ENTRY THREATS AND PRICING IN THE GENERIC DRUG INDUSTRY

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Abstract—We use the unique regulatory environment of the pharmaceutical industry to examine how potential competition affects generic drug pricing. Our identification strategy exploits a provision of the Hatch-Waxman Act that awards 180 days of marketing exclusivity to the first valid generic drug applicant against the holder of a branded drug patent. In smaller drug markets, we find that price falls in response to an increase in potential competition. We also find that few manufacturers enter these markets, indicating this price reduction is an effective deterrent. In contrast, we find that generic incumbents accommodate entry in larger drug markets.

I. Introduction

It is recognized that an incumbent may deter potential competitors by taking strategic actions that reduce the profitability of entry. However, the use of price as a strategic entry deterrent is controversial since it may be profitable for the incumbent to raise price after entry has occurred, making its commitment to a low, entry-deterring price incredible. Depending on the theoretical model used to explain the link between the incumbent’s pre-entry price and an entrant’s expected profits, the effect of potential competition can vary from being extremely strong to entirely ineffectual in constraining market power (Gilbert 1989a, 1989b). This wide range of theoretical outcomes highlights the need for empirical analysis to determine the real-world importance of potential competition.

Ideally, one would measure the effect of exogenous changes in potential competition after controlling for other relevant industry factors. In practice, it has proved difficult to account for changes in potential competition since often they are unobservable. Consequently, empirical evidence of potential competition is far more limited than support for the impact of actual competition (see section II).

We use a unique regulatory feature of the pharmaceutical industry to identify the effect of potential competition on price. Our identification strategy exploits a provision of the Hatch-Waxman Act that awards 180 days of marketing exclusivity to the first firm that files an Abbreviated New Drug Application (ANDA) with a valid paragraph IV certification (see section IV). The marketing exclusivity period protects the designated first filer from competition with other generic entrants. Two changes occur once the exclusivity period expires. First, there may be variation in actual competition as other generic drug manufacturers enter the market. Second, regardless of whether entry occurs, there is the threat of additional entry that does not exist during the exclusivity period. Since the Hatch-Waxman Act creates observable variation in potential competition and actual competition is directly observed, we can separately identify the impact of both on price.2

Our analysis of the effect of potential competition employs a treatment control group framework. The treatment group consists of generic drugs that received marketing exclusivity during the initial 180 days. We measure the change in price between the exclusivity period and the following period where the Hatch-Waxman Act does not prohibit entry. When measuring this price change, we control for factors that vary between the two periods, including the number of actual competitors. We compare this to a counterpart price change for drugs that were not granted an exclusivity period. The key difference between the two sets of drugs is that the former experiences a change in potential competition after the first 180 days, while the latter does not. Our difference-in-difference estimator uses this variation to capture the impact of potential competition on generic drug prices.

We find mixed evidence of price being used as a strategic entry deterrent in the generic drug industry. For small drug markets, where it is easier to deter entry due to lower expected profits, we find that price falls in response to an increase in potential competition. Few manufacturers enter these markets following expiration of the Hatch-Waxman exclusivity period, indicating this price reduction is an effective deterrent. In contrast, in larger drug markets where entry deterrence is less likely to be successful, the incumbent maintains a high price until forced to respond to actual competition.

We undertake several additional analyses to test the robustness of the results. First, we use an alternative control group consisting of drugs that had an unsuccessful paragraph IV challenge. This addresses potential selection bias regarding which drugs are challenged. Limiting the sample in this manner provides the same conclusions in both small and large markets. The analysis also survives a falsification test that examines whether price changes are significantly different at other points during the product cycle when no drug is subject to exclusivity restrictions. Next, we test whether certain manufacturers are more likely to enter using a paragraph IV challenge, which could result in firm-specific differences that are correlated with exclusivity. To the contrary, we are unable to reject independence between manufacturer and entry method. Finally, we control for the potential endogeneity of the number of generic entrants using price.

1 The more widely known provisions of the Hatch-Waxman Act establish the ANDA approval process for generic drugs. This regulatory change significantly increased generic entry (Berndt, 2002). The validity of an application implies that any patent claims made in the application are true. Those claims may be tested in the courts.

2 Generic drugs are homogeneous products with little differentiation across manufacturers. As such, entry deterrence is most likely to occur using price.
using both an instrumental variable and reduced-form approach and obtain similar results.

The layout of the paper is as follows. Section II reviews the preceding literature. Section III details the data set employed. We discuss our identification approach in section IV. Section V presents the econometric methodology and reports results. Section VI concludes.

II. Literature Review

In early models of potential competition, the incumbent commits to sell the “limit quantity” (and charges the corresponding “limit price”) where the residual demand faced by a potential entrant is insufficient to support profitable entry (Bain, 1949; Modigliani, 1958; Sylos-Labini, 1962; Dixit, 1979). Factors that affect the feasibility of a limit pricing strategy include fixed entry costs, returns to scale, and product differentiation. The key assumption in the limit pricing framework is that the incumbent commits to sell the limit quantity regardless of whether entry actually occurs. This assumption has been criticized in the subsequent literature since, if entry occurs, the profit-maximizing strategy for the incumbent may be to accommodate the entrant by reducing output. When this is recognized by a forward-looking potential entrant, limit pricing may not be a credible entry deterrent.

One way of overcoming this weakness of the limit pricing framework is to incorporate cost uncertainty into the model (Salop, 1979; Milgrom & Roberts, 1982). If an entrant cannot observe the incumbent’s costs, the incumbent may deter entry by setting a low price to signal it is a low-cost firm (or to hide the fact that it is a high-cost firm). A related explanation is that the incumbent might set a low price to signal to potential competitors that demand is sufficiently elastic that entry would be unprofitable.

An alternative approach to modeling the effect of potential competition is the “contestable markets” theory (Baumol, Panzar, & Willig, 1982). This framework relies on several strong assumptions that include zero sunk costs of entry and that an entrant can capture the entire market by undercutting the incumbent’s price. In a contestable market, a monopolist incumbent is so constrained by potential competition that it cannot make positive profits. Otherwise, entry could profitably occur since the entrant is assumed to have the same costs as the incumbent.

These models provide conditions under which potential competition may affect incumbent pricing. Some of them can reasonably be applied to the generic drug industry. In particular, it seems plausible that the incumbent generic might set a low price to signal to prospective entrants that demand is elastic. In addition, for some types of generic drugs, there are meaningful interfirm cost differences. Our identification strategy does not require that we distinguish between these (or other) explanations. Instead, we test the key implication of models where price is a strategic entry deterrent: the incumbent reduces price in response to an increase in potential competition.

Relatively little empirical research examines the effects of potential competition. In their reviews of the literature, Gilbert (1989a, 1989b) and Bergman (2003) discuss the problem of measuring potential competition and separately identifying its impact from correlated market factors that also affect price. Due to these difficulties, empirical research has largely focused on the airline industry, where institutional factors facilitate the measurement of potential competitors (Morrison & Winston, 1987; Strassmann, 1990; Kwoka, 2001; Goolsbee & Syverson, 2008). This research generally finds that the incumbent responds to potential entry by lowering price, but the impact of a potential entrant is less than the effect of a realized entrant. Of course, this finding may not apply to industries that face different competitive conditions.

A. Empirical Pharmaceutical Literature

The prescription drug industry has been used extensively to evaluate the effect of entry on price. This is due to both the importance of the industry to the overall economy and because the large number of independent, yet comparable, drug markets facilitates statistical analysis. Researchers generally find that the impact of realized entry differs for branded and generic drugs (Caves, Whinston, & Hurwitz, 1991; Grabowski & Vernon, 1992; Griliches & Cockburn, 1994; Lu & Comanor, 1998; Reiffen & Ward, 2005; Regan, 2008). While generic drug prices decline in the number of generic manufacturers, branded drug prices either increase or stay the same in response to generic entry.

A small set of papers analyzes the impact of potential competition in the pharmaceutical industry. These papers focus on branded drugs, which compete using a variety of strategic variables that can potentially be used to deter entry. Ellison and Ellison (2011) develop a theory that relates investment (broadly defined) to market size. They show that under certain conditions, investment is nonmonotonic when firms engage in strategic entry deterrence.

5 Kyle (2006) and Scott Morton (1999) show that entry decisions depend on firm specialization, suggesting that there are significant cost differences across firms.

6 A few papers examine the effect of potential competition in other industries. For example, Savage and Wirth (2005) and Lee et al. (2006) consider the cable television and telecommunications industries, respectively. Below, we discuss papers that focus on prescription drugs.

7 The intuition for this result is that it is unnecessary to deter entry in small markets (where entry costs are a sufficient deterrent), while it is impossible to deter entry in large markets (due to their higher profitability). Entry deterrence occurs only in intermediate-sized markets, creating a nonmonotonicity.
While Ellison and Ellison find some support for nonmonotonicity with respect to advertising and research and development in branded drug markets, they find little evidence that branded drugs use price to deter entry. Bergman and Rudholm (2003) analyze Swedish data and find that branded drug prices decline following an increase in potential competition due to patent expiration. Cool, Roller, and Leleux (1999) exploit the New Drug Application (NDA) approval changes in the 1962 amendment to the Food, Drugs, and Cosmetics Act, as well as the presence of firms facing generic competition after March 2003. We also exclude over-the-counter medications, vitamins, and decongestants, drugs that are distributed in sales channels that IMS does not survey. In addition, they often change active ingredients over time, which makes them difficult to track from year to year. These restrictions lead to a data sample of 312 drugs, of which 123 were granted a 180-day exclusivity period under the Hatch-Waxman Act.

A striking feature of the data is that dollar sales are highly skewed. The smallest drug in our sample represents less than $1 million in annual sales, while the largest drug has over $2.5 billion in sales, where market size is measured as annualized branded drug sales in the quarter prior to first generic entry. Drugs with market size above (below) the median are defined as large (small) markets.

### III. Data

Our analysis employs monthly wholesale data from IMS Health.9 This data set reports sales for every oral solid prescription medication distributed in the United States over the period January 2003 to December 2008.10 Sales are reported separately by drug, which is defined as a unique combination of molecule, dosage form, strength, and therapeutic class. For example, the 10 mg and the 20 mg tablet formulations of benazepril, an ACE inhibitor, are two distinct drugs in our sample. We undertake the analysis at this disaggregated level because the Hatch-Waxman exclusivity period is granted separately for each particular formulation. The IMS data are combined with information from the FDA regarding when the Hatch-Waxman exclusivity period occurs for each drug (where applicable).

Data from the quarter prior to first generic entry are used to measure the market size of each drug. Due to this need for pre-entry data, we restrict the data set to drugs that first faced generic competition after March 2003. We also exclude over-the-counter medications, vitamins, and decongestants, drugs that are distributed in sales channels that IMS does not survey. In addition, they often change active ingredients over time, which makes them difficult to track from year to year. These restrictions lead to a data sample of 312 drugs, of which 123 were granted a 180-day exclusivity period under the Hatch-Waxman Act.

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A striking feature of the data is that dollar sales are highly skewed. The smallest drug in our sample represents less than $1 million in annual sales, while the largest drug has over $2.5 billion in sales, where market size is measured as annualized branded drug sales in the quarter prior to first generic entry. Market size is a key determinant of the number of entrants in drug markets (Frank & Salkever, 1997; Scott Morton, 1999). Similar to Reiffen and Ward (2007), in much of our analysis we split the sample into small and large drug markets. We do so based on whether a drug’s market size is above or below the median. Table 1 shows that on average, there are 2.7 generic manufacturers in small drug markets compared to 5.8 manufacturers in large drug markets. Our analysis considers whether this difference in the number of generic entrants affects the use of price as a strategic entry deterrent.

We motivate our empirical analysis by comparing price trends for generic drugs with and without an exclusivity period. Following standard practice in the literature (Caves...
et al., 1991), we scale each generic price by the corresponding branded drug’s preentry price to arrive at a price measure that can be compared across drugs. For each generic drug \( d \) in time \( t \), we calculate \( p_{dt} = \frac{p_{gd}}{p_{bd}} \), where \( p_{bd} \) and \( p_{gd} \) are branded and generic drug prices, respectively. Note that \( p_{bd} \) does not have a time subscript since it corresponds to the branded drug’s price in the quarter prior to generic entry. When calculating the generic drug price \( p_{gd} \), we aggregate across all generic manufacturers of a given drug, weighting by volume sales (price is calculated as total dollar sales across all generic manufacturers divided by total quantity).

Figure 1 presents the mean price ratio \( p_{dt} \) for drugs with and without a Hatch-Waxman exclusivity period. During the exclusivity period, drugs with exclusivity are approximately 30% more expensive on average, a price difference that persists for the full six-month exclusivity period. After the Hatch-Waxman exclusivity period ends, the two price series start to converge and are quite similar by month 8. These price trends are the result of changes in both actual and potential competition. Once the Hatch-Waxman exclusivity period ends, additional generic competitors enter the market, and future entry becomes a threat. The goal of this study is to determine to what extent the price decline that follows the end of the exclusivity period is due to actual versus potential competition.

IV. The Hatch-Waxman Act and Identification of Potential Competition

The Hatch-Waxman Act changed the laws governing generic drug entry by instituting the Abbreviated New Drug Application (ANDA) approval process for generic drugs. Under the terms of this approval process, a generic drug applicant seeking FDA approval can rely on the clinical trial evidence provided in the reference drug’s original New Drug Application (NDA) if it can demonstrate bioequivalence. This was a major change since, prior to the Hatch-Waxman Act, the generic filer was required to conduct its own clinical trials. Due to the expense of performing clinical trials, generic firms have rarely entered without an ANDA submission since passage of the act.

In its application to the FDA, the generic drug must certify that it will not violate any patents listed in the FDA’s Orange Book. If the reference drug has listed patents, the generic drug must either wait until the patents expire to begin marketing the drug or must specify in the filing why it does not violate the patents (the patent is invalid or the
patent is valid but they do not violate the patent). Generic drugs that challenge the reference drug’s patents in their ANDA filings are technically seeking certification under paragraph IV of the relevant provision in the Hatch-Waxman Act. A generic drug filing a paragraph IV certification must notify the reference drug that it is challenging its patents. The patent holder then has the opportunity to file an infringement suit against the generic drug applicant. The Hatch-Waxman Act includes a provision that rewards the first generic drug applicant to file a valid paragraph IV application with a 180-day exclusivity period. During this period, no other generic drugs are granted approval through an ANDA. The 180-day exclusivity begins when the first filer markets its generic or after a court finds the reference drug’s patents not to be infringed, if earlier. The branded drug manufacturer can introduce an “authorized generic” during the exclusivity period using the authority of its NDA. All other firms, however, must wait until the exclusivity period expires before receiving ANDA approval, at which point they can begin marketing their generic drug.

Figure 2 provides a time line that summarizes the first-filing generic manufacturer’s incentive to engage in strategic entry deterrence for drugs that enter using a paragraph IV certification. There is little incentive for the first filer to engage in entry deterrence at the beginning of the exclusivity period; that would be a costly exercise without any offsetting benefit since entry by independent generic firms is prohibited by the Hatch-Waxman Act. After the exclusivity period ends, however, the incumbent firm may find entry deterrence to be a profitable strategy since entry is no longer restricted by the act.

Although expiration of the exclusivity period clearly delineates when independent firms can enter the market, it is possible that firms initiate a strategy of entry deterrence prior to the end of exclusivity. This may be the case, for example, if it takes time to implement a price change or if the incumbent wants to signal its pricing strategy to potential entrants. Similarly, the transition to an entry-deterring price may not be finished prior to expiration of the Hatch-Waxman exclusivity period. For these reasons, the pricing strategy during the transition period surrounding expiration of the exclusivity period is likely a mixture of the price strategies employed in the prior and subsequent periods.

An incumbent would like to defer an entry-deterring price reduction in order to reap higher profits for as long as possible. Consequently, the transition period surrounding the end of the exclusivity period is likely to be relatively short. However, we are not aware of any institutional features that provide guidance regarding its duration. Our analysis therefore explores several specifications for the transition period. We employ a one-month transition window in the baseline model, but also consider a two-month window, as well as no transition period at all.

The analysis compares prices in the “before” period, which consists of the first part of the exclusivity period where entry deterrence is not optimal, to prices in the post-exclusivity “after” period that follows the transition to an entry deterring price (if optimal). Since the pricing strategy during the transition window is unclear, we do not use this period to identify the effect of potential competition. A price decline following expiration of the exclusivity period, holding all else constant, would be evidence that price is used as a strategic entry deterrent. Our analysis recognizes that various factors may affect the change in price between these two periods. Most notably, entry may occur. In addition, the Hatch-Waxman exclusivity period is potentially correlated with age effects that may affect drug pricing. To account for these factors, we employ a difference-in-difference estimator that compares the change in price for drugs that have an exclusivity period to the price change for drugs that do not.
Specifically, we estimate the effect of potential competition on generic drug prices using a commonly employed two-stage method (Donald & Lang, 2007). In the first stage, we calculate each drug’s price change after the exclusivity period or after the first six months following initial generic entry for drugs without an exclusivity period. When calculating these price changes, we control for other factors that affect price, including changes in actual competition. In the second stage, we test whether the price change for drugs granted an exclusivity period under the Hatch-Waxman Act differs from the price change for nonexclusive drugs. Since the key difference between the two sets of drugs is that one experiences a change in potential competition on completion of the Hatch-Waxman exclusivity period while the other does not, our difference-in-difference estimator measures the effect of potential competition on generic drug prices.

This approach of using a control group, and including additional controls to account for any differences between the two groups, has been widely applied in prior research. Our estimation strategy is closely related to the method Bergman and Rudholm (2003) and Ellison and Ellison (2011) used to measure the effect of potential competition on branded drug prices. These studies use expiration of the branded drug’s patent as a source of variation in potential competition in a similar manner to how we exploit expiration of the Hatch-Waxman exclusivity period.

A key benefit of the Hatch-Waxman Act is that it provides an exogenous source of variation in potential competition since the act was written decades prior to the entry events studied in this paper. A second advantage of our study is that we analyze the effect of the Hatch-Waxman Act across a large number of drug markets. Our focus on numerous, independent events that occur at different points in time provides a robust source of variation in potential competition. In addition, the diverse timing of these events allows us to control for calendar time and age effects in a flexible manner.

One might argue that generic entry is very difficult (or impossible) to deter because generic manufacturers often submit their ANDA many months in advance of marketing their product. Obviously, actions taken by the first filer will not affect decisions that other generic manufacturers have already taken, such as an ANDA submission. However, it may still be possible to deter generic entry since the entry process entails significant other costs that are not yet sunk. This is more than a theoretical possibility; during our sample period, there are firms with ANDA submissions that never enter. Moreover, a strategy of entry deterrence can also dissuade generic manufacturers who have not submitted their ANDA (for whom the associated costs are not yet sunk). Our data show that delayed entry is relatively common; in 25% of drugs, we observe additional generic entry more than a year after the first generic enters the market. For these reasons, one should not reject the possibility that the first filer could successfully engage in strategic entry deterrence (whether or not, in practice, such behavior is prevalent is the focus of our empirical analysis).

V. Empirical Analysis

Our difference-in-difference estimator is implemented in two stages. In the first stage of the price analysis, we estimate equation (1) to obtain each drug’s change in price between the exclusivity and nonexclusivity periods after controlling for a set of variables $X_d$ that includes the number of competitors in the market as well as other factors (as discussed below):

$$\ln p^g_{dt} = \phi_{d} + \phi_{t} + \delta_{d}^0 PRE_{dt} + \delta_{d}^1 TRANS_{dt} + \delta_{d}^2 POST_{dt} + X_{dt} \beta + \epsilon_{dt}. \quad (1)$$

Dependent variable $\ln p^g_{dt}$ is the log price of generic drug $d$ in month $t$, where, as discussed in section III, each drug is defined as a unique combination of molecule, dosage form, strength, and therapeutic class. Variables $\phi_{d}$ and $\phi_{t}$ are drug and time fixed effects, respectively. $PRE_{dt}$, $TRANS_{dt}$, and $POST_{dt}$ are dummy variables for three mutually exclusive periods corresponding to the before, transition, and after event windows. Note that coefficients $\{\delta_{d}^0, \delta_{d}^1, \delta_{d}^2\}$ for these variables have a drug $d$ subscript indicating a separate effect is estimated for each drug (we interact $PRE_{dt}$, $TRANS_{dt}$, and $POST_{dt}$ with a set of drug fixed effects).

We treat a month as being part of the exclusivity period if the end of marketing exclusivity occurs on day 28 of the month or later. That is, a month is treated as occurring during the exclusivity period only if it is almost entirely composed of exclusive days, with at most three nonexclusive days. The before window is defined to correspond to the Hatch-Waxman exclusivity period or the first six months after initial

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14 See Bertrand, Duflo, and Mullainathan (2004) and the citations contained there for discussion of the difference-in-difference estimation approach. Bertrand et al. recommend the two-stage estimation strategy that we employ.

15 Age is measured as months since first generic entry.

16 For example, generic drugs with ANDAs submitted following the first filer might face patent litigation after the 180-day exclusivity period if the first-filing generic drug won patent litigation on infringement grounds without addressing patent validity.

17 There were 280 ANDA withdrawals of unapproved drugs between 2006 and 2008 (Food and Drug Administration, 2006, 2007, 2008). We are unable to analyze formally ANDA submissions that never entered due to the difficulty of matching the relevant FDA information to IMS manufacturing data. Complications arise due to generic firm mergers, the inter-firm sale of ANDA rights, matching of dosage forms between different data sources, and timing discrepancies between when a drug is approved and marketed.

18 We use a two-stage method to control for serial correlation, which can cause the standard errors of difference-in-difference estimates to be significantly understated. Both Donald and Lang (2007) and Bertrand et al. (2004) find this is a particularly robust approach relative to alternative methods (both in theory and in Monte Carlo experiments).

19 Each time period is a particular month (for example, December 2008).
generic entry for drugs without an exclusivity period. The transition period is the single month following the before period, which generally contains a mixture of exclusive and nonexclusive days (for drugs with an exclusivity period).\textsuperscript{20} The after window is the following twelve months.\textsuperscript{21}

Equation (1) contains additional variables $X_{d,t}$ that control for changes occurring between the before and after periods. This set includes fixed effects for the number of months elapsed since first generic entry. In addition, we control for changes in actual competition by including a set of dummy variables for the number of generic manufacturers.\textsuperscript{22} For small drugs, sales sometimes occur irregularly; one or two months without sales can represent standard business practice rather than exit. We assume a manufacturer has exited a particular drug market only after four consecutive months of zero sales.\textsuperscript{23} Authorized generics are included in the count of manufacturers. To account for the possibility that the competitive effect of an authorized generic differs from the impact of an independent generic manufacturer (Reiffen & Ward, 2007; Federal Trade Commission, 2009), we include an indicator for the presence of an authorized generic and interact this variable with the number of generic manufacturers and its square.

Estimates from equation (1) are used to calculate $\Delta \ln p_{d,t} = \tilde{\alpha} - \tilde{\beta} d_{t}$, the change in log price between the before and after windows after controlling for the number of generic manufacturers and the other variables. This measure is the dependent variable in the second stage of the price analysis:\textsuperscript{24}

$$\Delta \ln p_{d} = \alpha \text{EXCL}_{d,t} + Z_{d,t}\gamma + v_{d}. \tag{2}$$

Variable \text{EXCL}_{d,t} is an indicator for whether drug $d$ had an exclusivity period. The model also controls for additional drug characteristics $Z_{d}$ that potentially explain the change in price between the event windows. This set of additional controls includes an indicator for whether the drug has an authorized generic, the drug’s market size percentile, a set of dummy variables for dosage form (for example, tablet, capsule), and a set of fixed effects for therapeutic class.\textsuperscript{25}

The key variable of interest in equation (2) is coefficient $\alpha$ on the exclusivity variable, \text{EXCL}_{d,t}. This effect is our difference-in-difference estimator and measures the change in price between the before and after periods for drugs with exclusivity relative to a control group of nonexclusive drugs. The key identification assumption is that nonexclusive drugs are a valid control group for drugs with an exclusivity period after controlling for variables $X_{d,t}$ and $Z_{d}$ in equations (1) and (2). Any remaining difference between the two sets of drugs is assumed to be due to potential competition; drugs with an exclusivity period face an increase in potential competition after the period ends, which does not occur for their nonexclusive counterparts. Our difference-in-difference estimator captures this change, allowing us to measure the effect of an increase in potential competition on generic drug prices. We use all nonexclusive drugs as the control group in the baseline model. As a robustness check, later in this section we consider an alternative control group consisting of drugs that submitted a paragraph IV certification but did not receive an exclusivity period.

The set of variables $Z_{d}$ is included in equation (2) in response to a potential concern that variation in demand or costs could explain price changes between the before and after periods. Drug form (for example, capsule, extended released tablet) controls for changes in the cost of making different types of drugs.\textsuperscript{26} We control for market size because it is correlated with preentry branded drug advertising. If such advertising lowers a drug’s own-price elasticity of demand, then larger drugs may experience greater price erosion after the branded drug reduces advertising following generic entry (as is commonly the case).\textsuperscript{27} More generally, we include therapeutic class to control for common demand shocks across related drugs. Finally, we control for the presence of an authorized generic based on a recent study by the FTC (2011), which finds that drugs where an authorized generic is present may evolve differently from other drugs.

Table 2 presents the first- and second-stage price regression estimates. Robust standard errors are reported that

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\textsuperscript{20} Later in this section, we consider alternative definitions for the transition period.

\textsuperscript{21} While each drug is observed for up to three years, our identification strategy focuses on the first nineteen months (six months of exclusivity, a one-month transition, and then twelve months post-exclusivity). The subsequent period (starting in month 20) is the omitted time category in the analysis. Recall that each drug is defined as a unique combination of molecule, dosage form, strength, and therapeutic class, since the Hatch-Waxman exclusivity period is granted separately for each particular formulation.

\textsuperscript{22} We treat a firm as having entered the market once it has positive sales. This provides a more accurate measure of firms that are actively marketing a drug relative to alternatives such as Orange Book Approval listings. To avoid overstating the number of entrants when a single firm markets under several labels, we exclude known repackagers when counting the number of entrants and combine labelers with similar names (for example, “Watson” and “Watson Labs”).

\textsuperscript{23} The date of exit is backdated to the period following the last observed sale. For example, if a manufacturer has positive sales in month 4 but zero sales in months 5 to 8, that manufacturer is considered to have exited between month 4 and 5.

\textsuperscript{24} In equation (2), each observation corresponds to a particular drug (in contrast, in equation (1) an observation is a drug-month combination). It is not possible to calculate $\Delta \ln p_{d,t}$ for 31 drugs where first generic entry occurs in the last seven months of the data (June 2008 or later), since the after period is never observed. The second-stage regression includes 281 drugs from the full sample of 312.

\textsuperscript{25} Therapeutic classes with fewer than five drugs in a given regression are grouped together into an “other” category. As before, market size is measured as the corresponding branded drug’s annualized sales in the quarter prior to first generic entry.

\textsuperscript{26} Generic entrants may challenge brand patents on infringement grounds with new and lower-cost technologies. This type of innovation may be more likely in some dosage forms than others.

\textsuperscript{27} Prior research shows that only large drugs advertise directly to consumers (Kaiser Family Foundation, 2003). This may explain our finding, reported in table 3, that the impact of market size is greater, and more statistically significant, for large drugs relative to small drugs.
entry deterrence is the cost of deterring potential competing manufacturers is an authorized generic, although this effect decreases in the number of competitors. \(^{28}\)

Cluster by molecule. This accounts for any correlation in unobserved characteristics across drugs with the same active ingredient (for example, 10 mg and 20 mg benazepril). The first-stage results demonstrate the importance of controlling for realized competition. Consistent with prior research, we find that additional competitors lead to lower prices. However, some of the individual coefficients are imprecisely estimated and are not always statistically significant at conventional levels. Competitor type also matters. Generic drug prices are higher when one of the competing manufacturers is an authorized generic, although this effect decreases in the number of competitors. \(^{28}\)

The key effect of interest from the second stage is the coefficient for whether a drug had an exclusivity period, which is our difference-in-difference estimator. The price of exclusive drugs falls by 11\% (\(e^{-0.118} = 0.89\)), relative to the price change for nonexclusive drugs, after the exclusivity period ends. However, this effect is not statistically significant at any conventional level (SE = 7.4\%).

A key determinant of whether a firm engages in strategic entry deterrence is the cost of deterring potential competitors. Prior research finds that generic entry is more likely to occur in larger drug markets (Frank & Salkever, 1997; Scott Morton, 1999). It is likely that entry deterrence is more costly in large markets due to their greater profitability. Consequently, an entry-deterring pricing strategy may not be profit maximizing in these markets. To test this hypothesis, we split the sample by market size. Drugs with market size above and below the median are referred to as large and small markets, respectively.

Table 3 reports results from estimating the model separately for small and large drug markets. The effect of the exclusivity period is very different for the two sets of drugs. In small drug markets, the price of exclusive drugs falls by 18\% (SE = 7.6\%) relative to nonexclusive drugs. This effect is statistically significant at the 5\% level. In contrast, in larger drug markets, price does not change in response to potential competition. This finding is consistent with the hypothesis that it is not profitable to deter entry in larger markets where entry is highly likely to occur. Instead, the incumbent generic manufacturer reduces price only when forced to respond to actual entry. \(^{29}\)

These results suggest that price is used as an entry deterrent in small drug markets but not in large drug markets. We next explore whether price is an effective entry deterrent. We perform this analysis by estimating analogs to equations (1) and (2), but use the log number of manufacturers rather than price as the dependent variable. The first-stage manufacturer regression is

\[
\ln m_{dt}^x = \theta_d + \theta_t + \lambda_d^{0} PRE_{dt} + \lambda_d^{1} TRANS_{dt} + \lambda_d^{2} POST_{dt} + X_{dt}^{m} \pi + \epsilon_{dt}. \quad (1')
\]

The dependent variable, \(\ln m_{dt}^x\), is the log number of manufacturers for generic drug \(d\) in month \(t\). Variables \(\theta_d\) and \(\theta_t\) are drug and time fixed effects, respectively. As before, \(PRE_{dt}\), \(TRANS_{dt}\), and \(POST_{dt}\) are dummy variables for three mutually exclusive periods corresponding to the before, transition, and after event windows. These variables are interacted with the set of drug fixed effects to obtain parameters \(\{\lambda_d^{0}, \lambda_d^{1}, \lambda_d^{2}\}\) for the three time periods. Equation (1') also contains an additional set of controls \(X_{dt}^{m}\) that is identical to its counterpart in equation (1), apart from excluding the number and type of manufacturers (for obvious reasons).

Estimates from equation (1') are used to calculate the dependent variable in equation (2'), \(\Delta \ln m_{dt} = \lambda_d^{1} - \lambda_d^{0}\), the change in log manufacturers between the before and after

\(^{28}\) While the coefficient estimate for the authorized generic dummy may appear to suggest that prices are considerably higher in markets with an authorized generic, the interactions between the authorized generic dummy and the number of manufacturers dampen this effect. In the average market with 4.2 manufacturers, the net impact on price of an authorized generic, holding the total number of manufacturers constant, is 15\% (SE = 9.3\%), which is not statistically significant at the 5\% level. The net impact of an authorized generic is statistically significant only when there are three or fewer manufacturers (including the authorized generic).

\(^{29}\) We also computed a “triple difference” estimator, where the final difference is between small and large drugs. This would be an appropriate estimator if one had a strong prior that entry deterrence is not possible for large drugs, although it would be downward biased if entry deterrence were employed in both small and large drug markets. While the triple difference estimate is virtually identical to the difference-in-difference result for small drugs, it is imprecisely estimated. Consequently, it is not statistically significant at any conventional level.
windows after controlling for $X_{dt}^m$ and the other variables in equation (1):

$$\Delta \ln m_d = \eta EXCL_d + Z_{dt}^m \mu + \nu_d.$$  

Analogous to equation (2), the variable $EXCL_d$ is an indicator for whether drug $d$ had an exclusivity period. As before, this variable’s coefficient is the difference-in-difference estimator, which measures the change in the number of manufacturers between the before and after periods for drugs with exclusivity relative to a control group of nonexclusive drugs. The model also controls for additional drug characteristics $Z_{dt}^m$ that potentially explain the change in number of manufacturers between the event windows. This set of controls omits the authorized generic indicator variable but is otherwise identical to the control variables in the analogous price equation (2).

If price is an effective entry deterrent in small drug markets, one should see relatively little entry following the end of the exclusivity period. Similarly, if firms accommodate entry in large drug markets, then entry should be observed following the end of exclusivity in those markets. The results from this analysis, reported in table 4, are consistent with these expectations. Substantial entry is observed in large drug markets. In these markets, the number of manufacturers increases 54% (SE = 21%) relative to the change for nonexclusive drugs. In contrast, small drug markets are observed with only a 17% (SE = 16%) change, which is not statistically significant at any conventional level. For smaller drugs, we cannot reject the hypothesis that the price reduction following an increase in potential competition is an effective entry deterrent.

Our analysis relies on two key assumptions. First, the number of generic entrants is treated as exogenous. While
our model flexibly controls for conditions that are fixed over time within a drug, or are the same across drugs for a given month, the results could suffer from bias if unobserved (drug-specific, time-varying) characteristics correlated with entry also affect price. Violation of this exogeneity assumption could not only bias the estimated impact of actual competition but could also affect the other estimates, such as the impact of potential competition. Second, the difference-in-difference methodology assumes drugs that did not receive an exclusivity period are comparable to observably similar drugs that were granted an exclusivity period. Unobservable differences between the treatment and control groups could also bias the estimated impact of potential competition. For the remainder of the paper, we undertake several additional analyses that address the likelihood of these potential biases, including relaxing the exogeneity assumption and consideration of an alternative control group. In addition, we examine whether our results hold under different assumptions for how the event windows are constructed.

A. Sensitivity Analysis

Recall that in our baseline specification, we use a 1-month transition period and a 12-month after period. We now examine the robustness of our results to alternative definitions for these event windows. Specifically, we consider using 0, 1, and 2 transition months, and after windows of 6, 12, and 24 months.

The results of these robustness checks are reported in the first column of table 5. As before, we find that for small drugs, price falls in response to potential competition. The estimated price decline ranges from 14% to 20%, depending on the specification. The only instance where the effect of potential competition is not statistically significant at the 5% level is when a two-month transition window is used in conjunction with a six-month after window. This effect is nearly statistically significant with a p-value of .051, however. As before, little price change is apparent in large drug markets. The point estimates are generally small in magnitude and are never statistically significant at any conventional level.

In the baseline model, we employ a control group consisting of all nonexclusive drugs. A potential problem is that manufacturers may not randomly decide which drugs should undergo a paragraph IV certification. Patent litigation is costly and is more likely to be profitable when the expected return from a successful patent challenge is higher. Consistent with this possibility, prior research shows that drugs facing paragraph IV challenges have higher revenues than drugs experiencing other types of generic entry (Panattoni, 2011; Federal Trade Commission, 2011). In our sample, we also find that exclusive drugs tend to have a larger market size than nonexclusive drugs. Our analysis accounts for this difference by explicitly controlling for market size. Nonetheless, we recognize the possibility that unobservable differences between the treatment and control groups may remain, potentially biasing our results.

We next consider an alternative control group that consists of nonexclusive drugs that filed a paragraph IV certification but did not have a Hatch-Waxman exclusivity period. This occurs when the first-to-file generic firm loses the patent litigation or reaches a settlement with the branded drug manufacturer prior to entry. Patent settlements involving paragraph IV drugs are generally agreements on when the first-filing generic firm may enter the market. The settlements do not involve post-entry activity such as pricing. See Federal Trade Commission (2010) for details.

### Table 5: Effect of the Hatch-Waxman Exclusivity Period on Generic Drug Prices, Alternative Event Windows and Control Groups

<table>
<thead>
<tr>
<th>Transition Period</th>
<th>After Period</th>
<th>Small Drug Markets</th>
<th>Large Drug Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group 1: All nonexclusive drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>6 months</td>
<td>-0.147</td>
<td>0.068**</td>
</tr>
<tr>
<td>None</td>
<td>12 months</td>
<td>-0.168</td>
<td>0.076**</td>
</tr>
<tr>
<td>None</td>
<td>24 months</td>
<td>-0.197</td>
<td>0.082**</td>
</tr>
<tr>
<td>1 month</td>
<td>6 months</td>
<td>-0.169</td>
<td>0.082**</td>
</tr>
<tr>
<td>1 month</td>
<td>12 months</td>
<td>-0.194</td>
<td>0.092**</td>
</tr>
<tr>
<td>1 month</td>
<td>24 months</td>
<td>-0.218</td>
<td>0.096**</td>
</tr>
<tr>
<td>2 months</td>
<td>6 months</td>
<td>-0.176</td>
<td>0.089*</td>
</tr>
<tr>
<td>2 months</td>
<td>12 months</td>
<td>-0.203</td>
<td>0.100**</td>
</tr>
<tr>
<td>2 months</td>
<td>24 months</td>
<td>-0.217</td>
<td>0.102**</td>
</tr>
<tr>
<td>Control group 2: Unsuccessful paragraph IV drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>6 months</td>
<td>-0.215</td>
<td>0.096**</td>
</tr>
<tr>
<td>None</td>
<td>12 months</td>
<td>-0.239</td>
<td>0.096**</td>
</tr>
<tr>
<td>None</td>
<td>24 months</td>
<td>-0.265</td>
<td>0.103**</td>
</tr>
<tr>
<td>1 month</td>
<td>6 months</td>
<td>-0.265</td>
<td>0.114**</td>
</tr>
<tr>
<td>1 month</td>
<td>12 months</td>
<td>-0.275</td>
<td>0.120**</td>
</tr>
<tr>
<td>1 month</td>
<td>24 months</td>
<td>-0.294</td>
<td>0.129**</td>
</tr>
<tr>
<td>2 months</td>
<td>6 months</td>
<td>-0.272</td>
<td>0.109**</td>
</tr>
<tr>
<td>2 months</td>
<td>12 months</td>
<td>-0.260</td>
<td>0.117**</td>
</tr>
<tr>
<td>2 months</td>
<td>24 months</td>
<td>-0.259</td>
<td>0.124**</td>
</tr>
</tbody>
</table>

Robust standard errors are reported that cluster by molecule. Statistical significance: **5%, *10%. Each estimate corresponds to the coefficient for the ‘‘had an exclusivity period’’ variable from the stage 2 regression. The model with a transition period of one month, an after period of twelve months, and using control group 1 corresponds to the baseline specification reported in table 3.
exclusive drugs since both had a paragraph IV certification. Evidence of this is seen in the market size of the two sets of drugs; we could not reject at any conventional level the hypothesis that exclusive drugs have the same average market size as unsuccessful paragraph IV drugs. The endogeneity of which drugs are certified under paragraph IV does not pose a problem to the analysis when this alternative control group is employed since both the treatment and control groups undergo the same selection process. The drawback of this alternative control group is that it is substantially smaller, leading to less precise results.

The second column of results in table 5 repeats the analysis after restricting the data set to drugs with a paragraph IV certification. For small drug markets, the alternative control group leads to stronger results. The estimated price decline ranges from 19% to 26%, depending on the specification. Each estimate is statistically significant at the 5% level. As before, we do not find a statistically significant effect in large drug markets.

Table 6 reports the results of similar robustness checks using the log number of manufacturers as the dependent variable. Qualitatively similar but less precise estimates are again obtained. The difference with our earlier set of results is that the change in the number of manufacturers in large drug markets is not statistically significant at the 5% level in one specification (where the p-value is .051, however). Generally, the results using the paragraph IV drugs confirm the findings from our baseline specification. In small markets, where entry deterrent pricing is observed, there is little change in the number of competitors. We cannot reject the hypothesis that price is an effective entry deterrent in these markets. In contrast, in large drug markets where entry deterrence is not observed, the number of manufacturers increases after the exclusivity period expires.

As a second robustness check, we undertake the following falsification test. Rather than comparing the price change between the before and after periods, we compute the price change between the after period and a "post-after" window corresponding to the following twelve months. We estimate the same model as before, but now include a post-after indicator variable for each drug. For both exclusive and nonexclusive drugs, there is no change in potential competition between these two periods since both the after and post-after windows follow expiration of the Hatch-Waxman exclusivity period. If the control group is valid, this test should not reveal a significant difference between the treatment and control groups.

The results from this analysis are generally supportive of our two control groups (nonexclusive drugs and unsuccessful paragraph IV drugs). In the log price regressions, we do not find a statistically significant difference between the treatment and control groups in either the small or the large drug samples. For smaller drug markets, this is also the case for the log manufacturer regressions. The falsification test

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31 In contrast, when the control group consists of all nonexclusive drugs, the difference in means is statistically significant at the 1% level.

32 Restricting the data to drugs with a paragraph IV certification leads to a sample of 195 drugs.
Drugs are employed as the control group. The difference in the number of observations exceeds the number of drugs due to entrant and the entry method employed. Note that the number of observations exceeds the number of drugs due to multiple initial entrants. While there are a few anomalies (for example, Barr is never an unsuccessful paragraph IV entrant in small drug markets), the table generally shows that generic manufacturers frequently enter using all three methods rather than each firm specializing in a particular entry method. To formally test this proposition, we performed a chi-squared test where the null hypothesis is that firm identity and entry method are independently distributed. The test fails to reject the null hypothesis. This finding offers further support that the treatment and control groups are similar in unobservable dimensions as well.

Our analysis thus far has made the implicit assumption that entry by generic firms is exogenous, which is the approach taken in much of the prior literature. Some researchers defend this assumption by appealing to institutional features specific to the regulatory approval of generic drugs (Reiffen & Ward, 2005; Grabowski, Ridley, & Schuman, 2007; Ching, 2010). Since it typically takes several years for the FDA to approve an ANDA, they argue that observed entry is largely unrelated to current factors that influence price. Alternatively, some believe that in the absence of strong and truly exogenous instruments, it is better to treat entry as exogenous instead of using potentially invalid instruments (Granlund, 2010). For these, and perhaps other, reasons the number of entrants is assumed exogenous in many studies of generic entry (Bergman & Rudholm, 2003; Berndt et al., 2007; Danzon & Chao, 2000; Ekelund & Persson, 2003; Grabowski & Vernon, 1992; Hollis, 2005; Lu & Comanor, 1998; Saha et al., 2006; Wiggins & Maness, 2004).

We are aware of only three exceptions where researchers account for the potential endogeneity of the number of entrants when estimating the impact of generic entry on price (Caves et al., 1991; Frank & Salkever, 1997; Regan, 2008). This strand of the literature takes a different approach and uses instrumental variables to account for the endogeneity of entry. A valuable exercise is to estimate the model using both methods to determine the sensitivity of the results. Reifen and Ward (2005) do so and are unable

### Table 7.—Method of Entry, by Manufacturer

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Number of Observations</th>
<th>Successful Paragraph IV</th>
<th>Unsuccessful Paragraph IV</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small drug markets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teva</td>
<td>27</td>
<td>37%</td>
<td>33%</td>
<td>30%</td>
</tr>
<tr>
<td>Barr</td>
<td>16</td>
<td>25%</td>
<td>0%</td>
<td>75%</td>
</tr>
<tr>
<td>Mylan</td>
<td>15</td>
<td>7%</td>
<td>33%</td>
<td>60%</td>
</tr>
<tr>
<td>Sandoz</td>
<td>14</td>
<td>7%</td>
<td>29%</td>
<td>64%</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>10</td>
<td>10%</td>
<td>20%</td>
<td>70%</td>
</tr>
<tr>
<td>Par</td>
<td>9</td>
<td>11%</td>
<td>33%</td>
<td>56%</td>
</tr>
<tr>
<td>Dr. Reddy’s</td>
<td>7</td>
<td>14%</td>
<td>43%</td>
<td>43%</td>
</tr>
<tr>
<td>Global</td>
<td>6</td>
<td>17%</td>
<td>0%</td>
<td>83%</td>
</tr>
<tr>
<td>Roxane</td>
<td>6</td>
<td>0%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Apotex</td>
<td>5</td>
<td>20%</td>
<td>40%</td>
<td>40%</td>
</tr>
<tr>
<td>Other</td>
<td>61</td>
<td>11%</td>
<td>33%</td>
<td>56%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>176</td>
<td>16%</td>
<td>29%</td>
<td>55%</td>
</tr>
</tbody>
</table>

| **Large drug markets** |                   |                        |                           |       |
| Teva         | 41                     | 44%                     | 29%                       | 27%   |
| Sandoz       | 26                     | 19%                     | 35%                       | 46%   |
| Mylan        | 19                     | 11%                     | 42%                       | 47%   |
| Watson       | 16                     | 19%                     | 38%                       | 44%   |
| Barr         | 13                     | 46%                     | 23%                       | 31%   |
| Par          | 13                     | 31%                     | 38%                       | 31%   |
| Roxane       | 13                     | 8%                      | 46%                       | 46%   |
| Dr. Reddy’s  | 12                     | 33%                     | 33%                       | 33%   |
| Apotex       | 10                     | 10%                     | 40%                       | 50%   |
| Actavis      | 9                      | 11%                     | 44%                       | 44%   |
| Other        | 72                     | 25%                     | 33%                       | 42%   |
| **Total**    | 244                    | 26%                     | 35%                       | 40%   |

*The table reports method of entry for each instance of initial generic entry. An observation is a manufacturer-drug pair. The number of observations exceeds the number of drugs due to multiple initial entrants (there are 156 small drugs and 156 large drugs in the sample). The p-value for a chi-squared test that manufacturer and method of entry are independently distributed is .47 (.22) for small (large) drugs.*

"Fails" only for large drug markets when all nonexclusive drugs are employed as the control group. The difference-in-difference estimate for this specification is 20% (SE = 9.4%), indicating that exclusive drugs have significantly more entry between the after and post-after windows than their nonexclusive counterparts. This suggests that it takes more than twelve months for entrants to respond fully to the expiration of the exclusivity period. Apart from this exception, however, the results from the falsification test are consistent with our control groups being valid. Indeed, the manufacturer test “passes” for large drug markets when unsuccessful paragraph IV drugs are the controls.

Next, we test whether firm participation differs between the treatment and control groups. If certain manufacturers are more likely to enter using a paragraph IV challenge, that might suggest our results are due to firm-specific differences rather than potential competition. Alternatively, similarity in this observable characteristic would provide supporting evidence that the treatment and control groups are similar in unobservable dimensions as well.

We group drugs according to entry method: (a) drugs with successful paragraph IV challenges (b) drugs with unsuccessful paragraph IV challenges, and (c) other nonexclusive drugs. The first group corresponds to the treatment group in the analysis. Our first control group is categories b and c combined, while our second control group is only b. Table 7 reports the joint distribution of the first generic entrant and the entry method employed. Note that the number of observations exceeds the number of drugs due to

34 The entry method for different formulations of the same molecule is usually (but not always) identical. We deleted duplicates when a given manufacturer entered using the same entry method for two different formulations of the same molecule (for example, 10 mg and 20 mg benazepril).

35 The p-value of the chi-squared test for small and large drugs is .47 and .22, respectively.

36 Berndt and Newhouse (2010) note, "Frank and Salkever [1997, Reifen and Ward [2005], Atanu, Grabowski, Birnbaum, Greenberg and Bizan [2006], and Berndt, Mortimer, Bhattacharjya, Parece and Tuttle [2007] all find that price and the extent of generic entry are jointly determined." While four of these five papers assume the number of entrants is exogenous (Frank and Salkever being the exception), these papers address the endogeneity of other variables, such as the generic sales share.

37 See also studies described in a review by Martin (2012) that posit entry is either random, because firms’ assessments of profit opportunities are imperfect or decided sufficiently far in the past to be uncorrelated with contemporary conditions.

38 As discussed below, Reifen and Ward (2005) also employ instruments as a robustness check.
to reject that the number of generic entrants is exogenous. Similarly, Regan (2008) concludes that the model where entry is assumed exogenous is the preferred specification when analyzing the impact of entry on the price of generic drugs. While these results suggest it may be reasonable to assume exogenous entry in this particular setting, this matter is still unsettled and the literature would benefit from additional analysis in this area.

We consider two alternative frameworks that allow for endogenous entry. First, following Caves et al. (1991) and Frank and Salkever (1997), we employ months since first generic entry as an instrument for the number of generic entrants. This measure is a key predictor of entry since it is no longer possible to identify the causal effect of the endogenous variables. This is not a significant concern here, however, because our key objective is to estimate the impact of potential competition rather than actual competition. Since we identify the impact of potential competition using exogenous variation created by the Hatch-Waxman Act, this effect is still identified using the reduced-form approach (even though the effect of actual entry is not).

Table 8 reports results for these alternative approaches to dealing with the endogeneity of entry. For ease of comparison, the first row reports results from our baseline model where entry is assumed exogenous. Model 2 corresponds to the instrumental variable methodology, and model 3 is the reduced-form specification. For small drug markets, similar point estimates are obtained across all models. This is true for both control groups (all nonexclusive drugs and unsuccessful paragraph IV drugs). In three of the four specifications where entry is endogenous, the effect of potential competition is statistically significant at the 10% level (with p-values between .074 and .077), while the effect is not statistically significant in the last specification (the point estimate)

**Table 8.—Effect of the Hatch-Waxman Exclusivity Period on Generic Drug Prices, Endogenous Entry**

<table>
<thead>
<tr>
<th>Control group 1: All nonexclusive drugs</th>
<th>Small Drug Markets</th>
<th>Large Drug Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1: Exogenous entry</td>
<td>Estimate</td>
<td>SE</td>
</tr>
<tr>
<td>Model 2: Endogenous entry,</td>
<td>-0.194</td>
<td>0.092**</td>
</tr>
<tr>
<td>Instrument using months since initial generic entry</td>
<td>-0.141</td>
<td>0.079*</td>
</tr>
<tr>
<td>Reduced-form specification</td>
<td>-0.202</td>
<td>0.112*</td>
</tr>
<tr>
<td>Control group 2: Unsuccessful paragraph IV drugs</td>
<td>Model 1: Exogenous entry</td>
<td>-0.275</td>
</tr>
<tr>
<td>Instrument using months since initial generic entry</td>
<td>-0.221</td>
<td>0.120*</td>
</tr>
<tr>
<td>Reduced-form specification</td>
<td>-0.225</td>
<td>0.152</td>
</tr>
</tbody>
</table>

*Robust standard errors are reported that cluster by molecule. Statistical significance: **5%, *10%. Each estimate corresponds to the coefficient for the “had an exclusivity period” variable from the stage 2 regression. Model 1 reports results from table 5 for a transition period of one month and an after period of twelve months. Model 2 uses a fourth-order polynomial in the number of months since first generic entry as the set of instruments for the number of generic entrants. Model 1 is a reduced-form specification that includes all exogenous variables but excludes the potentially endogenous entry variables.

Our second approach is to estimate a reduced-form model that controls for all of the exogenous variables, including fixed effects for months since first generic entry, but excludes the potentially endogenous entry variables. As Greene (2003) and Wooldridge (2010) explain, simultaneous equations model that is a function of exogenous and endogenous variables can be rewritten as a reduced-form model that is solely a function of the exogenous variables. The drawback from relying on the reduced-form model is that it is no longer possible to identify the causal effect of the endogenous variables. In addition, since the presence of an authorized generic is potentially endogenous, we drop this control from the second-stage regression. This is of minor consequence since it has little explanatory power.
mate is similar, but with a substantially larger standard error, resulting in a p-value of .149). For large drug markets, the effect of potential competition is not statistically significant at any conventional level, although the point estimates vary a fair amount across the specifications (in both sign and magnitude).42 Our general conclusion from this analysis, given the similarity of the results to our prior findings, is that endogeneity bias is unlikely to affect strongly our earlier estimates regarding potential competition.

VI. Conclusion

The importance of potential competition in constraining market power has long been recognized as a theoretical matter. However, empirical evidence regarding the effects of potential competition is relatively limited despite its importance in understanding the strategic behavior of firms. We add to the empirical literature by developing an identification strategy that uses the Hatch-Waxman 180-day exclusivity period as an exogenous source of variation in potential competition that varies over time and across drugs.

We find that the incumbent in smaller drug markets lowers price in response to an increase in potential competition, and this price reduction is an effective entry deterrent. In larger drug markets, the incumbent accommodates entry by lowering price only after competing manufacturers enter the market. This pricing strategy leads to a significant increase in the number of competitors once the Hatch-Waxman exclusivity period ends. Overall, our results show that price can be an effective entry deterrent in certain circumstances where the cost of deterring entry is not too high.

It may be inappropriate to generalize our findings to other industries. Product differentiation is negligible in generic drug markets, such that firms compete almost exclusively on price. In more differentiated markets, firms may employ other strategic actions to deter entry, either as a replacement for or in addition to using price as a strategic entry deterrent. The importance of price as a strategic entry deterrent in more differentiated industries is an area for future research.

42 The relatively more extensive entry into large drug markets likely explains why the results for large markets are more sensitive to how entry is modeled.

REFERENCES


