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Henry G. Grabowski; John M. Vernon

Journal of Law and Economics, Vol. 35, No. 2. (Oct., 1992), pp. 331-350.

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BRAND LOYALTY, ENTRY, AND PRICE COMPETITION IN PHARMACEUTICALS AFTER THE 1984 DRUG ACT*

HENRY G. GRABOWSKI and JOHN M. VERNON
Duke University

IN 1984, Congress enacted a new law that greatly affected the economics of the pharmaceutical industry in the United States. It has been characterized as the most important legislation affecting competition in the pharmaceutical industry since the 1962 Kefauver-Harris Amendments to the Food and Drug Act. This 1984 law, known as the Drug Price Competition and Patent Term Restoration Act (hereinafter the 1984 Act), facilitated the entry of generic drug products after patent expiration while it also restored part of the patent life lost during the premarket regulatory process for new introductions.¹

Market entry by generics was relatively limited prior to 1984 because of costly Food and Drug Administration (FDA) requirements that had to be met by the imitative products. That is, generic drugs often would have to duplicate many of the pioneer's tests to gain market approval after patent expiration. As a result of the 1984 law, generic products need only demonstrate bioequivalence to the pioneer's brand, and generic entry has increased significantly. This has provided a body of very interesting data to analyze the pattern of entry and the pricing strategies followed by the entrants and incumbents.

In this article, we make use of data covering the sales and prices of the pioneer and generic products for eighteen drug products, generally over the time period 1984–88. A number of issues are examined. First,

* Earlier versions of this article were presented at the Second World Congress on Health Economics, the Applied Econometric Association Meetings, the American Economic Association Meetings, and Workshops at Duke University and University of California, Los Angeles. We benefited from the comments from several participants at these meetings as well as those from an anonymous referee.

¹ For an early analysis of this law, see Henry Grabowski & John Vernon, *Longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 76 *Am. Econ. Rev. Papers & Proc.* 195 (1986).

we characterize the typical pattern of generic prices over the early years postentry, the pricing responses by pioneers, and the resulting market shares of the two parties. The current strong interest in theoretical modeling of entry-detering strategies makes this empirical evidence particularly timely.

Another issue that we examine through regression analysis is the relationship between generic entry in a drug category and the perceived profitability of that category. In addition, we consider the structure of prices and market shares among generic firms in the initial period after entry to see whether the lowest-price firms capture the largest shares.

The article is organized as follows. Section I provides some background on the pharmaceutical industry. It also reports on the data that we gathered and describes and interprets the stylized facts of pricing patterns and market-share results. Section II examines the pioneer's pricing response to entry in greater detail. Section III is concerned with the determinants of generic entry and the general structure of generic prices and market shares. Section IV provides a brief summary and concluding comments.

I. PRICE COMPETITION THROUGH GENERIC ENTRY

A. *Background*

Pharmaceuticals have often been cited in the literature as a particularly extreme example of first-mover pricing advantages. Theoretical models by Richard Schmalensee² and Cecilia Conrad³ explain this phenomenon, and F. M. Scherer and David Ross⁴ have provided a recent survey of the empirical literature for the pharmaceutical industry. They conclude that, "under conditions like those found in pharmaceuticals, first movers have natural product differentiation advantages that permit them to charge high prices and retain substantial market shares."⁵

Historically, the strong brand loyalty in pharmaceuticals for innovative brands over generic competitors has been rooted in several institutional considerations. First, physicians generally gained experience with a new drug during its period of patent exclusivity. When patents expired and

² Richard Schmalensee, *Product Differentiation Advantages of Pioneering Brands*, 72 *Am. Econ. Rev.* 349 (1982).

³ Cecilia A. Conrad, *The Advantages of Being First and Competition between Firms*, 1 *Int'l. J. Indus. Org.* 353 (1983).

⁴ F. M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* (3d ed. 1990).

⁵ *Id.* at 592.

cheaper substitutes became available, many physicians were insensitive to the lower-price opportunities and continued to prescribe the brand name product. Furthermore, state antisubstitution laws instituted in the 1950s and 1960s prohibited pharmacists from substituting the cheaper generic brands.⁶

In addition, there were supply-side constraints on generic entry. Under the 1962 Kefauver-Harris Amendments, generic products could not rely on the safety and efficacy evidence submitted by pioneers for post-1962 drug introductions. Unless the relevant data were publicly available in the scientific literature, a generic competitor had to duplicate many of the pioneer's tests to gain approval. Our earlier article found this had a major inhibiting effect on the speed and degree of entry by generic products.⁷ An exception was in the antibiotics category, where entry did not require duplicative safety and efficacy testing. In contrast to other therapeutic categories, antibiotics has been characterized by rapid entry, significant generic prescriptions, and strong price competition.⁸

An analysis by Meir Statman illustrates the historical brand-loyalty advantages possessed by pioneering brand vis-à-vis their generic entrants.⁹ Statman examined twelve (nonantibiotic) drug compounds whose patents expired during the 1970s. He found only marginal market-share gains by generic entrants, even several years after patent expiration. For example, the average pioneer's market share (in revenues) two years after patent expiration was 99 percent. (We should note that, in eight cases, the market share was 100 percent, indicating that no entry took place.) Similar results also emerged from other analyses, with only major antibiotic products systematically deviating from this observed pattern.

Since the mid-1970s, however, there have been a number of institutional changes in pharmaceuticals that should increase the degree of price sensitivity. First, the state antisubstitution laws have been universally repealed. The new substitution laws allow pharmacists to dispense lower-priced generics in the place of prescribed brands (subject to physician override provisions that vary from state to state). In addition, third-party payers such as Medicaid have instituted requirements limiting reimbursements to generic levels. These programs have been imitated by many private insurers. The growth of managed health programs and health

⁶ See Henry Grabowski & John Vernon, Substitution Laws and Innovation in the Pharmaceutical Industry, 43 L. & Contemp. Probs. 43 (1979).

⁷ Grabowski & Vernon, *supra* note 1, at 195.

⁸ David Schwartzman, Innovation in the Pharmaceutical Industry (1976).

⁹ Meir Statman, The Effect of Patent Expiration on the Market Position of Drugs, in *Drugs and Health: Economic Issues and Policy Objectives* (Robert B. Helms ed. 1981).

maintenance organizations (HMOs) have also encouraged generic utilization.

Alison Masson and Robert Steiner have performed an analysis of the initial period after the new state substitution laws.¹⁰ They found that these new laws have indeed increased the market's price sensitivity and the amount of generic usage. Nevertheless, they still observe a surprising degree of brand loyalty for pioneering brands. In their 1980 sample of forty-five drugs, they found that generics accounted for only 23.3 percent of prescriptions. Two recent related studies also find that brand-name products retain large market shares relative to lower-priced generic entrants.¹¹ Both provide an analysis of some of the factors underlying this phenomenon.

None of the existing literature, however, has focused on the post-1984 period.¹² As noted above, the passage of the 1984 Drug Price Competition Act was a key event in facilitating the entry of generic-drug manufacturers into the marketplace. As a result of the 1984 Act, generic firms now enter the market much more rapidly after patent expiration and enter in abundant numbers. The entry situation for all pharmaceuticals now closely resembles what formerly held only for antibiotics. Hence, an analysis of competition between pioneer and generic products in the post-1984 period appears warranted.

B. Data Samples

In order to examine the effect of this entry on market prices and shares, we have assembled data for a sample of eighteen major products first

¹⁰ Alison Masson & Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (Staff report, Federal Trade Commission, Bureau of Economics 1985).

¹¹ Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 *J. Law & Econ.* 299 (1988); and Richard E. Caves, Michael D. Whinston, & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S Pharmaceutical Industry: An Exploratory Analysis*, *Brookings Papers on Economic Activity: Microeconomics* (1991).

¹² The study by Caves, Whinston & Hurwitz, *supra* note 11, examined a sample of thirty drugs with patent expiration between 1976 and 1987. There is a significant overlap with our sample, but several of the drugs in their sample experienced initial competition prior to the passage of the Drug Price Competition and Patent Restoration Act in September 1984. They also employ pooled samples throughout their analysis, thereby generally averaging the experiences of the 1970s and early 1980s chronicled by prior researchers (Statman, *supra* note 9; Masson & Steiner, *supra* note 10). Their very different findings on the post-1984 period are reported below. There is no real attempt to isolate the effect of the 1984 Act beyond a general trend variable that is utilized to capture various structural changes during the 1980s. This variable is insignificant for the drug-store market where the lion's share of the sales for the drugs in our sample are made.

exposed to generic competition over the period 1983–87. The criterion that we used to include a product on this list was fifty million dollars or more in sales at the time of patent expiration. Pharmaceutical sales are highly skewed in sales value.¹³ Given this, generic competition will be directed especially toward the products that have achieved the largest markets.

There were eighteen products that satisfied the threshold criterion of fifty million dollars in sales at the time of patent expiration.¹⁴ For each of the eighteen products, we identified the most popular dosage sizes from the data audits of IMS America Inc.¹⁵ These data sources also provide an estimate of total sales of each dosage size by manufacturers and wholesalers to drugstore and hospital outlets. Sales are expressed in both dollars and physical units. Using this information, we computed prices at various time intervals for the pioneer products, the generic entrants, and the overall market. All of these prices represent the average cost per unit paid by drugstores and hospitals for the most frequently consumed dosage size of each product. We also computed market shares for the pioneer and generic products in units at the same points in time after entry.

C. Descriptive Statistics

The general pattern is that generic products enter at a significant discount to the pioneering product with which they compete. Moreover, in generic prices, there is a strong downward price dynamic over time. By contrast, the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms in the time period after entry. Average market price,¹⁶ however, decreases over time as the lower-priced generic products achieve significant gains in market share.

Table 1 provides a summary of our findings for the eighteen drugs. The first row indicates that the average market price declined by a little more than 10 percent per year in the first two years after generic entry. The second row shows that the average pioneer price index rose 7 percent in the first year after entry and an additional 4 percent in the second year

¹³ Henry Grabowski & John Vernon, A New Look at the Returns and Risks to Pharmaceutical R&D, 36 *Mgmt. Sci.* 804 (1990).

¹⁴ For a list of the products and the date of generic entry, see Table A1 in the Appendix. As also shown in Table 1, drugs with patent expiration after 1984 had entry within the same year as or the year immediately after the patent expiration.

¹⁵ IMS America Inc., U.S. Drug Store and Hospital Sales (1983–87) (hereinafter IMS).

¹⁶ Average market price refers to total dollars for pioneers and generics divided by total units.

TABLE 1
SUMMARY OF GENERIC DRUG FINDINGS

	At Date of Entry	One Year after Entry	Two Years after Entry
Average market price index	1.0	.89 (.10)	.79 (.12)
Average pioneer price index	1.0	1.07 (.07)	1.11 (.10)
Average generic price index	1.0	.78 (.15)	.65 (.16)
Average ratio of generic price to pioneer price	.61 (.11)	.46 (.14)	.37 (.13)
Average generic market share in units	.09 (.09)	.35 (.12)	.49 (.11)
Average number of generic suppliers	N.A.	17.2 (3.8)	25.1 (6.8)

NOTE.—Each value is an unweighted average of the values for the eighteen drug categories. The price indexes take the date-of-entry price as unity. Hence, for example, the average category price two years postentry is 79 percent of its value at the date of entry. The market price equals total dollars of sales for the leader and generics divided by total units. No attempt has been made to deflate prices for inflation. Average generic market share in units at date of entry is the share during the first month of generic marketing. Population standard deviations are given in parentheses; N. A. = not applicable.

after entry. At the same time, generic prices fell to 78 percent of their initial value at the end of the first year and 65 percent at the end of the second year. This steep price decline together with the growing market share obtained by the generics is what causes overall market prices to decline.

The different behavioral responses of pioneering and generic firms causes the gulf in prices between them to increase significantly over time. As shown in Table 1, generic prices averaged 61 percent of the leader price during the first month after entry, and this declined to 46 percent one year after entry and then to 37 percent two years after entry.

The last row in Table 1 shows the movement over time in average market share (in units) achieved by the generics. This increases from 9 percent in the first month after entry to 35 percent one year after entry and to 49 percent two years after entry. Furthermore, two years after entry, these products average seventeen and twenty-five separate generic suppliers, respectively.¹⁷ This is a dramatically higher rate of generic

¹⁷ This refers to the average number of firms supplying products at the wholesale level as reflected in the data audits of IMS (*id.*). It should be noted that the average number of Abbreviated New Drug Applications (ANDAs) approved by the FDA for these products is less than the number of firms marketing the product, so that some firms rely on the ANDAs of other firms. This issue is considered further below.

penetration than observed by Statman in his study of the 1970s.¹⁸ As noted above, Statman found only marginal gains by the generic entrants even several years after patent expiration.

The results reported in Table 1 indicate that average market prices decline as a result of the significant increase in usage of lower-priced generics. In this regard, we computed a descriptive regression of the market price index on generic market share, each measured two years after generic entry. Letting LMP represent the log of the market price index and LGS represent the log of generic market share, the equation is

$$\begin{array}{rcl} \text{LMP} = & -.70 & - .61\text{LGS}, \\ & (-11.10) & (-7.54) \end{array}$$

where the adjusted $R^2 = .78$, $n = 17$, and the t -statistics are in parentheses.

The statistical results are strong. There is a negative relationship that states that the higher generic penetration is, the lower the market price will be. Each 10 percent market-share gain by generics is associated with a market-price decline of 6.1 percent two years after entry.

II. THE EFFECT OF GENERIC ENTRY ON PIONEER PRICES

In this section, we examine the effect of generic entry on the pricing pattern of pioneers. The descriptive statistics in Table 1 indicate merely that pioneer prices in current dollars rose, on average, by 11 percent in the twenty-four months immediately after entry by the first generic competitor. Here, we first examine how pioneer prices were changing before entry and estimate statistically whether the pattern changed after entry. We then compare these results with the patterns for the Producer Price Index (PPI) of the therapeutic category to which each of these products belongs.

The data base used for this analysis consists of annual prices of the eighteen pioneer products in drugstores from 1980 to 1990.¹⁹ In order to have at least five years in the preentry period for all products, the series

¹⁸ Statman, *supra* note 9.

¹⁹ This analysis focuses on drugstore prices; hospital prices are omitted. Since hospital prices are governed by a different process (contractual bidding), they can follow a different trend line than drugstore prices. Moreover, the observed trend in overall drug prices will be influenced by changes in the composition of a firm's hospital and drugstore sales over time. In order to prevent this from confounding changes in the trends associated with generic entry, we focus only on the drugstore sector. The dominant component of sales for the drugs in our sample is through retail pharmacies.

begin in 1978 for one product and in 1979 for four products. We also obtained the PPI for the relevant therapeutic categories for this period.²⁰

A. Regression Analysis

We first estimated regressions of each product's price on time and allowed for a slope change in the postentry period. Nominal prices were deflated by the gross national product implicit price deflator. The specification is given below:

$$\log(\text{Price}) = a_0 + a_1 \text{Time} + a_2 \text{DumT}.$$

Time is the year; DumT is (time - T^*) if Time is greater than T^* and zero otherwise; T^* is the year in which generic entry occurs. The variable DumT is constructed to insure that the time-trend segments join in T^* . Hence, the annual rate of price change is a_1 in the preentry period and ($a_1 + a_2$) in the postentry period.

The estimated coefficient for the rate of price increase, a_1 , is positive and statistically significant for seventeen of the eighteen products.²¹ The other product's estimated coefficient for a_1 is negative but not statistically significant. The average rate of price increases across all products derived from these regressions is 8.4 percent.

The prevailing pattern for the slope-change coefficient in the postentry period is negative. In particular, the estimated coefficient for a_2 takes on this negative sign for fourteen of the eighteen products.²² Only two of these negative coefficients, however, are statistically significant at 10 percent confidence intervals or better. Hence, the conclusion at this stage is that only two products (Haldol and Keflex) qualify as possible cases in which generic entry moderates the pioneer's rate of price increase.

The next step is to compare the patterns for these two products with the pattern for the relevant therapeutic category's PPI. The comparison

²⁰ The study by Caves, Whinston, & Hurwitz, *supra* note 11, used a pooled sample spanning both the pre- and post-1984 period to estimate the effects of entry on the prices of brand-name pioneers. They found a small but statistically significant negative effect. They did not attempt to look at differences across products or differentiate between behavior in the pre- and post-1984 Act.

²¹ While we do not report the actual eighteen regressions here, interested readers can obtain tables of the regressions from the authors. We should note that the one case with a negative coefficient was Motrin, which experienced competition from the introduction of an over-the-counter version during this period.

²² Two of the four products with positive coefficients were also statistically significant indicating that these products actually showed a price-rate increase in the postentry period. These products, however, increased their prices from a base-period rate in the preentry period that was well below the mean for the average rate of increase in their therapeutic class. Hence, this increase is subject to alternative interpretations.

is necessary since a reduced rate of price increase in the postentry period may be due to a general competitive change affecting the therapeutic category as a whole, and it is desirable to try to distinguish this possibility from the specific generic-entry effect.

For each product, a regression for the therapeutic category PPI (with T^* corresponding to the product) was estimated. Haldol's rate of increase was 14.5 percent, falling to 2.5 percent postentry. The deflated PPI for psychotherapeutics had rates of 10.8 percent preentry and 9.0 percent postentry. Since Haldol's relative decline was substantially greater than its therapeutic category, we concluded that generic entry led to the moderation in Haldol's rate of price increase. We concluded the same for Keflex. Its rate of price increase was 6.6 percent preentry and only 4.4 percent postentry. By comparison, its therapeutic category (anti-infectives) had a rate of price increase of 4.3 percent both pre- and post-entry.

Overall, the effect of generic entry on pioneer pricing is not very significant in economic terms. There is no indication, for example, that any pioneers decreased their nominal prices in response to the much-lower generic prices or attempted any kind of entry-detering price strategies. Recall from Table 1 that the ratio of generic to pioneer price averages .37 two years postentry. Furthermore, the highest ratio for any drug in the sample is only .58. Also, the two products that exhibited a statistically significant decrease from prior trends continued to increase their real prices by at least 2.5 percent per year.

B. Interpretation of Findings

Rather than attempting to match the prices of the lower-priced generics, the originators have continued to increase prices at an average rate that exceeds general inflation. It may seem surprising that, in the face of the high rates of generic entry, these firms have generally chosen not to decrease prices. The literature contains some examples of incumbent firms that respond to entry by cutting prices and other examples where they keep prices unchanged. It is, perhaps, the most common view, however, that the incumbents will be forced to lower their prices if entrants enter with especially low prices.

The rationality of pharmaceutical companies not matching lower generic prices can be understood in terms of a segmented-market model.²³

²³ A recent theoretical analysis using a segmented market model of pharmaceutical pricing is presented in Richard G. Frank & David Salkever, *Pricing, Patent Loss, and the Market for Pharmaceuticals* (Working Paper No. 3803, Nat'l Bur. Economic Research, August 1991).

In particular, it is reasonable to assume that the market is segmented between two groups—a price-sensitive group and a group that has strong brand loyalties to the incumbent. The strength of brand loyalties is demonstrated by the fact that, on average, pioneers keep about half their market in units despite the fact that generics are roughly one-third the price of pioneers (measured two years after entry).²⁴ If the pioneer can keep half the market at the unchanged price as opposed to keeping the whole market by lowering the price to one-third its original level, simple calculations show the wisdom of choosing the unchanged-price strategy.²⁵

One qualification to these results should be noted: our eighteen drug products are all oral prescription drugs sold primarily through retail pharmacies to outpatients rather than to hospitals or other institutions. As part of a case involving a contested patent, one of the authors examined the data on pricing patterns for a few injectable products first experiencing generic competition in the period 1986–88. Injectables are sold almost exclusively to hospitals where the degree of brand loyalty is considerably less. In this case, it was found that the more prevalent pattern is for the incumbent firm to cut prices in the face of generic competition, although not to the lowest level of the generic entrants.²⁶ These contrasting patterns for outpatient and inpatient drugs show that pricing policies will be influenced by the relative sizes of the different market segments. If the price-sensitive segment of the outpatient market were to continue to expand in relative terms in the case of future patent expirations, then the

²⁴ Here, of course, we are referring to the ratio of the wholesale price of generics to pioneers—as reported in Table 1. In fact, the relevant price ratio to the ultimate consumer is the retail-drug-store ratio. For our sample, the retail price ratio of generics to pioneers averages 65 percent compared to 45 percent at the wholesale level (measured one year postentry). This suggests that drugstores have higher markups for generics than on the pioneers. In a companion paper that we are in the process of writing, we have analyzed the margins for the generic and pioneer products at retail drugstores. Absolute margins for generics are higher than for pioneers, despite their lower cost to the drugstores. This means that price reductions at the manufacturer level stimulated by the 1984 Act are not fully passed on to the ultimate consumers.

²⁵ Using our average estimate of marginal cost at the date of entry as 25 percent of price (from Section III) and assuming that overall market demand is perfectly inelastic, profits will fall by 89 percent with price cutting and by only 50 percent with the price unchanged. Of course, this type of calculation is meant merely to illustrate the strong incentives for incumbents with significant brand loyalty to pursue a “market-harvesting” rather than a price-cutting strategy. A more extensive analysis would examine the effect of the pioneer’s pricing policies on the rate of generic entry. Some results on this issue are presented in Section III.

²⁶ The selection criteria for this admittedly small sample involved products with annual sales of at least ten million dollars (at the time of entry) and no close substitute or modified version of the product with patent protection. It was found that four of the five incumbent firms decreased their price in the period after generic entry. The average price decline for these branded products was 14 percent one year after initial entry. The sample of products was calcium leucovorin, cytarabine, vancomycin, clindamycin, and methyldopa.

pricing policies for incumbent brands are likely to move in the direction of those observed for the hospital market.

Finally, it is important to observe that firms can employ product-differentiation strategies to thwart generic competition. In at least four cases (Catapres, Inderal, Calan/Isoptin, and Indocin), a significant variant of the original product was introduced around the date of generic entry. The most successful variation was a "slow-release" dosage form of Calan/Isoptin, introduced in December 1986. Within two years, the slow-release version accounted for 81 percent of pioneer sales. Hence, shifting patients from the original formulation, subject to severe price competition, to a new formulation, insulated from price competition, is apparently an important strategy that can be employed at least in some instances.²⁷ This is an issue that warrants further research.

III. THE DETERMINANTS OF GENERIC ENTRY AND PRICES

As observed above, generic prices in our sample move on a rapid downward dynamic path over time. These markets have apparently been characterized by easy entry conditions, at least since 1984. Furthermore, over the long run, one could reasonably expect that entry and competition would push generic drugs prices down to a level approaching the marginal cost of production.

A. *Determinants of Entry*

In this section, we will examine the factors influencing generic entry and prices. In a number of economic models in which a dominant firm experiences entry from a competitive fringe, it is assumed that the rate of entry will be a function of the difference between the dominant firm's price and the potential entrants minimum unit cost.²⁸ In other words, the rate of entry will increase with the entrant's profit opportunities, but it also can be retarded by barriers producing brand loyalty for the dominant firm's product.

We will test whether the degree of entry by the generic firms in our eighteen-drug sample can be explained by such a relationship. In particular, we estimate the following equation:

$$X_{i,t=1} = f(\pi_{i,t=0}, \overline{BL}_{i,t=0}), \quad (1)$$

²⁷ All four modified versions of these products obtained patent protection utilizing the new mode of delivery as the basis. In addition, some obtained parallel market-exclusivity rights as a new dosage form under the 1984 Act. See the U.S. Food and Drug Administration Approved Product List (annual) ("the Orange Book").

²⁸ See, for example, Darius W. Gaskins, Jr., *Dynamic Limit Pricing: Optimal Pricing under Threat of Entry*, 3 J. Econ. Theory 306 (1971).

where

- $X_{i,t=1}$ = number of generic suppliers for product i at the end of first year, $t = 1$;
 $\pi_{i,t=0}$ = profitability to generics of entering the market for product i at time of initial entry, $t = 0$; and
 $\overline{BL}_{i,t=0}$ = a set of brand loyalty entry barrier variables for product i at time of initial entry.

The profitability variable, $\pi_{i,t=0}$, is further defined as the percentage markup of pioneer price over marginal cost at the point of initial entry. In symbolic terms one has

$$\pi_{i,t=0} = (PP_{i,t=0} - MC_i)/PP_{i,t=0}, \quad (2)$$

where

- $PP_{i,t=0}$ = pioneer's price at time $t = 0$; and
 MC_i = marginal cost of production for product i .

A key issue is how to measure the marginal cost of each drug (MC_i) in order to compute their profitability. Our basic procedure was to make the assumption that competition would eventually force the generic price down to marginal cost and to estimate marginal cost as the asymptote toward which the generic price was falling.²⁹

Figure 1 illustrates our approach by plotting the trend in generic prices for the drug Lorazepam. Generics began competing with Lorazepam in September 1985. The average generic-price data is plotted at six-month intervals running from 1985 through mid-1988. Figure 1 also shows a regression of the generic price for Lorazepam on the reciprocal of time. The estimated equation is

$$GP_t = 5.34 + 175.3 (1/t), \quad (3)$$

(2.89) (3.91)

where the adjusted $R^2 = 0.74$. Hence, for Lorazepam, the intercept indicated a long-run marginal cost of 5.34 cents per pill. This is the value that we used for MC for this product.³⁰ This estimated value for marginal cost is 21 percent of the pioneer's price at initial entry.

²⁹ In order to utilize this approach, one needs sufficient entry to insure relatively rapid convergence toward the long-run asymptotic value for generic prices. Otherwise, bias could be introduced into equation (1) if the estimate for the long-run asymptotic value for generic prices was itself a function of entry. Fortunately, given our sample of big selling drugs, there are a large number of entrants in each case (see Table 1).

³⁰ We elected not to deflate the generic prices because of the short time period and concern about a valid price index. For example, the producer price index over this period dropped from a high in 1984 to a low in 1986 and returned to its 1984 value in 1987. This pattern does not seem to be appropriate for pharmaceuticals.

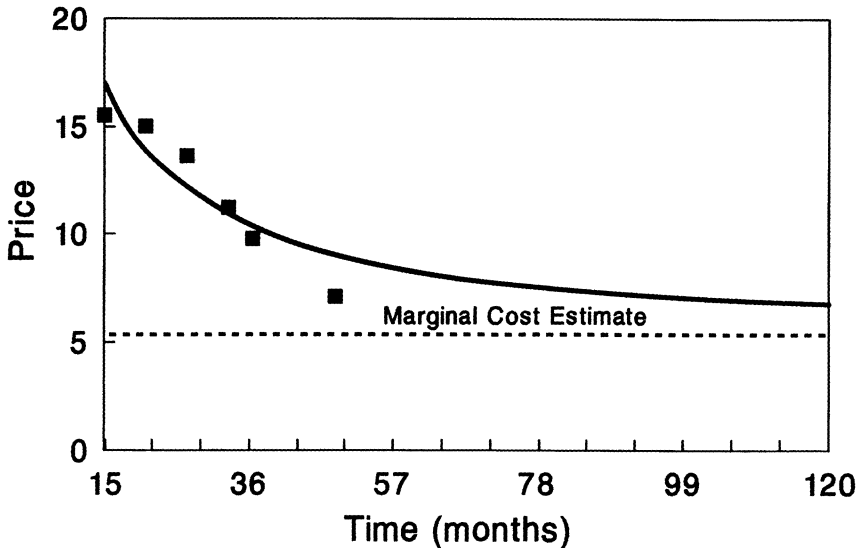


FIGURE 1.—Lorazepam price trend

A similar procedure was employed to calculate the marginal-cost values for the other drugs in our samples.³¹ In one case (clorazepate), we had insufficient data after generic entry to fit a regression and therefore dropped this drug from the sample for the estimation of equation (1). Hence, we use a total of seventeen observations.

Equation (1) also includes brand-loyalty entry variables as potential determinants of entry. As one proxy for brand-loyalty entry barriers, we have followed the approach of Mark Hurwitz and Richard Caves³² and used the number of years the drug was marketed under an exclusive patent. This variable is denoted as YPAT below. Hurwitz and Caves's assumption is that the pioneer's goodwill stock is proportional to the number of years of market exclusivity. A second market-barrier measure included in equation (1) is the promotion to sales ratio of the pioneer in the year immediately prior to initial generic entry. This variable, which is also employed in the prior literature, is denoted as ADS.

In addition to these variables, we also experimented with some dummy variables associated with various drug characteristics relating to the eco-

³¹ In two cases, the regression yielded a negative intercept (diazepam and clonidine). For these two cases we substituted the predicted value of generic price for $t = 60$ (or, five years after generic entry). We should note that in neither case did marginal cost become negative until at least sixteen years postentry.

³² Hurwitz & Caves, *supra* note 11.

conomic incentives to consume lower-priced generic products.³³ For example, one might expect that there would be greater incentives for consumers of drugs for chronic diseases to seek out generic drugs, given the greater inherent savings potential, and hence that more firms would enter such markets, other things being equal. Our sample of drugs does not include many products for acute illnesses, so this was not a fruitful dichotomy. In addition, we also employed therapeutic class dummies (for example, cardiovasculars, psychotherapeutics, and so on) as proxies for differences in underlying characteristics that might influence generic usage, but none of these variables proved significant and they were omitted from our final specification.

The estimated coefficient values for equation (1) are given below. The prefix "L" indicates the log of the variable previously defined above:

$$\begin{array}{rcccc} LX = & 2.96 & + & .62L\pi & - & .06LADS & - & .04LYPAT, & (4) \\ & (11.33) & & (3.93) & & (-1.49) & & (-.40) \end{array}$$

where the adjusted $R^2 = 0.48$, and $n = 17$. The estimated equation (4) indicates strong support for higher expected profits leading to greater entry. That is, the t -statistic for the coefficient of $L\pi$ is 3.93. Given the logarithmic specification, the estimated value can be interpreted in terms of percentage changes. In particular, a 10 percent decrease in profit margins at the time of entry gives rise to a 6 percent decrease in the number of entrants at the end of the first year. This estimated relation is quite consistent with the observed tendency on the part of the firms in our sample not to attempt any real entry deterrence through significant price decreases. Given that the mean number of generic suppliers after one year in our sample is seventeen, equation (4) indicates that it would take, on average, very significant price cuts and margin decreases to deter one or two additional suppliers from entering the market.³⁴

While the two brand-loyalty variables have the expected negative effect, neither is statistically significant.³⁵ The t -statistic of LADS, the log of advertising to sales of the pioneer, is relatively higher than that of LYPAT, but neither is significant at the usual level required. The lack of significant explanatory power for these entry-barrier variables is consistent with the high degree of entry observed across the board. The minimum number of entrants at the end of the first year is ten firms. Given the

³³ Size of the market in sales was also attempted. It was not significant—probably because all of our drugs have large sales volumes. The simple correlation between the number of generic suppliers and size is only .11.

³⁴ At the sample mean, a decrease of 10 percent in a firm's profit-margin value would deter approximately one entrant using the coefficient values of equation (4).

³⁵ One reason for the poor performance of YPAT may be that only two of the seventeen markets had fewer than twelve years of market exclusivity—hence, there may not have been enough observations in the low numbers of years to detect a difference.

relatively large sales volume of the products in our sample (fifty million or more in sales at the time of entry), neither the costs to obtain FDA approval or other factors appear to be significant entry barriers.³⁶

B. The Variability of Shares and Prices across Generic Firms

While average generic prices move on a steady downward path over time, there is considerable variation in the prices charged by particular firms at any point in time. In this section, we provide a very preliminary analysis of the structure of market prices and shares across the generic firms in our sample. In particular, we are interested in examining whether the firms with the lowest prices achieve the highest shares, as one would expect in a competitive commodity-type business. In addition, we are interested in investigating what other factors might explain firm shares in the generic submarket.

The analysis of generic prices in this section, as in the case of pioneer prices in Section II, is focused on the drugstore market. This eliminates one major source of variability in generic drug prices. Even concentrating solely on the retail drugstore, there is still considerable variability in generic drug prices. Detailed data are presented in the Appendix that show the mean minimum and maximum prices in the generic submarket for each of the eighteen products in our sample. One indication of the significant variability in generic prices is the fact that, in half of the eighteen generic products, the maximum price observed is over 50 percent greater than the minimum price, as measured one year after initial entry.

With this degree of price variability, a key economic question is whether firms with the lowest prices are gaining above-average market shares. This is the normal situation in these markets: the firm with the very lowest price had the largest market share one year after initial entry for nine of the eighteen products in our sample. Nevertheless, while price is obviously a critical factor in explaining generic shares, there are clearly other factors at work as well. For example, several firms' products had prices more than 50 percent greater than the minimum and still had a significant share of the generic market.³⁷

³⁶ We also estimated equation (4) using the number of ANDAs approved by the FDA during the first year rather than the actual number of generic suppliers (see note 4 *supra*). This variable was also related to profitability in a statistically significant fashion, but the *t* values and overall fit of the equation were reduced. In addition, we further observed that the decline in the market shares of pioneering brands was more strongly correlated with the number of suppliers than with the number of ANDAs. Hence, the former variable would appear to be the more preferable one to utilize in the present situation.

³⁷ For four of these products, the actual market leader's price was more than 50 percent higher than the minimum price, and these firms attained market shares of between 30 and 40 percent one year after initial entry.

We considered two possible explanations of the generic products with above-average prices and market shares. First, it could reflect a preference for so-called branded generics—that is, generics marketed by a subsidiary of a research-oriented pharmaceutical firm under the parent firm's name. A preliminary analysis of this issue suggested that the market indeed was generally willing to pay a premium for the branded generics, but these products overall were able to obtain only very small shares in the eighteen markets. In only one instance was the market leader a branded generic, and branded generics achieved only an 11.3 percent average share of the generic submarket across all eighteen products.

A second hypothesis for the large shares obtained by certain higher-priced generic firms is the first-mover advantage. In particular, industry representatives suggest that, if a generic firm can get several months lead time over its rivals, it will have a significant market advantage.³⁸ An examination of the market leaders in our sample indicates that for virtually all products, the market leader is an early entrant.³⁹ There are few cases, however, where the initial lead time is more than a month or two and several products are characterized by simultaneous entry within the same calendar month.⁴⁰ In general, our data are consistent with the hypothesis of first-mover advantages in generic drug markets, but our sample does not allow one to explore this issue in a very comprehensive or formal way because, for most products, there is relatively rapid entry by several competitors.

The preliminary analysis of generic prices and market shares undertaken in this section indicates that price is undoubtedly the most important variable explaining generic shares, but that other factors, such as first-mover advantages and perceptions of quality differences among suppliers, may also be important in specific circumstances.⁴¹ This would appear to be a significant and interesting issue for future research.

³⁸ This results from the fact that, once pharmacies begin stocking a particular generic supplier's product, they will have a preference to continue using that product (given its recognizable shape, size, and color to repeat-purchase customers). Under this hypothesis, while the first mover will still have to respond to the lower prices of later entrants, it will have significant advantages in terms of retaining high market shares, and it also may be able to trade off market share and prices over the short run.

³⁹ The market leader at the end of the first year is the first (or tied for first) entrant in one-half of the eighteen cases. In four other cases, the market leader entered within one month of initial entry. Moreover, in no case did the market leader enter with a lag of more than three months from initial entry.

⁴⁰ The initial entrant's lead time is longer than three months for only one product. In this case, the original entrant had more than half the drug-store market after one year at a price that was not the lowest in the market but one below the mean for that product.

⁴¹ Generic firms are permitted a 20 percent variance plus or minus by the FDA in their bioavailability compared to the pioneering brand. This may also explain usage patterns for particular products.

IV. SUMMARY

As a result of the 1984 Act and related factors, the degree of generic competition experienced by major products upon patent expiration has increased dramatically in the United States. We performed an analysis of eighteen drugs first experiencing generic competition after 1983. These products have been subject to a wave of generic competition leading to a significant loss in market share to generics that sell at much lower unit prices. The typical product in our sample lost about half the market to generics two years after initial entry.

The pioneering firms did not attempt to deter entry through their pricing strategies. Rather, in most cases, the firms continued to increase their prices at the same rate as prior to entry. Only a few products experienced statistically significant price-trend declines postentry relative to other products in their therapeutic class. The decisional approach of the pioneering firms therefore could be characterized as a "harvesting" strategy, that is, the maintenance of premium price positions while market shares erode over time.

We also made several interesting findings with respect to generic competition. First, our regression analysis on the determinants of entry did not indicate the existence of any significant barriers to entry. The number of suppliers across these products was found to be statistically related to the profitability of entry. After initial entry occurred, we found that average generic prices for each of the products moved on a sharp downward path over time. There was, however, considerable variability in the distribution of generic prices for each product. As expected, we found that the lowest-price generic supplier captured the largest market shares for several of the products. Nevertheless, other factors also appeared to be at work in determining the market shares of generic firms (for example, perceived quality differences, first mover advantages, and so on). This is an interesting issue for future research.

In summary, the 1984 Act has generally achieved one of its primary objectives—facilitating the availability of low-price generic drug substitutes to consumers after patent expiration. At the same time, it has also significantly curtailed the expected revenues to innovative firms from the latter phases of their drug's life cycle. Whether this will have a significant deterrent effect on future new drug innovation remains an open issue. The 1984 Act sought to avoid this outcome by increasing patent terms for some new-drug introductions. The net effects of the 1984 law on the incentives for drug innovation is another important question for future research.

APPENDIX

TABLE A1

GENERIC DRUGS IN SAMPLE

Generic Name	Pioneer Brand Name	Manufacturer	Year of Patent Expiration	Date of Generic Entry
Thioridazine	Mellaril	Sandoz	N.A.	May 1983
Indomethacin	Indocin	Merck	1981	May 1984
Tolazamide	Tolinase	Upjohn	N.A.	October 1984
Methyldopa	Aldomet	Merck	1984	November 1984
Chlorpropamide	Diabinese	Pfizer	1984	November 1984
Ibuprofen	Motrin/Ruifen	Upjohn/Boots	1985	July 1985
Lorazepam	Ativan	Wyeth	1985	September 1985
Diazepam	Valium	Roche	1985	September 1985
Propranolol	Inderal	Ayerst	1985	September 1985
Metoclopramide	Reglan	Robins	1985	July 1985
Flurazepam	Dalmane	Roche	1985	February 1986
Doxepin	Sinequan/Adapin	Pfizer/Pennwalt	1986	April 1986
Haloperidol	Haldol	McNeil	1986	June 1986
Clonidine	Catapres	Boehringer Ingelheim	1986	July 1986
Verapamil	Calan/Isoprin	Searle/Knoll	1986	September 1986
Perphen/Amityptiline	Triavil/Etrafon	Merck/Schering	1986	September 1986
Cephalexin	Keflex	Lilly	1987	April 1987
Clorazepate	Tranxene/Azene	Abbott/Endo	1987	June 1987

SOURCE.—Food and Drug Administration Approved Drug Product List (Orange Book) (1981–87) for year of patent expiration; PMA Patent Status of Medicinals; IMS America, Inc., U.S. Drug Store and Hospital Market (1983–87) for date of generic entry.

NOTE.—N.A. = not available.

TABLE A2
THE VARIABILITY IN GENERIC PRICES

GENERIC DRUG	GENERIC MARKET PRICES		GENERIC MARKET LEADER	
	Mean	Range	Price	Share
Thioridazine	10.4	8.2-12.4	12.1	17.7
Indomethacin	13.4	10.5-15.2	10.5	28.8
Tolazamide	18.3	16.0-22.1	19.1	25.0
Methyl dopa	9.8	9.5-12.9	9.5	86.3
Chlorpropamide	5.0	2.6-7.6	3.2	27.0
Ibuprofen	7.8	7.8-7.8	7.8	60.6
Lorazepam	13.9	11.9-16.9	11.9	24.5
Diazepam	5.6	4.1-6.8	6.2	34.7
Propranolol	7.6	6.4-9.9	6.4	43.6
Metoclopramide	10.9	8.1-16.7	8.1	21.3
Flurazepam	15.0	13.9-17.4	15.0	40.0
Doxepin	9.9	9.2-12.5	9.8	54.1
Haloperidol	36.1	24.5-42.3	37.5	40.8
Clonidine	6.3	4.0-9.8	9.8	31.6
Verapamil	12.9	11.5-14.8	11.5	57.9
Perphen/Amitriptyline	14.0	7.8-20.9	7.8	20.0
Cephalexin	50.4	20.1-76.9	76.9	30.5
Clorazepate	18.5	15.2-21.7	19.9	30.8

NOTE.—Prices are expressed in cents per pill of the most popular dosage size for each drug at a point in time approximately one year after entry; these prices represent the cost to pharmacies of generic drugs purchased through wholesale distributors. Generic market leader shares are computed as a percentage of the total units supplied by all firms other than the brand-name pioneer's product. Data are based on IMS America, Inc.'s monthly drugstore sales audit for the last month in each quarter (that is, March, June, September, and December) that is the closest to one year after entry for each drug.

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