GENERIC ENTRY AND THE PRICING
OF PHARMACEUTICALS

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ABSTRACT

During the 1980s the share of prescriptions sold by retail pharmacies that was accounted

for by generic products roughly doubled. The price response to generic entry of brand-name

products has been a source of controversy. In this paper we estimate models of price responses

to generic entry in the market for brand-name and generic drugs. We study a sample of 32 drugs

that lost patent protection during the early to mid-1980s. Our results provide strong evidence that

brand-name prices increase after entry and are accompanied by large price decreases in the price

of generic drugs.

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I. Introduction

Since the passage of the Waxman-Hatch Act in 1984 there has been a dramatic increase in entry of generic drugs into markets for pharmaceutical products. The Waxman-Hatch Act eased the testing requirements for entry by generic drugs. This legislation accompanied by the expiration of patents on a large number of high sales volume brand-name drugs is altering the competitive dynamics of pharmaceutical market place. During the 1980s the share of prescriptions sold by retail pharmacies that were accounted for by generics roughly doubled. The price response of brand-name drugs was surprising and remains controversial (OTA, 1993). Prices for drugs were observed to rise in response to generic entry (see for example Grabowski and Vernon 1992). At the same time these conclusions were questioned by recent empirical analyses (Wiggins and Maness 1994). In their analysis of the market for anti-infective drugs they found a response to entry that is consistent with the predictions of traditional market models; pioneer (or brand-name) price declines as entry expands. In this paper we estimate models of price responses to generic entry in the markets for generics and brand-name drugs for a broad sample of drugs that lost patent protection between the years 1983 and 1987.

The price models estimated below examine the experiences of 32 drugs that lost patent protection during the mid 1980s. We make use of information on transactions prices paid by retail pharmacies. All the drugs studied experienced significant entry by generics during the first years off patent. Our results provide strong evidence that brand name prices increase after

entry but are accompanied by large decreases in the price of
generic products. The net effect is a reduction in the average
price of a prescription for an off patent drug.

The paper is organized into 5 sections. The second section
takes up some theoretical considerations for the empirical model
of prices and examines existing evidence on price responses to
entry from the literature. The empirical implementation of the
pricing models are described in the third section. The fourth
section presents estimation results. A discussion of the
implications of the findings appears in the fifth and final
section of the paper.

II. Background

A. Theoretical Considerations

The theoretical point of departure for the empirical models
estimated below is the model of Frank and Salkever (1992). Their
model was developed to explain the positive correlation between
generic entry and brand-name price levels. In that analysis the
demand side of the market for a particular drug is conceived as
consisting of two major segments, one that is price insensitive
and a second that is price responsive. The price insensitive
component might consist of the patients of physicians in fee for
service practice, while the insensitive component would consist
of prescriptions filled on behalf of enrollees in HMOs and
patients in hospitals. Entry of generics leads price sensitive
buyers to shift to generics, leaving only price insensitive
buyers to purchase brand-name products. This causes the brand-
name producers' demand function to shift inward and to become
less elastic, allowing the profit maximizing brand-name firm to

raise its price.

The model posits that brand-name drug manufacturers behave as von Stackelberg price leaders. That is, a brand-name drug producer is a dominant firm that makes its profit maximizing pricing decisions taking account of the reaction to its pricing choices in the generic market. Producers of generic versions of brand-name products are viewed as fringe firms playing a Nash-Cournot non-cooperative game. Each firm takes the brand-name producer's price and the behavior of rival generic producers as given in making its profit maximizing pricing decision. The implications of this model for empirical analyses are several:

a) The price equation for generic product price can be written as:

(1) $P_g* = P_g*(n, P_b)$

where P_g* is the equilibrium price of a generic product, n is the number of generic producers, and P_b is the brand-name producer's price.

b) The price equation for brand-name price can be written as:

(2) $P_b = P_b(n, w)$

where w is a vector in input prices. The reduced form brand-name price equation suggests that generic entry affects price through the effect of generic price on brand-name demand. Frank and Salkever (1992) show that $dP_b/dn < 0$ unless entry increases brand-name demand, marginal costs are decreasing or entry makes the demand curve less elastic (steeper). There is little support for the first two conditions in the empirical literature (OTA, 1993, Comanor 1986 and Scherer 1993). Thus we posit that a positive partial correlation between n and P_b would primarily reflect the

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impact of generic entry on the brand-name demand curve.

B. Evidence from the Literature

Three recent empirical analyses have estimated the relationship dP_b/dn and have arrived at substantially different conclusions. Grabowski and Vernon (1992) examined the effect of generic entry on prices for 18 high sales-volume pharmaceutical products that were first exposed to generic competition during the years 1983 through 1987. For each drug the authors examined prices prior to entry and prices 1 year following generic entry. Grabowski and Vernon (1992) specified regression models that had as the dependent variable the ratio of generic to brand-name price and three independent variables: 1) the number of generic product sellers, 2) the total dollar of sales in the market for the chemical and 3) a time dummy variable. The estimated coefficient for the impact of the number of generics on the ratio of generic to brand-name price was negative and significantly different from zero. This result is consistent with the descriptive information reported by Grabowski and Vernon (1992) showing brand-name price rising relative to generic prices subsequent to generic entry.

Caves, Whinston and Hurwitz (1991) are concerned that simple pre-post entry brand-name price comparisons or simple regression of price on number of generic entrants may lead to underestimates of the downward impact on prices that generic entry may really have. They suggest that other omitted factors may have caused brand-name prices to rise overtime. Specifically they argue that after 1982 the producer price index (PPI) for pharmaceutical rose

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sharply relative to indices of labor and material costs.[1] The authors therefore take great pains to minimize the effect from unobservable time-varying factors which might be responsible for the types of results reported by Grabowski and Vernon (1992).

Caves, Whinston and Hurwitz (1991) studied the experience of 30 drugs that went off patent between 1976 and 1987. These drugs studied represent all drugs in therapeutic classes where "important" drugs lost their patent protection. In the regression models of brand-name prices, reported by Caves, Whinston and Hurwitz (1991), more than 50 individual intercepts were included to account for each of the year-therapeutic category combinations in their data. The regression results therefore represent an analysis of deviations in individual drug prices from the therapeutic category-year group average changes in each year. The regression model also included time related dummy variables, a linear time trend and a quadratic time trend in order to capture discontinuities in price behavior around the time of patent expiration.

The measure of generic entry used in the model was the number of Amended New Drug Applications for marketing of a new chemical entity, actual entry was not directly measured. In some specifications entry was treated as endogenous. The estimated regressions found that initial entry by generic products led to reductions in brand-name price of about 2%. Entry by 20 generics

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[1] Berndt, Griliches and Rosett (1990) point out that the PPI was substantially biased in an upward direction. They argue that the reason for this bias is there were important differences in the drugs included in the PPI sample and the universe of pharmaceutical products.

results in price decreases of 17%. These were viewed as very small price responses to entry. The responses were somewhat larger in markets where hospital share of sales were larger. Caves, Whinston and Hurwitz (1991) also estimate a regression model that was quite similar to the one estimated by Grabowski and Vernon (1992) and obtained very similar results. In view of the enormous complexity of the models estimated by Caves, Whinston and Hurwitz (1991) it would be important to understand the sensitivity of their results to the specific model chosen by the authors.

Wiggins and Maness (1994) have recently studied price competition in the market for anti-infectives over the period 1984 to 1990. The anti-infectives studied include 98 compounds. Some of the drugs studied had been off-patent for many years (e.g. penicillin), while others more recently became prone to generic competition. Following Caves, Whinston and Hurwitz (1991), Wiggins and Maness include a number of fixed effects to control for unobserved factors that might influence price. The specific fixed effects specified include one set for type of anti-infective, a second set indicated if the product was introduced in a given year, and the third set was a vector of year specific dummy variables. The specification used for estimating the model of pioneer brand prices reflected a Cournot formulation and allowed for a non-linear impact of exogenous entry.

The model was estimated using data on brand-name prices only. The estimated coefficients showed that market entry by generics results in significant reductions in the price of anti-infective products. The entry by other brand-name products was

estimated to lower price but was significant only at the 10% level. Descriptive information reported by Wiggins and Maness (1994) suggests that there are three observations in the data where there are few (or zero) entrants accompanied by high prices (Panel C, Figure 2). They speculate as to why their results differ from other studies; they offer sample size and use of fixed effects as two explanations. They also suggest, as do other students of the pharmaceutical industry, that anti-infectives have followed a different pattern from the larger universe of pharmaceutical products (Scherer 1993 OTA, 1993). It is therefore, important to use a large sample with careful attention to unmeasured factors to determine the extent to which analyses based solely on data from the anti-infective market generalizes to the industry.

III. Empirical Implementation

The empirical analysis of pharmaceutical pricing reported below estimates parameters for models of both brand-name and generic products. These empirical models correspond to equations (1) and (2) discussed above. The unit of observation in these models is either the brand-name compound-year or the generic compound-year. We make use of a data set that consists of drugs that first faced competition during the period 1984-1987. The econometric models estimated include both single equation models where the number of competitors is treated as exogenous (such as in the work of Grabowski and Vernon 1992, and Wiggins and Maness 1994) and two-stage least squares models where the number of competitors is endogenous.

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A. Data

Between 1984 and 1987 83 compounds faced generic competition for the first time. All these drugs lost patent protection between 1979 and 1987. From this group of products, drugs were eliminated if a) they became over the counter products which no longer required a prescription for purchase (e.g. ibuprofen), b) they were combination products, or c) were not sold to drug stores in quantity (these include injectibles and infusibles which account for a very small part of the outpatient market). After applying the above exclusion criteria 45 drugs remained in the sample.[2]

Several of the drugs reported zero sales during the 1980s and were thus eliminated from the data base, reducing the sample to 41 compounds. Antibiotics were eliminated from the sample due to the complicated licensing arrangements that exist in this area which made defining entry and patent loss hazardous. The resulting sample of drugs for analysis was 32.[3]

Information on dollar sales volume, unit sales volume and generic market share were obtained from IMS America Inc. MIDAS system using the United States Drugstore and Hospital data base for the years 1980 through 1991. According to IMS, in 1986 these

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[2]The data on volume and prices of drugs were originally collected by Stephen Schondelmeyer on behalf of the U.S. Office of Technology Assessment. We are grateful to Judy Wagner for making these data available to us.

[3]The drugs included in the analysis had average sales of $80 million in the year prior to patent loss.

data covered 98% of pharmaceutical sales in the U.S. Data on years for which a name-brand was sold prior to patent loss, market entry date for generics, number of non-originator firms, and whether drugs are used primarily to treat chronic, acute or sub-acute conditions were added to the IMS data set. The definitions of key variables and their data sources are listed on Table 1. All data were aggregated to the year level from quarterly reports of sales.

The main dependent variables in the analyses reported here are the average transactions revenue per extended unit of a drug. An extended unit is defined as the most basic unit measure of volume for a given product such as a capsule or a gram for drugs sold by weight. The extended unit varies by product. Thus, the dependent variable is the manufacturer dollar sales based on transactions data divided by the number of extended units.[4] For generics the dependent variable is the sum of generic sales (across producers) divided by the sum of extended units sold. The main right hand side variable of interest in this analysis is the number of generic sellers in the market (NMFT). This variable was constructed by using information from the USP DI (or Orange Book) for 1987, 1990 and 1991. The NMFT variable counts the number of non-originator drug sellers in the market in each year post patent expiration.

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[4]All dollar sales figures were deflated by the CPI All-Items Index.

B. Estimation

In order to estimate the impact of generic entry on market prices three sets of models were estimated for the prices of brand-name and generic drugs. We first estimate single equation fixed effects models where NMFT is treated as exogenous.[5] In this model we make use of time and compound specific fixed effects to control for unobserved secular trends (e.g. input prices) and time invariant (compound specific) unobservables. The second specification relaxes the assumption that NMFT is exogenous. Following Caves, Whinston and Hurwitz (1991) use the amount of time off patent as one instrument. A two stage least squares fixed effect estimator is used for this model.

The third model also makes use of a two-stage estimator. In this specification we include an indicator of demand for overall demand for a compound and the age of the market as well as the time off patent as an instrument in the first stage. The demand is measured as the sales in the year prior to patent expiration. The age of the market is a second instrument; it is viewed as an indicator of entry friction stemming from loyalty to the originator brand and habit by physicians in their prescribing patterns. Since these two variables are time invariant we used a variance component estimator instead of the fixed effects model. In the second stage a fixed effects estimator is used.[6] The

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[5]Of particular concern are trends in shifting market composition. That is enrollment in managed care plans grew during the period. The time fixed effects were introduced to account for these trends.

[6]It is worth noting that we estimate two versions of the first stage variance components model.

Hausman test led to a rejection of the consistency of the variance components estimator in the second stage in all specifications.

IV. Results

A. Descriptive Findings

Figure 1 shows the behavior of brand-name prices subsequent to market entry by generic producers. The vertical axis measures the current brand-name price relative to the pre-patent price. The horizontal axis measures the time, in years, since the initial entry into the market by generics. Note that the data suggest an upward drift in real brand-name prices. These data are consistent with the observations made by Grabowski and Vernon (1992). The Figure shows that shows a 50% rise in brand-name price five years post generic entry. The trend runs counter to the notion that brand-name producers engage in vigorous price competition with generic entrants. Figure 2 offers a analogous view of the behavior of generic prices during the period following initial market penetration. Note that three years after generic entry generic prices are less than 50% of the brand-name price. These data are supportive of the view that the generic market represents a highly competitive fringe to the brand-name drug market.

Figure 3 presents information on the behavior of generic prices relative to brand-name prices as the number of firms selling a compound increases. The graph in Figure 3 suggests that expanded entry is consistent with a downward drift in the ratio of generic to brand-name price. The relationship is not monotonic as was observed in the time path of prices. This indicates that the timing of entry by generics does not occur continuously

overtime. Figure 4 shows the number of generic entrants in relation to the years since patent protection was lost. The graph reflects the fact that on average about five generic producers enter a market during the first post-patent year of the brand-name product. During the subsequent three years entry is considerably slower with three additional generic producers entering on average. These data are consistent with robust competition in the market for generic products.

B. Econometric Estimates

In this section we present the results from our econometric models of pharmaceutical prices. We begin by examining the estimates for our model of the number of generic entrants into the market for specific compounds subsequent to loss of patent protection. Table 2 reports one fixed effect and two variance components regressions for the number of generic entrants (NMFT). The first column reports the fixed effect estimates. The likelihood ratio tests indicates that both the time and compound specific fixed effects are significantly different from zero (240.69 and 338.62 respectively). The coefficient estimate for the Yrs Off variable is significantly different from zero. The magnitude of the coefficient implies that for each year post-patent protect there is about one additional entrant into the market for a particular drug.

The variance components regressions are presented in the second and third columns of Table 2. Two specifications are presented, with and without a linear time trend. The pre-patent loss brand name level of sales of the drug is included as a proxy for the overall demand for the compound. The results reported in

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the second column suggest that the pre-patent loss sales have a significant positive impact on subsequent generic entry. The estimated elasticity evaluated at the mean of sales and number of entrants is 0.47, indicating that a 10% difference in pre-patent loss sales result in 4.7% more entrants post-patent. The number of years for which the brand-name drug was sold had no significant impact on entry.[7] Thus the brand name selling period does not seem to be the source of friction for entry by generics. The measure of years off patent shows that for each year post patent there is on average one new entrant.

The results reported in the third column are qualitatively similar. The estimated coefficient for years off patent varies across the models from 0.734 to 1.45. The fixed effects result lies between the other two specifications. The rather strong estimates for the time trend effect in Table 2 suggest that the entry process has become substantially easier over the time period studied. This is consistent with the objectives of the Waxman-Hatch Act.

Table 3 reports the estimates for the brand-name price regressions. Recall that these estimates are all based on fixed effects models that include separate intercepts for each compound and each year. The first column of Table 3 reports regression results for a model where the number of generic competitors is assumed to be exogenous. Unobserved factors that affect both entry and brand-name price are posited to be accounted for by the fixed effects. In that model the impact on brand-name price of a

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[7]Recall that this variable is time invariant so that it is excluded from the 1st stage fixed effects model.

change in the number of competitors dP_b/dn is estimated to be positive and significant at conventional levels (0.05). The parameter estimate suggests that each new entrant will result in roughly a 0.7% increase in the brand name price.

The estimated models reported in the second and third columns of Table 3 each treat the number of competitors as endogenous. The model in the second column uses a first stage model that corresponds to the first column of Table 2. The third column uses a first stage model that corresponds to the second column of Table 2. The results for the two stage models indicate stability in the coefficient estimates for the number of competitors. The estimates for both two stage models of the impact of generic entry are significantly different from zero at conventional levels. The range of the estimates is quite small (0.007 to 0.016). It should be noted that the 0.007 and the 0.016 estimates are significantly different from one another at close to the 0.05 level. The evidence is therefore consistent with the view that generic entry drives brand-name prices up.[8]

Table 4 reports two stage fixed effects generic price regression results. All three specifications treat the number of competitors as endogenous. The coefficient estimates for the NMFTHAT variable are quite consistent across the three specifications. In all cases the coefficient estimates are

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[8] We also examined the possibility that drugs used regularly for chronic conditions may display different price dynamics. We therefore interacted a dummy variable representing chronic use with the level of generic competition in our pricing models. In all cases we failed to reject the hypothesis that drugs used for different types of illnesses had different price responses to competition.

negative and significantly different from zero at conventional levels. The parameter estimates indicate that each additional entrant reduces the average price of a generic product by between 5.6% and 7.2%. Thus moving from the sample mean of about 3 competitors to 6 competitors would reduce prices by between 17% and 22%. The coefficient estimate for the brand-name price was estimated to be consistently positive but was never significantly different from zero.[9] This is probably due to the fact that the between compound variation in brand name price is considerably greater than the within variation. Thus, the inclusion of compound specific fixed effects may lead to the imprecision in the coefficient estimate for the brand-name price variable.[10]

V. Implications and Conclusions

Pricing in the pharmaceutical industry has often received a great deal of attention from policy makers (U.S. Senate 1961). Recently questions concerning the competitive dynamics in the industry have resurfaced because of the renaissance in the generic drug industry (Scherer 1994). In particular, the puzzling rise in the prices of brand-name products subject to generic competition ran counter to simple explanations based on

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[9]We tested the exogeneity of the brand-name price variable using a Hausman test and were unable to reject exogeneity of the variable.

[10]We recognize the possibility of endogeneity of brand name price from unique characteristics of markets for specific compounds that are observable to the firm but not the researcher. However, if these features are stable overtime the fixed effects model should control for these features.

traditional conceptions of competition. These observations have led to a series of theoretical and empirical analyses of pricing in markets for pharmaceuticals. These analyses have reached different conclusions. In the work reported here we examined a sample of drugs with relatively large sales that have recently lost patent protection and faced competition from generics for the first time during the mid-1980s. Our data set represents the experience of drugs in a variety of therapeutic categories (except antibiotics) and reflect drugs that lost patent during the time period where the Waxman-Hatch Act changed the rules governing generic entry.

Our econometric analysis leads us to several conclusions regarding price behavior in this market. First, it is clear that more competition among generic drug producers results in substantial price reductions for those drugs. Second, increased competition from generics does not result in aggressive responses in price behavior by brand-name producers. We found no evidence of brand-name price reductions stemming from market entry by generic producers. In fact, the evidence we did uncover supports small price rises in response to expanded competition.

The substantial shift in market share from brand-name to generic producers (40% - 50%) along with the significantly reduced price of generic substitutes (25% - 30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen.

One important limitation to our analysis should be noted. This study focused on competition at the level of the compound. That is, generics were assumed to compete with brand-name drugs and generic products that were the same chemical compound.

Competition among drugs is more complicated than this. HMOs, managed care organizations and some physicians make choices among drugs within a therapeutic class. We have not accounted for therapeutic competition in this analysis. Future work on price dynamics in this industry should be expanded to take account of this more complicated set of competitive dynamics.

In sum, our results are consistent with notions of market segmentation on the demand side between classes of buyers with differing sensitivity to price. The absence of brand name price reductions due to generic competition, alongside large decreases in generic prices from intensified competition support this view. The implication of the empirical findings is that on balance the Waxman-Hatch Act had its intended effect of increasing price competition in the market for pharmaceutical products. The specific mechanisms through which price competition has taken place was, however, a surprise and is different from predictions based on simple versions of market models.

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Table 1. Variable Descriptions

Variable	Definition	Mean (SD)
NMFT	Number of Generic Entrants (Source: USP DI and Orange Book)	3.62 (5.29)
Mkt Age	Age of market in terms of time the brand name product was sold (Source: Paul deHaen International)	13.78 (7.73)
Yrs Off	Year since the patent expired (Source: FDA and telephone contact with originator firm)	1.35 (2.01)
P_G	Average revenue per generic extended unit (Source: IMS)	0.15 (0.15)
P_B	Average revenue per brand name extended unit (Source: IMS)	0.29 (0.21)
QPre	Number of extended units sold pre-patent loss	0.36×10^6 (0.55×10^6)

Table 2. 1st Stage Entry Regressions Dependent Variable: NMFT[1]

Variable	Fixed Effects	Variance Components	Variance Components
QPre	– –	0.53×10^{-5} (4.09)	0.51×10^{-5} (4.05)
Mkt Age	–	0.020 (0.20)	0.026 (0.27)
Yrs Off	0.900 5.13	0.734 (1.80)	·1.475 (9.62)
Time	– –	0.750 (1.85)	– –
Constant	4.588 ·9.40	-3.693 (1.23)	1.041 (0.68)
N	179	179	179

[1] t statistic in parentheses

Table 3. Brand Name Price Regression[1] (Dependent Variable: In P_B)

Variable	Fixed Effects	TS Fixed Effects	TS Fixed Effects
NMFT	0.007 (2.25)	- -	- -
NMFTHAT	- -	0.011 (2.97)	0.016 (3.96)
Constant	-1.487 (101.97)	-1.479 (95.12)	-1.486 (101.38)
N	343	179	179

[1] t statistics in parentheses
[a] 1st stage fixed effects model
[b] 1st stage variance components with time trend

Table 4. Generic Price Regressions[1] (Dependent Variable: ln P_G)

Variable	TS Fixed Effect	TS Fixed Effect	TS Fixed Effect
NMFTHAT	-0.073[a] (3.83)	-0.097[b] (2.58)	-0.102[c] (2.49)
ln P_B	0.074 (0.41)	0.089 (0.30)	0.082 (0.02)
Constant	-1.480 (5.06)	-1.337 (2.65)	-1.510 (2.97)
N	154	154	154

[1] t statistics in parentheses
[a] 1st stage fixed effects model
[b] 1st stage variance components with time trend
[c] 1st stage variance components with no time trend