savings by insurers, more than $10.2 billion (a 14.4% reduction in expenditures). This is due to the substantially lower cost to insurers when consumers purchase generics over brand name products and with the advanced timing of generic entry on Prozac. Finally, this advanced timing of generic entry also results in a small net gain to consumers, despite the broadening of Prozac’s market exclusivity to temporarily restrict the entry of “me-too”s. The overall effect on social welfare is a $10.5 billion gain.

The above policy experiment addresses the current debate in the pharmaceutical literature on limiting the incentives of “me-too” drugs. This is achieved by modifying the patent breadth and length of the high-value innovation and maintaining the same entry decisions for subsequent entrants. For the second policy experiment, I relax this assumption on the entry decisions by “me-too” innovators. This provides a more robust approach to estimate the social welfare impact.

VII.4 Endogenous Entry

VII.4.1 Entry Re-optimization

I now consider the impact of allowing “me-too” innovators to re-optimize their decision to enter Phase III clinical trials under the modified policy. I implement this by focusing on innovators that were observed to enter the market under the current policy and comparing their entry costs to their expected profits. Hence, an innovator will save its investment costs of Phase III if it chooses not to continue. For simplicity, I assume that entry of previously unseen products does not occur under the modified policy. Under the current policy, innovators enter in a sequential order \( f_1, ..., f_n \) and then realize profits \( \Pi_1,ante, ..., \Pi_n,ante \), respectively. It is also assumed that this order reflects the

\[49\]

For example, consider two generic firms, A and B, where Firm A enters two months before Firm B. Under the counterfactual, Firm A will still enter two months before Firm B, even though overall both enter the market earlier.

\[50\]

As discussed in Section III.1, innovators gain significant information on the safety and efficacy of their innovations during Phase II of clinical trials. I assume that this is sufficient to make an informed decision.
order in which innovators reach their decision point at the end of Phase II clinical trials. Finally, I assume a full information game where innovators see the product qualities, development costs, and time to market entry of all the other potential market entrants. Therefore, innovator $f$ can anticipate the impact of the modified policy on the timing of when product $j$ would be allowed to enter the market.

Let $C_{fj}$ be innovator $f$’s fixed Phase III clinical trial costs for product $j$ and assume $C_{fj} \sim \mathcal{F}_N(\mu, \sigma^2|0 \leq \kappa < C_{fj} < V_{ante}^{fj})$, where $C_{fj}$ is independent across innovators and products, $V_{ante}^{fj}$ is innovator $f$’s net present discounted profit from product $j$ under the current policy, $\kappa$ is a lower bound on costs, and $\mathcal{F}_N$ is a truncated normal distribution:

$$\mathcal{F}_N = \frac{\Phi(\frac{C_{fj}-\mu}{\sigma}) - \Phi(\frac{\kappa-\mu}{\sigma})}{\Phi(\frac{V_{ante}^{fj}-\mu}{\sigma}) - \Phi(\frac{\kappa-\mu}{\sigma})}. \quad (16)$$

Innovator $f$ will choose to send product $j$ to Phase III clinical trials under the modified policy if $C_{fj} < V_{fj}^{post}$, where $V_{fj}^{post}$ is innovator $f$’s net present discounted profit from product $j$ under the modified policy.\footnote{Given that these products were approved by the FDA under the current policy, they would still be approved under the modified policy. The question is merely one of timing if products continue on to Phase III.}

In order to estimate the probability of each possible market outcome under the modified policy, I apply the following simple algorithm:

1. Draw $C_{fj}$ for each product.
2. Determine the re-optimized decision for each product using backward induction.
3. Repeat Steps 1 and 2 $N$ times.
4. Finally, calculate $\lambda_n$, the probability of each possible market outcome, $n = 1, ..., N$.

When simulating the entry re-optimization, I use estimates (in December 2010 dollars) calculated by DiMasi et al. (2003) for average Phase III costs, $\mu = $143 million, and standard deviations, $\sigma = $118 million, for approved drugs. DiMasi et al. (2003) also estimated that the average length of time from the start of Phase III to drug approval is 52 months. I use this estimate to calculate $V_{fj}$ for innovator $f$ and product $j$. Finally, I set $\kappa$ to be $1$ million.

### VII.4.2 Social Welfare under Endogenous Entry

The social welfare calculation under endogenous entry is a simple analog of the exogenous case that includes probability weights for the $N$ market outcomes. The equations corresponding to (12)-(15) for the counterfactual with endogenous entry for “me-too” are given by:

$$CV_{t,n} = -\frac{M_t}{\alpha} \left[ \ln \left( s_{0t}^{ante} \right) - \ln \left( s_{0tn}^{post} \right) \right], \quad (17)$$
\[ CV = \sum_{n=1}^{N} \lambda_n \left[ \sum_{t=1}^{T} CV_{t,n} \cdot (1 - d^t)^{t-1} \right], \]  (18)

\[ \Pi^{ins} = \sum_{n=1}^{N} \lambda_n \left( \sum_{t=1}^{T} \left( \sum_{j=1}^{J} \left[ (p_{j,t}^{ante} - c_{j,t}^{ante}) s_{j,t}^{ante} - (p_{j,t}^{post} - c_{j,t}^{post}) s_{j,t}^{post} \right] \cdot M_t \cdot (1 - d^t)^{t-1} \right) \right), \]  (19)

and \[ \Pi^{diff} = \sum_{n=1}^{N} \lambda_n \left\{ \sum_{t=1}^{T} \left[ \sum_{f=1}^{F} \left( \Pi_{f,t}^{post} - \Pi_{f,t}^{ante} \right) \cdot (1 - d^f)^{t-1} \right] \right\}. \]  (20)

Let \( I_{jn}^{PhaseIII} \) be the expenditure saved when innovation \( j \) is abandoned rather than taken to Phase III clinical trials, discounted to time \( t = 1 \) using the rate \( d^f \). The total expenditure saved across all such abandoned innovations is given by

\[ I_{jn}^{PhaseIII} = \sum_{n=1}^{N} \lambda_n \left( \sum_{j=1}^{J} I_{jn}^{PhaseIII} \right). \]  (21)

Finally, the discounted social welfare effect is then given by

\[ SC = CV + \Pi^{ins} + \Pi^{diff} + I_{jn}^{PhaseIII}. \]  (22)

VII.4.3 Results under Endogenous Entry

As before, the “me-too” drugs may enter the market starting in September 1995. The first two rows of Table 7 provide the lower and upper bound values that plugged into the truncated normal distribution in equation (16). To calculate the upper bound, the net present profit of each product is discounted back to the start of Phase III clinical trials. This is assumed to be 52 months prior to the original market entry date for all products. Note that all of the products have an upper bound that is substantially higher than distribution mean of $143 million. The average and standard deviation of draws from step (1) of the algorithm are given in the middle two rows of Table 7. Given that the “me-too” innovators make their decisions in sequential order, backward induction is used to determine the market outcome for each set of cost draws. The probability of entry for each drug is provided in the fifth row of the table. Zoloft will always go into Phase III clinical trials and eventually enter the market, while Celexa and Paxil will do so 88% and 48.5% of the time, respectively. The saved expenditure weighted by market outcome is given in the last row of the table.

The impact of the policy switch on the “me-too”’s is shown in Table 8. The first row matches the results in the first row of Table 5. Intuitively, it is expected that profit loss for the “me-too” brands would be lower, given the ability to reoptimize the entry decision. This can be seen by summing the saved expenditure and the change in product profit. The impact on the “me-too” generics is more
dependent on the entry decisions by the corresponding innovators. If a brand product is abandoned by its innovator, generic entry on that molecule is assumed to never occur. Interestingly, while generics of Paxil experience substantial losses, those on Zoloft actually benefit. This is likely due to the reduced level of competition when generic versions of Paxil do not enter the market.

The net welfare effect for each segment of the market is provided in Table 9. This time, the impact on generic versions of Prozac is larger due to the limited competition when the other “me-too” products are abandoned. The fourth and fifth rows of the table shows that the other products on the market also enjoy this benefit. Overall, the producers gain nearly $149 million in direct profit. By abandoning their products, these innovators also saved $127 million in Phase III expenditures. Not surprisingly, insurer saving are also larger under the modified policy with endogenous entry, reflecting the higher consumption of generic fluoxetine. The consumers welfare calculation shows that consumers still prefer the modified policy, but that their benefit is tempered by the decrease in products variety on the market. Overall, the social welfare gain is nearly $11.4 billion, which is larger than the modified policy with exogenous entry.

VIII Conclusion

This paper provides the first empirical assessment of the trade-off between patent breadth and patent length. I draw on key insights from the theoretical literature, which highlights the importance of the market structure and shape of the demand curve in determining optimal patent policy. I first estimate demand parameters to determine insured consumers’ product substitution patterns. Incorporating the estimated demand parameters into a model of supply, I then back out firms' marginal costs of production, allowing me to perform counterfactual analyses. I use 20 years of retail prescription sales data on the market for antidepressants along with advertising, targeted to physicians and nurses, for each drug. Demand estimates indicate that consumers consider products within each therapeutic class to be much closer substitutes than those across classes.

Using estimates from the static models of demand and supply, I consider two policy simulations. The first modifies the patent of the first-in-class groundbreaking drugs to address the debate in the pharmaceutical policy literature on the value of limiting the development of “me-too” drugs. Specifically, I expand the patent breadth and limit the patent length of the groundbreaking antidepressant drug, Prozac, in order to temporarily restrict the subsequent “me-too” products from entering the market. Estimates show that under this modified policy, Prozac is able to generate equivalent net present discounted profit under patent protection with an effective patent length that is 43% shorter than under the original policy. Assuming all “me-too” products eventually enter the market, I find small welfare gains for producers and consumers along with substantial gains to insurers in the form of expenditure savings. Even if gains by manufacturers of generic Prozac (fluoxetine) were ignored, the net social effect is still positive.
The second policy simulation extends the first, by allowing the “me-too” innovators to anticipate the impact of the modified policy and reoptimize their entry decisions during their respective drug development processes. Those innovators that abandoned their drugs save their remaining investment expenditures. Through simulations, I find that while Zoloft would always proceed through Phase III clinical trials and onto the market, Paxil and Celexa would only do so with probabilities of only 48.5% and 88%, respectively. As expected, producers’ welfare improves with their ability to reoptimize their entry decisions. In cases where the products do not enter the market, consumers lose the value of “me-too” entry as well as the generics that would have followed on each molecule. However, this loss is still overshadowed by the gain of earlier generic entry on fluoxetine. Insurers now realize even greater gains as consumers who would have otherwise purchased Paxil and Celexa, turn to generic fluoxetine instead.

My results indicate the potential for meaningful social gains from exploring modified patent policies. A weakness is that while the assumptions simplify the problem, some also limit the generalizability of my conclusions. For example, I abstract away from any uncertainty consumers may have of the quality of new products introductions. If consumers learn about this quality from each other, then the higher counterfactual price on Prozac would induce more price-sensitive consumers to switch to generic versions. In turn, this would speed up consumers’ learning process as well as the adoption rate of these generics. Therefore, the modified patent policy could potentially further increase the competitive pressure on Prozac’s innovator after patent expiration. A second example is that it is unlikely that insights from this analysis can be extended to the biologics (large molecules) segment of the industry, given that their innovation and patenting is conducted differently. However, the policy framework may be applicable to other industries like chemicals and agriculture, where innovation costs may be high relative to imitation costs, and secrecy provides insufficient protection due to the possibility of reverse engineering.

To allow for a more robust policy framework, many of these assumptions can be relaxed. Chief among these is the assumption that all products that follow the first-in-class drug provide only an incremental benefit. Ongoing research allows the FDA (or another independent agency) to formalize the distinction between high-value and “me-too” drugs according to a clearly defined margin of value. Thus, high-value innovators that may be second-in-class or later observe clear guidelines necessary to enter the market without additional delay. To limit the inherent risk for products that are in close competition to be first-in-class, a compromise may allow the second innovator to enter the market without delay if it reaches the FDA review within some period of time after the first-in-class molecule (Hollis, 2004). It is left for future work to examine the effects of relaxing other assumptions, including those restricting the dynamic behavior of insurers and other market participants.
Appendix A

Suppose consumers choose from an assortment of products which belong to two levels of groupings. Let $g$ index the upper level and $m_g$ index the lower, subgroup level. The indirect utility that consumer $i$ gets from product $j$ at time $t$ is given by

$$u_{ijt} = \delta_{jt} + \psi_{ijt}$$

where

$$\delta_{jt} = x_{jt}\beta_j + \alpha p_j + \gamma \ln(a_{mg}) + \xi_{jt}$$

and

$$\psi_{ijt} = \zeta_{igt} + (1 - \sigma_g)\zeta_{im_g} + (1 - \sigma_g)(1 - \sigma_{mg})\varepsilon_{ijt}.$$ 

I now define $\eta = [1 - (1 - \sigma_g)(1 - \sigma_{mg})] \in [0, 1)$ and so,

$$\sigma_{mg} = 1 - \frac{1 - \eta}{1 - \sigma_g}. \tag{23}$$

The market share of product $j$ as a fraction of the total lower-nesting group is equivalent to the probability of a consumer purchasing a product from among those in the subgroup $m_g$:

$$s_{j/m_g} = \frac{e^{\delta_{j}/(1-\eta)}}{D_m} \quad \text{where} \quad D_m = \sum_{k \in J_{mg}} e^{\delta_k/(1-\eta)}. \tag{24}$$

Similarly, the market share of subgrouping $m_g$ as a fraction of the total upper-nesting group is equivalent to the probability that a consumer purchases from among the product within subgrouping $m_g$ from among those in group $g$

$$s_{mg} = \frac{D_m^{(1-\sigma_{mg})}}{D_g} \quad \text{where} \quad D_g = \sum_{k \in J_g} D_m^{(1-\sigma_{mg})}. \tag{25}$$

Next, the probability that a consumer chooses a product from grouping $g$ from among all products is given by

$$s_{g} = \frac{D_g^{(1-\sigma_{g})}}{D} \quad \text{where} \quad D = \sum_{k \in J} D_g^{(1-\sigma_{g})}. \tag{26}$$

Finally, the probability of the consumer choosing the outside option and not purchasing any of the products in the market is given by

$$s_0 = \frac{1}{D}. \tag{27}$$

The overall market share for product $j$ is

$$s_j = s_{j/m_g} \cdot s_{mg} \cdot s_{g} = e^{\delta_{j}/(1-\eta)} D_m^{-\sigma_{mg}} D_g^{-\sigma_{g}} D^{-1}. \tag{28}$$
Taking natural logs of this equation and substituting in the natural log of (5) gives

\[
\ln(s_j) = \frac{\delta_j}{1 - \eta} - \sigma_{m_g} \ln(D_m) - \sigma_g \ln(D_g) + \ln(s_0).
\] (29)

Rearranging this equation and combining it with the natural logs of (2) and (3) allows for the following steps:

\[
\ln(s_j) - \ln(s_0) = \frac{\delta_j}{1 - \eta} - \sigma_g \left[ (1 - \sigma_{m_g}) \ln(D_m) - \ln(s_{m_g}) \right] - \sigma_{m_g} \ln(D_m)
\]

\[
= \frac{\delta_j}{1 - \eta} + \sigma_g \ln(s_{m_g}) - \left[ \sigma_{m_g} + \sigma_g (1 - \sigma_{m_g}) \right] \ln(D_m)
\]

\[
= \frac{\delta_j}{1 - \eta} + \sigma_g \ln(s_{m_g}) - \eta \ln(D_m)
\]

\[
= \frac{\delta_j}{1 - \eta} + \sigma_g \ln(s_{m_g}) - \eta \left[ \frac{\delta_j}{1 - \eta} - \ln(s_{j/m_g}) \right]
\]

\[
= \delta_j + \sigma_g \ln(s_{m_g}) + \eta \ln(s_{j/m_g}).
\] (30)

**Appendix B**

The price elasticity, \( \eta_{s_j,c_k}^{elast} \), is the sensitivity of product \( j \)'s market share to changes in product \( k \)'s copay:

\[
\eta_{s_j,c_k}^{elast} = \frac{\partial s_j}{\partial c_k} \cdot \frac{c_k}{s_j}
\] (31)

where \( s_j = s_{j/m_g} \cdot s_{m_g} \cdot s_g = e^{\delta_j/(1 - \eta)} D_m^{-\sigma_{m_g}} D_g^{-\sigma_g} D^{-1} \).

For \( j = k \),

\[
\frac{\partial s_j}{\partial c_j} = \frac{\alpha}{1 - \eta} D_m^{-\sigma_{m_g}} D_g^{-\sigma_g} D^{-1} e^{\delta_j/(1 - \eta)}
\]

\[
- \sigma_{m_g} \frac{\alpha}{1 - \eta} e^{2\delta_j/(1 - \eta)} D_m^{-\sigma_{m_g}-1} D_g^{-\sigma_g} D^{-1}
\]

\[
- \sigma_g (1 - \sigma_{m_g}) \frac{\alpha}{1 - \eta} e^{2\delta_j/(1 - \eta)} D_m^{-2\sigma_{m_g}} D_g^{-\sigma_g-1} D^{-1}
\]

\[
- (1 - \sigma_g) (1 - \sigma_{m_g}) \frac{\alpha}{1 - \eta} e^{2\delta_j/(1 - \eta)} D_m^{2\sigma_{m_g}} D_g^{-2\sigma_g} D^{-2}
\]

\[
= \frac{\alpha}{1 - \eta} \left[ s_j - \sigma_{m_g} s_{j/m_g} s_j - \sigma_g (1 - \sigma_{m_g}) s_{j/m_g} s_{m_g} s_j - (1 - \eta) s_j s_j \right]
\]

\[
= \frac{\alpha}{1 - \eta} s_j \left[ 1 - \sigma_{m_g} s_{j/m_g} - \sigma_g (1 - \sigma_{m_g}) s_{j/m_g} s_{m_g} - (1 - \eta) s_j \right].
\] (32)
For $j \neq k$, but $m_j = m_k$,

$$
\frac{\partial s_j}{\partial c_k} = -\sigma_m \frac{\alpha}{1 - \eta} e^{\delta_k/(1-\eta)} e^{\delta_j/(1-\eta)} D_m^{-\sigma_m - 1} D_g^{-\sigma_g} D^{-1}
- \sigma_g (1 - \sigma_m) \frac{\alpha}{1 - \eta} e^{\delta_k/(1-\eta)} e^{\delta_j/(1-\eta)} D_m^{-2\sigma_m} D_g^{-\sigma_g} D^{-1}
- (1 - \sigma_g) (1 - \sigma_m) \frac{\alpha}{1 - \eta} e^{\delta_k/(1-\eta)} e^{\delta_j/(1-\eta)} D_m^{-2\sigma_m} D_g^{-2\sigma_g} D^{-2}
= -\frac{\alpha}{1 - \eta} [\sigma_m s_{k/m_g} s_j + \sigma_g (1 - \sigma_m) s_{k/m_g} s_{m_g} s_j + (1 - \eta) s_k s_j]
= -\frac{\alpha}{1 - \eta} s_j [\sigma_m s_{k/m_g} + \sigma_g (1 - \sigma_m) s_{k/m_g} s_{m_g} + (1 - \eta) s_k] \quad (33)
$$

For $m_j \neq m_k$, but $g_j = g_k$,

$$
\frac{\partial s_j}{\partial c_k} = -\frac{\alpha}{1 - \eta} s_j [\sigma_g (1 - \sigma_m) s_{k/m_g} s_{m_g} + (1 - \eta) s_k] \quad (34)
$$

For $g_j \neq g_k$,

$$
\frac{\partial s_j}{\partial c_k} = -\alpha s_k s_j \quad (35)
$$

The own-price elasticity is then

$$
\eta_{\text{own}} = \frac{\alpha}{1 - \eta} c_{jt} [1 - \sigma_m s_{j/m_g} - \sigma_g (1 - \sigma_m) s_{j/m_g} s_{m_g} - (1 - \eta) s_{jt}] . \quad (36)
$$

For the analysis in this paper, the most meaningful cross-price elasticities are those within a therapeutic class, but across molecules (lower level nests) and those across therapeutic classes (upper level nests):

$$
\eta_{\text{class}} = -\frac{\alpha}{1 - \eta} c_{jt} s_{jt} \quad \text{and} \quad (37)
$$

$$
\eta_{\text{molec.}} = -\frac{\alpha}{1 - \eta} c_{jt} [\sigma_g (1 - \sigma_m) s_{k/m_g} s_{m_g} + (1 - \eta) s_{kt}] \quad (38)
$$

respectively.

References


CBO (1998): *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry*, United States Congressional Budget Office.


Table 1: Drug Details and Summary Statistics

<table>
<thead>
<tr>
<th>Drug Characteristics</th>
<th>Prescription Prices ($)</th>
<th>Brands</th>
<th>Generics</th>
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<tr>
<td>SSRI</td>
<td>sertraline</td>
<td>Zoloft</td>
<td>1992m2</td>
</tr>
<tr>
<td>SSRI</td>
<td>paroxetine</td>
<td>Paxil</td>
<td>1993m1</td>
</tr>
<tr>
<td>SSRI</td>
<td>citalopram</td>
<td>Celexa</td>
<td>1998m8</td>
</tr>
<tr>
<td>SSRI</td>
<td>escitalopram/oxalate</td>
<td>Lexapro</td>
<td>2002m8</td>
</tr>
</tbody>
</table>


<sup>a</sup> Selected sample of the top selling antidepressants.
<sup>b</sup> First patent expiration values are missing if the patents are still active on December 2010.
<sup>c</sup> Generics refers to the number of generic producers that compete under a given molecule.
<sup>d</sup> Values of retail prices reflect the mean across the market prices corresponding to each patient record. Based on 124,380 patient records.
<sup>e</sup> Values of copayments reflect the mean across 876 plans in the data. Each plan sets distinct copayments.
<sup>f</sup> Insurer expenditures are the difference between the retail price and the patient copay.
### Table 2: Copay Regression\(^a\)

<table>
<thead>
<tr>
<th>Regressor</th>
<th>Coefficient</th>
<th>Std. Err.</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \phi )</td>
<td>0.4277</td>
<td>(0.0189)</td>
</tr>
<tr>
<td>Brand (binary)</td>
<td>0.5885</td>
<td>(0.0135)</td>
</tr>
<tr>
<td>( \gamma_0 )</td>
<td>0.3607</td>
<td>(0.0795)</td>
</tr>
</tbody>
</table>

\(^a\) Dependent variable is \( \psi_{\text{jt}} \). Estimated at the patient-prescription-month level. Based on 194,367 observations. Co-pays are taken from insurance plan listings. Heteroskedasticity-robust standard errors are reported.

### Table 3: IV Regression Results \(^a\)

<table>
<thead>
<tr>
<th>Regressor</th>
<th>Coefficient</th>
<th>Std. Err.</th>
<th>Coefficient</th>
<th>Std. Err.</th>
<th>1(^st) Stage F-Stat.</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{nest parameters} )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \ln(\text{molec. share of class}) )</td>
<td>0.5574</td>
<td>(0.0295)</td>
<td>0.5574</td>
<td>(0.0295)</td>
<td>70.1</td>
</tr>
<tr>
<td>( \ln(\text{prod. share of molec.}) )</td>
<td>0.6504</td>
<td>(0.0238)</td>
<td>0.6504</td>
<td>(0.0238)</td>
<td>77.6</td>
</tr>
<tr>
<td>Copay</td>
<td>-4.5683</td>
<td>(0.3591)</td>
<td></td>
<td></td>
<td>127.7</td>
</tr>
<tr>
<td>Ln(detailed)</td>
<td>0.0582</td>
<td>(0.0095)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand (binary)</td>
<td>2.8652</td>
<td>(0.2016)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( \text{Months on Mkt} )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 1</td>
<td>-0.4817</td>
<td>(0.6365)</td>
<td>-0.4817</td>
<td>(0.6365)</td>
<td></td>
</tr>
<tr>
<td>Month 2</td>
<td>-0.4716</td>
<td>(0.6338)</td>
<td>-0.4716</td>
<td>(0.6338)</td>
<td></td>
</tr>
<tr>
<td>Month 3</td>
<td>-0.4673</td>
<td>(0.6442)</td>
<td>-0.4673</td>
<td>(0.6442)</td>
<td></td>
</tr>
<tr>
<td>Month 4</td>
<td>-0.4693</td>
<td>(0.6441)</td>
<td>-0.4693</td>
<td>(0.6441)</td>
<td></td>
</tr>
<tr>
<td>Month 5</td>
<td>-0.4582</td>
<td>(0.6561)</td>
<td>-0.4582</td>
<td>(0.6561)</td>
<td></td>
</tr>
<tr>
<td>Month 6</td>
<td>-0.4916</td>
<td>(0.6325)</td>
<td>-0.4916</td>
<td>(0.6325)</td>
<td></td>
</tr>
<tr>
<td>Month 7</td>
<td>-0.4788</td>
<td>(0.6271)</td>
<td>-0.4788</td>
<td>(0.6271)</td>
<td></td>
</tr>
<tr>
<td>Month 8</td>
<td>-0.4782</td>
<td>(0.6340)</td>
<td>-0.4782</td>
<td>(0.6340)</td>
<td></td>
</tr>
<tr>
<td>Month 9</td>
<td>-0.5260</td>
<td>(0.6079)</td>
<td>-0.5260</td>
<td>(0.6079)</td>
<td></td>
</tr>
<tr>
<td>Month 10</td>
<td>-0.5061</td>
<td>(0.6230)</td>
<td>-0.5061</td>
<td>(0.6230)</td>
<td></td>
</tr>
<tr>
<td>Month 11</td>
<td>-0.4788</td>
<td>(0.6130)</td>
<td>-0.4788</td>
<td>(0.6130)</td>
<td></td>
</tr>
<tr>
<td>Month 12</td>
<td>-0.6328</td>
<td>(0.4272)</td>
<td>-0.6328</td>
<td>(0.4272)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Dependent variable is \( \ln(s_{\text{jt}}) \) − \( \ln(s_{\text{0t}}) \). Based on 31,872 observations. All standard errors are clustered at the quarter-molecule level.

### Table 4: Price Elasticities: January 1995

<table>
<thead>
<tr>
<th>Class</th>
<th>Molecule</th>
<th>Own-Price Elasticity</th>
<th>NGA</th>
<th>SSRI</th>
</tr>
</thead>
<tbody>
<tr>
<td>NGA</td>
<td>Bupropion hcl</td>
<td>-2.4468</td>
<td>0.2602</td>
<td>0.0722</td>
</tr>
<tr>
<td>NGA</td>
<td>Nefazodone hcl</td>
<td>-3.1590</td>
<td>0.2756</td>
<td>0.0722</td>
</tr>
<tr>
<td>NGA</td>
<td>Trazodone hcl</td>
<td>-1.6101</td>
<td>0.4183</td>
<td>0.0722</td>
</tr>
<tr>
<td>NGA</td>
<td>Venlafaxine hcl</td>
<td>-2.4716</td>
<td>0.1927</td>
<td>0.0722</td>
</tr>
<tr>
<td>SSRI</td>
<td>Fluoxetine hcl</td>
<td>-1.7482</td>
<td>0.0045</td>
<td>0.4385</td>
</tr>
<tr>
<td>SSRI</td>
<td>Paroxetine hcl</td>
<td>-2.9028</td>
<td>0.0045</td>
<td>0.7780</td>
</tr>
<tr>
<td>SSRI</td>
<td>Sertraline hcl</td>
<td>-2.1597</td>
<td>0.0045</td>
<td>0.8006</td>
</tr>
</tbody>
</table>

\(^a\) Source: SDI Monthly Data over the period 1991 to December 2010. The elasticity in the \( i \)th row and \( j \)th column is the average demand elasticity across products in molecule \( i \) with respect to the price of products in nest \( j \).
Table 5: Impact of Modified Policy on “Me-Too” Drugs with Exogenous Entry

<table>
<thead>
<tr>
<th>Change in:</th>
<th>Change in Levels</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zoloft</td>
<td>Paxil</td>
</tr>
<tr>
<td>effective patent life(^a)</td>
<td>-3.58</td>
<td>-2.67</td>
</tr>
<tr>
<td>PV(brand profit)(^b)</td>
<td>-2932</td>
<td>-621</td>
</tr>
<tr>
<td>PV(generic profit)(^b)</td>
<td>-1</td>
<td>-4</td>
</tr>
</tbody>
</table>

\(^a\) Effective patent life is in years.
\(^b\) All dollars are in millions and discounted to January 1991 with a rate of 11%.

Table 6: Present Value Welfare Under Exogenous Entry

<table>
<thead>
<tr>
<th>Change In</th>
<th>Dollars(^a)</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prozac profit(^b)</td>
<td>16</td>
<td>0.6%</td>
</tr>
<tr>
<td>generic Prozac profit(^b)</td>
<td>4042</td>
<td>275.4%</td>
</tr>
<tr>
<td>‘me-too’ brand profit(^b)</td>
<td>-3794</td>
<td>-64.0%</td>
</tr>
<tr>
<td>‘me-too’ generic profit(^b)</td>
<td>-6</td>
<td>-0.5%</td>
</tr>
<tr>
<td>other SSRI profit(^b)</td>
<td>-39</td>
<td>-2.4%</td>
</tr>
<tr>
<td>other non-SSRI profit(^b)</td>
<td>-183</td>
<td>-2.0%</td>
</tr>
<tr>
<td>all firms’ profit(^b)</td>
<td>36</td>
<td>0.1%</td>
</tr>
<tr>
<td>insurer savings(^c)</td>
<td>10202</td>
<td>-14.4%</td>
</tr>
<tr>
<td>consumer welfare(^c)</td>
<td>312</td>
<td>1.6%</td>
</tr>
<tr>
<td>social welfare</td>
<td>10550</td>
<td>9.4%</td>
</tr>
</tbody>
</table>

\(^a\) Dollars are in millions and discounted to January 1991.
\(^b\) Firms’ profits are discounted at 11%.
\(^c\) Insurer savings and consumer welfare are discounted at 5%.

Table 7: Distribution Bounds and Average Costs of Phase III Clinical Trials\(^d\)

<table>
<thead>
<tr>
<th></th>
<th>Zoloft</th>
<th>Paxil</th>
<th>Celexa</th>
</tr>
</thead>
<tbody>
<tr>
<td>lower bound(^b)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>upper bound(^b)</td>
<td>3198</td>
<td>630</td>
<td>630</td>
</tr>
<tr>
<td>mean(cost)(^c)</td>
<td>169</td>
<td>170</td>
<td>168</td>
</tr>
<tr>
<td>sd(cost)(^c)</td>
<td>98</td>
<td>99</td>
<td>98</td>
</tr>
<tr>
<td>Prob(entry)(^c)</td>
<td>100%</td>
<td>48.5%</td>
<td>88.0%</td>
</tr>
<tr>
<td>(t_{Phase III})</td>
<td>–</td>
<td>113</td>
<td>14</td>
</tr>
</tbody>
</table>

\(^a\) All dollar values are in millions.
\(^b\) Lower and upper bounds of the products’ respective truncated normal distributions. The upper bounds are calculated as the net present value profit of each product, discounted to the start of Phase III clinical trials, 52 months prior to market entry.
\(^c\) Based on 10,000 random draws for each product.
Table 8: Impact of Modified Policy by Molecule

<table>
<thead>
<tr>
<th>Change in:</th>
<th>Change in Levels</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zoloft</td>
<td>Paxil</td>
</tr>
<tr>
<td>effective patent life&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-3.58</td>
<td>-2.67</td>
</tr>
<tr>
<td>PV(brand profit)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>-2864</td>
<td>-725</td>
</tr>
<tr>
<td>PV(generic profit)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>35</td>
<td>-237</td>
</tr>
</tbody>
</table>

<sup>a</sup> Effective patent life is in years.
<sup>b</sup> Phase III clinical trial costs are weighted by entry decisions and then discounted or inflated to January 1991.
<sup>c</sup> Profits are calculated according to equation (20), then weighted by entry decisions and discounted to January 1991. All dollars are in millions.

Table 9: Present Value Welfare Under Endogenous Entry

<table>
<thead>
<tr>
<th>Change In</th>
<th>Dollars&lt;sup&gt;a&lt;/sup&gt;</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prozac profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>16</td>
<td>0.6%</td>
</tr>
<tr>
<td>generic Prozac profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4226</td>
<td>287.8%</td>
</tr>
<tr>
<td>'me-too' brand profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-3844</td>
<td>-64.9%</td>
</tr>
<tr>
<td>'me-too' generic profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-220</td>
<td>-18.5%</td>
</tr>
<tr>
<td>other SSRI profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>85</td>
<td>5.2%</td>
</tr>
<tr>
<td>other non-SSRI profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-113</td>
<td>-1.3%</td>
</tr>
<tr>
<td>all firms’ profit&lt;sup&gt;b&lt;/sup&gt;</td>
<td>149</td>
<td>0.6%</td>
</tr>
<tr>
<td>saved expenditure&lt;sup&gt;b&lt;/sup&gt;</td>
<td>127</td>
<td>-1.3%</td>
</tr>
<tr>
<td>insurer savings&lt;sup&gt;c&lt;/sup&gt;</td>
<td>10905</td>
<td>-15.4%</td>
</tr>
<tr>
<td>consumer welfare&lt;sup&gt;c&lt;/sup&gt;</td>
<td>194</td>
<td>1.0%</td>
</tr>
<tr>
<td>social welfare</td>
<td>11375</td>
<td>10.1%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Dollars are in millions and discounted to January 1991.
<sup>b</sup> Firms’ profits are discounted at 11%.
<sup>c</sup> Insurer savings and consumer welfare are discounted at 5%.