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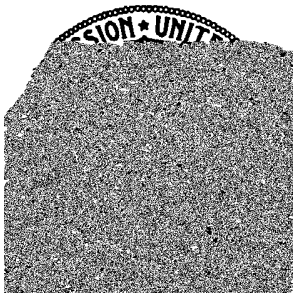

Entry Threats and Pricing in the Generic Drug Industry

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ENTRY THREATS AND PRICING IN THE GENERIC DRUG INDUSTRY

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Abstract

We provide the first analysis of potential competition in the generic drug industry. Our identification strategy exploits a provision of the Hatch-Waxman Act that rewards 180 days of marketing exclusivity to the first generic drug applicant against the holder of a branded drug patent. This provision creates observable drug-level variation in both actual and potential competition that allows us to identify their separate effects. We find mixed evidence of price being used as a strategic entry deterrent. In smaller drug markets where entry is more easily deterred, we find that price falls in response to an increase in potential competition. We also find that few manufacturers enter these markets after the Hatch-Waxman exclusivity period, indicating this price reduction is an effective deterrent. In contrast, in larger drug markets the incumbent accommodates entry by lowering price only after competing manufacturers enter the market.

Keywords: potential competition, entry deterrence, pharmaceutical, pricing

JEL Classification Codes: L11, L13, L65

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ENTRY THREATS AND PRICING IN THE GENERIC DRUG INDUSTRY

I. Introduction

It is well recognized that an incumbent may deter potential competitors by taking strategic action that reduces 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,b). This wide range of theoretical outcomes highlights the need for empirical analysis to determine the real-world importance of potential competition.

infringe on the FDA's Orange Book patents, or that the relevant Orange Book patents are invalid.[2] The Hatch-Waxman Act encourages generic firms to incur litigation costs by rewarding 180 days of marketing exclusivity to the first to file an ANDA with a paragraph IV certification.[3] This marketing exclusivity period protects the designated first-filer from competition with other generic entrants.[4] Following the end of the exclusivity period, two changes occur. 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 both actual and potential competition, we can separately identify their impact on price.

Our analysis of the effect of potential competition on price employs a treatment-control group framework.[5] 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 other 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,

[2] In these instances, the FDA may not approve the generic drug until 30 months after the generic files its drug application with the FDA or after a favorable decision in the patent litigation, if earlier.

[3] Prior to 2003, the first-to-file generic manufacturer could be distinguished by the exact minute a drug application was submitted. If several firms provided valid applications on the same day, the FDA would grant exclusivity to the first applicant. This provision has since been relaxed and now multiple firms can be designated as the first-filer.

[4] As noted in footnote 3, the FDA may designate multip

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.

The layout of the paper is as follows. Section II reviews the preceding literature. Section III details the dataset employed. Our identification approach is discussed 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).[6] 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

[6] See Gilbert (1989a,b) and Bergman (2003) for discussion of strategic entry deterrence via non-price mechanisms. For example, Spence (1977) and Dixit (1980) analyze investment in capacity.

entrant by reducing output. When this is recognized by a forward-looking potential entrant, limit pricing may not be a credible entry deterrent.[7]

One way of overcoming this weakness of the limit-pricing framework is to incorporate cost uncertainty into the model (Salop 1979, Milgrom and 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 it is a high cost firm.

An alternative approach to modeling the effect of potential competition is the "contestable markets" theory (Baumol et al. 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.

The models described above provide avenues through which potential competition may affect incumbent pricing. However, each model provides a very different description of the nature of potential competition. Moreover, the models characterize conditions under which potential competition does not lead to lower prices. This wide range of theoretical outcomes highlights the need for empirical analysis to determine the importance of potential competition.

Relatively little empirical research examines the effects of

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.[8]

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 the impact of realized entry differs for branded and generic drugs (Caves et al. 1991, Graboski and Vernon 1992, Griliches and Cockburn 1994, Lu and Comanor 1998, Reiffen and Ward 2005, Regan 2008). Whilf co6,gener]TJ 0.0005 Tc -0.0011 Tw 121a6iTJ 0. [ries thgs)T

different therapeutic classes, to identify the effects of potential competition on branded drugs.[9] They find that firm profitability is curbed by the threat of competition.

All of these papers analyze the impact of potential competition on branded drugs. To our knowledge, our study is the first to analyze the impact of potential competition on generic drug prices. As noted above, a large number of studies show that the effect of actual competition by generic manufacturers significantly differs for branded and generic drugs. This suggests that the literature's findings regarding potential competition in the branded drug industry may not apply to generic drugs. Consequently, it is important to analyze the effect of potential competition specifically in that industry.

III. Data

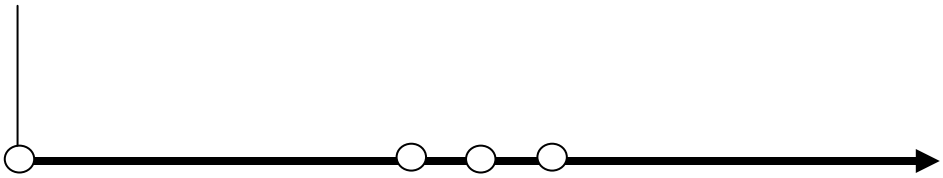
Our analysis employs monthly wholesale data from IMS pharmaceutical services. This dataset reports sales for every oral solid prescription medication distributed in the United States over the period January 2003 to December 2008.[10] Sales are reported separately by drug, which

competitors enter the market and there is the threat of future entry. 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

In this section, we describe in further detail how the Hatch-Waxman Act allows us to identify the effect of potential competition on generic drug pricing. Consider the following timeline of the first-filing generic manufacturer's incentive to engage in strategic entry deterrence for drugs that enter via a paragraph IV certification.

Hatch-Waxman Timeline



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

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 non-exclusive drugs. Since the key difference between the two sets of drugs is that one experiences a change in potential competition upon 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.[11] Our estimation strategy is closely related to the method used by Bergman and Rudholm (2003) to measure the effect of potential competition on branded drug prices. Bergman and Rudholm use the expiration of the branded drug's patent as a source of variation in potential competition in the same manner we exploit the 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 product life-cycle effects in a flexible manner.

V. Empirical Analysis

Our difference in difference estimator is implemented in two stages. In the first stage, we estimate equation (1) to obtain each drug's change in price between the exclusivity and non-

[11] See Bertrand et al. (2004) and the citations contained therein for discussion of the "difference in difference" estimation approach. Bertrand et al. recommend the two-stage estimation strategy that we employ.

exclusivity periods after controlling for a set of variables X_{dt}

business practice rather than exit. We assume a manufacturer has exited a particular drug market only after four consecutive months of zero sales.[15] Authorized generics are included in the count of manufacturers.[16] To account for the possibility that the competitive effect of an authorized generic differs from the impact of an independent generic manufacturer (Reiffen and 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 $\ln p_d \quad {}^{2}_{d} \quad {}^{0}_{d}$, the change in log price between the before and after windows after controlling for the number of generic manufacturers and the other variables contained in X_{dt}. This measure is the dependent variable in the second stage of the analysis.[17]

(2) $\ln p_d \quad EXCL_d \quad Z_d \quad {}_d$

Variable $EXCL_d$ 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

price between the before and after periods for drugs with exclusivity relative to a control group of non-exclusive drugs. The key identification assumption is that non-exclusive drugs are a valid control group for drugs with an exclusivity period after controlling for variables X_{dt} 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 non-exclusive 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 non-exclusive 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.

Table 2 presents the first and second stage regression estimates. Robust standard errors are reported that cluster by molecule. This accounts for any correlation in unobserved characteristics across drugs with the same active ingredient. 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.[19]

In the second stage results, the key effect of interest is the coefficient for whether a drug had an exclusivity period, which is our difference in difference estimator. The price of exclusive

[19] 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 13.8% (SE=8.1%), 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).

drugs falls by 11.8% (SE=8.4%) after the exclusivity period ends, relative to the price change for non-exclusive drugs. However, this effect is not statistically significant at any conventional level.

A key determinant of whether a firm engages in strategic entry deterrence is the cost of deterring potential competitors. It is likely that entry deterrence is costlier 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 19.4% (SE=9.2%) relative to non-exclusive 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.

These results suggest that price is used as an entry deterrent in small drug markets, but not in large drug markets. We now explore whether price is an *effective* entry deterrent by estimating equations (1) and (2) using the log number of manufacturers as the dependent variable, rather than price.[20] 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.

[20] Of course, controls for the number of manufacturers are omitted from the model.

unobservable differences between the treatment and control groups may remain, potentially biasing our results.

We now consider an alternative control group that consists of non-exclusive 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 manufacturer prior to entry.[21] These non-exclusive drugs are more similar to 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 non-exclusive paragraph IV drugs.[22] 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.[23]

The second column of results in Table 5 repeats the analysis after restricting the dataset 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 22% to 29%, 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

[21] 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.

[22] In contrast, when the control group consists of all non-exclusive drugs the difference in means is statistically significant at the 1% level.

[23] Restricting the data to drugs with a paragraph IV certification leads to a sample of 195 drugs.

manufacturers in large drug markets is not statistically significant in one specification. However, it is almost significant at the 5% level with a p-value of .051. 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 final robustness check, we undertake th

windows than their non-exclusive counterparts. This suggests that it takes more than 12 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.

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

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Table 1:
Summary Statistics

	(i) All Drug Markets		(ii) Small Drug Markets		(iii) Large Drug Markets	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Fixed Characteristics:						
Had an Exclusivity Period	0.39	0.49	0.25	0.43	0.54	0.50
Had an Authorized Generic	0.49	0.50	0.29	0.46	0.68	0.47
Tablet	0.68	0.47	0.68	0.47	0.68	0.47
Capsule	0.12	0.32	0.13	0.34	0.10	0.30
Extended Release Tablet	0.13	0.33	0.10	0.30	0.15	0.36
Extended Release Capsule	0.04	0.18	0.04	0.19	0.03	0.18
Other Dosage Form	0.04	0.21	0.06	0.23	0.03	0.18
Time-varying Characteristics:						
Generic Price, Relative to Branded Drug Pre-Entry Price	0.47	0.30	0.57	0.27	0.37	0.28
Months Since First Generic Entry	22.86	16.43	23.02	16.31	22.69	16.54
Number of Generic Manufacturers	4.2	3.4	2.7	2.0	5.8	3.8
Number of Drugs	312		156		156	
Number of Drug-Months	10,787		5,545		5,242	

Notes: IMS wholesale price data, April 2003 to December 2008. Branded drug price is measured in the quarter prior to first generic entry. 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.

Table 2:
Effect of the Hatch-Waxman Exclusivity Period on Generic Drug Prices

Stage 1 Regr

	Est	SE	
Authorized Generic (AG) Present	0.514	0.176	*
AG × # Manufacturers	-0.109	0.055	*
AG × # Manufacturers Squared	0.005	0.003	
Manufacturers = 2	-0.091	0.035	*
Manufacturers = 3	-0.087	0.056	
Manufacturers = 4	-0.109	0.065	
Manufacturers = 5	-0.221	0.077	*
Manufacturers = 6	-0.295	0.082	*
Manufacturers = 7	-0.362	0.108	*
Manufacturers = 8	-0.406	0.126	*
Manufacturers = 9	-0.455	0.152	*
Manufacturers = 10	-0.581	0.173	*
Manufacturers > 10	-0.819	0.246	*

	Est	SE	
Had an Exclusivity Period	-0.118	0.084	
Had an Authorized Generic	0.039	0.087	
Market Size Percentile	-0.581	0.131	*
Capsule	-0.106	0.146	
Extended Release Tablet	0.168	0.060	*
Extended Release Capsule	0.006	0.089	
Other Dosage Form	-0.237	0.152	

Table 3:
Effect of the Hatch-Waxman Exclusivity Period on Generic Drug Prices, Separately by Small and Large Drug Markets

Stage 1 Regression
Dep Variable: Log Price

	Small Drug Markets			Large Drug Markets		
	Est	SE		Est	SE	
Authorized Generic (AG) Present	0.185	0.099		0.733	0.258	*
AG × # Manufacturers	-0.023	0.053		-0.174	0.061	*
AG × # Manufacturers Squared	0.006	0.005		0.008	0.003	*
Manufacturers = 2	-0.038	0.026		-0.181	0.117	
Manufacturers = 3	-0.046	0.050		-0.183	0.107	
Manufacturers = 4	-0.099	0.079		-0.198	0.098	*
Manufacturers = 5	-0.195	0.094	*	-0.332	0.095	*
Manufacturers = 6	-0.387	0.102	*	-0.300	0.102	*
Manufacturers = 7	-0.479	0.138	*	-0.351	0.128	*
Manufacturers = 8	-0.598	0.175	*	-0.381	0.144	*
Manufacturers = 9	-0.614	0.189	*	-0.424	0.154	*
Manufacturers = 10	-0.612	0.182	*	-0.536	0.176	*
Manufacturers > 10	-0.754	0.252	*	-0.799	0.227	*

	Small Drug Markets			Large Drug Markets		
	Est	SE		Est	SE	
Had an Exclusivity Period	-0.194	0.092	*	0.000	0.108	
Had an Authorized Generic	-0.066	0.070		0.065	0.138	
Market Size Percentile	-0.374	0.202		-0.752	0.307	*
Capsule	-0.123	0.128		-0.126	0.215	
Extended Release Tablet	-0.012	0.054		0.278	0.095	*
Extended Release Capsule	0.011	0.065		-0.014	0.094	
Other Dosage Form	-0.114	0.111		-0.165	0.363	

Table 4:
Effect of the Hatch-Waxman Exclusivity Period on Number of Generic Manufacturers, Separately by Small and Large Drug Markets

	Small Drug Markets		Large Drug Markets	
	Est	SE	Est	SE
Had an Exclusivity Period	0.154	0.134	0.432	0.162 *
Market Size Percentile	0.544	0.242 *	0.968	0.381 *
Capsule	0.083	0.134	0.181	0.334
Extended Release Tablet	0.265	0.213	-0.251	0.122 *

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

Table 6:
Effect of the Hatch-Waxman Exclusivity Period on Number of Manufacturers, Alternative Event Windows and Control Groups

		Control Group 1: All Non-Exclusive Drugs				Control Group 2: Non-Exclusive Paragraph IV Drugs			
		Small Drug Markets		Large Drug Markets		Small Drug Markets		Large Drug Markets	
		Est	SE	Est	SE	Est	SE	Est	SE
None	6 months	0.180	0.118	0.386	0.126 *	-0.050	0.199	0.404	0.130 *
None	12 months	0.150	0.126	0.406	0.147 *	-0.050	0.201	0.395	0.160 *
None	24 months	0.160	0.119	0.486	0.160 *	-0.026	0.197	0.454	0.185 *
1 month	6 months	0.196	0.129	0.429	0.136 *	-0.080	0.224	0.434	0.145 *

Figure 1:
Average Price by Exclusivity