Int. J. of the Economics of Business,
Vol. 13, No. 1, February 2006, pp. 15–38

Generic Competition in the US Pharmaceutical Industry

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ABSTRACT *We develop a simultaneous equations estimation framework to understand the interactions among generic entry, prices, and market shares. We base our estimates on a panel data sample of 40 brand-name drugs that first experienced generic competition during the period July 1992–January 1998. We find that generic share and price are simultaneously determined, while the number of generic entrants is a key determinant of generic market share and the generic-to-brand price ratio. In addition, we find generic competition to be particularly intense for blockbuster drugs, which experience significantly more generic entrants, price erosion, and generic penetration than other drugs.*

Key Words: Generic Entry; Competition.

JEL Classifications: I11, L11.

1. Introduction

Generic competition has intensified in the US prescription drug industry and become a major source of health care cost savings since the mid-1980s. The Congressional Budget Office (CBO) estimated that purchasers saved between $8–10 billion in 1994 by substituting generics for brand name drugs (CBO, 1998). Recently, several leading brand name drugs have experienced generic competition

The authors wish to thank Ernst Berndt and Arthur Havenner for their excellent comments on an earlier version of the paper. Research support from Mark Spelber and Sarah Whitney and editing support from Amelia Greenberg are gratefully acknowledged. Any errors that remain are ours.

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– e.g., Prozac, Vasotec and Taxol – and many more commercially significant brand name drugs will face generic competition in the next five years.

In this paper, we seek to understand the process of generic competition better by developing a model that captures the interactions among generic entry, prices, and market shares using a simultaneous equations framework. The model is estimated on a panel data sample of 40 drugs first exposed to generic competition over the period July 1992–January 1998.

The next section of this paper considers the historical and institutional factors encouraging the growth of the generic industry and summarizes prior findings reported in economic literature. Section 3 discusses the structure of the model and our estimation methodology. Section 4 describes the characteristics of the dataset and our sample. Section 5 discusses the estimation results. Section 6 contains a preliminary analysis of the impact of generic entry on brand price. The final section provides a brief summary and conclusions.

2. Background

2.1. Important Industry Developments

The growth of the generic drug industry over the past two decades has been affected by important changes on both the demand and supply sides. One key event was the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act. This act significantly reduced the costs and time of entry for generic drugs by establishing an Abbreviated New Drug Application (ANDA) procedure. With an ANDA, generic firms need only show that their products are bioequivalent to the branded product in order to gain Federal Drug Administration (FDA) approval.[1] In addition, the law established a research exemption so that generic firms could perform their bioequivalence testing and receive conditional FDA approval prior to the expiration of the brand product's patents. The 1984 law also tried to strike a balance between generic price competition and drug innovation by providing brand name firms with the opportunity for patent term extension to compensate for time lost during the clinical testing and regulatory approval stages.[2]

On the demand side, the development of the generic industry has been aided by the growth of managed care and the more intensive coverage of prescription drugs by health insurers.[3] Pharmacy benefit management firms (PBMs) have evolved as managers of pharmaceutical reimbursement programs for both HMOs and employers and have actively promoted the use of generic drugs as a cost-saving measure (Berndt, 2002). Generic competition has also been encouraged through various benefit designs, including a tiered formulary in which generics are placed in the least costly co-payment tier.[4] PBMs also provide incentives to pharmacists in the form of higher fees for generics, compared to branded products.[5] In addition, PBMs often monitor and attempt to alter physicians' prescribing habits among those who disproportionately prohibit generic substitution. Grabowski and Mullins (1997) found that these various incentive measures can save payers 10% or more of their total drug budget.

Thus, there have been powerful institutional forces at work accelerating the degree of generic competition since the mid-1980s. This is reflected in the fact that 47% of prescription drug units consumed in the United States in 1999 were

widely prescribed branded products scheduled to go off patent in the next five years, the percentage of generic utilization is likely to increase in the years ahead.

2.2. *Prior Economic Studies of Generic Competition*

Several economic studies have examined the characteristics and determinants of generic competition after the passage of the 1984 Hatch-Waxman Act. Caves *et al.* (1991) conducted an early exploratory analysis of generic competition using a sample of 30 drugs that went off patent between 1976 and 1987. Their analyses spanned the period prior to Hatch-Waxman and a few years after its passage. They found that the initial generic drug entered the market at a significant discount to the branded product (40% on average) and this discount grew larger as the number of generic competitors expanded over time. However, even with a significant number of generic competitors in the market, the average market shares[6] of the generic products were relatively small in this period. In this regard, their analysis was consistent with a number of studies of the pre-1984 period that found the impact of generic competition on branded sales to be very limited.[7]

Several papers have focused on generic price. In two related studies, Grabowski and Vernon (1992, 1996) examined a sample of 40 branded products that faced generic competition between 1984 and 1993, when the intensity of generic competition increased significantly.[8] Using a regression model in which the number of generic competitors was driven by the expected profitability of entry, they found that the price of a generic product tended toward marginal cost over a multi-year time frame.[9] In a recent paper, Reiffen and Ward (2002) estimated a structural model of the relation between generic drug prices and the number of ANDA approvals, and concluded that eight or more ANDAs were generally sufficient to cause generic prices to converge to long run marginal cost.

Another subject of prior studies has been generic market share. Grabowski and Vernon (1996) found that the speed at which generics captured market share was positively related to the size of the brand product's pre-entry sales, the therapeutic class of the product, and the calendar date of generic entry. Greater rates of generic utilization were observed for more recent time cohorts of brand products. In particular, by the early 1990s, generic shares averaged about two-thirds of a molecule's unit sales one year after the initiation of generic competition.

Fiona Scott Morton examined generic entry decisions in two recent papers. In the first paper, Scott Morton (1999) showed that firms are more likely to venture into markets in which they have some experience, e.g., in form, therapy or ingredient. In addition, firms have a tendency to enter large markets and markets where the drug treats a chronic condition. In a second paper, Scott Morton (2000) looked at factors that might thwart generic entry, including switching costs, FDA regulations, and brand firm advertising. Using a sample of 98 drugs with patent expirations from 1986 to 1992, she found that generic entry was positively related to brand revenue and price elasticity, and negatively affected by FDA regulations.[10] She also found no evidence that brand advertising has deterred generic entry.

A number of investigators dating back to Caves *et al.* (1991) have considered the response of brand firms to generic entry and whether branded firms have pursued entry-deterring strategies. There is little evidence to support the hypothesis of entry deterrence. First, with respect to promotional activities,

the pre-entry period (Caves *et al.*, 1991).[11] Ellison and Ellison (2000) find that the trends in advertising and product proliferation are non-monotonically related to the probability of generic entry: advertising is reduced and presentation proliferation increased in the period preceding patent expiration among drugs that face an intermediate probability of entry. Second, there is scant evidence that brand firms take pre-emptive actions or match generic prices, except when they offer selective discounts to their large institutional customers (CBO, 1998). Rather, most studies have found that branded drug firms continue to raise prices after generic entry, although there is some disagreement about whether generic entry has positively or negatively affected the *rate* of increase in these prices.[12] Grabowski and Vernon observe specific cases where brand name firms have pursued a two-tier strategy, entering the generic market either through a subsidiary firm or in partnership with a generic firm. Even in these latter situations, however, entry has not been effectively deterred and generic price competition has remained intense.

2.3. *Objectives of Our Analysis*

Our study builds on the studies discussed above, but contributes to the literature in several dimensions. First, we explicitly account for the interaction between three key variables: generic entry, generic share, and generic-to-brand price ratio. We posit that these variables are part of a simultaneously determined system; specifically, generic entry affects the share of generic suppliers and the price of generics. These two variables are then endogenously determined. That is, generic share depends on, and is influenced by, generic price. While a few papers in the existing literature have acknowledged the endogeneity of generic entry,[13] prices, or shares, to our knowledge ours is the first paper to adopt a simultaneous estimation procedure to address the issue of the endogeneity of all of the key variables. Our empirical results clearly show that generic share influences and is influenced by prices, corroborating our model's econometric estimation framework.

Second, our study examines a relatively large sample of drugs that experienced generic competition between July 1992 and January 1998. The analysis of more recent data is particularly relevant in light of the marked growth of generic drug sales fuelled by the dominant role of managed care and PBMs in the 1990s.

Finally, we adopt an estimation framework that is appropriate for panel data. Our estimation approach allows and corrects for heteroskedasticity and serial correlation of errors. That is, we allow for idiosyncratic differences across drugs (cross sectional units) through the heterogeneity of error variances. Additionally, since we have time series observations on each drug, we allow for drug-specific serial correlation of errors. The ordinary least squares (OLS) model is a special case of this more general estimation approach. Our results demonstrate that the OLS estimation framework yields, in many cases, seriously erroneous inferences about the determinants of generic competition.

Our empirical results provide valuable insights into the determinants of generic entry, prices, and generics' market share. We find generic competition to be particularly intense for 'blockbuster' drugs, which we define as drugs having pre-generic annual sales of $500 million or more. Specifically, we find that blockbuster drugs average two more generic entrants annually compared with non-blockbusters. We further find that the number of generic entrants, in turn, directly affects the level of generics' share and price. Blockbuster drugs thus experience

generic penetration than non-blockbuster drugs. We also find that the extent of HMO coverage has a positive impact on the market share garnered by the generics. Additionally, generic prices are significantly and positively related to the costs of drug production.

Our results also include a preliminary analysis of brand prices. In contrast to prior studies' findings based on data from earlier time periods, our results indicate that brand prices *do* respond to generic competition: each additional entrant on average is associated with a 0.2% *decline* in brand price. Nevertheless, unless the number of generic competitors is large, brand prices continue to rise in absolute terms. Consistent with prior studies, we do not find any evidence of entry-deterrent pricing by brand manufacturers.

3. Econometric Model Specification

The objective of the econometric model is to explain the determinants of three key variables for each drug: P, S, and N, where P denotes the average generic-to-brand price ratio, S represents the share of the group of generic substitutes of a branded drug, and N is the number of generic manufacturers of that compound.

The number of generic manufacturers for the i^{th} drug at time t is defined as follows:

$$N_{it} \equiv N_{it-1} + E_{it}, \tag{1}$$

where E_{it} is the number of generic entrants for i^{th} drug at time t. The number of entrants, in turn, is determined by:

$$E_{it} = f\left(N_{it-1}, X_i^E, \varepsilon_{it}^E\right) \tag{2}$$

where X^E is a set of exogenous variables related to the conditions of entry faced by generics, and ε^E denotes random errors. All variables on the right hand side of (2) are thus pre-determined, that is, (2) is not a simultaneous equation and therefore can be estimated directly.

By contrast, for each drug the generic-to-brand price ratio (P) and the share for all generics (S) are jointly-determined (i.e., endogenous) variables. The simultaneous equation framework determining these variables is:

$$P_{it} = g\left(S_{it}, N_{it}, X_{it}^P, \varepsilon_{it}^P\right) \tag{3}$$

$$S_{it} = h\left(P_{it}, N_{it}, X_{it}^S, \varepsilon_{it}^S\right) \tag{4}$$

where X^P and X^S are sets of exogenous variables that affect the price ratio and generic share, and ε^P and ε^S are random errors. Note that while the number of generics (N) affects the generic-to-brand price ratio and generic share, it is a pre-determined variable since it is fully determined by information available at time $t-1$.

Equation (3) includes exogenous variables affecting the intensity of price competition on the supply side of the market. Equation (4) includes exogenous variables affecting the intensity of demand by managed care and other purchasers. Equation (3) is identified by excluded demand side shifts (i.e., HMO coverage),

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