Pricing, Patent Loss and the Market for Pharmaceuticals*

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> . . . whole drugs which the best employed apothecary, in a large town, will sell in a year, may not perhaps cost him above thirty or forty pounds. Though he should sell them, therefore for three or four hundred, or at a thousand percent profit, this may frequently be no more than reasonable wages . . .
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> Adam Smith
> *The Wealth of Nations*, 1776

I. Introduction

Over the past twenty years public policy makers have often attempted to balance concerns over price levels of prescription drugs with the desire to encourage innovation in the pharmaceutical industry. The Drug Price Competition and Patent Term Restoration Act of 1984 very clearly reflects the determination of policy makers to simultaneously address issues of price control and technical progress. The 1984 Act increased returns to innovation by extending the period of patent protection to take into account the time between receipt of a patent and Food and Drug Administration (FDA) approval of a drug for sale in the market.

The 1984 Act also reduced the testing requirements for approval of new generic brands of existing chemical entities, thus reducing entry barriers in markets where patents have expired. The expected outcome from eased entry conditions for generic substitutes was substantially enhanced price competition and lower prices for brand name drugs. In fact, prices for brand name drugs have tended to increase following entry by generics. Wagner and Duffy [28] examined price changes for top selling generics and name brands. They show substantial price increases in brand name prices accompanying large reductions in generic prices as entry of generics occurs. Grabowski and Vernon [9] examined data on 18 major orally-administered drug products subject to generic competition between 1983 and 1987, and found that the name brand price increased by an average of 7% one year subsequent to generic entry and 11% two years following generic entry.

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The main goal of this paper is to examine how entry by generics can lead to price increases for brand name drugs. We take as a point of departure the observation made frequently by others that the demand side of the market for prescription drugs consists of two segments [10; 28; 27; 9]. One segment (consisting largely of hospitals, HMOs and Medicaid patients) is sensitive to differences between brand-name and generic prices, while the other (mainly comprised of individuals purchasing drugs in a retail outlet based on prescriptions from office-based physicians), is not sensitive to these price differences.[1] We examine models based on this characterization of demand to determine the circumstances under which price increases in response to market entry by generics will occur.[2]

A second facet of our analysis concerns the simultaneous response of brand-name advertising and brand-name price to generic entry. Since there is some evidence from two recent studies [10; 3] that advertising tends to fall with generic entry, we explore the conditions under which this can occur in tandem with a positive price response to entry.

The paper is organized into five sections. The next section presents a simple brand name pricing model based on market segmentation. In addition to describing the conditions under which generic entry increases brand-name price in this model, we also consider whether recent institutional trends in the health sector, which are changing the relative magnitudes of the two segments of market demand, will alter these condtions. The simple model is extended to incorporate advertising in the third section. The fourth section reviews recent empirical evidence of price increasing entry and advertising responses to entry. A final section offers conclusions and observations on future research and policy directions.

II. A Simple Market Segmentation Model

Background

We noted above that one could view the demand for brand-name prescription drugs as composed of two segments, one in which buyers are sensitive to prices of generic equivalents and one in which they are not.[3] Recent developments in the health care sector have enlarged the cross-price sensitive segment of the market. Hospitals are increasingly being paid under reimbursement arrangements which create incentives to reduce the costs per admission [13; 18]. Foremost among these arrangements has been the introduction of the Medicare Prospective Payment System (PPS). The per case prospective payment approach to reimbursement, adopted under PPS, pays hospitals a fixed amount for each admission based in part on a patient's diagnosis.[4] Thus the marginal revenues stemming from any treatment activities subsequent to admission are zero. This creates strong

1. Medicaid is a major purchaser of pharmaceutical products. A number of states will only reimburse sellers for the price of a generic product if one exists. Others deny reimbursement for costly drug products. The reimbursable products are listed in a state's Medicaid *formulary*.

2. Grabowski and Vernon [9] offer a specific example where a profit-maximizing firm would increase price in response to entry. Our purpose is to provide a more general characterization of the cases where this would be true.

3. There have been a number of models in the literature that are concerned with entry which leads to price increases in oligopolistic or monopolistically competitive markets [17; 19; 20]. These models generate price increases in response via one of two general mechanisms. The first is to assume economies of scale [19]. A second approach is for entry to both shift demand curves and to make them less elastic [17; 20]. Our analysis takes the second general approach.

4. The PPS system bases its payments on the national historical average costs of care for patients falling into each of approximately 470 diagnostic clusters. In addition, hospitals may receive special adjustments to their payment rate based on whether they are teaching hospitals, serve disproportionate shares of indigent patients, etc.

incentives for hospitals to be price sensitive in their input purchasing activities. Pharmaceuticals represent an important set of treatment inputs.

The new financial incentives appear to have altered the behavior of hospitals over time. Hospitals are increasingly adopting policies that are aimed at reducing pharmaceutical costs. Stolar [24] reports that from 1985 to 1987 the portion of hospitals with a policy of an automatic exchange of therapeutic alternatives, based on price, increased from 47.5% to 52.5%. In addition, the percentage which placed restrictions on certain high cost drugs grew from 25.7% in 1985 to 27.7% in 1987. These data suggest that a significant share of hospitals are making generic vs. brand name price comparisons in pharmaceutical purchasing, and that this share is growing over time.

A second part of the cross-price sensitive segment of the market for pharmaceuticals consists of Health Maintenance Organizations (HMOs). HMOs provide health care coverage and services for roughly 11% of the U.S. population [11]. They generally offer relatively extensive coverage for prescription pharmaceuticals [8]. Since HMOs receive a fixed payment for providing individuals with an agreed upon set of health care services (usually with little or no cost sharing), HMOs usually receive no marginal revenue associated with any services. The HMO's incentive is to treat each case as economically as possible. HMOs are therefore likely to be sensitive to generic vs. brand name price differences. This is supported by data from Weiner et al. [30] that on average 31% of all HMO pharmacy claims are for generics, while in insurance plans that cover fee-for-service medical practice the generic share of claims is only about 14%.[5]

A recent survey of HMOs ascertained the extent of therapeutic substitution of generic for brand name pharmaceuticals [5]. Approximately 31% of the surveyed HMOs used therapeutic substitution. Thirty-six percent of the HMOs that did not make use of therapeutic substitution refrained because it would violate state law.

Medicaid programs account for roughly 50% of third party payments for pharmaceutical products. State Medicaid programs have adopted several strategies for encouraging use of generic substitutes by beneficiaries [12]. One approach is to set reimbursement levels to pharmacists for drugs at the price of the generic products in the chemical class, if they exist. Another approach, used by one third of the states, is to define a set of drugs for which Medicaid will reimburse sellers. Some very costly drugs are excluded from this Medicaid formulary and are therefore not eligible for reimbursement [7].

Assumptions

Our analysis of brand name price responses to market entry begins by assuming that the brand name producer is a dominant firm that incorporates price responses of generics to its own pricing decisions while the generic producers are fringe firms that take the brand name price as given. (Thus, our model is a Stackelberg game.) Data on market shares of brand name and generic products are consistent with this characterization [4; 10]. The profit maximizing brand name producer is assumed to face a product market that is divided into two segments: loyal customers (D_L) whose demand is unaffected by the price of generic substitutes and a cross-price-sensitive segment (D_S) whose demand is influenced by both the brand name and generic prices [17].

Our one period model assumes that barriers to entry for generics are low, as is implied by

5. Research by Statman [23] and Bond and Lean [2] suggest that physicians have considerable loyalty to name brand drugs regardless of price. This is in part evidenced by very low rates of generic prescribing by office based physicians [15; 10].

the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 [28], and that the costs of changing both brand name and generic prices are low. This implies that future entry decisions will not be affected by the current brand name price. The brand name firm is assumed to be aware of this and hence sets price in each time period taking as exogenous the number of current and future generic producers, denoted by n.[6] The generic market is characterized by a Nash equilibrium among the n identical firms who take brand name price (P_b) as given.[7]

The Model

The brand name producer's demand function is

$$Q_b = D_L(P_b) + D_S(P_b, P_g) \tag{1}$$

where Q_b is the name brand quantity demanded, P_b and P_g are the brand name and generic prices respectively, and D_L and D_S represent the loyal and cross-price sensitive segments of the brand name firm's demand function. The market demand function for the n identical generic producers is $D_G(P_g, P_b)$ and the equilbrium value of P_g is $P_g^*(n, P_b)$.[8] This is the profit maximizing value of P_g in a Nash non-cooperative game. Substituting the expression for P_g^* into equation (1), and denoting the brand name producer's cost function by $C(Q_b)$, we write the brand name firm's profit function as

$$\begin{aligned}\pi = P_b\{D_L(P_b) + D_s[(P_b, P_g^*(n, P_b)]\} \\ C\{D_L(P_b) + D_S[P_b, P_g^*(n, P_b)]\}.\end{aligned} \tag{2}$$

Maximization of profit with respect to own price (P_b) yields the first order condition

$$\begin{aligned}d\pi/dP_b = 0 = [dD_L/dP_b + \partial D_S/\partial P_b + (\partial D_S/\partial P_g)(\partial P_g^*/\partial P_b)]\cdot \\ (P_b - (dC/dQ_b)) + D_L(P_b) + D_S[P_b, P_g^*(n, P_b)].\end{aligned} \tag{3}$$

Note that the first term of (3), which summarizes the demand response to a change in P_b, must be negative for the first order condition to hold. The demand response consists of the direct effects on the two segments of the demand function plus an indirect effect which works through the price reaction function that is determined in the sub-market for generics. For given values of n, $D_L(P_b) + D_s[P_b, P_g^*(n, P_b)]$ can be viewed as the reduced-form demand curve for the brand-name firm. Equation (3) requires that this reduced-form demand curve be negatively sloped.[9]

6. Thus, we exclude the possibility of "limit price" behavior. Tirole [25] points out that limit pricing is unlikely under the assumptions we have outlined. He notes that incumbent (brand-name) price may be correlated with productive capacity commitment; however, capacity constraints are probably not an important consideration in producing pharmaceuticals (though they may become more important in the market for biologically-produced products). Moreover, the Milgrom-Roberts [16] explanation of limit pricing where incumbent price is an imperfect signal of incumbent cost is also of limited relevance in the pharmaceutical context where production costs are small relative to prices and relative to total firm expenditures on drug development, production, marketing and distribution.

7. In order to examine the sensitivity of our results to the assumption that the generic price is endogenous to the brand-name firm, we also examined a Bertrand model in which this firm takes generic price as exogenous. The analytical results closely parallel the findings reported here.

8. The relationship between P_g^* and n can also be derived from more general models where n identical firms have non-zero conjectural variations with respect to each other's output. See for example Waterston [29].

9. If $\partial P_g/\partial P_b > 0$, the reduced form demand curve will be less own-price elastic than the ordinary demand curve for the brand name drug.

The effect of entry by generics on name brand price can be assessed by total differentiation of equation (3) to obtain an expression for dP_b/dn. Using this expression, we examine the conditions under which market entry will increase name brand price ($dP_b/dn > 0$). (Algebraic detail is supplied in the appendix).

We can express dP_b/dn as:

$$\begin{aligned} dP_b/dn = &\{(P_b - (dC/dQ_b))[(\partial^2 D_S/\partial P_b \partial P_g)(\partial P_g^*/\partial n) + \\ &(\partial^2 D_S/\partial P_g^2)(\partial P_g^*/\partial n)(\partial P_g^*/\partial P_b) + (\partial D_S/\partial P_g)(\partial^2 P_g^*/\partial P_b \partial n)]\}/ - SOC + \\ &\{(\partial D_S/\partial P_g)(\partial P_g^*/\partial n)\}/ - SOC - \{(d^2C/dQ_b^2)[(\partial D_S/\partial P_g)(\partial P_g^*/\partial n)]\cdot \\ &[dD_L/dP_b + \partial D_S/\partial P_b + (\partial D_S/\partial P_g)(\partial P_g^*/\partial P_b)]\}/ - SOC, \end{aligned} \tag{4}$$

where SOC is the right-hand-side (r.h.s.) of the second-order condition (A1 in the appendix) and must be negative. With $\partial D_S/\partial P_g > 0$ and $\partial P_g^*/\partial n < 0$, the second right-hand term in (4) must be negative. The third right-hand term must also be non-positive, since the reduced-form demand curve slopes downward, unless there are decreasing marginal costs for the brand-name firm. The first bracketed term on the right hand side of (4) is the mark-up of name brand price over marginal cost (which must be positive). The second bracketed term is the effect of generic entry on the slope of the reduced form demand curve. The sign of this term is difficult to determine a priori. The slope of the price-sensitive portion of the reduced-form demand curve summarizes heterogenous responses of individual cross-price sensitive buyers to price increases which may be of two types: reducing the quantity purchased to some non-zero amount and reducing purchases to zero. The reduction in P_g^* as n increases could affect this slope by affecting either or both types of responses. If for example, the purchasers with the strongest own-price response are more likely to reduce their purchases to zero as P_g^* falls, this will result in a steeper slope for the reduced-form demand curve since the remaining cross-price sensitive purchasers have (by assumption) weaker price responses.

Equation (4) shows that dP_b/dn can not be positive unless either 1) entry increases the demand for the brand name drug, 2) marginal costs are decreasing for the brand-name product or 3) entry makes the reduced-form demand curve steeper (less elastic). Of course, the first of these possibilities seems rather implausible since it would require that generic prices rise with entry or that brand-name demand falls when generic prices rise (implying that the products are gross complements in demand). The empirical evidence of the impact on demand suggests at least small reductions in brand name market shares following market entry [23]. Little systematic empirical work on the nature of returns to scale has been reported in the literature. There is, however, little reason to believe that the marginal production costs of a specific drug would be decreasing, nor has this claim appeared in industry studies [4]. This leaves the third possibility, that entry makes the reduced-form demand curve steeper, as the most plausible explanation for $dP_b/dn > 0$.

Variations in Market Shares of Loyal and Cross-Price-Sensitive Consumers

We have already cited evidence pertaining to HMO's, hospital purchasing practices, and Medicaid which suggests that the relative market share of price-sensitive consumers has been increasing. We now consider the implications of this trend for brand-name prices and for the responses of these prices to generic entry. We begin by reformulating the brand-name demand function in equation (1) as a weighted sum

$$Q_b = (1 - \alpha)D_L(P_b) + \alpha D_S(P_b) \tag{1a}$$

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