Other

Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry

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Objective. To analyze the effect of multiple-source drug entry on price competition after patent expiration in the pharmaceutical industry.

Data Sources. Originators and their multiple-source drugs selected from the 35 chemical entities whose patents expired from 1984 through 1987. Data were obtained from various primary and secondary sources for the patents' expiration dates, sales volume and units sold, and characteristics of drugs in the sample markets.

Study Design. The study was designed to determine significant factors using the study model developed under the assumption that the off-patented market is an imperfectly segmented market.

Principal Findings. After patent expiration, the originators' prices continued to increase, while the price of multiple-source drugs decreased significantly over time. By the fourth year after patent expiration, originators' sales had decreased 12 percent in dollars and 30 percent in quantity. Multiple-source drugs increased their sales twofold in dollars and threefold in quantity, and possessed about one-fourth (in dollars) and half (in quantity) of the total market three years after entry.

Conclusion. After patent expiration, multiple-source drugs compete largely with other multiple-source drugs in the price-sensitive sector, but indirectly with the originator in the price-insensitive sector. Originators have first-mover advantages, and therefore have a market that is less price sensitive after multiple-source drugs enter. On the other hand, multiple-source drugs target the price-sensitive sector, using their lower-priced drugs. This trend may indicate that the off-patented market is imperfectly segmented between the price-sensitive and insensitive sector. Consumers as a whole can gain from the entry of multiple-source drugs because the average price of the market continually declines after patent expiration.

Key Words. Multiple-source drugs, patent, Drug Price Competition and Patent Term Restoration Act, price competition, pharmaceutical industry

Over the past several years, many pharmaceutical industry regulations have focused either on containing total drug expenditures through increased price competition or on stimulating innovation. The balance between competition and innovation is not easy to maintain, because it depends on a complex tradeoff between patent benefits and costs. Patents protect pioneering firms from pure price competition, enabling them to recover sunk research and development expenditures, thereby encouraging further research investment. However, a lack of competition leads to market prices in excess of the marginal cost of the product. In order to address both issues—stimulating price competition after patent expiration and encouraging innovatory research and development activities—the Drug Price Competition and Patent Term Restoration (DPC/PTR) Act was passed in 1984 (Flannery and Hutt 1985; Shacknai 1985). Because competition patterns subsequent to patent expiration were expected to change after the DPC/PTR Act passed, this study evaluates the effect of multiple-source drugs[1] (MSDs) entry on price competition in the off-patented market.

BACKGROUND

Pricing behavior in the pharmaceutical industry is a complex issue, which is highly dependent on how the market is classified and defined. Satterthwaite (1979) and Rosenthal (1980) developed a general theoretical model to explain the effect of new firm entry on prices in monopolistically or oligopolistically competitive markets. They suggested that the entry of new firms into a particular market shifts the demand curve for the originator, making it less elastic. This oligopolistic model has been applied to the pharmaceutical industry to explain price competition after MSD entry into markets (Reekie 1975). However, the application of these kinds of models to the pharmaceutical industry has been criticized because conditions of competition in the industry are complex, and price competition does occur in the multiple-source market after patent expiration (Cocks and Virts 1974; Schwartzman 1979).

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One of the complications in price competition is the difference in pricing strategies used by originators and MSDs. Most originators choose a price-skimming strategy to maximize profit because their demand is inelastic, but MSDs choose a penetration pricing strategy because the demand that they face is elastic (Reekie 1978; Teeling-Smith 1975). However, it has recently been argued that the price of a new drug depends on the extent of its therapeutic advance (Lu and Comanor 1998). A drug representing important therapeutic gains chooses a price-skimming strategy, while a drug that duplicates the actions of currently available drugs prices at comparable levels.

Although an off-patented originator initially faces more competition than it did before patent expiration occurs, it can still maintain its price and yet keep a significant portion of its market share. This is possible because (1) new entrants face the high cost of disseminating the information necessary to assure consumers that the MSDs are therapeutically equivalent to the original product (Scherer 1985); and (2) patents, in effect, give an originator a first-mover advantage, especially if the originator invests heavily in promotional expenditures to develop brand loyalty (Santerre and Neun 1996). If the pioneers, during the time the product is protected by patent, convince consumers that their brand performs satisfactorily, consumers will consider the product a standard and may not rationally judge subsequent entrants. Thus, late entrants in the market do not always expect pioneering brands to lower their prices (Schmalensee 1982). A study by Statman (1981) revealed that, although MSDs captured increasing market share, only a quarter of originators lowered their prices per prescription in drug stores after patent expiration.

The dramatic changes caused by passage of the DPC/PTR Act have inspired many research studies. Caves, Whinston, and Hurwitz (1991) found that the prices of originators initially increased, even after patent expiration, until an MSD entered the off-patented market. However, the originator prices started to decline modestly with an increase in the number of generic entrants. Grabowski and Vernon (1992, 1996) also found that originators continued to increase prices at the same rate as before MSD entry, despite the fact that MSDs entered the market offering huge discounts and continued to decrease their prices sharply over time.

Frank and Salkever (1992) developed a theoretical model that an originator's price will increase if MSD entry leads to a substantial decline in the price elasticity of the originator's demand. If the MSD entrants rely on price discounts to appeal to the price-sensitive sector, then the residual demand left to the originator will be more price inelastic than the overall market

demand. Frank and Salkever's theory is consistent with the empirical findings of Grabowski and Vernon.

Many previous studies examined the effect of patent expiration on price competition, but their conclusions are not always consistent. The inconsistencies may stem from the fact that competition patterns changed after the passage of the DPC/PTR Act, and definition of the markets studied was different. The economic market for this study is the market of pharmaceutical agents whose patents have expired, and who face competition from other pharmaceutical companies that produce the same chemical entity, either under a different brand name or as a generic. This is because generic substitution usually occurs within the same chemical entity and, to a lesser extent, among therapeutic alternatives (James 1981; Schwartzman 1976).

METHODS

Study Model

This study models the price of a drug as $P = f\ (D,\ C,\ V)$, where D is the demand for the drug, C is the cost of producing the drug, and V is a vector of competition. The demand for a drug reflects consumers' price sensitivity and knowledge of the substitutability among drugs, both of which differ depending on the class of the trader. A retail trader, such as a retail pharmacy or a consumer, is less price sensitive than an institutional trader such as a hospital or a managed care firm, because of prescription drug coverage by third-party payers and patient preferences for "higher-quality" drugs. Physicians often prescribe brand name drugs, because they are more familiar with brand names and they often lack information on drug prices and on generic substitutability (Hurwitz and Caves 1988). In contrast, hospitals and managed care organizations often mandate generic substitution and occasionally therapeutic substitution of prescription drugs by creating and enforcing formularies.

Average costs and marginal costs change with volume because of the learning curve and economies of scale in many industries. However, economies of scale in the drug production process have been found to be unimportant (Reekie 1978; Walker 1971). As a result, the originator's pricing strategy is more market-oriented than cost-oriented.

The level of competition in a market can be affected by the degree of substitution occurring for prescribed drugs, reactivity of competitors, and regulatory constraints. During the period of patent protection, originators can

set a monopolistically competitive price to maximize profits. Originators may also engage in price discrimination attributable to different demand elasticities of various trade classes, but information asymmetries between the originator company and buyers may prevent perfect price discrimination.

The condition for the expected price of a market before and after patent expiration can be mathematically written as:

$$E(PO_{i,t}|MSMD_{i,t} = 0) \tag{1}$$

$$E\left[\sum_{j=1}^{n}(PM_{i,j,t} \times MSEMD_{i,j,t}) + PO_{i,t}(1 - MSMD_{i,t})|MSMD_{i,t} > 0\right] \tag{2}$$

where $PO_{i,t}$ is price per defined daily dose[2] (DDD) of originator in market i at time t, $MSMD_{i,t}$ is the market share of all multiple-source drugs in terms of DDD in market i at time t, $PM_{i,j,t}$ is price per DDD of each multiple-source drug j in market i at time t, and $MSEMD_{i,j,t}$ is the market share of each multiple source drug j in terms of DDD in market i at time t.

Equation 1 is the expected price of the originator if an MSD does not enter the market before patent expiration, that is, *MSMD* is equal to 0. Equation 2 represents the expected weighted average price of the market after any MSDs enter the market, that is, *MSMD* is greater than 0.

After patent expiration, the price and quantity sold of both originators and MSDs depend on the market structure of the price-sensitive and insensitive subsectors. An off-patented market can be classified into one of the following categories: (a) an undifferentiated market, (b) a perfectly segmented market, or (c) an imperfectly segmented market. An undifferentiated market can be characterized as one where the originator has not developed brand name loyalty or other advantages. Entry of MSDs increases competitive pressures and reduces prices for all equivalent drugs. In fact, the price of an off-patented originator in this market should be the same as an MSD, because competition is based solely on price and each brand is treated as equivalent.

In a perfectly segmented market, an originator is perceived as completely different from its competitors by some customers. Therefore, the market has two distinct subsectors: price elastic and price inelastic. Because consumers in one sector of this market do not react to the price charged in the other sector, the originator can continue to charge higher prices in the relatively inelastic sector, while MSDs charge lower prices in the elastic sector.

In an imperfectly segmented market, off-patented drugs are only slightly differentiated and are very close substitutes. Price competition that affects one sector may also affect the other because the imperfectly segmented sectors are linked through cross-price effects. Therefore, the entrance of MSDs leads to diverging price trends rather than to a downward trend of all prices (regardless of sector) together. This model was applied in this study because it is expected that consumers eventually switch from the originator to an MSD as the price of the MSD decreases and consumers learn that MSDs are perfect substitutes for the originator.

The following regression equations were developed to analyze the impact of MSD entry on the prices of originator drugs:

$$PO_{i,t} = f(APM_{i,t}) \tag{3}$$

$$APM_{i,t} = g(HHI_{i,t}, NM_{i,t}, YAPE_{i,t}, MKTC_i) \tag{4}$$

Where $APM_{i,t}$ is the average price of MSDs in market i at time t, $HHI_{i,t}$ is the Herfindahl index in market i at time t, $NM_{i,t}$ is the number of multiple-source drug firms in market i at time t, $YAPE_{i,t}$ is the number of years after patent expiration in market i at time t, and $MKTC_i$ is a vector related to the characteristics of market$_i$.[3]

The average price of MSDs is a function of market concentration[4] and the number of years since patent expiration. The vector of the characteristics of particular markets also affects the average price of the MSDs because the perceived severity of an illness and the duration of therapy necessary to treat a condition may influence the consumer's price sensitivity to the drug. For example, if a drug is more frequently used for mild and chronic diseases, consumers are more sensitive to the price of that drug. Increased sensitivity to drug prices results in increased elasticity of demand, which in turn reduces the average price for the corresponding MSDs.

Equations 3 and 4 suggest that the number of MSDs has no direct effect on the originator's demand; however, the average price of MSDs does. Therefore, these equations can be combined for the price of the originator as a function of the variables of the average price of the corresponding MSDs:

$$PO_{i,t} = f[g(HHI_{i,t}, NM_{i,t}, YAPE_{i,t}, MKTC_i)] \tag{5}$$

The preceding equation suggests that $\partial(PO)/\partial(NM)$ would be greater than 0 if the entry of an MSD caused the demand curve of the less price-sensitive market to be more inelastic (i.e., steeper) by lowering the average price of MSDs. It is expected that the decline in the price of MSDs leads to

increase in the price of the originator in the progressively more price-inelastic sector, irrespective of time after patent expiration.

Since all exogenous variables that influence the price of MSDs are the same as the variables affecting the average price of MSDs, the specification for the price of MSD j in market i at time t ($PM_{i,j,t}$) can be written as:

$$PM_{i,j,t} = f(HHI_{i,t}, NM_{i,t}, YAPE_{i,t}, MKTC_i) \quad (6)$$

The price difference between the originator and the multiple-source drugs in market i at time t ($PDIF_{i,t}$) is:

$$PDIF_{i,t} = f(HHI_{i,t}, NM_{i,t}, YAPE_{i,t}, MKTC_i, MKGRD_{i,t}) \quad (7)$$

Where $MKGRD_{i,t}$ is the market growth rate of market i in terms of DDD from time $t-1$ to time t. While originator firms invest in promotional activities during the temporary monopoly established by the patent, the market grows (Santerre and Neun 1996). However, after the patent expires, originator firms usually reduce or discontinue these promotional activities causing the rate of growth to decline in the off-patent period. Therefore, it is expected that as the market growth rate decreases, the price difference will be greater.

The rate of entry of MSDs is a function of potential profit, size, and growth rate of a market (Mansfield 1962; Yip 1982). A rapidly expanding market attracts more firms to enter the market. However, market entry into a static or slow-growing market is more difficult and costly to achieve, because market share gains must be made at the expense of competitors who are motivated to defend their share (Lidstone and Collier 1987). The larger the market size, the more MSDs will enter, and entry may not occur unless the market is much greater than the size of the monopoly break-even level of demand (Bresnahan and Reiss 1990). The larger the potential profitability of the off-patented market, the more likely MSDs are to enter the market, leading to greater price competition. The following equation is used to test the number of MSDs in market i at time t (i.e., $NM_{i,t}$):

$$NM_{i,t} = f(MKGRD_{i,t}, MKTSZ_{i,t}, PRO_i, YAPE_{i,t}, MKTC_i) \quad (8)$$

Where $MKTSZ_{i,t}$ is size of market i relative to total prescription drug market at time t, and PRO_i is potential profit in market i.

DATA SOURCES

Data were collected from the following sources: The Pharmaceutical Manufacturers Association's *Statistical Fact Book* and *Reports of Patents on Medical*

Products; the Office of Technology Assessment; the IMS U.S. Drugstore and U.S. Hospital database; and the Food and Drug Administration. Sample drugs were selected from chemical entities whose patent expired during the four-year period from 1984 through 1987. This period was chosen because the DPC/PTR Act had just lowered entry barriers for MSDs. Eighty-three chemical entities that went off patent during this period were identified; after exclusion 35 chemical entities were selected[5] (see appendix for sample drugs).

Specific data for each manufacturer's sales in dollars and the number of units sold in the United States were pooled for each drug, strength, and dosage form. Drug sales and unit volumes represented combined sales to drugstores and hospitals. The data do not include sales made directly to other sources, such as mail order distributors, health maintenance organizations, and governments.

DATA ANALYSIS

The utilization of panel data for this study provides several advantages over the use of conventional cross-sectional or time-series data, but it poses issues related to heterogeneity and selectivity biases (Hsiao 1992). Because ignoring parameter heterogeneities among cross-sectional units could lead to inconsistent or meaningless estimates of interesting parameters, the usual least squares method would lead to potentially biased estimates. To resolve these problems, regression models were applied using the ordinary least square (OLS), random effects, and fixed effects models. The random effects model assumes individual specific constant terms to be independently distributed across drug classes, while the fixed effects model views the differences across drug classes as parametric shifts of the regression function. The appropriate model between the fixed effects and random effects models was determined using the Hausman test for orthogonality of the random effects model and the regressors (Greene 1996).

RESULTS

Descriptive Statistics

Table 1 presents the trends of the originators, MSDs, and total markets before and after patent expiration. The dollar sales volume for the market initially increased after patent expiration, but later it declined. However, the quantities sold in the off-patented market continued to increase. By the fourth year after

patent expiration, originators' sales had decreased approximately 12 percent in dollars and 30 percent in quantity. During the same period, the originators' market share had declined to 78 percent of its original market share in dollars and 57 percent in quantity.

Similar trend comparisons between originators and MSDs are presented in Table 2. The prices of MSDs were about 70 percent of the originator price at the time of MSD entry, but they declined rapidly to approximately 30 percent of the originator price three years after entry. MSDs increased their sales twofold in dollars and threefold in quantity; they possessed approximately half of the total market (50.45 percent) in quantity and one-quarter of the total market (25.17 percent) in dollars three years after their entry into the market.

Regression Results

Regression results from the study model with hypothesized explanatory variables are presented in this section. Because prices are different across multiple-source markets, both the price of the originator and the average price of multiple-source drugs were normalized to obtain a more consistent and meaningful estimate of the coefficient.[6]

The regression results in Table 3 indicate that the prices of the originator and MSDs were negatively correlated ($p < .01$), with a one percent decrease in the normalized average price of MSDs directly resulting in a 0.56 percent increase in the normalized price of the originator. The average price of the MSD depended significantly on the number of years that had passed

Table 1: Trends of Originators and Their Markets Before and After Patent Expiration

*Year**	*−4*	*−3*	*−2*	*−1*	*0*	*1*	*2*	*3*	*4*
Sales ($)									
Originators	0.68	0.72	0.82	0.93	1.00	0.98	0.97	0.93	0.88
Total market	0.66	0.70	0.80	0.91	1.00	1.04	1.07	1.06	1.06
Number of DDDs									
Originators	0.92	0.93	0.98	1.01	1.00	0.93	0.87	0.78	0.69
Total market	0.88	0.89	0.94	0.97	1.00	1.05	1.09	1.12	1.14
Originators' Market Share (%)									
Dollars ($)	99.08	99.20	99.30	99.35	97.32	91.47	87.02	82.71	77.72
Number of DDDs†	99.10	99.22	99.32	99.35	95.78	85.46	76.21	66.13	56.84

* Year relative to patent expiration; 0 is year of patent expiration.

†DDD = defined daily dose.

Table 2: Trends of Multiple-Source Drugs (MSDs) After Market Entry

*Year After Entry**	*0*	*1*	*2*	*3*
Price per DDD Ratio				
MSD to originator	0.69	0.56	0.45	0.32
MSD to chemical market	0.70	0.63	0.58	0.49
Sales ($)				
MSD		1.00†	1.84	2.07
Originator		1.00	0.88	0.84
Total market		1.00	0.94	0.88
Sales in Number of DDDs				
MSD		1.00†	2.15	3.14
Originator		1.00	0.82	0.75
Total market		1.00	1.02	1.05
Market Share (MS) in Dollars‡		(%)	(%)	(%)
MS of MSD as % of originator		22.41	36.38	38.93
MS of MSD as % of total market		17.09	24.38	25.17
Market Share (MS) in Number of DDDs‡				
MS of MSD as % of originator		44.01	87.10	129.84
MS of MSD as % of total market		27.36	41.76	50.45

* Number of years after entry of MSDs; 0 is the year of MSD entry.

† Index is based on first full year of sales after entry. Since MSDs enter the market throughout the year, entry-year sales cannot be compared to consecutive year's sales.

‡ Market share of an MSD for each year is based on the fiscal year sales of MSDs. Depending on the time of entry, the first year's sales of an MSD is for a partial year.

since patent expiration ($p < .01$). As the off-patented markets became less concentrated, the average price of MSDs in the market decreased, but the impact of market concentration variables such as HHI and NM were insignificant for the average price of MSDs.

The results of Equation 5 show the indirect effects of the study variables on the price of the originator. There were no significant direct effects of the HHI and the number of MSD firms (NM) on the price of the originator. Instead, as the model predicted, the HHI and the number of MSD firms affected the price of the originator through the average price of the MSDs. As the number of MSD firms increases, the market becomes less concentrated. Then, as the average price of MSDs decreases, the PO increases. During our study period, the average price of MSDs decreased 0.049 units each year after patent expiration, but in contrast, the originator price increased 0.073 units each year.

Table 3: Regression Results

	Dependent Variables					
Equation	*Price of Originator*† *(3)*	*Average Price of MSDs*‡ *(4)*	*Price of Originator (5)*	*Price of MSDs (6)*	*Price Difference*§ *(7)*	*Number of MSDs (8)*
Appropriate Model††	*Fixed*	*Fixed*	*Fixed*	*Random*	*Fixed*	*Fixed*
Normalized Average MSD	−0.5589 (−5.798)***	–	–	–	–	–
Herfindahl Index	–	0.00001 (1.105)	−0.000005 (−0.181)	0.00003 (5.497)***	0.00002 (5.479)***	–
Number of MSDs	–	−0.0030 (−1.062)	−0.0019 (−0.265)	−0.0034* (−1.773)	−0.0030 (−1.975)**	–
Market Growth Rate (in quantity)	–	–	–	–	0.0016 (4.209)***	0.0237 (0.673)
Market Size	–	–	–	–	–	0.6856 (0.317)
Profitability	–	–	–	–	–	1.1496* (0.189)
Severity of Illness	–	–	–	0.0786 (0.575)	–	–

(*continued*)

Table 3: *Continued*

	Dependent Variables					
Equation	*Price of Originator*† *(3)*	*Average Price of MSDs*‡ *(4)*	*Price of Originator (5)*	*Price of MSDs (6)*	*Price Difference*§ *(7)*	*Number of MSDs (8)*
Appropriate Model††	*Fixed*	*Fixed*	*Fixed*	*Random*	*Fixed*	*Fixed*
Duration of Treatment	–	–	–	−0.1815 (−1.309)	–	–
Number of Years After Patent Expiration	–	−0.0489 (−4.888)***	0.0725 (3.260)***	−0.0494 (−8.161)***	0.0704 (−14.705)***	4.0537 (19.428)***
Constant	–	–	–	0.5997 (5.505)***	–	–
F-value	33.617	101.457	9.723	124.754	413.300	114.709
Significance	.0001	.0001	.0001	.0001	.0001	.0001

Note: *t*-statistics are in parentheses: *Significant at $\alpha = .10$; ** significant at $\alpha = .05$; *** significant at $\alpha = .01$.

† Price of originator is normalized by dividing PO_t by $PO_t = 0$.

‡ Average price of MSDs is normalized by dividing APM_t by $PO_t = 0$.

§ Price difference between originator and MSDs is normalized by dividing PM_t by PO_t.

†† Appropriate model was selected by the Hausman test.

Regression results in Table 3 show that the price of MSDs is significantly influenced by the Herfindahl index ($p < .05$), number of MSDs ($p < .10$), and number of years after patent expiration ($p < .01$). The less concentrated the market, the lower the price of the MSDs. Whenever multiple-source drugs were more frequently used to treat severe and acute illnesses, the consumers were less sensitive to the price, causing the price of MSDs to be relative higher than those MSDs frequently used in mild and chronic cases. However, these variables did not have significant effects.

The results from the model for the price difference between originators and MSDs (Equation 7) is provided in Table 3. Because the absolute price differences between the originator and the MSDs vary across different chemical entities, the price difference was normalized by dividing the price of the MSD by the price of its originator rather than by using the simple, absolute price differences between originators and MSDs. The fixed effects model shows that the Herfindahl index, market growth rate in DDDs, and the number of years after patent expiration are significant at the .01 level, and that the number of MSDs is significant at the .05 level. The difference in price between the originator and MSDs increases as entry of MSDs increases. This indicates that the price difference becomes larger as the market becomes less concentrated. The effect of market growth rate on the price ratio of an MSD to the originator showed that a one percent decline in market growth in terms of DDDs resulted in a 0.16 percent decline in the price ratio.

The last column of Table 3 presents the results for the number of MSDs in the market. The number of MSDs significantly increased as time passed after patent expiration ($p < .05$). Results also suggest that a market with potential for larger profit is likely to have a greater number of MSDs entering the market ($p < .10$). Because cost data were not available to calculate true potential profit, the difference between the originator's price at the time of patent expiration and the lowest MSD's price in a certain market during the study period was used as a proxy variable to measure potential profit in this market. The originator's price represented the maximum possible price that a new entrant could charge. It was assumed that the firm charging the lowest price for multiple source drugs was only making normal profits, so its price could be used as a proxy for marginal cost. The difference between these two, therefore, is a reasonable proxy for potential profit.

As shown in the table, a market with higher sales volumes and growth is likely to have a greater number of MSD firms entering the market; however, the effects of these variables are not statistically significant.

DISCUSSION

The results of this study provide evidence that the off-patented market works as suggested by the Stackelberg leader-follower market model, under the assumption that the pharmaceutical market is imperfectly segmented between price-sensitive and insensitive sectors. Because originator firms have first-mover advantages in the market, they most often try to concentrate their sales activities in the price-insensitive sector. Within the study period, first-mover advantages enabled originators to maintain their sales volume.

As time passes after patent expiration, even if MSDs must set lower prices, more MSDs enter the price-sensitive sector as long as a new entrant can still potentially earn a profit. Therefore, MSDs in the price-sensitive sector behave as cournot firms in that they determine their prices after observing the prices of the originator and other MSDs. As the number of MSDs in a cournot model continuously increases, the sales per MSD decreases but the total sales of all MSDs increases. This causes the potential profit to decrease, further reducing the price of MSDs to the point of their marginal cost. Because the price-sensitive and insensitive sectors are imperfectly segmented in addition to the fact that consumers in the price-sensitive sector assume the efficacy of MSDs to be equivalent, the decreased average price of MSDs induces marginally price-insensitive consumers to switch from the originator's product to an MSD. This causes the demand curve for originators to become more inelastic. In response, the originator company increases its price to maximize profits, as long as marginal costs are constant through the relevant range.

This study could not find any evidence of limit pricing or preparatory pricing by originators in order to discourage or limit the entry of MSDs after patent expiration, as suggested by an empirical model in which monopolists do not delay subsequent entry of firms as long as the market size is large (Bresnahan and Reiss 1990). However, the results of this study provide evidence that MSD entry occurs regardless of market size and causes the average price of MSDs to fall.

The price trends of MSDs in this study are consistent with the findings of previous studies. The price trend found for originators contradicts the results of some, but not all, previous studies (Caves, Whinston, and Hurwitz 1991; Grabowski and Vernon 1992, 1996). The price trends of originators provide evidence of a model where, if sellers face more competitors and give more weight to their captive market, sellers will increase their prices (Rosenthal 1980). The differences among results may be attributed to a change

that occurred in the marketing strategies after the passage of the DPC/PTR Act. Before the Act, originators may have decreased their off-patented drug's prices to compete with the limited number of MSDs who could comply with the restrictive regulations. After 1984, originators would have been forced to drop their price to near-marginal cost in order to compete directly with many MSDs. Therefore, originators may instead target the price-insensitive sector with brand name drugs and target the price-sensitive sector with their own MSDs.

One of the strengths of this study is the use of DDDs to combine quantities across a specific drug's strengths and dosage forms. Although drug price competition is influenced by price per day of drug therapy, most previous studies examined price trends of selected strengths and dosage forms of specific drugs, which may have biased their results due to sample selection problems. A maximum time period of seven years was examined, but this time frame may not be sufficient to find factors that affect long-term price trends after patent expiration. Future researchers may need to explore longer time periods following patent expiration.

The results of this study may provide policymakers with important information regarding the impact of regulation on competition in the pharmaceutical industry. Because a tradeoff between benefits and costs of regulation exists, regulations should be implemented at the point where the dollar value of the last unit of benefit equals the cost of obtaining the regulation and should increase competition to the point where marginal benefit from enhanced competition equals marginal cost from increased competition.

CONCLUSION

After patent expiration, the originators' prices continued to increase, while the price of multiple-source drugs decreased significantly over time. This study demonstrates that an MSD competes not only directly with other MSDs entering the price-sensitive sector, but also indirectly with the originator targeting the less price-sensitive sector. The average price in an off-patented market shows a slower downward trend than would otherwise be expected because the market is adversely affected by the initial transition to a more competitive market. Consumers as a whole can gain from the increased competition that results from easy entry of the lower-priced multiple-source drugs.

APPENDIX

Multiple-Source Drugs Used in the Study

Generic Name	*Brand Name*	*Patent Expiration*	*MSDs Entry*
Acetohexamide	Dymelor	5/1984	3/1987
Amiloride	Midamor	11/1984	9/1986
Baclofen	Lioresal	10/1986	5/1988
Beclomethasone	Vanceril	4/1984	None
Carbamazepine	Tegretol	8/1986	6/1986
Cefadroxil	Duricef	1/1987	1/1981
Cephalexin	Keflex	4/1987	4/1987
Cephradine	Velosef/Anspor	12/1986	1/1987
Clindamycin	Cleocin	2/1987	9/1998
Clonidine	Catapres	7/1986	7/1986
Clorazepate	Tranxene	6/1987	7/1987
Danazol	Danocrine	6/1984	2/1988
Desipramine	Norpramin	7/1986	7/1987
Diazepam	Valium	2/1985	8/1985
Disopyramide	Norpace	12/1985	4/1985
Doxepin	Sinequan	1/1986	4/1986
Flurazepam	Dalmane	1/1985	12/1985
Haloperidol	Haldol	4/1986	5/1986
Lactulose	Chronulac	8/1986	8/1988
Lorazepam	Ativan	1/1985	8/1985
Maprotiline	Ludiomil	8/1986	1/1988
Meclofenamic acid	Meclomen	4/1985	12/1986
Mesoridazine	Serentil	4/1985	None
Methyldopa w/Hydrochlorothiazide	Aldoril	1/1984	3/1986
Metoclopramide	Reglan	4/1985	8/1985
Molindone	Moban	1/1987	None
Oxazepam	Serax	1/1984	3/1987
Perphenazine	Trilafon	2/1986	10/1987
Propranolol	Inderal	8/1985	7/1985
Sucralfate	Carafate	3/1986	None
Temazepam	Restoril	7/1985	12/1985
Thiothixene	Navane	3/1984	7/1987
Trazodone	Desyrel	4/1985	10/1986
Verapamil	Isoptin	7/1986	12/1986

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NOTES

1. A multiple-source drug (MSD) is a drug marketed by any firm other than the originator after patent expiration. The drug contains the same active ingredients, strength, and dosage form as the originator. MSDs are identified by chemical name or a generic brand name.
2. Defined Daily Dose (DDD) of a drug is the usual daily dose that a typical patient would take per day. DDD is not dependent on strength, dosage form, or number of times per day the medication must be taken, but it is dependent on total daily dosage in milligrams or grams. The use of DDDs allows for aggregation of the quantity of drug product sold across different strengths and dosage forms of the drugs.
3. The vector in the variable *MKTC* contains two dummy variables: (a) perceived severity of illness, which is classified and coded as either mild = 0 or severe= 1; and (b) duration of treatment as acute = 0 or chronic = 1.
4. The level of market concentration was measured by the Herfindahl index and the number of MSDs in a market. The Herfindahl index provides an indication of market concentration, but it does not provide a perfect assessment of potential price collusion. If there is a leader and followers in the market, that is, if one firm dominates many small firms, it is easy to maintain market discipline. When many small firms are in the market, it may be difficult to coordinate price. Therefore, the Herfindahl index and the number of firms have related but distinct effects on the price of MSDs.
5. The classes of products excluded from the 83 samples were (a) over-the-counter drugs; (b) combination drugs (except for methyldopa with hydrochlorothiazide); (c) injectables, intravenous, and diagnostic drugs; (d) drugs used exclusively in the hospital setting; and (e) drugs for which the patent expiration year or multiple-source entry was found to be earlier than the patent year obtained from the FDA.
6. Price of originators was normalized by originator price at time t divided by its price at the time of patent expiration. Average price of MSDs was also normalized by average price of MSDs at time t divided by its originator price at the time of patent expiration.

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