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ABSTRACT

Patent protection spurs innovation by raising the rewards for research, but it usually results in less desirable allocations after the innovation has been discovered. In effect, patents reward inventors with inefficient monopoly power. However, previous analysis of intellectual property has focused only on the costs patents impose by restricting price-competition. We analyze the potentially important but overlooked role played by competition on dimensions other than price. Compared to a patent monopoly, competitive firms may engage in inefficient levels of non-price competition—such as marketing—when these activities confer benefits on competitors. Patent monopolies may thus price less efficiently, but market more efficiently than competitive firms. We measure the empirical importance of this issue, using patent-expiration data for the US pharmaceutical industry from 1990 to 2003. Contrary to what is predicted by price competition alone, we find that patent expirations actually have a negative effect on output for the first year after expiration. This results from the reduction in marketing effort, which offsets the reduction in price. The short-run decline in output costs consumers at least $400,000 per month, for each drug. In the long-run, however, expirations do raise output, but the value of expiration to consumers is about 15% lower than would be predicted by a model that considers price-competition alone, without marketing effort. The non-standard effects introduced by non-price competition alter the analysis of patents' welfare effects.

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A. Introduction

Intellectual property spurs innovation by raising the rewards for discovery, but it does so by granting an inefficient monopoly in the event of discovery. There is thus a trade-off between ex ante and ex post efficiency. According to standard theory, the additional research and development (R&D) induced by a patent must be weighed against the output loss from monopoly. The theory implies that patent expiration leads to increased competition, lower prices, and higher market output. However, Figure 1 suggests that the predicted reductions in output may not be that commonplace. The figure depicts the percentage change in quantity—comparing the month before patent expiration to the month after—for a sample of US pharmaceutical products whose patents expired between 1992 and 2002.[2] For about 40% of drugs, output actually *falls* after patent expiration, and expands only modestly for many others.

The figure suggests there may be more to a patent expiration than a change in price-competition alone. We argue that the standard price-competition theory of IP must be extended to include non-price competition, which may induce monopolists to provide more or less quantity than competitive firms. For example, while monopolists have incentives to restrict quantity through higher prices, they may also have more incentives to promote their product through advertising, they may have more or less incentive to provide durability of goods, and they may have greater incentive to vertically integrate with upstream or downstream firms. All these types of non-price competition can change the impact of monopoly on output. In the case of marketing, for instance,

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[2] Specifically, the figure shows the percentage decline and growth in prescriptions filled, between the month before and the month after expiration. More detail on the data is given in Section C.

increased competition from patent expirations can reduce output when the reduction in marketing outweighs the impact of price reductions.

Motivated by this finding, this paper examines the effect that non-price competition, particularly marketing, has on the static and dynamic efficiency of patents. We analyze the competing effects of patents on output, and their implications for consumer welfare. In contrast to the standard analysis of price-competition, we show that output does not always rise with patent expiration, and that output growth may not always be a good indicator of welfare gains from patent expiration.

We empirically examine the impact of marketing on the welfare effects of patent expirations in the US pharmaceuticals market 1990-2003. The drug industry is a natural one in which to analyze the relationship between R&D and marketing, because it is among the highest-spending industries along both dimensions. The industry spends approximately 15% of sales on marketing, and 16% of sales on R&D.[3] By comparison, 2% and 3% of US GDP are allocated to advertising and R&D, respectively.

We use the timing of patent expirations as instruments for the industry supply-price of a drug, and industry-wide marketing incentives. Changes in supply induced by patent expiration allow us to identify the demand for drugs as a function of both price and advertising effort. The estimated demand function implies that in the short-run (one-year), output falls after patent expiration, because the reduction in advertising more than offsets the reduction in price. During this short-run period, consumers are estimated to lose at least $400,000 of welfare each month, for each drug whose patent expires. Not until several years have elapsed does the price effect dominate the reduced advertising.

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[3] Many drugs have seen dramatic increases in direct-to-consumer advertising (DTC) since the change in FDA guidelines on such advertising took place in 1997.

In the long-run, patent expiration benefits consumers, but the reduction in advertising reduces the total gain to consumers from patent expiration by about 15%.

Our project integrates a great deal of work that has separately considered advertising and intellectual property. In the economic analysis of advertising, Kaldor (1949) gives a good early analysis of advertising that discusses both positive and normative economic issues. Dixit and Norman (1978) and Telser (1962) provide an initial discussion of the meta-preference approach to welfare analysis of advertising developed formally and systematically by Becker and Murphy (1996). There are also summary treatments of advertising in Tirole (1988), Shapiro (1982), Schmalensee (1996), and Bagwell (2005). Several papers have studied the unique aspects of pharmaceutical advertising: Rosenthal et al (2002) study direct-to-consumer advertising, while Bhattacharya and Vogt (2003) provide an interesting analysis of how brand loyalty and patent incentives explain time-series patterns in drug pricing and provision. In the economic analysis of intellectual property, an equally extensive literature tackles the question of how to generate efficient R&D effort. There is a large literature analyzing the effects and desirability of public interventions affecting the speed of technological change, including: Nordhaus (1969), Loury (1979), Wright (1983), Judd (1985), Gilbert and Shapiro (1990), Klemperer (1990), Horstman et al (1993), Gallini (1992), Green and Scotchmer (1995), and Scotchmer (2004). Less effort has been devoted to studying the joint problem of advertising and intellectual property, even though the interaction between these two factors has many important normative and positive implications, particularly for the marketing of pharmaceuticals in the US.

The paper is briefly outlined as follows. Section B considers the impact of non-price competition on the welfare effects of patents, and discusses calculations of consumer welfare. Section C estimates demand as a function of price and advertising, and uses these estimates to infer changes in consumer surplus from patent expiration. Section D concludes.

B. Non-Price Competition and Intellectual Property

To consider the welfare effects of non-price competition on patents, define W_M and W_C as the annual level of welfare (social surplus) under monopoly and competitive provision of an invention, respectively. The net present value of welfare associated with a patent of length τ years is then given by:

$$W(\tau) = v(\tau))W_M + [v(\infty) - v(\tau)]W_C$$

$v(\tau)$ is the date zero present value of a claim that pays one dollar for τ years. Similarly, the net present value of profits associated with this patent is given by:

$$\pi(\tau) = v(\tau)\pi_M$$

To represent technological investment induced by intellectual property protection, define the increasing, differentiable, and strictly concave function *m(r)* as the probability of discovering an invention, as a function of R&D investments r. The privately optimal R&D associated with a patent of length τ is characterized by that which maximizes expected profits:

$$r(\tau) = \arg\max_r m(r)\pi(\tau) - r \qquad (1)$$

This level of R&D induces the expected social surplus from a given patent length:

$$ES(\tau) = m(r(\tau))\big(W(\tau)\big) - r(\tau) \qquad (2)$$

If patents are the only means of providing rewards to inventors, the best society can do is to maximize social surplus over all possible patent lengths. This optimal patent length is given by the following first-order necessary condition:

$$r_\tau[m_r W(\tau)-1] \geq m(-W_\tau) \qquad (3)$$

The marginal gains from raising R&D levels through IP (left-hand side) are made up of the extra R&D induced by the patent extension, r_τ, times the net social value of that extra R&D, $m_r W(\tau)-1$, which consists of the marginal social gain from more invention net of research spending. The optimal patent life equates this marginal benefit of an extension with the marginal cost of the extension, which is the welfare cost of an additional year of monopoly (on the right-hand side).

The definition of the welfare associated with a given patent length $W(\tau)$ further illuminates the marginal cost of patent expiration

$$\frac{dW}{d\tau}=\frac{dv}{d\tau}\left[S_M+\pi_M-S_C\right]$$

where S_M and S_C are consumer surplus under monopoly and competition, respectively, and π_M represents monopoly profits. When only price-competition matters, this effect is always negative at every point in time, because $S_C > S_M + \pi_M$, due to the deadweight loss from monopoly. In other words, patent-extension has a positive cost that needs to be weighed against its dynamic benefits. However, when we consider marketing, and other forms of non-price competition, this effect becomes more complicated. Monopoly always provides too high a price, but it may provide a more efficient level of non-price competition. For example, fear of free-riding by competitors may cause competitive firms to under-provide advertising, as for generic drug manufacturers who do not market a homogeneous good like a drug molecule. In this case, patent expiration has offsetting effects on social efficiency, and the welfare effect of patent expiration becomes indeterminate. If the under-provision of advertising outweighs the price increase of monopoly then $S_M + \pi_M > S_C$. If this is true for all points in time, patents are costless, and optimal patent length is infinite.

As non-price competition affects welfare, this leads to the question of how we can infer changes in social welfare from changes in output, in the presence of such competition. Given price-competition alone, output growth after patent expiration is a necessary and sufficient condition for a gain in static welfare. However, the introduction of non-price competition breaks the equivalence in sign between output changes and welfare changes. The new relationship depends on how and whether advertising affects consumer utility and information. The welfare change is $\Delta \equiv W_C - W_M = S_C - S_M - \pi_M > 0$. Though profits are always positive with monopoly and straightforward to measure, the consumer surplus terms are more difficult to characterize generally, and will depend on the nature and function of advertising, as we discuss below.

B.1 Advertising as Information

We first consider the consumer welfare effects of patents when advertising confers no direct utility upon consumers, but provides only information about a product. In this case, advertising does not affect the true value of a good to consumers, but it does affect its perceived value. Let $p(x,a)$ represent inverse demand as a function of quantity (x) and advertising (a). Price falls in quantity, but rises in advertising. We denote by $p(x)$ the full information demand curve defined by

$$\lim_{a\to\infty} p(x,a) = p(x), \forall x.$$

The change in welfare due to patent expiration is given by the change in true social surplus — that is, social surplus evaluated at the true, fully informed demand curve. We can define this as Δ_{NC}, according to:

$$\Delta_{NC} \equiv S_C - S_M = \int_{x_M}^{x_C} p(q)dq - (p_C x_C - p_M x_M) \tag{4}$$

Monopoly and competitive quantities are defined as x_M and x_C, respectively. The equilibrium consumer prices under competition and monopoly are given by p_C and p_M, and similarly for equilibrium quantities x_C and x_M.

Since advertising moves observed demand towards the true demand curve, we can use observed consumer surplus as a lower bound on the true consumer surplus, according to:

$$\int_{x_M}^{x_C} p(q)dq \geq \int_{x_M}^{x_C} p(q, a_M)dq \ \textit{iff} \ x_C \geq x_M$$

Based on this inequality, our empirical analysis uses the observed change in consumer welfare as a bound on the true change in welfare. In particular, we construct the estimator:

$$\tilde{\Delta}_{NC} \equiv S_C - S_M = \int_{x_M}^{x_C} p(q, a_M)dq - (p_C x_C - p_M x_M) \tag{5}$$

$\tilde{\Delta}_{NC} \leq \Delta_{NC}$ if and only if patent expiration raises quantity. This allows us to infer the direction of change in consumer welfare from our estimator.

1. Suppose $\tilde{\Delta}_{NC} < 0$. This implies that $x_C < x_M$. Therefore, $0 > \tilde{\Delta}_{NC} \geq \Delta_{NC}$.
2. Suppose $\tilde{\Delta}_{NC} > 0$. This implies $x_C > x_M$, and $0 < \tilde{\Delta}_{NC} \leq \Delta_{NC}$.

B.2 Advertising as Consumption

When advertising confers utility directly, the consumer welfare effect of patent expiration satisfies

$$\Delta_C \equiv S_C - S_M = \int_0^{x_C} p(q, a_C)dq - \int_0^{x_M} p(q, a_M)dq - [p_C x_C - p_M x_M]$$

Consider the case when a monopoly advertises more but at higher prices:

$$a_M \geq a_C, p_M \geq p_C \tag{6}$$

Under these conditions, it is possible that patent expiration can raise output while still lowering welfare: the decline in price raises output and welfare, but the reduction in advertising has a direct negative effect on welfare. If the welfare cost of reduced advertising exceeds the gain from extra output, ex post welfare can fall with patent expiration. On the other hand though, it continues to be true that a reduction in output signals a reduction in (gross) ex post welfare, because advertising always falls with patent expiration. Output growth is therefore a *necessary*, but not *sufficient*, condition for a welfare gain.

These results can be easily illustrated by Figure 2, which illustrates the change in gross surplus that occurs at patent expiration, when advertising provides utility. In that case, a patent expiration lowers price and shifts demand inward. Region G and L show the respective gain and loss in gross social surplus attributable to a reduction in advertising and price. Note that region G exists only if output rises with the reduction in advertising and price. Therefore, if output contracts upon expiration, welfare is always decreased, while if output expands the welfare impact is ambiguous and depends on the respective sizes of G and L. When advertising has value in itself, therefore, care must be taken when inferring changes in welfare from changes in output. For example, it is possible that the optimal patent life is infinite, even when patent expiration increases output.

Another possibility raised by marketing and similar forms of non-price competition is differential marketing to consumers with different willingness to pay. While price discrimination may be difficult, discrimination through marketing is much easier. This applies to the promotion of drugs to doctors, called “detailing”, in pharmaceutical markets. Differential advertising across may act as a form of price discrimination. Since advertising cannot be resold, it is more easily implemented than traditional forms of price-discrimination. Thus, advertising may act to lower the inefficiencies associated with patents, which arise because the monopolist cannot price-discriminate, and thus lower the marginal cost of patent extension. Discriminatory advertising may lower or even remove the dead-weight losses associated with patent monopolies.

C. Empirical Analysis

This section investigates the empirical impact of non-price competition on consumer welfare, in the context of marketing in the pharmaceutical industry. Our approach is to use patent expirations as a means of identifying the demand curve for pharmaceuticals, where demand depends on both price and advertising effort. These estimates are then used to calibrate a calculation of how much patent expiration benefits (or costs) consumers. In this particular empirical case of direct-to-physician advertising in the pharmaceutical industry, advertising is unlikely to have direct utility benefits for consumers. Therefore, in this application, we confine our attention to the case where advertising is purely informative.

C.1 Model and Approach to Welfare Estimation

The basic framework for this analysis will be the following demand function:

$$\ln x_{it} = \beta_0 + \beta_1 \ln p_{it} + \beta_2 \ln a_{it} + \phi_i + M(t) + \varepsilon_{it} \tag{7}$$

In this equation, p_{it} is the price of molecule i in month t, x_{it} is the corresponding quantity of the molecule, and a_{it} is a measure of advertising. (In some specifications, we will use as a regressor a_{it} instead of $\ln a_{it}$.) There is also a molecule fixed-effect, ϕ_i and a polynomial or step function time trend, $M(t)$.

We are particularly interested in using the demand function to ascertain the effects of patent expiration on quantity and on welfare. It is straightforward to assess the quantity effects, but estimating the welfare changes (in terms of consumer surplus) requires more discussion.

The demand function (and its associated inverse demand) implies forms for the changes in consumer surplus we discussed above. Consider first the case without advertising, where $\beta_2 = 0$, and the empirical demand curve is exactly equal to consumer's true valuations. Net consumer surplus is defined by:

$$\Delta \equiv \left\{ \int_{x_m}^{x_c} p(q)dq - \left(p_C x_C - p_M x_M \right) \right\} \tag{8}$$

Substituting in the logarithmic form for the inverse demand function, and integrating yields the final expression:

$$\Delta = \exp\left(\frac{-\beta_0 - \phi_i - M(t=-1)}{\beta_1} \right) \left(\frac{\beta_1}{1+\beta_1} \right) \left(x_C^{1+\frac{1}{\beta_1}} - x_M^{1+\frac{1}{\beta_1}} \right) - \left[p_C x_C - p_M x_M \right] \tag{9}$$

The time trend is evaluated at $t = -1$, the last month of patent protection. This expression can be calculated in the short-run and the long-run.

Short-run consumer surplus is the gain that accrues from the increase in quantity observed in the first few months immediately following patent expiration. The term x_C is thus defined as competitive quantity immediately after expiration, and the same goes for p_C.

Long-run consumer surplus, on the other hand, is the total gain that would accrue if the patent were never in place. Since long-run competitive quantity is unobserved, we estimate it by assuming that the long-run competitive price is equal to marginal cost. The demand curve then implies an associated long-run quantity, based on the estimated price elasticity of demand. Further details on the methods for estimating short- and long-run consumer surplus appear in the appendix.

In the case of purely informative advertising, the true expected change in consumer surplus is given by:

$$\Delta_{NC} = \left\{ \int_{x_M}^{x_C} p(q)dq - \left(p_C^* x_C - p_M^* x_M \right) \right\} \tag{10}$$

Above, we defined the bound on this quantity:

$$\tilde{\Delta}_{NC} = \left\{ \int_{x_M}^{x_C} p(q, a_M)dq - \left(p_C^* x_C - p_M^* x_M \right) \right\} \tag{11}$$

The functional form of the demand curve provides an explicit expression for this term:

$$\tilde{\Delta}_{NC} = \exp\left(\frac{-\beta_0 - \phi_i - M(t=-1) - \beta_2 \ln a_M}{\beta_1} \right) \left(\frac{\beta_1}{1+\beta_1} \right) \left(x_C^{1+\frac{1}{\beta_1}} - x_M^{1+\frac{1}{\beta_1}} \right) - \left[p_C x_C - p_M x_M \right] \tag{12}$$

C.2 Data

The IMS Generic Spectra database contains data on 101 unique molecules, whose patents expired between 1992 and 2002.[4] For each one, it reports 6 years of monthly

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[4] The full data include 106 molecules, but 5 are dropped. We drop Aventyl (Eli Lily, patent expiry in July 1992), Prinivil (Merck, patent expiry in June 2002), and Betoptic (Alcon, patent expiry in June 2000), because generic sales for these drugs include other branded products, creating a mismeasurement problem. We also dropped Bumex

data, which span 3 years prior to and 3 years after patent expiration. The monthly data include prices, quantities, and advertising effort. Table 1 lists the variables we have available. Drug quantity is available in grams. Prices are estimated as total revenues from the drug divided by grams of the drug sold; IMS collects both the revenue and grams data. Revenue data are collected at the retail level (through both retail and hospital pharmacies). IMS then adjusts the revenue data, using proprietary estimates of drug mark-ups, to estimate the implied wholesale revenue. The result is an estimate of the wholesale price paid to the pharmaceutical company. Therefore, in the case of a patented drug, this can be thought of as the price paid to the monopolist, rather than the price paid by insured or uninsured consumers. We also have three measures of advertising: monthly expenditures on medical journal advertisements, monthly visits to doctors by the company's sales representatives (called "detailing visits" in the parlance of the industry), and the number of drug samples dispensed by representatives to doctors. From the MIDAS database, we also have data on the number of competitors who produce a generic form of the molecule, applicable when the molecule is no longer on patent.

Price, quantity, and advertising data are available separately for the branded and generic producers of the molecule, and for the overall market. Total market price is constructed as total revenues divided by total grams, and similarly for the branded and generic prices. In estimating market demand, we use total market prices and quantities.

Table 2 reports a breakdown of the 101 included molecules by therapeutic class and advertising status. We call a drug "fully advertised" if it reports some advertising activity in each of the three advertising categories we have, and vice-versa. Drugs not

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(Roche, patent expiry in January 1995), and Toradol (Roche, patent expiry in May 1997), both of which had a duplicate formulation in the data.

fully advertised account for about 28% of the molecules, but less than 10% of total revenues. Not surprisingly, advertising effort is much higher for heavily used drugs.

C.3 Descriptive Analysis

C.3.1 *Patent Expiration and Changes in Quantity*

An initial examination of the data reveals some interesting patterns that suggest the interplay of quantity-restriction and advertising effects. Figure 1 demonstrates that for about 40% of drugs, the total market quantity consumed falls in the month immediately after patent expiration. The figure depicts the percentage change in quantity from the month immediately prior to expiration to the month immediately following expiration. This suggests that patent expiration is doing more than simply removing the monopolist's incentive to restrict quantity. Over longer intervals of time, the proportion of drugs with decreases in quantity rises, likely due to the additional effect of secular declines in the demand for a molecule.

Figure 4 depicts trends in price and quantity for the average drug, as a function of time until (or after) the month of expiration. As others have noted, before expiration, price tends to rise and quantity to fall over time. Bhattacharya and Vogt (2003) argue that this occurs because a drug is an "experience good" in the sense that consumers have to use it before they can judge its value. Therefore, inducing more use by lowering the price can lead to permanent increases in consumption by creating "loyal customers." The incentive to lure in more customers is highest early in the life of the patent, and erodes as the month of expiration looms. This is consistent with the trends in price and quantity prior to expiration.

After patent expiration, the price of the branded drug remains largely unchanged, even rising slightly, while the price of generic forms falls precipitously. Moreover, while total quantity rises immediately after expiration, much of this gain disappears after the passage of three years without a patent. These trends differ from those one might expect when quantity-restriction is the only effect of monopoly, in which case prices can be expected to fall for both branded and generic drugs, and quantity can be expected to increase.

The deviations from the typical expectations we have about patent expiration seem related to advertising. Drugs that are "incompletely advertised," according to the definition above, tend to behave according to the standard theory of monopoly. Compare Figure 5 and Figure 6, which show trends, respectively, for advertised and non-advertised drugs. Trends for the less advertised drugs look fairly standard: after patent expiration, quantity rises and remains at a permanently higher level. Moreover, the price of the branded drug falls after expiration, although it always remains higher than the generic price. In contrast, for the more advertised drugs, the brand price steadily rises after expiration, and total market quantity ends up falling after expiration, after a brief initial rise.

The effect of monopoly on advertising incentives is one way of understanding these divergent patterns. For less advertised drugs, where the incentive to advertise is weaker or absent, patent expiration eliminates the incentive to restrict quantity, but has no other effects. With advertising, however, the patent expiration has competing effects, which can lead to ambiguous changes in total market quantity.

C.3.2 ***Trends in Advertising***

Figures 7, 8, and 9 document trends in journal advertising, detailing visits, and samples dispensed. Advertising expenditures decline throughout the life of the product, since the pay-off to advertising falls with the length of the patent horizon. At the month of patent expiration, there is a short-lived jump in advertising, as generic firms spend some effort publicizing their product. This jump is most pronounced and longest-lived in the case of journal advertising, and much smaller (indeed, nearly negligible) in the case of detailing visits and samples dispensed.

The nature of these three types of advertising activities differs considerably. We focus primarily on journal advertising, because it best represents the dispensation of information about the drug to physicians, which is the focus of our theory. In contrast, detailing visits dispense information, but they also provide perquisites and gifts to individual physicians, which we do not explicitly model. In addition, from the point of view of measurement, attributing a detailing visit to a particular drug is much more difficult than attributing journal advertising expenditures. Finally, samples dispensed provide consumers with information about the drug, if they take the samples, but they can also work to crowd out short-term purchases of the drug directly.

Figures 7, 8, and 9 also suggest an empirical reason for the focus on journal advertising: Patent expiration is associated with a large jump in journal advertising, but not in the other two forms. Therefore, expiration is likely to be a more powerful instrument for identifying the effects of journal advertising, but a rather weak instrument in the other two contexts.

C.4 Identifying the Demand for Drugs

To identify the demand for drugs, our approach is to isolate movements along the demand curve, as distinct from shifts of the curve itself. The general strategy is to treat "large" changes in price and advertising sufficiently "close" to the date of expiration as being related to the patent expiration, and not to shifts in the demand curve. Motivated by this general idea, we pursue two distinct but related strategies for identifying the demand for drugs:

1. Identify dips or bumps in price and advertising around the date of patent expiration. These short-run changes are used to calculate demand elasticities;

2. Identify trend breaks in price and advertising. These changes are used to calculate demand elasticities.

We call these strategies "the expiration window" strategy, and "the trend break" strategy, respectively. To lay out our approaches, we first present estimates of quantity demanded as a function of price, without considering advertising. This turns out to be a reasonable way to approximate the price effects, since we confine ourselves to using the change in quantity that happens in the first one to three months after patent expiration. Over this short window, there are no statistically significant changes in advertising effort, relative to the date of patent expiration. There are insignificant decreases in detailing and samples, and an insignificant increase in journal advertising. Therefore, advertising effort can be thought of as roughly constant. Throughout the analysis, we employ two distinct but related identification strategies, explained below.

C.4.1 *Expiration Window Strategy*

Formally, this strategy involves estimating the following first- and second-stage equations via Instrumental Variables:

$$\ln(P_{dm}) = \alpha_0 + \alpha_1 Expired_{dm} + \phi_d + \gamma_{6-month} + \eta_{dm} \quad (13)$$

$$\ln(Q_{dm}) = \kappa + \varepsilon_D \ln(P_{dm}) + \phi_d + \gamma_{6-month} + \varepsilon_{dm} \quad (14)$$

For each drug d, and month m, we use data on price P_{dm}, and quantity in grams Q_{dm}. The model includes a drug fixed-effect, ϕ_d, and a dummy for a 6-month interval of time, $\gamma_{6-month}$. The set of 6-month intervals is centered around the date of patent expiration, so that one of the identified intervals spans two months prior to expiration, and three months following expiration, with the month of expiration in the middle.

To identify the elasticity of demand, this strategy uses the change in the market price and quantity of the drug between the three-month period immediately prior to expiration and the three-month period immediately after expiration. The estimated price elasticity of demand is given by the average (across all drugs) of $\frac{\%\Delta Q}{\%\Delta P}$, where changes are calculated from the earlier three-month interval to the immediate post-expiration period.

This point is illustrated graphically in Figure 10. The 6-month interval dummies slice up the entire period into 6-month windows. As a result, the "Expiration" variable computes the effect of expiration within a 6-month window. This amounts to comparing the three months immediately prior to expiration to the three months immediately following it. The identifying assumption is that changes immediately adjacent to the month of expiration are driven by the effect of expiration on prices (and, later, advertising), but not by unobserved changes in demand.

C.4.2 ***Trend Break Strategy***

The "expiration window" strategy uses changes in price and quantity immediately adjacent to the month of expiration. An alternative approach is to fit trends in price and quantity, and identify trend breaks that occur at expiration. This approach uses all the months of data in constructing the trend and its associated break, but it focuses on the apparent shocks to the trend that accompany patent expiration.

Formally, this strategy involves estimating the following first- and second-stage equations via Instrumental Variables:

$$\ln(P_{dm}) = \alpha_0 + \alpha_1 Expired_{dm} + \phi_d + MonthPoly + \eta_{dm} \quad (15)$$

$$\ln(Q_{dm}) = \beta_0 + \varepsilon_D \ln(P_{dm}) + \phi_d + MonthPoly + \varepsilon_{dm} \quad (16)$$

The only formal change required by this strategy is the use of a polynomial in month $MonthPoly$ instead of a dummy for an interval of time. The expiration variable identifies the break in the polynomial trend that occurs at expiration for price and quantity. These trend breaks, which imply percentage changes in quantity and price, are then used to estimate a demand elasticity. This approach is depicted graphically in Figure 11. A common polynomial time trend is fitted for percentage changes over time in the prices and quantities of each drug. Aberrations in that trend at the date of expiration are attributed to the expiration itself. These are assumed independent of unobserved changes in demand and used to estimate movement along the demand curve.

C.5 The Effects of Quantity-Restriction by Monopolists

The results of these estimation strategies are given in Table 3. The table reports IV coefficients, along with FGLS standard errors. It reports the first- and second-stage results for 4 versions of the model. The first two models employ the 6-month time interval fixed-effect, while the last two employ a cubic in month. The models also differ in their measurement of expiration: some use the first month after expiration as the beginning of the off-patent period, while others use the second month.

The estimated elasticities range from–0.73 to –1.89. Economic theory can help pin down the elasticities further. The theory of monopoly predicts that the absolute value of the demand elasticity is equal to the inverse of the monopoly markup. In the case of drugs, the markup is approximately 80 to 90 percent, since the long-run price of generic equivalents tends to be approximately 10 to 20 percent of the brand price at the date of expiration.[5] This implies that the demand elasticity at expiration is predicted to be approximately –1.1. This number lies within the 95% confidence interval of all four estimates, and is close to the midpoint of the interval containing all our point-estimates.

The first-stage estimates suggest that patent expiration immediately lowers price by four to seven percent. This is predicted to raise quantity by a similar percentage,

[5] This is based on our analysis of MIDAS data on long-run generic prices.

according to the elasticity of 1.1. In the long-run, however, price falls by 80 to 90 percent. Given the likely demand elasticities, patent expiration raises quantity by more than 90 percent, all else equal (including advertising incentives).

C.6 The Effects of Advertising-Promotion

To identify the effects of advertising, we must extend the strategies given above. Unobserved changes in demand are likely to affect the incentive to advertise. While advertising is roughly constant over the first three months immediately following expiration, there are significant changes within 9 months of expiration, as we will show. As a result, advertising can neither be regarded as a constant quantity, nor an exogenous variable in demand estimation, and we need an additional source of identifying variation to estimate the effects of both price changes and advertising effort.

C.6.1 *Extending the Identification Strategies*

We obtain additional identifying variation by extending the strategies presented above. Earlier, we used changes in price and quantity at the precise moment of patent expiration. In reality, however, the effect of expiration is not immediate. Competitors enter slowly and at an uncertain pace, due in part to the vagaries of the FDA approval process. If expiration has lagged effects, we can obtain more identifying variation. We adapt the expiration window strategy by considering 12-month intervals, rather than the tighter 6-month windows, and using three instruments — the month after expiration, four months after expiration, and seven months after expiration. Formally, this is implemented by the following model:

$$\ln(P_{dm}) = \alpha_0 + \alpha_1 Expired_{dm} + \alpha_2 Expired\_4_{dm} + \alpha_3 Expired\_7_{dm} + \phi_d + \gamma_{year} + \eta_{dm} \quad (17)$$

$$Adv_{dm} = \delta_0 + \delta_1 Expired_{dm} + \delta_2 Expired\_4_{dm} + \delta_3 Expired\_7_{dm} + \phi_d + \gamma_{year} + \eta_{dm} \quad (18)$$

$$\ln(Q_{dm}) = \kappa + \varepsilon_D \ln(P_{dm}) + \varepsilon_A Adv_{dm} + \phi_d + \gamma_{year} + \varepsilon_{dm} \qquad (19)$$

The variable Adv_{dm} is journal advertising. The dummy variables $Expired\_4$ and $Expired\_7$ denote, respectively, the fourth month after expiration, and the seventh month after expiration. The variable γ_{year} represents a 12-month interval. These intervals are arrayed such that one interval begins two full months after expiration and ends 9 full months after expiration. This alignment is depicted graphically in Figure 12. We have two endogenous regressors and three instruments, leaving us with an overidentified model.

In a similar manner, we extend the "trend break" strategy to allow for trend breaks just after patent expiration, as well as four months after, and seven months after. Formally, this requires estimating the pair of equations:

$$\ln(P_{dm}) = \alpha_0 + \alpha_1 Expired_{dm} + \alpha_2 Expired\_4_{dm} + \alpha_3 Expired\_7_{dm} + \phi_d + MonthPoly + \eta_{dm} \qquad (20)$$

$$Adv_{dm} = \alpha_0 + \alpha_1 Expired_{dm} + \alpha_2 Expired\_4_{dm} + \alpha_3 Expired\_7_{dm} + \phi_d + MonthPoly + \eta_{dm} \qquad (21)$$

$$\ln(Q_{dm}) = \beta_0 + \varepsilon_D \ln(P_{dm}) + \varepsilon_A Adv_{dm} + \phi_d + MonthPoly + \varepsilon_{dm} \qquad (22)$$

This once again provides us with three instruments to identify two endogenous regressors and test an overidentifying restriction.

C.6.2 *Results*

The results of extending the expiration window strategy are given in Table 4. The table reports estimates from three different models. The first is the "naïve" model that treats advertising as an exogenous variable. The second and third treat it as endogenous, but differ in specifying advertising as a level variable or a logarithm. This specification difference has little impact on the estimates.

The naïve model delivers a price elasticity around 1.7, and an advertising elasticity of just 0.03. The latter elasticity is considerably below the predictions of theory, which suggests that the ratio of advertising to price elasticities ought to equal the share of advertising in sales,[6] which is about 0.15 in the pharmaceutical industry (Pharmaceutical Research and Manufacturers of America, 2006a, b).

The more structural models in the table demonstrate that this naïve elasticity is in fact too low. This suggests that firms choose to advertise molecules with lower initial demand. The two structural models yield elasticities of 0.25 and 0.17, statistically indistinguishable from each other and from the predictions of theory. Since theory predicts a price-elasticity of 1.1, the advertising elasticity should be around 0.17. While the advertising elasticities are estimated with reasonable precision, even in these demanding specifications, the price elasticity estimates become more imprecise with fairly wide confidence intervals. They continue to be statistically indistinguishable from the theoretical prediction of 1.1, but the decreased precision robs this result of some content. Both structural models pass an overidentification test.

Table 5 displays the results of extending the trend break strategy, which uses a cubic in month to capture secular time trends in price, quantity, and advertising. These results largely reinforce the findings of Table 4. The naïve advertising elasticity is very small, while the structural elasticities are nearly identical to the theoretical predictions of 0.17. Once again, the price elasticities lose some precision, but continue to be statistically similar to the predictions of theory. Finally, the overidentified models pass the overidentification test.

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[6] This well-known result, often referred to as the Dorfman-Steiner Theorem, follows most simply from the analysis of a static monopoly maximization problem (Dorfman and Steiner, 1954).

C.7 Consumer Surplus from Patent Expiration

Estimating the demand functions allows us to infer the changes in consumer surplus associated with patent expiration. Conceptually, we estimate two kinds of welfare changes: (1) Cost of quantity-restriction, and (2) Cost of patents. The cost of quantity-restriction is the cost of the higher prices, induced by patents. The overall cost of patents, on the other hand, combines this cost with the value of increased output due to higher advertising. Theoretically, therefore, the cost of quantity-restriction must always be positive, but the cost of patents may be negative.

We estimate each of these quantities in the short-run and the long-run. We define the short-run as the first seven to nine months after patent expiration: the price and advertising changes that take place over this initial period define short-run costs. The long-run welfare changes are the total gains that would accrue to consumers in a long-run steady-state. These are computed using the following observations: in the long-run, competition drives price to marginal cost and advertising effort to zero. Since mark-ups in the pharmaceutical industry are 80-90%, therefore, we assume that in the long-run, price falls by 90%, while advertising falls by 100%. More detail on the calculation of these consumer surplus changes appears in the appendix.

A key issue is what elasticities to use for advertising and price. The choice of advertising elasticity is straightforward. We obtained 4 estimates: 0.25, 0.17, 0.15, and 0.17. Since 0.17 is the theoretically predicted elasticity, based on the aggregate share of advertising in sales, and since it is both the median and mode estimate, we use this. There is more variability in the price estimates. Observe that the intersection of all the 95% confidence intervals around the price elasticities yields the interval: [0.52, 1.20]. In other words, none of our models can reject any elasticity inside this interval. To pin down an elasticity within this interval, we once again turn to theory, which predicts an elasticity that is the reciprocal of the monopoly markup. This yields an elasticity of 1.1.

In addition to the elasticities, we need to estimate the short-run impact of patent expiration on price. To obtain this, we estimate a constrained three-equation model, where we force the price and advertising elasticities to match the values above. Table 6 displays the resulting estimates, along with the associated changes in consumer surplus.

The per-molecule cost of quantity restriction to consumers is $790,000 in the short-run. Conceptually, this means that 7 months after patent expiration, consumers receive $790,000 of additional value per month (from one molecule) due to the reduction in price alone. This cost rises to $9.6 million in the long-run. In other words, the price reduction delivered by a competitive market, compared to the last month of a patent monopoly, would yield $9.6 million of value to consumers per month. Observe that these are all monthly costs.

These calculations do not account for the effect of patents in encouraging advertising and thus raising quantity. The total impact on consumers must include the effect of decreased advertising in the wake of a patent expiration. The table shows that in the short-run, patent expiration actually makes consumers worse off, by $400,000 per month. This is because the reduction in advertising offsets the short-run price reductions. In the long-run, however, consumers still benefit from patent expiration, but by less than the cost of quantity-restriction alone. In the long-run, competition creates $8.3 million of additional value for consumers, per month. This is approximately 16% lower than the value created by the price reduction alone.

D. Conclusion

Patents are generally believed by economists to be second-best methods of stimulating innovation, because they reward it with inefficient monopoly power. However, this reasoning neglects the impact of monopoly on forms of non-price competition, like marketing considered here. Our empirical analysis of the US pharmaceutical market suggested that considering advertising reduces the estimated long-run cost of patents by about 15%. Moreover, in the short-run, patent expirations actually harm consumers, because the reduction in output from decreased advertising to physicians is worth more than the increase in output from lower prices. The costs of patents thus seem somewhat overstated in the long-run, and may even be negative in the short-run.

The paper suggests several avenues of future research. First, our analysis seems to generalize to other forms of non-price competition. If the monopoly power induced by patents has effects beyond quantity-restriction, those effects may offset or exaggerate the traditional costs of patents. In particular, advertising—when viewed as a complement to the good advertised—resembles general quality provision. Therefore, quality competition might have similar effects on the analysis of intellectual property.

Second, using patent-expirations as an exogenous increase in competition may prove useful to test theories of market structure or estimate demand parameters in other markets. For example, our data shed light on the often-debated question of whether increased competition reduces advertising. Other predictions about the effects of market structure on industry conduct may well be useful to test with patent expiration behavior.

Third, our findings may alter the welfare interpretation of generic entry upon patent expiration. Generic entry clearly lowers price, but it also lowers advertising. It is necessary to consider both effects to capture the full value (or cost) of generic entry. At a minimum, our analysis suggests that considering price reductions alone leads to an upward bias in the estimation of welfare effects.

In general, little is known about efficient patent design in presence of non-price competition. More work is needed to better understand this issue, particularly in industries such as US pharmaceuticals where output declines often result from patent expirations.

Appendix

This appendix describes the methods for calculating short-run and long-run consumer surplus.

<u>Standard Consumer Surplus</u>

In the text, we derived an explicit expression for standard consumer surplus, consistent with the econometric specification of the demand curve:

$$\Delta = \exp\left(\frac{-\beta_0 - \phi_i - M(t=-1)}{\beta_1}\right)\left(\frac{\beta_1}{1+\beta_1}\right)\left(x_c^{1+\frac{1}{\beta_1}} - x_m^{1+\frac{1}{\beta_1}}\right) - \left[\hat{p}(x_c)x_c - \hat{p}(x_m)x_m\right] \quad (23)$$

The function $\hat{p}(x) = \exp\left(\frac{\ln x - \beta_0 - \phi_i - M(t=-1)}{\beta_1}\right)$ is the empirical inverse demand function. Operationally, we define x_m as the quantity in the last month of patent protection, at $t=-1$.[7] Conceptually, x_c is the quantity that would obtain in the absence of a patent. The definition of x_c drives the distinction between short-run and long-run consumer surplus.

For the short-run consumer surplus calculation, we use the change in price associated with the short-run expiration of the patent, or α_1 from the first-stage estimating equation. This leads to:

$$x_c^{short-run} = x_m(1+\alpha_1\beta_1) \quad (24)$$

[7] Here and elsewhere, x_c is defined as x_m, multiplied by the percent change in quantity implied by the expiration of the patent. This percent change is defined as the percent change in price associated with expiration, multiplied by the price elasticity of demand.

The long-run consumer surplus uses the quantity that would be associated with marginal cost production. Since marginal cost is 90% lower than the last observed monopoly price, the long-run competitive quantity can be obtained as:

$$x_c^{long-run} \equiv x_m\left(1-0.9(\beta_1)\right) \tag{25}$$

<u>Consumer Surplus with Informational Advertising</u>

In this case, consumer surplus can be written as:

$$\tilde{\Delta}_{NC} = \left\{\int_{x_m}^{x_c} p(q,a_m)dq - \left(p_c x_c - p_m x_m\right)\right\} \tag{26}$$

The form of the demand function allows us to rewrite this as:

$$\tilde{\Delta}_{NC} = \exp\left(\frac{-\beta_0 - \phi_i - M(t=-1) - \beta_2 \ln a_m}{\beta_1}\right)\left(\frac{\beta_1}{1+\beta_1}\right)\left(x_c^{1+\frac{1}{\beta_1}} - x_m^{1+\frac{1}{\beta_1}}\right) - \left[\hat{p}(x_c)x_c - \hat{p}(x_m)x_m\right]$$

This is similar to the expression above, but with a term for advertising added. We use spending on journal advertising in the last month of patent protection in order to estimate $\ln a_m$; since we are estimating the fitted demand function, it is appropriate to use the advertising measure that is included in the regression.

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Table 1: Monthly Molecule-Level Variables Available in IMS Generic

Variable	Definition
Quantity	Grams of the drug sold by retailers
Price	Revenues[1] divided by grams sold
Journal Advertising	Total cost of journal advertising space
Detailing Visits	Visits by pharmaceutical rep's to physicians
Samples	Number of drug samples dispensed to physicians
Generic Competitors	Number of competing producers of the molecule

Note: All variables are available monthly, 36 months prior to and since expiration. All data are taken from the IMS Generic Spectra database, except for "Generic Competitors," which comes from the MIDAS database.

[1]Revenues are collected for both retail and hospital channels and converted to reflect ex-manufacturer prices and quantities. No adjustments are made for confidential rebates to health plans.

Table 2: Types of molecules represented in IMS Generic

	Number of Drugs		
2-digit USC Category	Not Fully Advertised	Fully Advertised	TOTAL
Analgesics		4	4
Anesthetics	2		2
Anti-arthritics		7	7
Hemostat modifiers		2	2
Antihistamines		1	1
Anti-infectives	2	3	5
Anti-malarials		1	1
Neurological Treatments	2	4	6
Gastro-Intestinal Drugs		6	6
Bile Therapy		1	1
Beta-Blockers		2	2
Cardiac Agents	2	4	6
Anti-neoplasm	3	3	6
Ace-Inhibitors	2	14	16
Anti-hyperlipidemic		3	3
Anti-Fungal Agents		2	2
Diabetes Therapy		3	3
Diuretics	1	1	2
Hormones	1	2	3
Musculoskeletal	2	1	3
Opthalmic		3	3
Psychotherapeutics	4	6	10
Sedatives		2	2
Tuberculosis Therapy	1		1
Anti-viral		2	
Immunologic		2	
TOTAL	22	79	101

Notes: "Fully advertised drugs" have, at some point in their life-span, nonzero advertising in each of the three advertising categories: journal advertising, contacts, and samples.

Table 3: Estimated Demand Elasticities for Drugs.

	Model 1		Model 2		Model 3		Model 4	
	ln(p)	ln(gms)	ln(p)	ln(gms)	ln(p)	ln(gms)	ln(p)	ln(gms)
Patent Expired for At Least One Month	-0.063 (0.015)***				-0.046 (0.018)**			
Patent Expired for At Least Two Months			-0.086 (0.015)***				-0.058 (0.019)***	
Ln Price		-1.325 (0.413)***		-0.734 (0.246)***		-1.889 (0.839)**		-1.385 (0.592)**
Time Trend	Cubic in Month				Half-Year Fixed Effects			
Observations	3299	3299	3299	3299	3299	3299	3299	3299
Short-run patent cost	$999,190		$792,426		$1,084,276		$999,902	
Long-run patent cost	$10,229,534		$5,798,111		$15,512,622		$11,247,911	

Notes: All models include molecule-specific fixed effects. 3-stage least squares standard errors in parentheses.
Based on all months prior to 24 months post-expiration.
* significant at 10%; ** significant at 5%; *** significant at 1%

Table 4: Effects of Price and Advertising on Pharmaceutical Demand, Using "Expiration Window" Estimation Method.

	Naïve Model[a]		Model 1			Model 2		
	ln(p)	ln(gms)	ln(p)	ln(journal)	ln(gms)	ln(p)	Journal[b]	ln(gms)
Patent Expired for At Least One Month	-0.051 (0.018)***		-0.073 (0.021)***	0.128 -0.137		-0.046 (0.018)**	1.169 (0.704)*	
Patent Expired for At Least 4 Months			-0.055 (0.018)***	-0.274 (0.096)***		-0.066 (0.018)***	-1.51 (0.499)***	
Patent Expired for At Least 7 Months			-0.062 (0.018)***	-0.421 (0.117)***		-0.062 (0.018)***	-1.352 (0.591)**	
Ln Price		-1.677 (0.685)**			-0.75 (0.419)*			-0.51 (0.373)
Ln Journal Advertising					0.245 (0.102)**			
Total Journal Advertising ($10K) [Implied Elasticity]	0.005 (0.000)***	0.01 (0.004)*** [0.03]						0.051 (0.024)** [0.17]
Time Trend				Year Fixed-Effects				
Overidentification Test (p-value)	N/A		0.3882			0.4662		
Observations	3299		1474			3299		

Notes: All models include drug-specific fixed-effects. 3-stage least squares standard errors appear in parentheses. Based on all months prior to 24 months post-expiration.

[a]Naive model uses half-year fixed-effects.

[b]Tens of thousands of dollars spent on journal advertising.

* significant at 10%; ** significant at 5%; *** significant at 1%

Table 5: Effects of Price and Advertising on Pharmaceutical Demand, Using "Trend Break" Estimation Method

	Naïve Model		Model 1			Model 2		
	ln(p)	Journal	ln(p)	ln(journal)	ln(gms)	ln(p)	Journal	ln(gms)
Patent Expired for	-0.065		-0.059	0.217		-0.033	1.328	
At Least One Month	(0.015)***		(0.018)***	(0.127)*		(0.017)*	(0.624)**	
Patent Expired for			-0.042	-0.225		-0.053	-1.389	
At Least 4 Months			(0.018)**	(0.114)**		(0.018)***	(0.524)***	
Patent Expired for			-0.055	-0.586		-0.071	-1.713	
At Least 7 Months			(0.017)***	(0.116)***		(0.016)***	(0.581)***	
Ln Price		-1.269			-0.547			-0.853
		(0.383)***			(0.336)			(0.437)*
Ln Journal Advertising					0.15			
					(0.049)***			
Total Journal	0.005	0.008						0.05
Advertising ($10K)	(0.000)***	(0.002)***						(0.020)**
[Implied Elasticity]		[0.03]						[0.17]
Time Trend	Cubic in Month							
Overidentification Test (p-value)			0.2491			0.2958		
Observations	3299		1474			3299		

Notes: All models include drug-specific fixed-effects. 3-stage least squares standard errors appear in parentheses. Based on all months prior to 24 months post-expiration.
* significant at 10%; ** significant at 5%; *** significant at 1%

Table 6: Estimated change in consumer surplus from patent expiration.

	Constrained Model		
	ln(p)	ln(journal)	ln(gms)
Patent Expired for	-0.073	0.083	
At Least One Month	(0.020)***	-0.133	
Patent Expired for	-0.044	-0.312	
At Least 4 Months	(0.017)***	(0.114)***	
Patent Expired for	-0.055	-0.53	
At Least 7 Months	(0.017)***	(0.117)***	
Ln Price			-1.1
			N/A
Ln Journal Advertising			0.169
			N/A
Time Trend		Year Fixed-Effects	
Observations		1474	
Short-run cost of quantity restriction		$790,956	
Long-run cost of quantity restriction		$9,578,893	
Short-run patent cost		-$397,789	
Long-run patent cost		$8,313,496	

Notes: 3-equation model is estimated, using the constraints that the price elasticity equals -1.1 and the ratio between the advertising and price elasticities is 0.15. As before, the models include drug fixed-effects. Costs of patents and quantity restriction are reported as the average cost for a particular molecule, and are calculated as described in the appendix. Costs, like all quantities, are on a monthly basis.

Figure 1: Distribution of quantity changes by molecule, from patent expiration to one month after expiration

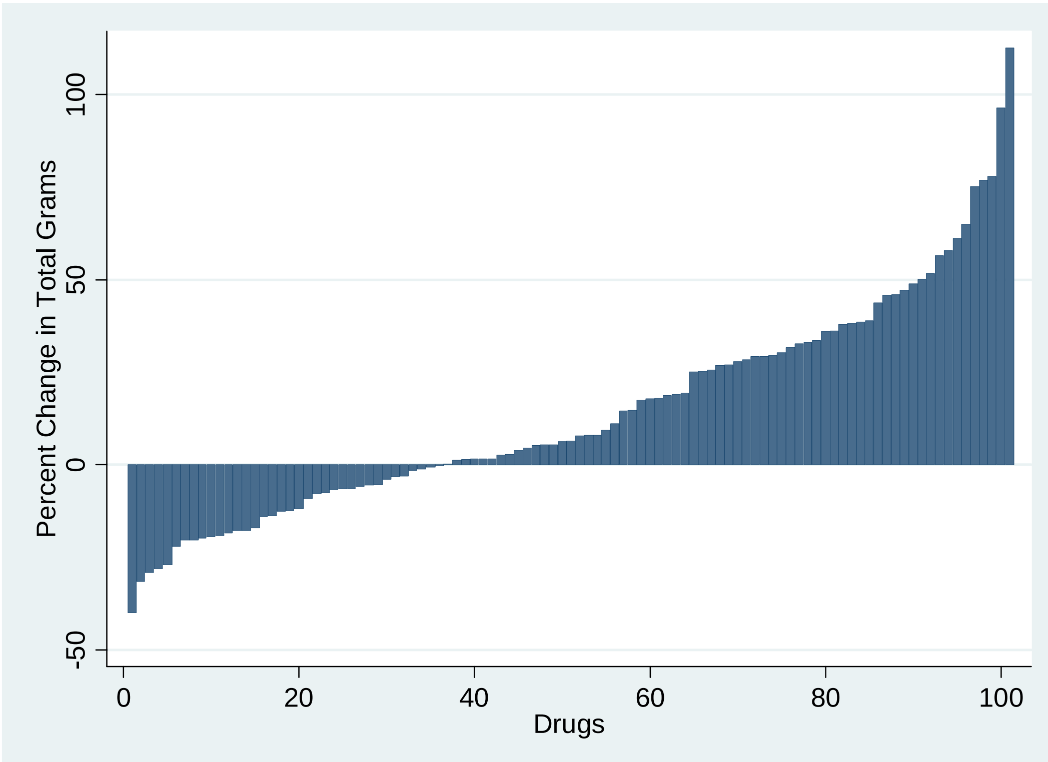

Figure 2: Gross Welfare Effects of Patent Expiration

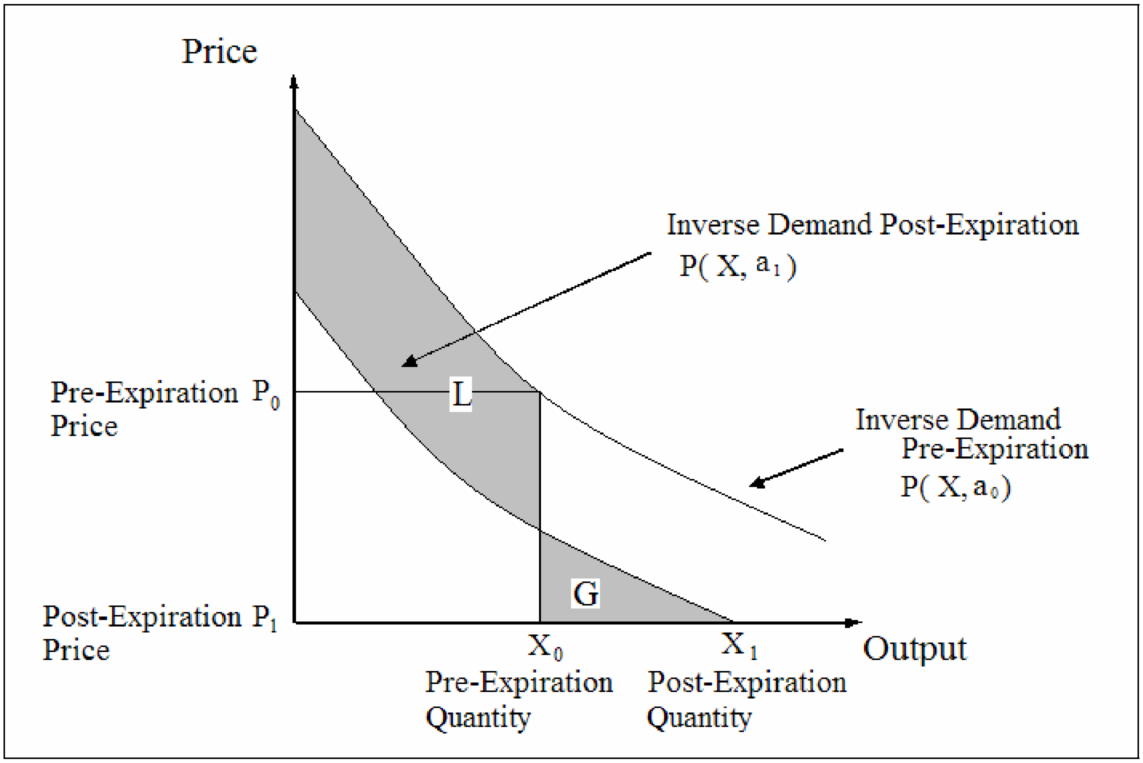

Figure 3: Static vs Dynamic Welfare Changes

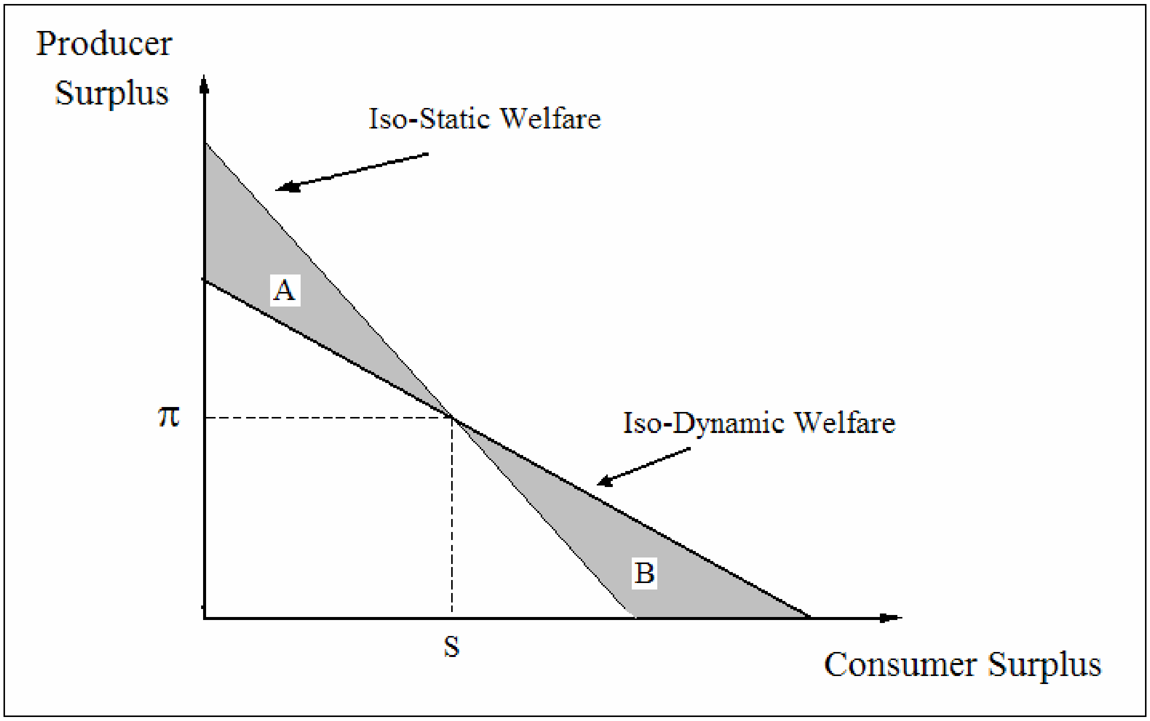

Figure 4: Trends in price and quantity for the average drug.

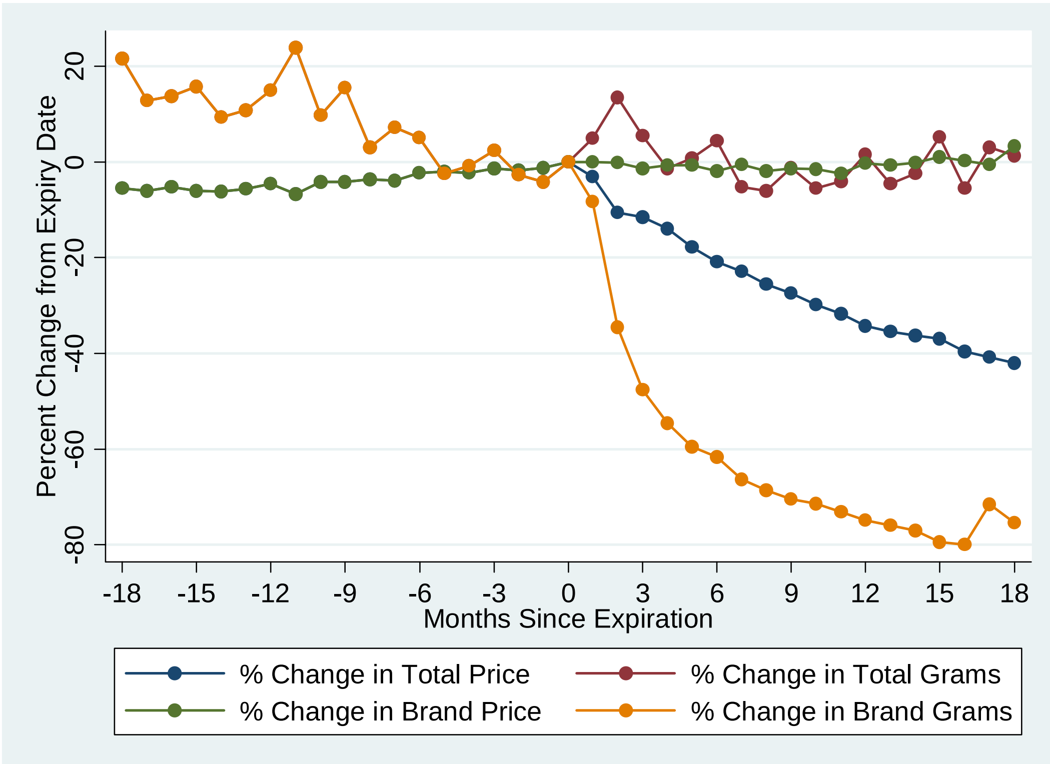

Figure 5: Mean trends in price and quantity for fully advertised drugs.

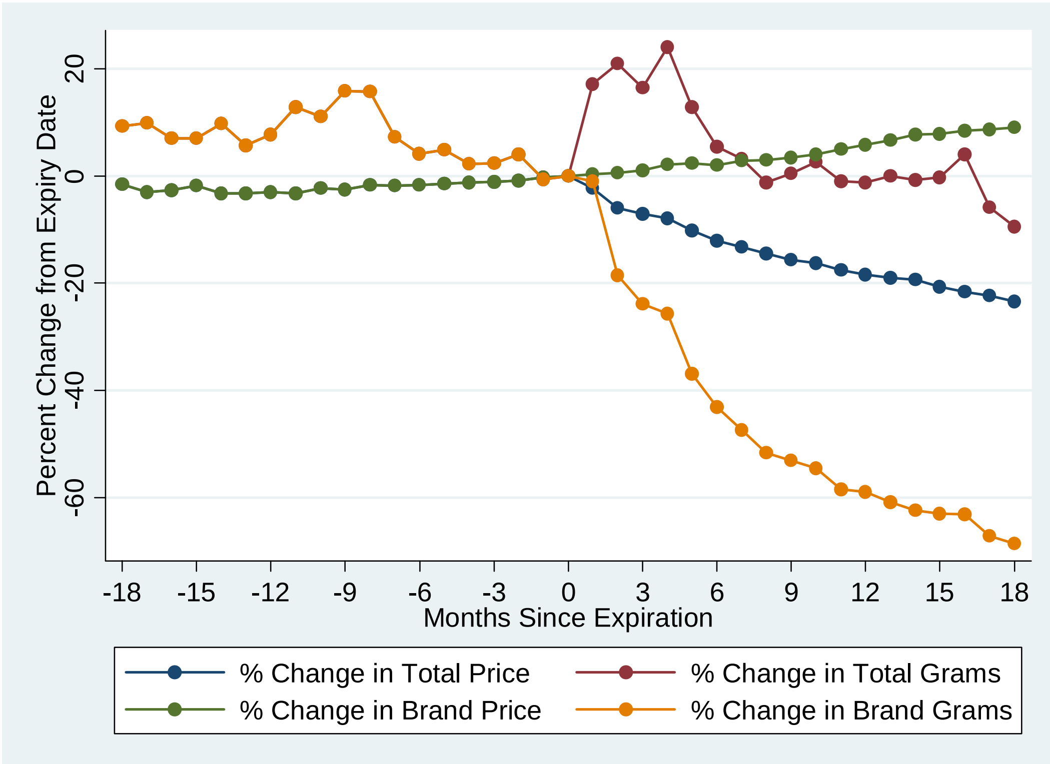

Figure 6: Mean trends in price and quantity for drugs not fully advertised.

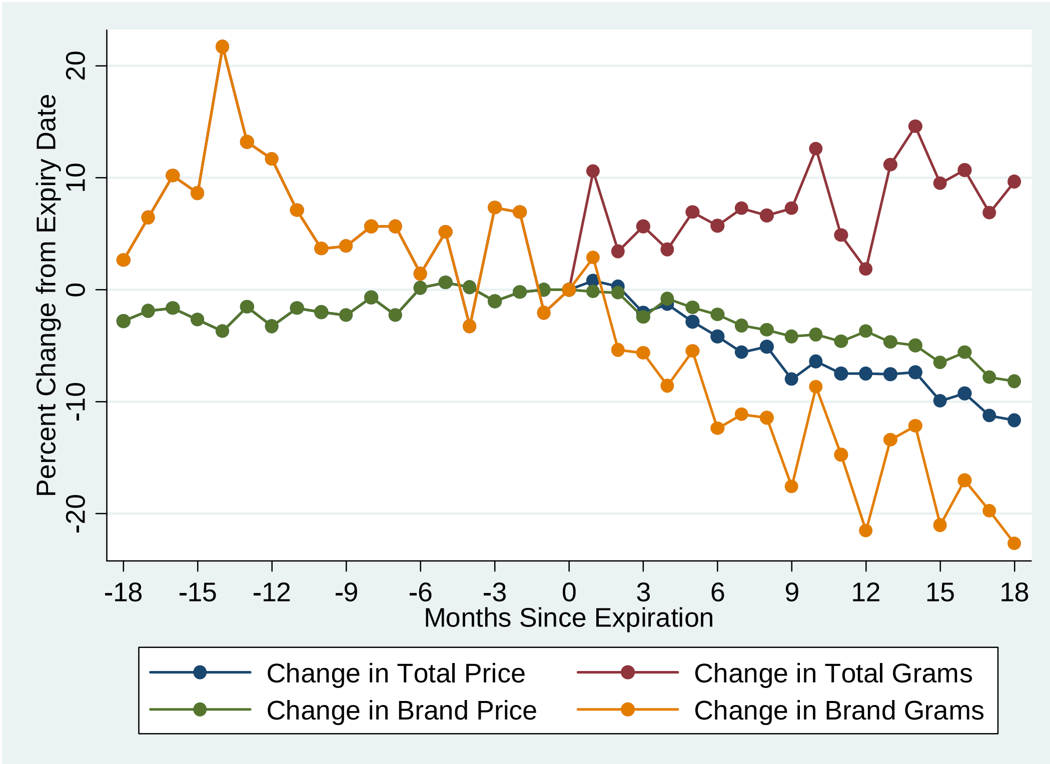

Figure 7: Mean monthly spending on journal advertising.

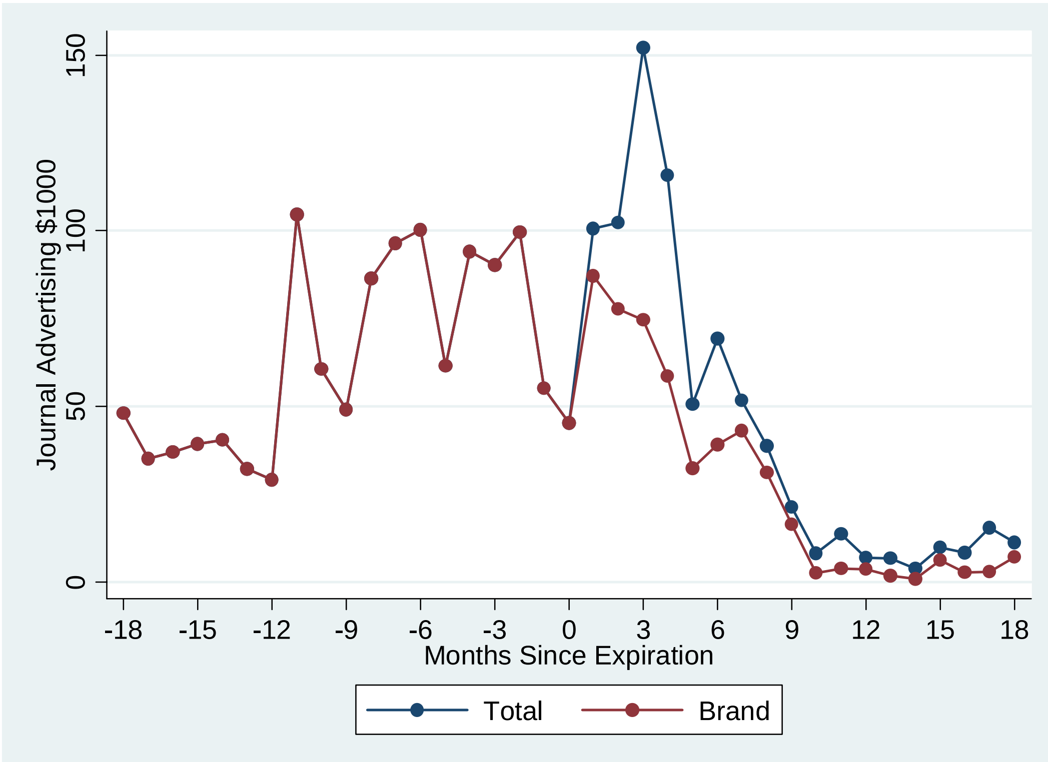

Figure 8: Mean monthly visits by pharmaceutical company representatives.

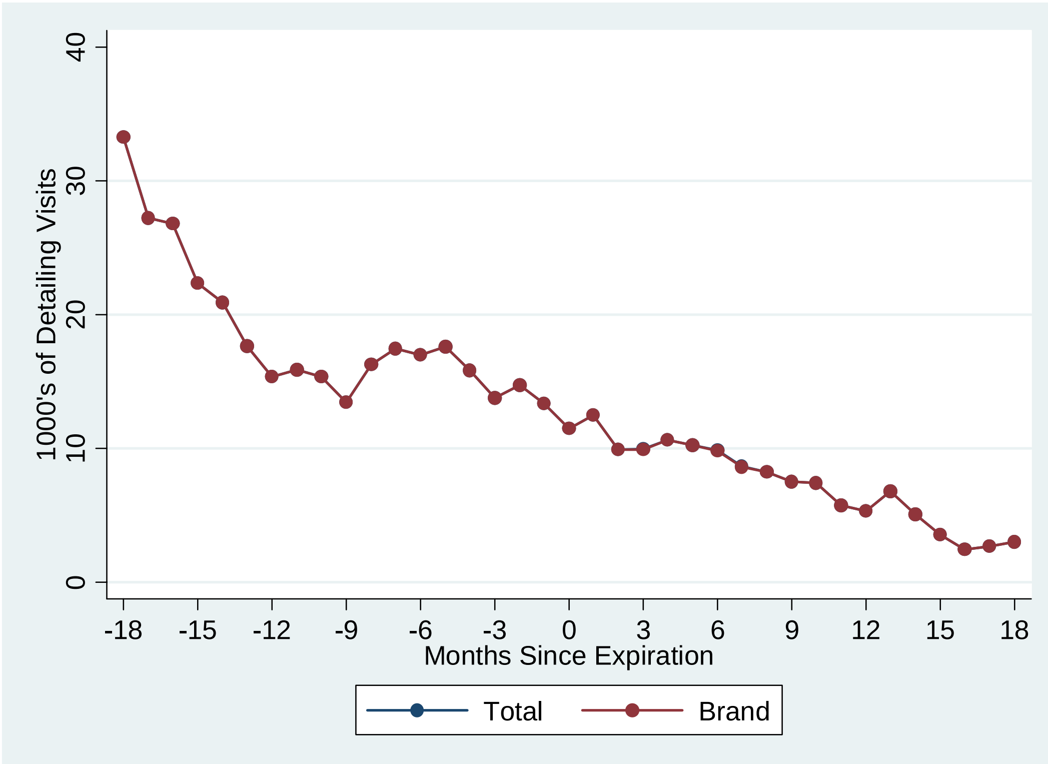

Figure 9: Mean monthly samples dispensed by pharmaceutical company

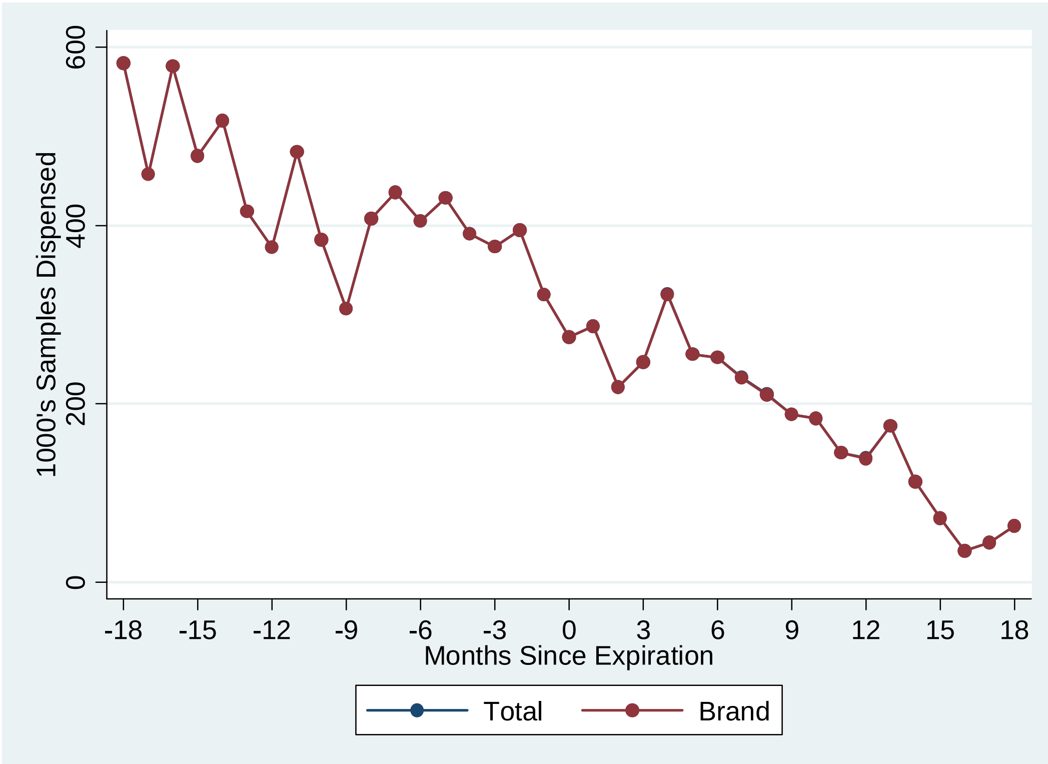

Figure 10: Graphical Depiction of "Expiration Window" Identification Strategy.

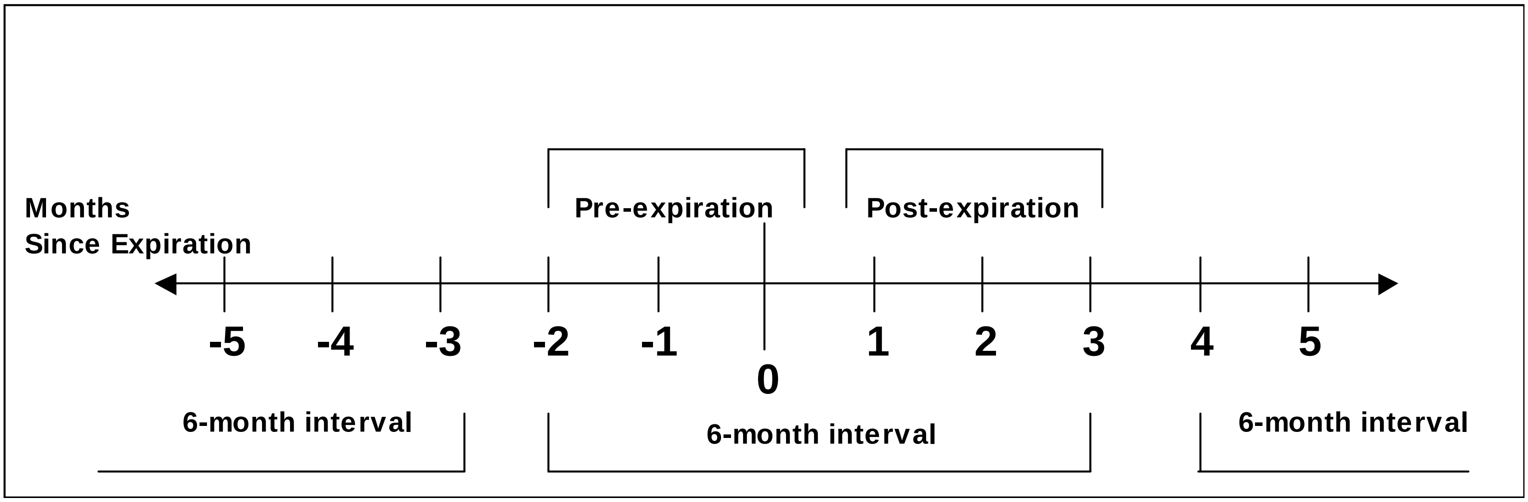

Figure 11: Graphical Depiction of "Trend Break" Identification Strategy

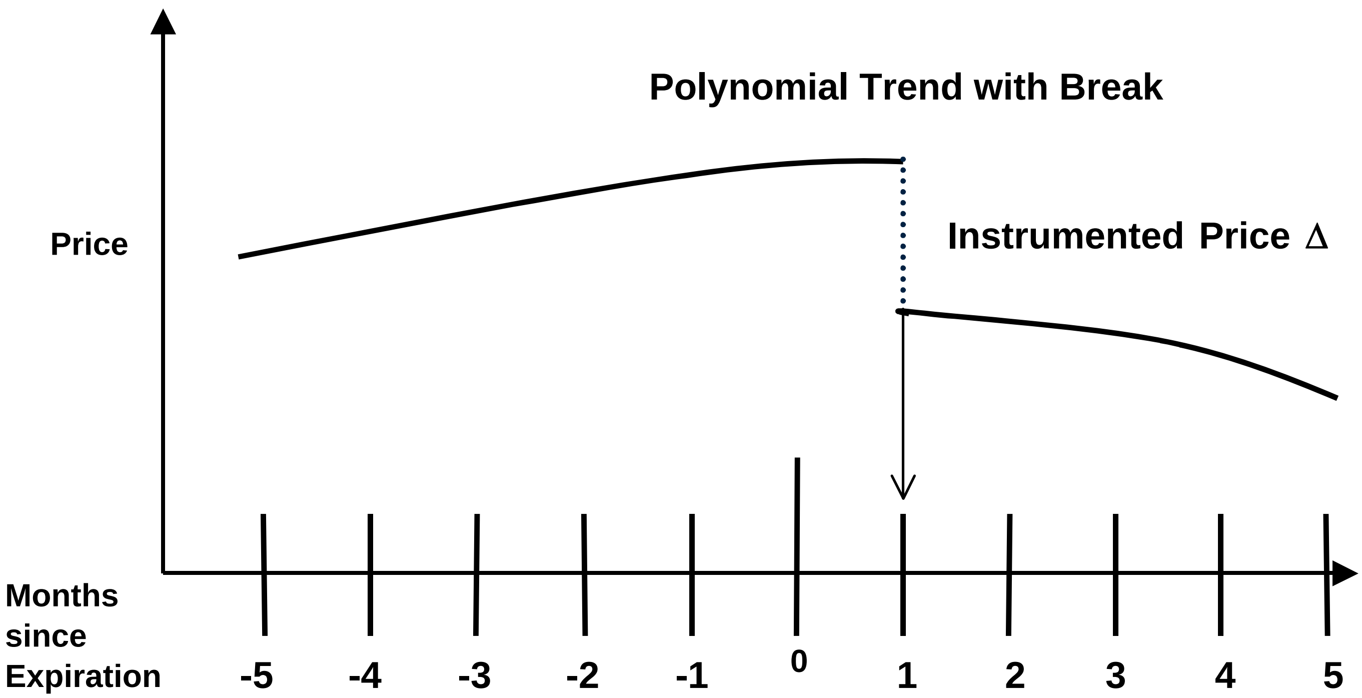

Figure 12: Graphical Depiction of "Expiration Window" Identification Strategy with Lagged Effects.