

Generic entry, price competition, and market segmentation in the prescription drug market

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Abstract

This paper studies the effects of generic entry on post-patent price competition for 18 prescription drugs recently exposed to competition. An independent, validating test of the “generic competition paradox” is conducted using a newly created data set. Each generic entrant is associated with an average 1% increase in the branded price. The one-way error component model accounts for intermolecular competition, market segmentation, and endogeneity of entry and finds branded prices increasing by 2%. Alternative definitions of entry suggest that price competition is confined to the generic market. The unique payer-type feature of the data offers empirical evidence supporting market segmentation.

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1. Introduction

The literature on off-patent prescription drug markets is often concerned with the effects of generic entry on branded prices. Some studies (e.g., [Wiggins and Maness \(2004\)](#), [Caves et al. \(1991\)](#)) have estimated a negative relationship while others (e.g., [Frank and Salkever \(1997\)](#), [Grabowski and Vernon \(1996, 1992\)](#)) have uncovered a positive relationship. Using a newly constructed data set on 18 oral solid prescription drugs, this study provides an independent test of the hypothesis that branded firms raise their price in

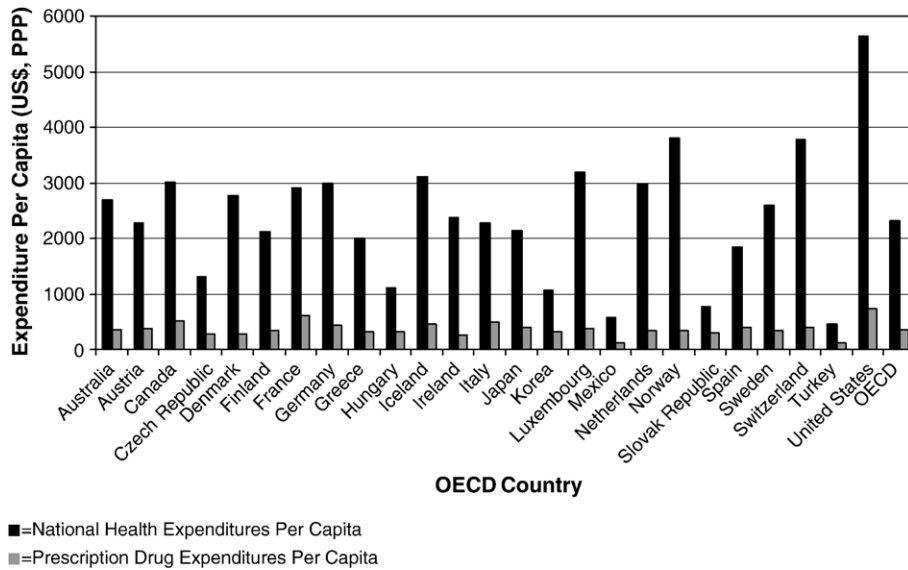
response to generic entry (i.e. the “Generic Competition Paradox” as coined by [Scherer \(1993\)](#)).

The most commonly accepted explanation to this “generic competition paradox” lies in the segmentation of the market (e.g., see [Frank and Salkever \(1992\)](#)).¹ When faced with generic competition, branded firms may forego the cross-price sensitive segment of the market in favor of the brand-loyal segment. This paper offers a generalized model of [Frank and Salkever \(1992\)](#) and conducts an empirical test of

¹ [Ellison and Ellison \(2007\)](#) offer two alternative explanations. One, prior to patent expiration an incumbent firm could lower its price to suggest to its potential competitors that they should do the same upon entry. Or two, branded firms could raise the price of an expiring strength to encourage patients to switch to other patent-protected strengths.

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Note: Health expenditure per capita: Austria (2002), Australia (2001), Hungary (2002), Ireland (2002), Japan (2002), Luxembourg (2002), Norway (2002), Sweden (2002), Turkey (2000).

Note: Prescription drug expenditure per capita: Austria (2002), Australia (2001), Hungary (2002), Ireland (2002), Japan (2002), Poland (2002), Sweden (2002), Turkey (2000), UK (2002).

Source of data: OECD Health Data, 2005

Fig. 1. National health and prescription drug expenditures per capita for selected OECD Countries, 2003.

the market segmentation theory with the unique payer-type feature of the data set. In total, the paper's findings suggest that price competition in the prescription drug market is confined to the generic market: generic entry has a positive effect on branded prescription prices (and a negative impact on generic prescription prices). Specifically, each generic entrant is associated with an average 1% increase in the branded price. When controlling for intermolecular substitution, market segmentation, and the endogeneity of entry, branded prices increase by an average 2%.

Prescription drug spending is one of the major factors behind the growing expenditures on health care services in the U.S. and abroad. Of the Organization for Economic Cooperation and Development (OECD) countries, the U.S. rates the highest in terms of total health and prescription drug expenditures per capita (see Fig. 1). Fig. 2 shows that during the last 15 years the rate of growth of prescription drug expenditures, both total and per capita, was higher than both the rate of growth of inflation and total health expenditures. The only exception to this was during the early 1990s when the U.S. witnessed the growth of managed care organizations which attempted to reign in the high cost of

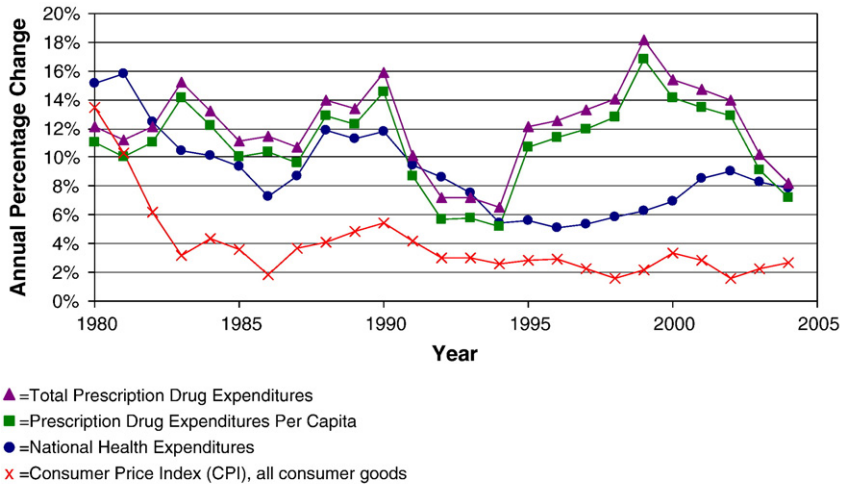
health care. This period also coincided with the 1992 Presidential elections where health care reform was one of the main platforms upon which Bill Clinton campaigned and won.² The price divergence between branded and generic pharmaceuticals is an important aspect of the public's growing concern over rising health care costs. Such concerns are well-grounded, especially in light of the recently enacted Medicare prescription drug plan and the upcoming Presidential elections where health care is already one of the leading issues.

This paper proceeds in the following manner: Section 2 provides the conceptual framework. Section 3 discusses the data used in the analysis. Section 4 presents the results and Section 5 concludes.

2. Conceptual framework

The conceptual framework for this paper borrows from Frank and Salkever's (1992) market segmentation model. This model examines the effect of generic entry on branded prices. Frank and Salkever (1992)

² For an analysis of the stock market's response to Clinton's failed health care reform proposal see Ellison and Mullin (2001).



Source of data: Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, and U.S. Bureau of Labor Statistics.

Fig. 2. Annual percentage change in prescription drug expenditures, national health expenditures, and inflation.

view the demand for branded pharmaceuticals to be composed of a price insensitive (i.e. brand-loyal) segment and a cross-price sensitive segment. They assume that the brand-loyal customers' demand is independent of the generic price while the market demand for the N identical generic drugs is determined by the cross-price sensitive segment. Kong (2000) offers a more general case of the Frank and Salvever (1992) model where both segments of the market consume both versions of the drug (i.e. branded and generic). This is more consistent with evidence on physician-prescribing behaviors (e.g., see Hellerstein (1999)) and patients' consumption choices. The basic set-up of Kong's (2000) model is presented in Kong and Seldon (2004).³ We begin by assuming a quadratic utility function,

$$U_i = X_0 + \frac{\alpha_i}{\beta_i} \sum_j X_{ji} - \frac{1}{2\beta_i} \sum_j X_{ji}^2 - \frac{\gamma_i}{\beta_i} \prod_j X_{ji}, \quad (1)$$

where X_0 is a numeraire good, i indexes the market segment (i.e. $i=1$ for the brand-loyal segment and $i=2$ for the cross-price sensitive segment), and j indicates a branded (b) or generic (g) drug. The first-order conditions associated with the constrained

maximization of (1) yield linear inverse demand functions,

$$P_b = \frac{\partial U}{\partial X_b} = \frac{1}{\beta_i} (\alpha_i - X_{bi} - \gamma_i X_{gi}), \quad (2)$$

$$P_g = \frac{\partial U}{\partial X_g} = \frac{1}{\beta_i} (\alpha_i - X_{gi} - \gamma_i X_{bi}), \quad (3)$$

or rewritten as demand curves,

$$X_{bi} = \frac{1}{1 - \gamma_i^2} [\alpha_i(1 - \gamma_i) - \beta_i P_b + \gamma_i \beta_i P_g], \quad (4)$$

$$X_{gi} = \frac{1}{1 - \gamma_i^2} [\alpha_i(1 - \gamma_i) - \beta_i P_g + \gamma_i \beta_i P_b], \quad (5)$$

where P_b is the branded price and P_g is the generic price. The parameters β and γ represent how sensitive the demand for each good is to changes in its own price and that of its competitor. Assuming $0 < \gamma < 1$ implies that the branded and generic drug are imperfect substitutes: when $\gamma=0$ the goods are completely independent and when $\gamma=1$ the goods are perfect substitutes. Furthermore, a sufficient condition for the second market segment to be more own- and cross-price

³ Kong and Seldon (2004) present a Stackelberg model for a branded, pseudo generic, and generic product. Kamien and Zang (1999) also discuss the implications of a branded firm producing its own generic (i.e. a pseudo generic).

⁴ Notice that the symmetry imposed by the utility function on the demand system implies that as the generic price decreases some of the original brand-loyal customers will switch from consuming the branded drug to the cheaper generic alternative.

sensitive is $\beta_2 > \beta_1$ and $\gamma_2 > \gamma_1$.⁴ The market demand for each drug can be expressed as a weighted average,

$$X_b = \theta X_{b1} + (1 - \theta)X_{b2}, \tag{6}$$

$$X_g = \theta X_{g1} + (1 - \theta)X_{g2}, \tag{7}$$

where θ represents the fraction of the brand-loyal segment’s demand. The formulation for the branded market demand is identical to that in Frank and Salkever (1992). Upon further simplification,

$$X_b = \bar{\alpha} - \bar{\beta}P_b + \bar{\gamma}P_g, \tag{8}$$

$$X_g = \bar{\alpha} - \bar{\beta}P_g + \bar{\gamma}P_b, \tag{9}$$

where $\bar{\alpha} = \frac{\theta\alpha_1}{1+\gamma_1} + \frac{(1-\theta)\alpha_2}{1+\gamma_2}$, $\bar{\beta} = \frac{\theta\beta_1}{1-\gamma_1} + \frac{(1-\theta)\beta_2}{1-\gamma_2}$, and $\bar{\gamma} = \frac{\theta\beta_1\gamma_1}{1-\gamma_1} + \frac{(1-\theta)\beta_2\gamma_2}{1-\gamma_2}$.

Profit-maximizing firms compete in a two-stage, Nash non-cooperative game (i.e. a Stackelberg model). The branded manufacturer behaves as a Stackelberg price leader, setting its price first. In determining their output decisions, the generic firms behave as followers and take the branded price as given, along with the behavior of their rival generic competitors. Rewriting Eq. (9) reveals that P_g is a function of P_b and X_g . Since each individual generic firm takes the branded price as given, along with the output decisions of their generic competitors, the only choice variable is its individual output. Thus, there are N generic firms who seek to maximize their profit,

$$\begin{aligned} \max_{x_{gN}} \pi_{gN} &= (P_g - c_g)x_{gN} \\ &= \left\{ \left(\frac{1}{\bar{\beta}} [\bar{\alpha} + \bar{\gamma}P_b - (x_{g1} + \dots + x_{gN} + \dots + x_N)] - c_g \right) x_{gN} \right\}, \end{aligned} \tag{10}$$

where n indexes the generic firm and c_g is the marginal cost of production. The N generic firms are assumed to be identical (i.e. $x_{g1} = \dots = x_{gN} = x_g$). Maximizing Eq. (10) produces the individual demand function,

$$x_g = \frac{1}{N+1} (\bar{\alpha} + \bar{\gamma}P_b - \bar{\beta}c_g), \tag{11}$$

and the market demand function,

$$X_g = Nx_g = \frac{N}{N+1} (\bar{\alpha} + \bar{\gamma}P_b - \bar{\beta}c_g). \tag{12}$$

Substituting Eq. (12) into Eq. (9) yields the equilibrium generic price,

$$P_g^* = \frac{\bar{\alpha} + \bar{\gamma}P_b}{(N+1)\bar{\beta}} + \frac{N}{(N+1)}c_g. \tag{13}$$

The branded firm (i.e. the Stackelberg leader) also seeks to maximize its profit,

$$\max_{P_b} \pi_b = (P_b - c_b)X_b, \tag{14}$$

where c_b is the branded firm’s marginal cost of production. Substituting Eq. (13) into Eq. (8) yields,

$$X_b = \bar{\alpha} - \bar{\beta}P_b, \tag{15}$$

where $\bar{\alpha} = \frac{\bar{\alpha}[(N+1)\bar{\beta} + \bar{\gamma}] + N\bar{\beta}\bar{\gamma}c_g}{(N+1)\bar{\beta}}$ and $\bar{\beta} = \frac{(N+1)\bar{\beta}^2 - \bar{\gamma}^2}{(N+1)\bar{\beta}}$. Maximizing Eq. (14) produces the equilibrium branded price,

$$\begin{aligned} P_b^* &= \frac{\bar{\alpha}}{2\bar{\beta}} + \frac{1}{2}c_b \\ &= \frac{\bar{\alpha}[(N+1)\bar{\beta} + \bar{\gamma}] + N\bar{\beta}\bar{\gamma}c_g}{2[(N+1)\bar{\beta}^2 - \bar{\gamma}^2]} + \frac{1}{2}c_b. \end{aligned} \tag{16}$$

The first-partial derivative of Eq. (16) with respect to N is positive when $c_g > \frac{\bar{\alpha}}{\bar{\beta} - \bar{\gamma}}$. So, if the marginal cost of the generic drug is relatively large, the branded price will increase with entry—a result that is in accordance with the predictions of the market segmentation theory. However, if $c_g \leq \frac{\bar{\alpha}}{\bar{\beta} - \bar{\gamma}}$, generic entry exerts downward pressure on branded prices. This is counter to the predictions of the market segment model and inconsistent with the “generic competition paradox” mentioned in the introduction.⁵ By comparison, Frank and Salkever’s (1992) simple model suggest that $\frac{\partial P_b^*}{\partial N} > 0$ when: 1) entry increases the demand for the branded drug; 2) c_b is decreasing; or 3) entry makes the reduced-from demand curve less elastic. Frank and Salkever (1992) rule out the first two cases and conclude that generic entry results in a steeper demand curve for the branded firm which then allows the branded firm to increase its price in order to maximize its total revenue in that submarket.

⁵ According to the predictions of a Bertrand model for homogenous producers of generic drugs, once there are two or more generic firms supplying the market the generic price will be driven down to the marginal cost of production. (This is further explored empirically in Section 4.2.) Branded drugs are always priced above their generic counterparts. However, if upon patent expiration a branded firm attempts to raise its price and charge a price that is too high (relative to the generic price and hence the generic marginal cost) it may be driven out of the market. Thus, the difference between branded and generic prices may be too large to offset the loss in utility the previously brand-loyal consumers would suffer by switching their habits and consuming a generic version of the drug. And so, if the marginal cost of the generic drug is particularly small the branded firm may lose its ability to raise its price in the post-patent expiration period.

Substituting Eq. (16) into Eq. (13),

$$P_g^* = \frac{1}{2\tilde{\beta}(N+1)} \left\{ \alpha \left[\frac{[2(N+1)\tilde{\beta}^2 - \tilde{\gamma}^2] + \tilde{\gamma}(N+1)\tilde{\beta}}{(N+1)\tilde{\beta}^2 - \tilde{\gamma}^2} \right] + N\tilde{\beta}c_g \left[\frac{[2(N+1)\tilde{\beta}^2 - \tilde{\gamma}^2]}{(N+1)\tilde{\beta}^2 - \tilde{\gamma}^2} \right] + \tilde{\gamma}c_b \right\}. \quad (17)$$

Kong (2000) proposes that the equilibrium generic price will decrease with entry (i.e. $\frac{\partial P_g^*}{\partial N} < 0$). By simplifying Eqs. (16) and (17) we see that:

$$P_b^* = P_b^*(\text{NUMGEN}, c_b), \quad (18)$$

$$P_g^* = P_g^*(\text{NUMGEN}, c_g). \quad (19)$$

The empirical implementation of Eqs. (18) and (19) is as follows: I have constructed an unbalanced panel of 18 branded drugs that experienced initial generic entry between February 1998 and February 2002. The units of observation are the branded (generic) drugs at one-month intervals. The analysis concerns the first month of entry through February 2002. The semi-log stochastic approximations to Eqs. (18) and (19) are,

$$\ln(P_{b_{dt}}^*) = \delta_0 + \delta_1 \text{NUMGEN}_{dt} + \delta_2 \text{NUMSUB}_{dt} + \delta_3 \text{Numpres}_{dt} + \delta_4 \% \text{Med_B}_{dt} + \delta_5 \% \text{Third_B}_{dt} + \delta_6 \text{POSTPAT}_{dt} + \varepsilon_{b_{dt}}, \quad (20)$$

$$\ln(P_{g_{dt}}^*) = \lambda_0 + \lambda_1 \text{NUMGEN}_{dt} + \lambda_2 \text{NUMSUB_G}_{dt} + \lambda_3 \% \text{ABREV}_{dt} + \lambda_4 \% \text{Med_G}_{dt} + \lambda_5 \% \text{Third_G}_{dt} + \lambda_6 \text{POSTPAT}_{dt} + \varepsilon_{g_{dt}}, \quad (21)$$

where NUMGEN (i.e. N) is the number of generic entrants, NUMSUB is the number of other available substitute therapies which equals the sum of the number of other branded (NUMSUB_B) and generic (NUMSUB_G) prescription drug substitutes, Numpres is the number of presentations, %Med_B (%Med_G) is the fraction of branded (generic) prescriptions that were dispensed to Medicaid patients, %Third_B (%Third_G) is the fraction of branded (generic) prescriptions that were dispensed to individuals with third-party insurance coverage (the omitted reference category is %Cash_B (%Cash_G)—the fraction of branded (generic) prescriptions paid out-of-pocket (i.e. cash)), %ABREV is the average percentage change in the pre-entry monthly branded revenue,

POSTPAT is the months since patent expiration (or months since initial generic entry), d indexes the drug, t indexes the time (i.e. month and year), and ε_b and ε_g are the error terms.^{6,7} NUMGEN differs from NUMSUB in that the former refers to the number of Food and Drug Administration (FDA) approved therapeutically equivalent (in terms of active ingredient, strength, dosage form, and route of administration) generic drugs available on the market whereas the latter refers to other available prescription drugs that contain different active ingredients but yet treat the same conditions. More information on substitutability is provided below and in Section 3. I initially assume a monotonic relationship between price and generic entry but other functional forms, as suggested by Eqs. (16) and (17), are explored in Section 4. The set of control variables follow Reiffen and Ward (2005).

Recent studies of the prescription drug market have focused not only on intramolecular (i.e. between a branded and its own generic) price competition but on intermolecular (i.e. between a generic, its own generic, and other branded and generic substitutes) competition as well. Ellison et al. (1997) and Berndt et al. (2003) investigate this issue for a single therapeutic category while Stern (1996) considers four therapeutic categories. Reiffen and Ward (2005) consider the number of other alternate prescription drugs available at the time of patent expiration along with a variable indicating whether there were multiple brands available. They argue that the inclusion of these demand-side variable should affect the branded price, to the extent that there is competition between brands, and varies between drugs. Using *ePocrates.com* I was able to identify other brands, and their generics, that could be prescribed in lieu of the chosen drug. Following Lu and Comanor (1998), substitutability is defined on the following basis: 1) the drug must have the same indication; 2) the drug must have the same or similar route of administration; 3) the drug must have the same mechanism of action; and/or 4) the drug must be in the same broadly defined chemical class.

A drug's presentation refers to the unique combination of strength and dosage form. I include the number of oral presentations that are available in a given month

⁶ Time since initial generic entry is used somewhat interchangeably with time since patent expiration since the latter is not observed and of little consequence unless it is accompanied by generic entry.

⁷ By comparison, Reiffen and Ward's (2005) and Frank and Salkever's (1997) price regressions use a linear time trend. POSTPAT is essentially just a time trend but allows for the possibility that the prices are related to the passage of time since patent expiration (or initial generic entry) as opposed to generic entry itself. Note that the results reported in Tables 3–5 are robust to alternative definitions of time (e.g., linear time trend, time/year dummies) as well.

and year. The *Electronic Orange Book (EOB)* was used to identify the date in which the first presentation of a drug was approved by the FDA. If, for example, a drug was available as a 10mg tablet and a 20mg capsule, NUMPRES would equal “2.” Reiffen and Ward (2005) include separate measures for the number of forms and strengths.

According to the theory of market segmentation, once a branded drug loses its patent and experiences generic entry, the branded firm focuses its marketing efforts on the remaining brand-loyal market segment. The branded firm takes advantage of this market segment’s greater price insensitivity and charges it a higher price (thereby increasing its total revenue from this submarket). The data set used for the empirical application of Eqs. (20) and (21) contains information on three payer-types—cash, Medicaid, and third party. (The data set is described in greater detail below.) The latter two payer-types have some type of prescription drug coverage while the former pays out-of-pocket. That being said, however, federal law authorizes the Centers for Medicare and Medicaid Services (CMS) to ensure that the federal government receives a good price for prescription drugs covered by state-run Medicaid programs.⁸

So, if generic entry contributes to increases in branded prices, as hypothesized, δ_1 would be positive. However, δ_2 would be negative if the intramolecular price competition created downward pressure on branded prices. Recently, Ellison and Ellison (2007) have suggested the use of presentation proliferation as a strategic tool of entry deterrence.⁹ By increasing the number of presentations available the branded firm increases the cost to the generic entrant of reproducing the entire product line thereby deterring entry which allows the branded firm to charge a higher price. If this is the case, δ_3 would be positive. If price competition is confined solely to the generic market, as suggested by the literature (e.g., Reiffen and Ward (2005), Wiggins and Maness (2004), Saha et al. (2003), Caves et al. (1991)) λ_1 would be negative (as would λ_2). If the average monthly change in branded revenue in the pre-entry period proxies post-entry demand then λ_3 would be positive. If the empirical application supports the theory of market segmentation, δ_4 (and λ_4) would be positive. The expected signs on δ_5 and λ_5 are less clear for reasons mentioned above, how-

ever. If real prices increase (decrease) with the passage of time since initial generic entry, δ_6 and λ_6 , would be positive (negative).

I assume that there is no correlation between ε_b and ε_g . I do, however, adopt a one-way error component framework in which ε is assumed to have a drug compound-specific effect, μ_d , and an idiosyncratic component, v_{dr} . When μ_d is assumed to be a fixed parameter, fixed-effects (FE) is used. When μ_d varies, random-effects (RE) is used. Note that when RE is used, μ_d is assumed to be uncorrelated with the other covariates in Eqs. (20) and (21). Furthermore, the time-invariance of some of the variables (e.g., NUMSUB_B, NUMPRES, % Δ BREV) necessitates a RE estimation strategy as in Reiffen and Ward (2005). While these variables do not have to be time invariant they are, however, for the period considered in this paper.

In the estimations that follow I also relax the assumption of exogenous generic entry. When μ_d is assumed to be a fixed parameter, one-way FE two-stage least squares (FE2SLS) is used. However, when μ_d is stochastic, Baltagi’s (1981) one-way error-components 2SLS (EC2SLS) is used. EC2SLS is just the RE counterpart of a classical error-components panel data regression. See Baltagi (1981) and Baltagi and Chang (2000). Intuitively, RE can be viewed as a weighted average of the between and within estimators and so one can think of EC2SLS as the weighted average of the 2SLS between estimator and the 2SLS within estimator.¹⁰ The first-stage identifying instruments include a variable indicating whether the initial generic entrants were granted six months of exclusive marketing rights, the number of abbreviated new drug applications (ANDAs) approved by the FDA, and the total branded prescriptions dispensed in the month prior to generic entry. These IVs are further explained in the following section.

⁸ Such ends are achieved through discounts, rebates, and other programs such as the Federal Upper Limit (FUL), the maximum allowable cost (MAC), and the wholesale acquisition cost (WAC) programs.

⁹ Another recently popular strategic tool of entry deterrence in the pharmaceutical industry is advertising. Recent analyses include Iizuka (2004) and Scott Morton (2000).

¹⁰ Ellison et al. (1997) use a two-stage budgeting problem while Stern (1996) uses a two level nested logit model to study both intra- and inter-molecular price competition. While discrete choice frameworks are desirable in many instances, such frameworks are not necessary or appropriate here. Studies addressing substitution patterns have typically focused on a single, narrowly defined therapeutic category that has often been subject to a relatively large amount of entry by generics and other brands — e.g., anti-ulcers and anti-infectives. The drugs in my data set span 14 distinctly different therapeutic categories and do not experience entry by other brands during the period of analysis. The focus of this paper is on patent expiration and the resulting competition between a branded prescription drug and its FDA-approved generics, not its substitute drug therapies. Furthermore, at this point I do not have price and quantity information on other substitute therapies. Additionally, my price and quantity data are at the prescription-level so it would be difficult to standardize these measures across the various presentations like Lu and Comanor (1997) and Stern (1996) do.

3. Data

Each May *MedAd News*, a monthly trade publication for the pharmaceutical industry, provides information on top-selling branded drugs that have lost or are expected to lose their patents (or on generics that have or are expected to see big sales) in the upcoming years. I used these annual tables to identify a set of drugs that lost their patents in recent years. I cross-referenced this set of drugs with information contained in the *EOB* to indirectly determine which patents did in fact expire. The *EOB* is an electronic database of approved (on the basis of safety and efficacy) drug products with therapeutic equivalence evaluations. Branded and generic drugs are deemed therapeutically equivalent when their active ingredient(s) are absorbed at comparable rates and amounts at the site of therapeutic action. Pharmacists in states with “permissive substitution laws” can substitute a therapeutically equivalent (cheaper) generic drug for the prescribed branded drug without consulting the prescribing physician.¹¹ While the *EOB* database is rich, information on expired patents and exclusivity is lacking. Thus, I approximated the date of branded patent expiration with the FDA’s earliest generic drug approval date.

From this set of drugs I eliminated: 1) injectables and infusibles because they are not typically sold to drugstores in large quantities due to their primary usage in hospitals; 2) over-the-counter (OTC) versions because they do not require a prescription;¹² 3) combination products because they concern two or more drug products; and 4) anti-infectives because they are primarily used to treat acute conditions.¹³ Ultimately, I confined my attention to the “oral solid” (tablets and capsules) prescription drugs that are used to treat chronic conditions.¹⁴ In the end, I was left with 18 branded drugs and their respective generics.¹⁵

NDC Health provided the data for this paper. NDC Health is a private firm that provides a broad range of

health information services to all segments of the health care industry. NDC Health’s *PHAST* database collects data on over 35,000 retail outlets in the United States. It is the largest sample currently used in the industry. This database provides information on retail and mail-order prescriptions at one-month intervals between January 1998 and February 2002.¹⁶ This is a higher frequency of observation (i.e. one-month intervals) than has been previously used in the literature and allows the timing and impact of generic entry to be more precisely gauged.¹⁷

The variables obtained for each of the 18 drug pairs from *PHAST* are: 1) the manufacturer; 2) the product; 3) the month and year; 4) the payment type; 5) the strength; 6) the total prescription count; and 7) the total prescription dollars. The payment types include cash, Medicaid, and third parties and works in concert with the total prescription count; when the pharmacist fills a prescription he/she indicates what type of payment is received, not the actual amount of the payment. The total prescription dollars represent the dollars the pharmacies pay to the drug manufacturers, not the dollars received when a prescription is filled. Therefore, the total prescription dollars are wholesale, not retail measures, and I deflate them with the Producer Price Index (PPI) for Pharmaceutical Preparations for each month as published by the Bureau of Labor Statistics (BLS).¹⁸ I use January 1998 as the base period.

Since most of the drugs here are available in multiple presentations (e.g., 20 mg capsule, 10 mg tablet), I had to ensure that I was dealing with a constant unit of observation when making comparisons across a particular branded and generic product. As is standard practice, the most “popular” strength based on the number of branded prescriptions filled from January 1998 through February 2002 (according to the *PHAST* reports) was used.

Table 1 lists the 18 drug pairs chosen for the study. The therapeutic market was obtained using the *Nursing Drug Handbook*. Half of the drugs are from the cardiovascular market while five others treat diseases/conditions affecting the central nervous system. There is

¹¹ See Hellerstein (1998) and Berndt (2002) for studies related to these state-specific substitution laws.

¹² See Berndt et al. (2003) for a study of the effects of going OTC for four anti-ulcer drugs.

¹³ The anti-infective market is unlike other therapeutic markets in that it has historically experienced much competitive entry by generics and other branded products. Furthermore, the abbreviated new drug application (ANDA) procedure established by the 1984 Waxman–Hatch Act does not apply to anti-infectives. See Ellison et al. (1997) and Wiggins and Maness (2004) for studies on the anti-infective market.

¹⁴ Because this paper focuses on oral solids I have not accounted for all drugs that lost their patent between February 1998 and February 2002.

¹⁵ One of my drug pairs actually consists of two branded drugs (Procardia XL and Adalat CC) because I was not able to distinguish between their respective generics.

¹⁶ The inherent differences between the retail and mail-order markets may be important for issues such as self-selection, but I do not have such information at my disposal. Also, because this is a nationally representative sample, I cannot account for the use of formularies across the various retail outlets.

¹⁷ Cook (1998) finds that generic entry has occurred at a more rapid pace in recent years.

¹⁸ See Griliches and Cockburn (1994) for alternative calculations to the standard price indexes and Berndt et al. (2003) for an application.

Table 1

The 18 oral solid drug pairs experiencing initial generic entry between February 1998 and February 2002

	Branded drug (generic drug)	Therapeutic market	Date of first generic entry	Maximum number of generic manufacturers	Total real prescription dollars in month prior to generic entry (millions)
1	Neoral (cyclosporine)	Immunomodulation	February 2000	2	\$7.10
2	Hytrin (terazosin hydrochloride)	Cardiovascular	August 1999	6	\$21.48
3	Mevacor (lovastatin)	Cardiovascular	December 2001	6	\$7.49
4	Cardura (doxazosin mesylate)	Cardiovascular	October 2000	10	\$13.51
5	Buspar (buspirone hydrochloride)	Central nervous system	March 2001	1	\$31.56
6	Daypro (oxaprozin)	Central nervous system	February 2001	7	\$10.53
7	Lodine & Lodine XL (etodolac)	Central nervous system	May 1998	11	\$4.05
8	Betapace (sotalol hydrochloride & Sorine)	Cardiovascular	May 2000	8	\$13.06
9	Kerlone (betaxolol hydrochloride)	Cardiovascular	November 1999	1	\$0.59
10	Vasotec (enalapril maleate)	Cardiovascular	August 2000	14	\$20.33
11	Pepcid (famotidine)	Gastrointestinal	April 2001	9	\$34.37
12	Procardia XL & Adalat CC (nifedipine)	Cardiovascular	March 2000	1	\$26.26
13	Zebeta (bisoprolol fumarate)	Cardiovascular	November 2000	2	\$2.07
14	Prozac (fluoxetine)	Central nervous system	July 2001	13	\$182.63
15	Eulexin (flutamide)	Anti-neoplastic	September 2001	4	\$3.29
16	Rocaltrol (calcitriol)	Hormonal	October 2001	1	\$1.69
17	Relafen (nabumetone)	Central nervous system	August 2001	1	\$13.33
18	Cordarone (amiodarone hydrochloride & Pacerone)	Cardiovascular	May 1998	9	\$14.34

Source of data: PHAST, EOB, and Nursing Drug Handbook.

one drug pair from each of the immunomodulation, gastrointestinal, anti-neoplastic, and hormonal therapeutic markets as well. The composition of the therapeutic market reflects the fact these drugs are popular oral solids. According to *MedAd News*, the top five grossing therapeutic markets are the cardiovascular, anti-infective, central nervous system, gastrointestinal, and respiratory tract market. The bulk of out-patient therapies in these markets are oral solids. Also included are the number of generic entrants and the total prescription dollars in the month prior to entry.¹⁹

The dependent variable used in the analysis is the log of the price per prescription. Reiffen and Ward (2005) and Frank and Salkever (1997) use the average revenue per unit of active ingredient for the most popular presentation of a drug. Ellison and Ellison (2007) note that there is not a monotonic relationship between the price of a drug and the amount of the active ingredient it contains. I do not have price data at the pill level so I use the total prescription dollars and total prescription count in constructing a similar price

measure; I divide the total prescription dollars (\$) by the total prescription count (R_x).²⁰ Both measures could be subject to a certain degree of measurement error because prescriptions do not always contain the same number of pills. Such detailed information was not available. However, all of the drugs contained in the data set typically treat chronic conditions so I would not expect large fluctuations in the number of pills per individual prescription each month. Recent studies (e.g., Richard and Van Horn (2004), Berndt et al. (2003), Coscelli (2000)) have addressed the habit persistence of patients in terms of their consumption (and physicians in terms of their prescribing) and the corresponding demand-side externalities. Any variation in the number of pills per prescription occurs both for branded drugs as well as for generic versions. Measurement error that varies across, but not within, each drug gets picked up in the drug compound effects (i.e. μ_b and μ_g). Variation in time should also be controlled for with the inclusion of the time trend. Furthermore, the use of a semi-log functional form

¹⁹ The drugs studied here may correspond to larger, more profitable markets where generic entry is more likely to occur and to a greater extent. To ensure that entry does occur some researchers (e.g., Grabowski and Vernon (1996)) impose a minimum threshold for sales. For studies related to market characteristics and probability of entry see Ellison and Ellison (2000) and Scott Morton (1999).

²⁰ While the total prescription dollars is intended to be the price the pharmacy actually pays for a prescription, it most likely does not include the rebates or discounts that are often offered or negotiated between insurers (or pharmaceutical manufacturers) and pharmacies as they are typically kept secret [Ellison and Snyder (2001)]. This is a limitation of all studies on this industry.

Table 2
Descriptive statistics

	Mean	Std. dev.	Nobs.
<i>Price variables</i>			
Real branded price [real Pb]			
Pre-entry	\$89.05	\$62.80	561
Post-entry	\$89.65	\$51.63	339
Pre- and post-entry	\$89.28	\$58.81	900
Real generic price [real Pg]	\$70.32	\$40.53	325
Ratio of generic to branded price	0.777	0.067	325
<i>Revenue variables</i>			
Real branded revenue (millions)			
Pre-entry	\$27.40	\$44.90	561
Post-entry	\$6.06	\$12.30	339
Pre- and post-entry	\$19.40	\$37.60	900
Real branded revenue in month prior to entry (millions) [BREV]	\$17.10	\$27.40	339
Average percentage change in real branded revenue pre-entry [%ΔBREV]	1.590	2.534	339
Real generic revenue (millions)	\$9.60	\$159.00	325
<i>Market share variables</i>			
Branded share of total prescriptions			
Pre-entry	0.415	0.281	325
Pre- and post-entry	0.785	0.329	886
Cash share of branded prescriptions [%Cash_B]			
Pre-entry	0.169	0.549	561
Post-entry	0.151	0.044	339
Pre- and post-entry	0.162	0.052	900
Medicaid share of branded prescriptions [%Med_B]			
Pre-entry	0.108	0.047	561
Post-entry	0.074	0.038	339
Pre- and post-entry	0.095	0.047	900
Third-party share of branded prescriptions [%Third_B]			
Pre-entry	0.723	0.060	561
Post-entry	0.775	0.045	339
Pre- and post-entry	0.743	0.060	900
Generic share of total prescriptions	0.585	0.281	325
Cash share of generic prescriptions [%Cash_G]	0.156	0.049	325
Medicaid share of generic prescriptions [%Med_G]	0.091	0.045	325
Third-party share of generic prescriptions [%Third_G]	0.753	0.062	325
<i>Prescription count variables</i>			
Branded prescriptions (thousands)			
Pre-entry	343.129	442.280	561
Post-entry	77.403	129.001	339
Pre- and post-entry	243.039	380.399	900
Branded prescriptions in month prior to entry (thousands) [BTOTRX]	224.204	277.069	339
Generic prescriptions (thousands)	145.060	188.120	325
<i>Other variables</i>			
Number of generic entrants [NUMGEN]	4.681	3.680	339

Table 2 (continued)

	Mean	Std. dev.	Nobs.
<i>Other variables</i>			
More than 1 generic entrant [DVNUMGEN]	0.693	0.462	339
1 generic entrant [DVNMGN1]	0.307	0.462	339
2 generic entrants [DVNMGN2]	0.127	0.333	339
3 generic entrants [DVNMGN3]	0.047	0.212	339
4 or 5 generic entrants [DVNMGN45]	0.133	0.340	339
6 or more generic entrants [DVNMGN6+]	0.386	0.488	339
Number of other branded and other generic substitutes [NUMSUB]			
Pre-entry	2.590	2.562	561
Post-entry	2.499	2.584	339
Pre- and post-entry	2.556	2.569	900
Number of other branded substitutes [NUMSUB_B]			
Pre-entry	2.032	2.300	561
Post-entry	1.782	2.219	339
Pre- and post-entry	1.938	2.272	900
Number of other generic substitutes [NUMSUB_G]			
Pre-entry	0.558	0.744	561
Post-entry	0.717	0.819	339
Pre- and post-entry	0.618	0.777	900
Number of oral solid presentations [NUMPRES]			
Pre-entry	2.727	1.217	561
Post-entry	3.103	1.501	339
Pre- and post-entry	2.869	1.343	900
Months since initial generic entry [POSTPAT]	13.047	10.975	339
EXCLSIX	0.071	0.257	339
ENTRY	0.377	0.485	900
Months of “effective patent” protection	137.167	43.043	18

Data is in one-month intervals.

Source of data: PHAST, EOB and ePocrates.com.

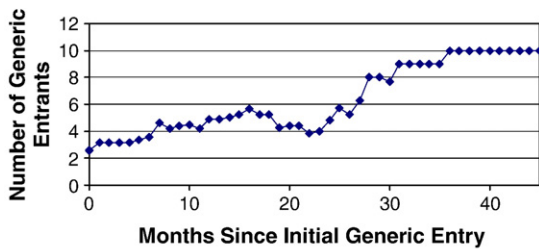
Nobs.: Number of observations.

helps to eliminate any potential bias.²¹ To determine the extent of the bias or to correct for it is not central to the aims of this paper.

4. Estimation and results

Table 2 provides the descriptive statistics for each variable used in the analysis, along with others that help characterize the market. An average of 13 months

²¹ Suppose that one is concerned that the number of pills per prescription varied. My measure of price is the price per prescription, i.e. $\frac{s}{R_x} = \frac{s}{pill} * \frac{\# \text{ of pills}}{R_x}$. Using the semi-log functional form, the random component, $\frac{\# \text{ of pills}}{R_x}$, of the dependent variable can be rewritten as $\ln(\# \text{ of pills}) - \ln(R_x)$, which resembles classical measurement error. While classical measurement error in the dependent variable is not typically a problem, it is a concern when it affects the regressors. Traditionally, such situations are fixed by instrumental variables (IV), if available.



Source of data: PHAST

Fig. 3. Average number of generic entrants.

of post-patent observations is used in the empirical analysis.²² The average “effective patent life” is 11.4 years.²³ The average number of generic entrants is 4.7, achieving a maximum of 14 for one drug. There is an average 2.6 generics in the first month of competition and this figure nearly doubles by the year’s end. See Fig. 3. The average number of substitute drugs is 2.6–1.9 competing with other brands and 0.6 other generics. The bulk of the other brands were approved in the pre-entry period while most of the other generics were approved in the post-entry period. There is an average 2.7 oral presentations per drug. The average price of a branded prescription pre-entry (post-entry) is \$89.05 (\$89.65). The average price of a generic prescription is \$70.25. Thus, the average generic to branded price ratio is 0.78.²⁴ On average, branded drugs constitute 43.3% of the prescription drug market and the generics account for the remaining 56.7%. Pre-entry, 16.9, 10.8, and 72.3% of the branded prescriptions were paid for in cash, by Medicaid, and by third parties, respectively. Post-entry these figures are 15.1, 7.4, and 77.5%. This compositional shift reflects and supports the notion of a segmented market which will be the focus further down in Section 4.3. The break-down by payer-types is similar for the generic market: 15.6% of the prescriptions are for cash-paying customers, 9.1% for Medicaid recipients, and 75% for individuals with some type of third-party coverage.

²² Comparatively, Grabowski and Vernon (1996) focus on the first and second year following initial generic entry and Reiffen and Ward (2005) consider up to three years after patent expiration.

²³ Comanor (1986) cites an average “effective patent life” of 15.7 years in 1962 and 13.1 years by the decade’s end. Similarly, Grabowski and Vernon (1996) note an average 12.4 (10) years in the early (late) 1970s. The shortest “effective patent life” (8.1 years) is in the years prior to the passage of the 1984 Waxman–Hatch Act.

²⁴ This figure may seem higher than expected but it is because it is based on the price per prescription and generic prescriptions may contain more pills than branded prescriptions. For example, a patient who opts for the generic drug may receive a three-month supply whereas a patient who consumes the branded drug may only purchase a one-month supply.

Fig. 4 displays the average generic to branded price ratio as a function of the months since initial generic entry. The declining ratio is evident and is consistent with Grabowski and Vernon (1996). Fig. 4 also shows the generics’ share of the prescription drug market. One month after entry, the generics control nearly 30% of the market. The branded market share is continually eroded by the influx of generic competition. One year later, the generics control nearly 60% of the market. The prominent divergence in branded and generic prescription drug shares around the 24th month of competition is likely due to the fact that, at this point, the sample includes only six drugs. Because there is an average 13 months of post-entry observation, the tail ends of these graphs should be interpreted with a degree of caution as they are based on fewer observations.

Fig. 5a and b depict the branded and generic price as a function of months since initial generic entry for two representative drugs. I normalized both prices by the branded price in the first month of competition. On average, the pre-entry price for the drugs in my sample is increasing. The increase is especially prominent for some drugs (Fig. 5a) and more modest for others (Fig. 5b). Lu and Comanor (1998) and Reekie (1978) have found that drugs offering important therapeutic gains are often priced high initially while drugs offering modest or marginal improvements are often priced low initially. In Dean’s (1969) language, a firm is either pursuing a price skimming or a price penetration strategy, respectively. Fig. 5a and b also reveal the price gap between branded and generic drugs that it is increasing (with entry).

4.1. Branded price regressions

The econometric estimation of Eqs. (20) and (21) make use of panel methods and employ a one-way error component framework.²⁵ First, Eq. (20) is estimated omitting the time-invariant NUMPRES. One-way RE is tested against one-way FE using the Hausman test. Based on the Hausman χ^2 test statistic I cannot reject the null hypothesis and so Table 3, column 1, provides the RE estimates [Greene (2002)].²⁶ Generic entry has a positive and statistically significant effect on the real price of a branded prescription; it increases the average price by 1%. Since RE allows me to incorporate time-invariant variables, I disaggregate NUMSUB into its branded (NUMSUB_B) and generic (NUMSUB_G) components and include NUMPRES as a regressor.

²⁵ See Baltagi and Chang (1994) for the use of RE with an unbalanced panel.

²⁶ An F -test supports the drug-specific effects.

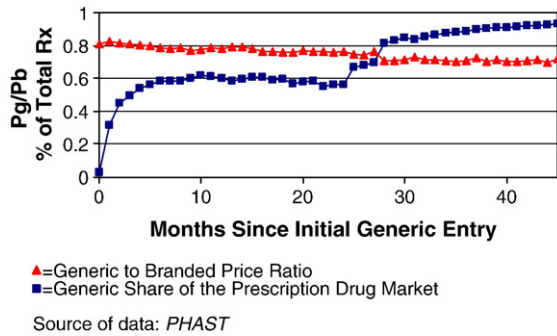


Fig. 4. Generic to branded price ratio and generic share of the prescription drug market.

Doing so makes my results more directly comparable to Reiffen and Ward (2005). Table 3, column 2, provides the results. Based on the coefficient estimates, own- and other-generic competition has a positive effect on branded prices while other-branded competition has a negative effect. The positive and statistically significant coefficient estimate on NUMSUB in column 1 is largely driven by the variation in NUMSUB_G as there were no other branded drugs approved during this time frame. The positive and statistically significant coefficient estimate on %Third_B suggests that a 10% increase in the fraction of branded prescriptions that are dispensed to customers with third-party insurance will increase the branded prescription price by 5.1%. The coefficient estimate on %Med_B is positive in column 1 and reverses sign in column 2 but never gains statistical significance. Similarly, the small coefficient estimates on POSTPAT are negative but never gain statistical significance which suggests a lack of time trend in the branded price.

The results reported in Table 3, columns 3–5, relax the assumption of exogenous generic entry. In my first-stage regression, I regress the number of generic entrants on the total branded prescriptions dispensed in the month prior to generic entry (BTOTRX), along with all the other exogenously determined regressors, but also employ a dummy variable that indicates whether the initial generic entrants were granted six months of exclusive generic marketing rights (EXCLSIX) and the number of ANDAs that the FDA approved as of a given date for the presentation of interest (ANDAPRES).²⁷

Title I of the 1984 Waxman–Hatch Act established an ANDA procedure for generics. Now, in seeking FDA marketing approval, generic manufacturers need only

establish the bioequivalency of their drug to an already marketed and approved branded version. Drugs are deemed bioequivalent when the active ingredient is absorbed at the same level and speed at the site of therapeutic action. This eliminates the costly and time-intensive clinical tests for generics. If a generic firm wishes to market its drug before the branded patent expires it must certify that the branded patent is invalid or will not be infringed upon by the manufacture, use, or sale of the generic drug. Under the Waxman–Hatch Act, the first successful generic firm to do so is granted 180 days of exclusive marketing rights. Eleven of the drugs in my data set made such certifications but only six were granted such rights. The 180 days of exclusive marketing was binding for only four of these six drugs; the other two drugs have been the subject of other litigation which has effectively prevented other generics from entering the market. Thus, EXCLSIX is assigned a value of “1” for the six months in which these four branded drugs faced competition from only one generic, as mandated by law; for all other months and drugs, this variable takes on a value of “0”.²⁸

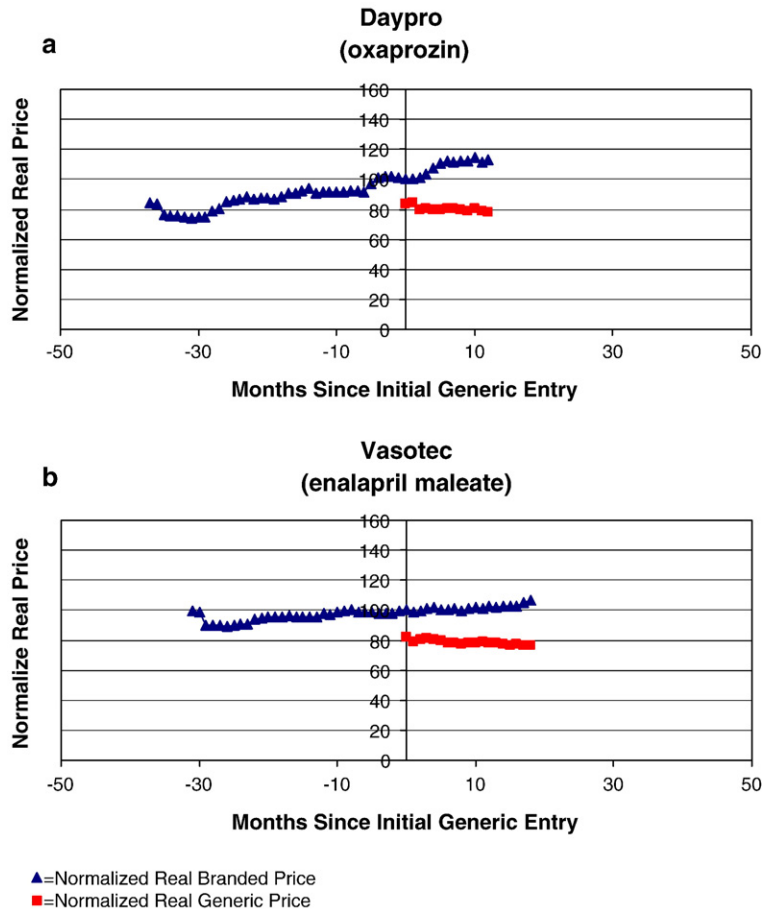
Under the assumption of endogenous generic entry, the benchmark estimation is one-way FE2SLS. Included with the results are the F -statistic on the excluded instruments and the partial R^2 .²⁹ The Durbin–Wu–Hausman (DWH) test is used as a specification test of one-way FE (i.e. OLS) versus one-way FE 2SLS (i.e. 2SLS). A generalized Hausman test is also used to test one-way EC2SLS versus one-way FE2SLS (i.e. RE versus FE) [Baltagi (2004, 2005)].³⁰ Based on these two tests, I conclude that NUMGEN is correlated with ε_t and RE (i.e. EC2SLS) is the most efficient way to proceed. Controlling for the endogeneity of generic entry with EC2SLS increases the coefficient estimate on NUMGEN; on average, an additional generic entrant increases the average branded prescription price by 2%. The effect of other generic competition is maintained while the estimated coefficient on %Third_B loses statistical significance and that on POSTPAT gains statistical significance. While statistically significant, the coefficient estimate on POSTPAT is

²⁸ The 180 days of exclusive marketing can be granted to more than one firm; generics can share exclusivity when there are multiple ANDAs filed on the same day. For studies related to generic entry and the timing of ANDAs see Reiffen and Ward (2005) and Scott Morton (2000, 1999).

²⁹ I am unaware of similar tests for RE.

³⁰ Reiffen and Ward (2005) use one-way RE and test the potential endogeneity of generic entry using a Hausman test. It is unclear, however, which Hausman test they are using. Baltagi (2004) notes that the usual Hausman test (i.e. $(\hat{\delta}^{FE} - \hat{\delta}^{RE})[\text{Var}(\hat{\delta}^{FE} - \hat{\delta}^{RE})](\hat{\delta}^{FE} - \hat{\delta}^{RE})$) can yield misleading inference in the presence of endogeneity.

²⁷ Reiffen and Ward (2005), Frank and Salkever (1997), and Caves et al. (1991) also use the pre-patent branded revenues as an identifying instrument in their 2SLS estimations.



Source of data: PHAST

Fig. 5. (a, b) Normalized price.

negative and quite small—its magnitude is only 0.08 times that of NUMGEN. Thus, it seems safe to attribute the rise in branded prices largely to the incidence of generic entry as opposed to the passage of time since patent expiration. See Table 3, column 4.

As before, the generalized Hausman test cannot reject the null hypothesis and so Table 3, column 5, provides the EC2SLS results which explicitly allow for estimation of the time-invariant variables. Note that the first-stage generic entry regression now includes BTOTRX in addition to EXCLSIX and ANDAPRES. Again, a branded drug’s own generic competitors increase its price by an average 2% while other generic (branded) competitors increase (decrease) its price by 6.1 (8.8)%. The larger estimates associated with other generic competition on branded prescription prices may be due to the fact that many of the other generic competitors have been on the market longer. This affords patients, physicians, and pharmacists more experience

and allows any quality uncertainty to be resolved. The statistical significance of the coefficient estimates on NUMSUB_G and NUMSUB_B may be somewhat exaggerated by its time-invariance as noted by Moulton (1986)—this is discussed in greater detail below. The coefficient estimates on NUMPRES and %Med_B never gain statistical significance.

4.2. Generic price regressions

Table 4, column 1, reports the estimated results of Eq. (21) omitting the time-invariant $\% \Delta \text{BREV}$ as a regressor.³¹ Again, the Hausman test cannot reject the

³¹ Note that 14 observations have been dropped due to inconsistencies in the data (i.e. months in which the generic prescription price was unreasonable which suggests errors in either the prescription dollars, the prescription count, or both). Including these observations, however, essentially leaves the results unchanged.

Table 3
Branded price regressions

Dependent variable	ln(real Pb)				
	One-way RE		One-way FE2SLS	One-way EC2SLS	
	(1)	(2)	(3)	(4)	(5)
NUMGEN	0.0104 (0.0016)***	0.0104 (0.0017)***	0.0199 (0.0032)***	0.0199 (0.0033)***	0.0198 (0.0034)***
NUMSUB	0.0684 (0.0059)***	–	0.0622 (0.0067)***	0.0608 (0.0068)***	–
NUMSUB_B	–	–0.0727 (0.0408)*	–	–	–0.0884 (0.0406)**
NUMSUB_G	–	0.0697 (0.0061)***	–	–	0.0609 (0.0069)***
NUMPRES	–	–0.0585 (0.0665)	–	–	–0.0442 (0.0663)
%Med_B	–0.0106 (–0.1980)	0.0025 (–0.2022)	–0.3539 (–0.2225)	–0.0497 (–0.3188)	–0.2900 (–0.2326)
%Third_B	0.5077 (0.1649)***	0.5232 (0.1684)***	0.1222 (0.2008)	0.4122 (0.3079)	0.1647 (0.2096)
POSTPAT	–0.0003 (0.0004)	–0.0003 (0.0004)	–0.0013 (0.0005)***	–0.0016 (0.0006)***	–0.0013 (0.0005)**
Constant	3.7515 (0.1837)***	4.1844 (0.2498)***	4.0336 (0.1655)***	3.8195 (0.2891)***	4.4477 (0.2691)***
R ² (within)	0.721	0.721	–	–	–
R ² (between)	0.090	0.050	–	–	–
R ² (overall)	0.111	0.099	–	–	–
DWH test (OLS vs. 2SLS)	–	–	$\chi^2(5)=11.39, p=0.0441$	–	–
1st -stage partial R ²	–	–	0.268	–	–
1st -stage F-stat on excl IVs	–	–	$F(2,315)=57.66, p=0$	–	–
Identifying IVs	–	–	EXCLSIX, ANDAPRES	EXCLSIX, ANDAPRES	EXCLSIX, ANDAPRES, BTOTRX
Nobs.	339	339	339	339	339

(Standard error).

*, **, *** = significant at the 10, 5, and 1% level.

Nobs.: Number of observations.

Drug dummies included.

Source of data: PHAST, EOB and ePocrates.com.

null hypothesis of RE, so % Δ BREV is included as a regressor in column 2. The coefficient estimate on NUMGEN is positive while that on NUMSUB_G is negative. Neither coefficient gains statistical significance, however. Nor does that on %Third_G. The negative and statistically significant estimated coefficient on %Med_G implies that a 10% increase in the fraction of generic prescriptions that are dispensed to Medicaid patients decreases the average price of a generic prescription by 4.6%. The coefficient estimate on POSTPAT is negative and statistically significant at the 5% level suggesting that on average, the generic prescription price decreases by 0.1% each year. As before, the assumption of exogenous generic entry is relaxed. The FE2SLS and EC2SLS results can be found in Table 4, columns 3–5. Controlling for the endogeneity of generic entry reverses the sign on the coefficient estimate of

NUMGEN—generic entry has a negative (albeit small and statistically insignificant) effect on generic prescription prices. While the other control variables are unaffected, the estimated coefficient on POSTPAT loses its statistical significance. The coefficient estimates on % Δ BREV in columns 2 and 5 are positive and show that in markets where the demand for the branded prescription was growing prior to entry, the generic firm can charge higher prices for its drugs. This variable never gains statistical significance, however. This could be due to: 1) the unbalanced nature of the panel; 2) the introduction of new, superior branded drugs as suggested by Suh et al. (1998); and/or 3) the decline in promotional efforts as a product nears the end of its life/patent-protected period as noted by Caves et al. (1991). In fact, the only statistically significant variable in the generic price regressions is %Med_G.

Table 4
Generic price regressions

Dependent variable	ln(real Pg)				
	One-way RE		One-way FE2SLS	One-way EC2SLS	
Estimation strategy	(1)	(2)	(3)	(4)	(5)
NUMGEN	0.0023 (0.0018)	0.0023 (0.0018)	-0.0012 (0.0039)	-0.0005 (0.0039)	-0.0011 (0.0038)
NUMSUB_G	-0.0024 (0.0068)	-0.0024 (0.0068)	0.0010 (0.0074)	-0.0030 (0.0079)	0.0006 (0.0074)
%ΔBREV	-	0.0138 (0.0561)	-	-	0.0095 (0.0653)
%Med_G	-0.4551 (0.1397)***	-0.4555 (0.1396)***	-0.4634 (0.1402)***	-0.4999 (0.1442)**	-0.4592 (0.1395)***
%Third_G	-0.0438 (0.0985)	-0.0434 (0.0984)	0.0087 (0.1099)	-0.1600 (0.1750)	0.0050 (0.1092)
POSTPAT	-0.0010 (0.0004)**	-0.0010 (0.0004)**	-0.0005 (0.0006)	-0.0002 (0.0007)	-0.0005 (0.0006)
Constant	4.2070 (0.1515)***	4.1941 (0.1643)***	4.1496 (0.0778)***	4.3043 (0.1978)***	4.1701 (0.1859)***
R ² (within)	0.071	0.071	-	-	-
R ² (between)	0.008	0.000	-	-	-
R ² (overall)	0.057	0.000	-	-	-
DWH test (OLS vs. 2SLS)	-	-	$\chi^2(4) < 0$	-	-
1st-stage partial R ²	-	-	0.2279	-	-
1st-stage F-stat on excl IVs	-	-	F(2, 301)=44.43, p=0	-	-
Identifying IVs	-	-	EXCLSIX, ANDAPRES	EXCLSIX, ANDAPRES	EXCLSIX, ANDAPRES, BTOTRX
Nobs.	325	325	325	325	325

(Standard error).

*, **, ***=significant at the 10, 5, and 1% level.

Nobs.: Number of observations.

Drug dummies included.

Source of data: PHAST, EOB and ePocrates.com.

While of the expected sign in columns 3–5 of Table 4, the economically and statistically insignificant coefficient estimate on NUMGEN warrants a closer look. To better account for the nature of competition in the generic drug market I considered a couple alternative specifications of NUMGEN. It is reasonable to assume that the most relevant matter for the generics is whether there are one or more generic manufacturers in the market. Thus, I defined a new variable, DVNUMGEN, which takes on the value of “1” if the number of generic entrants is greater than one and “0” otherwise. This alternative construction of NUMGEN is consistent with Bertrand price competition among generic suppliers of homogeneous drugs. The predicted Bertrand generic price is equal to marginal cost when there are two or more generic suppliers serving the market. The results to this alternative specification can be found in Table 5, column 5. The estimated coefficient on DVNUMGEN remains negative and if statistically significant, would suggest that collectively these latter entrants lower the average generic price by 0.6%, relative to the first generic.

Another re-definition of NUMGEN, as suggested by Reiffen and Ward (2005), includes a set of dummy variables. Rather than include dummy variables for each entrant, and to ease the interpretation, I created a set of dummies corresponding to one entrant (DVNMGN1), two entrants (DVNMGN2), three entrants (DVNMGN3), four or five entrants (DVNMGN45), and six or more entrants (DVNMGN6+). DVNMGN1 is the omitted reference group. The groupings were chosen accounting for the fact that the average number of generic entrants is 4.7. As noted by Reiffen and Ward (2005), using such a re-definition of generic entry imposes no specific structure on the relationship between price and entry, thus allowing for the marginal effect of each additional generic firm to vary with the number of competing firms in the market. Table 5, column 6, provides the results to this specification. The coefficient estimate on DVNMGN2 is negative and statistically significant at the 12.3% level. Thus, relative to the first entrant, the second entrant lowers the average generic price by 1.7%. The coefficient estimates on the latter two dummy variables are also negative and

Table 5
Alternative price regressions

Dependent variable	ln (real Pb)				ln (real Pg)		
	One-way RE						
Estimation strategy	(1)	(2)	(3)	(4)	(5)	(6)	(7)
NUMGEN	–	–	0.0132 (0.0042)***	–	–	–	0.0090 (0.0083)
DVNUMGEN	0.0114 (0.0087)	–	–	–	–0.0063 (0.0091)	–	–
DVNMGN2	–	–0.0055 (0.0093)	–	–	–	–0.0167 (0.0108)	–
DVNMGN3	–	0.0346 (0.0130)***	–	–	–	0.0165 (0.0141)	–
DVNMGN45	–	0.0650 (0.0112)***	–	–	–	–0.0009 (0.0115)	–
DVNMGN6+	–	0.0911 (0.0127)***	–	–	–	–0.0053 (0.0133)	–
NUMSUB_B	–0.0632 (0.0438)	–0.0729 (0.0325)**	–0.0757 (0.0516)	–0.0130 (0.0223)	–	–	–
NUMSUB_G	0.0802 (0.0062)***	0.0759 (0.0060)***	0.0925 (0.0243)***	0.0557 (0.0057)***	–0.0011 (0.0068)	–0.0037 (0.0069)	0.0027 (0.0454)
NUMPRES	–0.0598 (0.0714)	–0.0536 (0.0530)	–0.0569 (0.0838)	0.0171 (0.0069)**	–	–	–
%Med_B	0.2695 (0.2110)	–0.4613 (0.2161)**	0.6145 (0.5685)	1.4922 (0.1561)***	–	–	–
%Third_B	0.8567 (0.1717)***	0.0978 (0.1852)	1.2530 (0.5500)**	1.5007 (0.0890)***	–	–	–
ENTRY	–	–	–	–0.6207 (0.0702)***	–	–	–
ENTRY × %Med_B	–	–	–	0.5386 (0.1021)***	–	–	–
ENTRY × %Third_B	–	–	–	0.7742 (0.0860)***	–	–	–
%Med_G	–	–	–	–	–0.4545 (0.1414)***	–0.4416 (0.1414)***	–0.5259 (0.6816)
%Third_G	–	–	–	–	–0.0072 (0.0964)	–0.0401 (0.1024)	0.3525 (0.8012)
%ΔBREV	–	–	–	–	0.0132 (0.0478)	0.0134 (0.0429)	0.0182 (0.0592)
POSTPAT	0.0006 (0.0004)	0.0002 (0.0004)	–0.0031 (0.0017)	0.0003 (0.0003)	–0.0005 (0.0004)	–0.0004 (0.0004)	–0.0046 (0.0027)*
Constant	3.9113 (0.2635)***	4.5316 (0.2248)***	3.5683 (0.3205)*	2.9935 (0.1529)***	4.1767 (0.1395)***	4.1995 (0.1360)***	3.8990 (0.6477)***
R ² (within)	0.644	0.756	0.768	0.692	0.068	0.083	0.138
R ² (between)	0.049	0.034	0.070	0.033	0.001	0.001	0.007
R ² (overall)	0.091	0.074	0.087	0.046	0.002	0.001	0.131
Nobs.	339	339	58	900	325	325	58

(Standard error).

*, **, *** = significant at the 10, 5, and 1% level.

Notes: Drug dummies included.

Source of data: PHAST, EOB and ePocrates.com.

increase in magnitude suggesting that the degree of price competition increases with entry.

Yet another estimation strategy involves averaging the prices across the months where the number of generic entrants is unchanged. Reiffen and Ward (2005) use this approach but warn that reducing the sample

size may reduce the statistical significance of their estimates. Moulton (1986) notes that this method should help eliminate the downward bias accruing to the standard errors when multiple observations with essentially unchanged exogenous variables are used. Thus, I re-estimated Eq. (21), omitting the time dummies, and

the results are reported in Table 5, column 7. As expected the standard errors on the estimated coefficients are larger. In sum, the preferred specification for the generic price regression is found in Table 5, column 6. For all the generic price regressions found in Tables 4 and 5, %Med_G is the only consistently statistically significant regressor. Its coefficient estimates imply that the generic prices decrease anywhere from 4.4 to 5% when there is a 10% increase in the fraction of generic prescriptions dispensed to Medicaid customers. While previous literature (e.g., Reiffen and Ward (2005), Saha et al. (2003)) has uncovered a negative effect of generic entry on generic price, the weaker results uncovered here may be due to differences in the time period analyzed, variable definition, or sample size. They may also occur if upon entry, the generics price their drugs at their marginal cost of production. Thus, there would not be any effect, per se, of continued entry on the generic prescription price.

These alternative definitions of generic entry were also used in the branded price specifications. The results can be found in Table 5, columns 1–3. The coefficient estimates from the alternative definitions of generic entry suggest that continued generic entry results in increased branded prices. The effects are most pronounced when the dummy variables are used to measure generic entry. See column 2. I also explored the possibility that the branded price responds positively to the mere occurrence of generic entry. The specification found in Table 5, column 4, uses all the observations I have for branded prices—pre- and post-entry. I defined a variable, ENTRY, which takes on the value of “0” in the pre-entry periods and “1” in the post-entry periods. ENTRY is interacted with %Med_B and %Third_B to capture how the changing market shares in the post-entry period affect the branded price. The estimated coefficient on ENTRY is negative while its interactions with %Med_B and %Third_B are positive, as is each regressor by itself. All of these coefficient estimates are statistically significant as well. Collectively these coefficient estimates imply that a branded firm is able to raise its price by attracting a larger customer base with some type of prescription drug coverage. The negative effects of generic entry can be somewhat offset by maintaining a large price insensitive customer base. In sum, the econometric estimates of Eqs. (20) and (21) suggest that price competition in the prescription drug industry is confined to the generic market. This is consistent with Reiffen and Ward (2005), Wiggins and Maness (2004), Saha et al. (2003), Frank and Salkever (1997), and Caves et al. (1991). These results clearly

and strongly lend support to the notion of market segmentation in the prescription drug industry.

4.3. Revenue regressions

When a market is segmented, like in the market for pharmaceuticals, firms can third-degree price discriminate and charge higher (lower) prices to their price insensitive (sensitive) customers and increase their total revenue. Accordingly, when a branded drug's patent expires, thereby exposing the firm to generic competition, the branded firm may choose to abandon their cross-price sensitive customers in favor of their brand-loyal customers to whom they can charge a higher price. This section focuses on the relationship between the segmentation of the prescription drug market and firm revenue. The data set used here is especially suited to such a purpose because the total prescription count is disaggregated by payer-type thus enabling one to determine exactly how branded and generic revenues are affected by the size of cash, Medicaid, and third-party market segments. Specifically,

$$\begin{aligned} \ln(\text{BrandRev}_{dt}) = & \phi_0 + \phi_1 \text{NUMSUB}_{dt} \\ & + \phi_2 \text{NUMPRES}_{dt} + \phi_3 \% \text{Med_B}_{dt} \\ & + \phi_4 \% \text{Third_B}_{dt} + \phi_5 \text{ENTRY}_{dt} \\ & + \phi_6 \text{ENTRY}_{dt} \times \% \text{Med_B}_{dt} \\ & + \phi_7 \text{ENTRY}_{dt} \times \% \text{Third_B}_{dt} \\ & + \phi_8 \text{POSTPAT}_{dt} + u_{bdt}, \end{aligned} \quad (22)$$

$$\begin{aligned} \ln(\text{GenericRev}_{dt}) = & \psi_0 + \psi_1 \ln(\text{BREV}_{dt}) \\ & + \psi_2 \% \text{Med_G}_{dt} + \psi_3 \% \text{Third_G}_{dt} \\ & + \psi_4 \text{POSTPAT}_{dt} + u_{gdt}, \end{aligned} \quad (23)$$

where BREV is the branded revenue in the month prior to initial generic entry and all other variables are defined as previously. By comparison, Reiffen and Ward (2005) address the market segmentation issue with a control for the percentage of individuals with health insurance who are covered by a fee-for-service arrangement, rather than some type of managed care. The data set used in the present study is better able to address this issue with the payer-type information. Moreover, I have information on branded sales—pre- and post-entry—and generic sales. Reiffen and Ward (2005) are only able to consider the latter.

Table 6 reports the results of these regressions. Column 1 shows that branded revenue is, not surprisingly,

Table 6
Revenue regressions

Dependent variable	In(real branded revenue)	In(real generic revenue)
	One-way RE	
Estimation strategy	(1)	(2)
NUMSUB	−0.2197 (0.0379)***	–
NUMSUB_G	–	−0.1749 (0.1055)*
NUMPRES	0.1949 (0.0437)***	–
%Med_B	23.0448 (1.148)***	–
%Third_B	10.4250 (0.6583)***	–
ENTRY	3.3189 (0.5221)***	–
ENTRY × %Med_B	1.1779 (0.7628)	–
ENTRY × %Third_B	−5.0101 (0.6389)***	–
%Med_G	–	31.7084 (2.2209)***
%Third_G	–	14.8458 (1.5685)***
ln(BREV)	–	0.8872 (0.1447)***
POSTPAT	−0.0300 (0.0019)***	0.0231 (0.0058)***
Constant	5.8346 (0.6466)***	−13.6971 (2.6402)***
R ² (within)	0.724	0.620
R ² (between)	0.150	0.486
R ² (overall)	0.224	0.325
Nobs.	900	325

(Standard error).

*, **, *** = significant at the 10, 5, and 1% level.

Nobs.: Number of observations.

Drug dummies included.

Source of data: PHAST, EOB and ePocrates.com.

negatively affected by the availability of substitute therapies. However, branded firms are able to increase their revenue by offering a wider product line which appeals to individual heterogeneity. This finding supports Ellison and Ellison's (2007) notion of presentation proliferation as a strategic tool of entry deterrence. For related studies see Kong and Seldon (2004) and Kamien and Zang (1999). The estimated coefficients on %Med_B and %Third_B are positive and statistically significant which implies that the bigger the segment of customers with some type of prescription drug coverage (i.e. Medicaid or third party), the larger the branded firm's revenue. The estimated coefficient on %Third_B in column 1 implies that branded revenue will increase by 10.4% when there is a 1% increase in the fraction of branded consumers who

have some type of third-party coverage. The large coefficient estimate on %Med_B (and %Med_G) may be somewhat surprising and perhaps a bit misleading—it is important to remember that only about 10% of prescriptions in my sample are dispensed to Medicaid patients. Concerning the interaction terms, the coefficient estimate on ENTRY × %Med_B is positive but not statistically significant while that on ENTRY × %Third_B is negative and statistically significant at the 1% level. The negative coefficient estimate on ENTRY × %Third_B could be due to the fact that many managed care organizations encourage generic substitution in order to cut costs. This is often accomplished with the use of restrictive formularies and/or high co-payments for (off-patent) branded drugs (i.e. tiered co-payments). In total, these findings lend support to the predictions of a segmented market: upon generic entry, branded firms charge their price insensitive customers (i.e. those with some type of prescription drug coverage) higher prices in order to increase their total revenue in this submarket. However, branded firms suffer great losses in market share which result in overall decreased total revenue. This story is consistent with the negative and statistically significant coefficient estimate on POSTPAT as well.

Table 6, column 2, provides the results to Eq. (23). A generic firm's revenue also increases as the size of its Medicaid and third-party market grows. Specifically, a 1% increase in the fraction of generic prescriptions that are dispensed to individuals with third-party insurance coverage increases generic revenues by 14.8%. A 10% increase in the branded firm's pre-entry monthly revenue increases the generic revenue by 8.9%. Consistent with past studies (e.g., Reiffen and Ward (2005), Scott Morton (1999), and Grabowski and Vernon (1996)), generic revenues are likely to be larger in markets that were profitable during the patent-protected period.

5. Conclusions

This paper examines how generic entry affects price competition in the U.S. prescription drug market for select pharmaceuticals that experienced initial generic entry between February 1998 and February 2002.³² While it is reasonable to expect that a branded drug's price would be higher than those of its generic competitors, branded firms are often able to maintain, or in some instances even to raise, their prices when confronted with generic entry into their market. The conventional economic reasoning that

³² Similar issues have been studied using non-U.S. data. See Bergman and Rudholm (2003) for a recent example from the Swedish pharmaceutical market.

an increase in the number of suppliers is associated with a decreased equilibrium price seems only to apply to the generic market. This paper offers an independent test of the relationship between patent expiration and prescription drug prices. A newly constructed data set is used to test the hypothesis that branded prices rise in response to generic entry.

A one-way error component framework is used to empirically test a more general and comprehensive form of Frank and Salkever's (1992) Stackelberg model. Random effects specification allows for explicit estimates of time-invariant variables and makes the results more comparable to Reiffen and Ward (2005). Overall, each generic entrant is associated with an average 1% increase in the price of a branded prescription. By comparison, Frank and Salkever (1997) report a 2.4% increase in the branded price, per extended unit, calculated at the sample mean.³³ Controlling for intermolecular substitution and accounting for the endogeneity of generic entry with instrumental variables causes the average price of a branded prescription to rise by an amount (2%) nearly identical to that found by Frank and Salkever (2.4%), with each generic entrant. Depending on the specification, Frank and Salkever (1997) estimate an average 3.7–5.5% increase in the per-unit branded price by relaxing the assumption of exogenous generic entry.³⁴ Consistent with the predictions of the market segmentation model, branded firms are able to charge higher prices as the fraction of their customers with third-party insurance coverage grows. The average \$20 price differential between branded and generic prescriptions grows with entry as the branded price rises (and the generic price falls). Alternative definitions of generic entry improve the results for the generic price regressions. These alternative definitions: 1) are consistent with Bertrand price competition amongst generic suppliers of homogeneous drugs; 2) capture the non-linearity of generic entry; or 3) remove the downward bias accruing to standard errors when multiple observations with essentially unchanged variables are used. These results suggest that price competition in the post-patent prescription drug market is confined to the generic market. Moreover, branded and generic firms are able to increase their revenues by

catering to the population with some type of prescription drug coverage (i.e. Medicaid or third party).

This paper tests and finds further evidence of the “generic competition paradox” with the principle empirical result that branded drug prices increase with generic entry. The economically and statistically small coefficient estimates on the months since initial generic entry suggest that there is very little time trend in the branded drug prices and thus we can largely, if not exclusively, attribute the increased branded prices to the incidence and continuation of generic entry. Other theories including price penetration, presentation proliferation, and habit persistence may be used to explain such an event and I plan to explore these in future work. This paper, however, delves further into the theory of market segmentation which is the most commonly accepted explanation to the rising branded prices observed in the post-patent expiration period and is especially well-suited due to the nature of the data set used here. The empirical observation that branded drug prices rise after patent expiration suggests that branded firms are third-degree price discriminating. The brand loyalty acquired during the period of patent protection, largely stemming from marketing efforts and patient-consumption and physician-prescribing patterns, coupled with the private nature of the health care industry in the U.S. enables branded firms to charge higher prices to their price insensitive customers that remain after the loss of patent protection thereby increasing their revenues in this submarket.

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³³ Using FE, Frank and Salkever actually report a 0.7% increase in the branded price due to generic entry. However, they use a linear functional form to explain branded prices but employ an elasticity formulation that is associated with a semi-log functional form. Correcting this calculation, an additional generic entrant is associated with a \$0.007 (2.4%) increase in the average revenue per extended branded unit.

³⁴ Frank and Salkever's first-stage generic entry regression is estimated by RE—with and without a time trend. However, their second-stage branded price regression is estimated by FE.

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