

**“BRANDED GENERICS” AS A STRATEGY TO LIMIT
CANNIBALIZATION OF PHARMACEUTICAL MARKETS**

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Abstract

This paper demonstrates how, by introducing a generic version of its previously-patented product, a branded firm can influence the equilibrium in the generic segment of the market for the product. This in turn can increase the firm's profits from selling the branded version. We then use structural estimates from previous literature to calculate the magnitude of the effects in the generic and branded segments.

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I. Introduction

Standard economic theory implies that incumbent firms' profits fall with the entry of rival firms selling similar products. Empirical evidence confirms that the profits of pharmaceutical firms producing the original, or "branded" version of that drug are substantially reduced by the entry of rivals producing unbranded or "generic" versions of their branded drugs.¹ It follows that actions the branded firms can take to forestall such entry can be profitable. It has been estimated that for a branded product with \$110 million in domestic annual sales in the early 1990s (approximately the average sales for the drugs we examine in this study), postponing the entry of generic competitors by one year would increase the branded firm's after-tax profits by about \$12 million.² With such an incentive to delay generic competition, it is not surprising that companies producing branded drugs have developed strategies to delay the entry of rivals.

Reports have alleged that branded producers have used a variety of delaying tactics to avoid this "cannibalization" of their profits in the branded segment. One common means is for the branded firm to introduce and promote a new form of the drug -- one with longer-lasting effects, or fewer side effects - just prior to patent expiration. Under the provisions of the Waxman-Hatch Act (see Levy, 1999 at 17), the new version of the drug will obtain three additional years of protection from generic competition, more if the new product is patented.³ A similar means of effectively reducing competition from generic producers is to establish

¹ See, e.g., Caves Whinston and Hurwitz (1991).

² See Cook (1998), Grabowski and Vernon (1994).

³ For example, the extended release form of nifedipine, Procardia XL, is patented. The patent for Procardia XL expired in 2003, whereas the initial patent for Procardia expired in 1991. Of course, the new version may provide benefits to consumers as well, so that this tactic can be welfare-enhancing.

secondary patents on the drug (e.g., on production processes or drug components).⁴ Another tactic is to challenge the generic firm's application for FDA approval to manufacture and sell the product (known as an Abbreviated New Drug Application, or *ANDA*). For example, to get an *ANDA* approved, the entrant is required to demonstrate bio-equivalence to the branded product.⁵ In several instances, the branded firm has questioned the bio-equivalence of the generic producer's product.⁶ It has also been alleged that at least one branded producer has made misleading public statements regarding the non-equivalence of the generic version of the drug.⁷ Finally, in some cases, the branded producer has acquired rival producers of the raw ingredient required to produce the generic product.

Another tactic to protect branded profit is to raise the equilibrium price of the generic drug, thereby mitigating the loss of branded sales to generic producers. One practice which has this effect was first used in the mid 1990s, and has recently reemerged. Beginning in late 1992, several producers of drugs with soon-to-expire patents introduced, or authorized the introduction of, generic versions of their important products just prior to patent expiration. We refer to such products as *branded generic* or *authorized generic* drugs. The first introductions of branded generic drugs by large drug companies such as SmithKline Beecham, Ciba, Syntex, Lilly and

⁴ See *Business Week*, 11/30/98, pp. 92-4 for some examples.

⁵ Bioequivalence means that the rate and extent of absorption of the active ingredient is identical to that of the innovator drug (Food, Drug and Cosmetic Act Section 505 (j)(7)(B)).

⁶ Of course, to the extent that the generic product is truly not bioequivalent, the challenge may be in consumers' interests.

⁷ Specifically, it is alleged that Dupont made misleading statements regarding generic versions of its drug Coumadin. See *Wall St. Journal*, 3/9/99, p. B-1.

Marion Merrell Dow were made during the 1993/4 period.⁸ While the strategic use of branded generics fell off during the late 1990s in the U.S., the practice has again come under public scrutiny with the use of an authorized generic by Proctor and Gamble in fall of 2003.

This paper examines the consequences of the introduction by patent holders of generic versions of their drugs on competition, profits and consumer welfare. That these introductions can harm other businesses seems clear; to the extent that the patent holder avails itself of the profitable opportunity to introduce a generic version of its product, an independent firm might be precluded from the opportunity. Harm to potential competitors, however, does not necessarily imply harm to consumers. A consumer welfare concern would arise if generic entry by the original patent holder would, through its impact on other firms' decisions, lead to higher prices for consumers, and a consequent reduction in (static) economic welfare.⁹

Entry by a branded generic could lead to higher long-run prices because it could “crowd out” multiple independent generic firms.¹⁰ Generic firms typically incur sunk costs related to

⁸ While the strategy of introducing branded generic products appears to have declined in the U.S. in the late 1990s, branded generic production remained quite common in Canada in this period. According to Hollis (2003), in Canada virtually every major drug that went off patent in the past few years has introduced a branded generic, and roughly 25% of all generic sales in Canada are made by the branded producer of the same drug, or a licensee of the branded firm. As Hollis notes, the difference between the extent of branded generic production in the two countries may be due to different regulatory environments that make delaying tactics easier to pursue in Canada. For example, in Canada any generic entrant must notify the patent-holder of its intention to enter.

⁹ This analysis is static in the sense that it takes the existence of the branded product as given, and estimates the effect of branded generic entry on generic prices. Allowing branded firms to gain more of the profits generated by a drug increases the incentive to innovate, and may lead to welfare gains through increased drug discovery.

¹⁰Kong and Selden (2004) model the effects of branded generic entry in the context of a market in which the branded generic replaces what would have been a single independent generic firm. Their model formalizes earlier analysis by Hollis (2003).

obtaining FDA approval well before the branded firm's patent expired. Because this approval process is highly stochastic, a generic firm is unsure as to when its application will be approved. Earlier approval leads to an earlier product launch, and consequently the opportunity to temporarily compete against fewer rivals. As such, a firm's profits are dependent on how many other generic producers are approved before it gets its ANDA approved. Generic firms can be thought of as entering a sort of lottery in which first approval is the first prize, second approval is second prize and so on. At the same time, we would expect that the number of entrants is directly related to the size of the prizes. Given this environment, branded generic entry can have a substantial effect on the equilibrium. Specifically, the patent holder can guarantee itself first prize for its branded generic because it can enter prior to patent expiration with a product that is already FDA approved. Since the first prize is a disproportionately large share of the total rents available, one branded generic, if it is anticipated, can discourage multiple potential entrants. In the long-run, there could be fewer firms competing and, consequently, higher equilibrium prices.¹¹ Assuming the cross-elasticity between generic and branded drugs is positive and economically significant, this in turn increases profits on the branded version of the drug.

¹¹ While Liang (1996) argues that the number of generic producers could fall, he does not link this to the change in prices. Liang's concern is that higher average prices for generics may result from branded generic entry because the patent holder can offer the first generic product on the market; it can "lock" buyers into long-term contracts at prices which exceed the (future) prices offered by independent generic producers. Unlike the explanation offered here, his explanation does not depend on independent generic producers raising their prices. Rather, in his explanation only the branded generic firm has a higher price. To the extent this raises average prices paid by buyers, it implies that buyers intentionally choose long-term contracts which are not in their self-interests.

This basic scenario was discussed by Morton H. Katz, vice-president of Clay Park Laboratories (an independent generic firm) and then-chairman of the National Association of Pharmaceutical Manufacturers (an association of independent generic manufacturers):

We are worried that a small, independent company will not risk hundreds of thousands of dollars and years of effort to receive an ANDA approval and introduce a product into a market already controlled by a fully distributed PMA's [i.e., an innovator drug company] generic version of its own branded product.

Without that competition, generic drug prices would not achieve the affordability that is offered today. (Goldberg, 1994)

The main purpose of our study is to determine the magnitude of the effect of branded generic entry on generic price, and the consequent effect on branded profits. Unfortunately, the effect of branded generic entry on generic prices cannot be directly measured, for two reasons. First there have been relatively few such introductions in the U.S. Second, the independent firms' decisions as to whether to file an ANDA must (if they are to have a chance at the first-mover profit) take place well in advance of patent expiration. Hence, it seems reasonable to assume that the branded firm's action in the instances in which it took place was not anticipated by independent generic producers at the time they began the ANDA process. And it is the *anticipation* of the branded firm's actions that we hypothesize will influence the generic producers' entry decisions. For these reasons, examining the effect of branded generic entry from these few instances is not likely to reveal its long-run consequences, and we instead use an indirect approach, based on the mechanism described above.

Our approach to determining the effect of branded generic entry on generic prices requires knowing three relationships: the effect of branded generic entry on expected independent generic profits; the effect of changes in expected independent generic profits on the number of generic entrants; and the effect of the change in the number of generic producers on generic prices. We estimate these relationships in a related paper (Reiffen and Ward, 2005, hereafter, R&W). Their estimates were made using data from the late 1980s and early 1990s. This time period corresponds to a period before branded generics were first introduced. As such, the estimates are appropriate for analyzing the decision-making of independent generic firms in a world without branded generics. In this study we use these estimates to determine how the equilibria absent branded generic entry differs from one in which the independent firm anticipate branded generic entry, and hence how the number of entrants changes with branded generic entry, and the consequences for the path of independent generic entry and prices. We find that for the average drug in our sample, generic prices rise by 1-2%.

To calculate the effect of this price change on branded profits, we simulate the effects on branded price and output using estimates from Caves, Whinston, and Hurwitz (1991, hereafter, CWH). CWH estimate structural parameters measuring, among other things, the effects that the number of generic producers have on equilibrium branded prices and sales. Combining these estimates with the generic price effects from R&W, we estimate that the branded generic strategy increases profits from branded sales by up to 1.5%.

Section II of this study presents some historical and institutional background with which to understand generic drug markets. Section III provides analysis of the means by which branded generic entry can affect generic market equilibria. Section IV presents our estimates of the

impact of branded generic entry on the number of generic producers, generic prices and branded profits, for drugs with different characteristics (e.g, different pre-patent expiration branded revenues). Concluding remarks can be found in Section V.

II. Background

A. THE FDA APPROVAL PROCESS

Before it is able to begin manufacture and sale of a new drug, a prospective manufacturer must obtain FDA approval. The process of getting a New Drug Application (NDA) approved by the FDA is both expensive and time consuming. The manufacturer must demonstrate, through a series of clinical trials, that the drug is safe and efficacious. It has been estimated that for the average new drug that obtained FDA approval in the 1990s, its producer had spent over \$335 million (in 2000 dollars) on development, and an additional \$478 million on clinical and other testing.¹² In addition, the clinical trial process took upwards of 8 years.

Prior to 1984, producing a generic version of most existing drugs involved a similar application process. Although the generic producer did not face the cost of determining which new drugs were technically feasible and economically viable, it still faced the hurdle of demonstrating safety and effectiveness of its version before it could get its NDA approved. The 1984 passage of the Waxman-Hatch Act reduced the regulatory burden for firms seeking to obtain FDA approval to produce and sell generic versions of existing drugs. Rather than meeting the previous standard of showing that its version of the drug is safe and efficacious, under the

¹² See J. DiMasi, R. Hansen, H. Grabowski and L. Lasagna (2003). This figure represents the expected cost of a successful drug, in the sense that it includes the cost of drugs which do not obtain an NDA.

Waxman-Hatch Act a firm can file an ANDA, which only requires demonstrating bioequivalence to a drug that already has been approved by the FDA. The firm must also show sound manufacturing procedures and that its product has sufficient shelf stability. This means that both a production facility and an approved source of raw material supply must be in place prior to filing an ANDA. The ability to file an ANDA, rather than an NDA, has reduced the cost of obtaining FDA approval considerably.

Not surprisingly, this expedited approval process has increased the number of firms producing generic versions of previously-patented drugs. Cook (1998) reports that for 13 major drugs with patents expiring between 1990 and 1993, 11 had generic entry within two months of patent expiration. In contrast, she notes that in Caves, Whinston and Hurwitz's (1991) study, only 2 of the top 13 drugs had generic entry within one year of patent expiration during the pre-Waxman-Hatch period (between 1976 and 1983).

While the time and expense required to enter production of a drug is lower, post-Waxman-Hatch, one element of the decision confronting a firm interested in generic production has not changed. Entry still requires a significant up-front expenditure, with a payoff that depends on the FDA's decisions with respect to that firm's application, as well as the timing of FDA approval of rivals' ANDAs for that drug. Simply put, the sooner a firm's application is approved, the sooner it can begin production and sales of the drug, and the higher the payoff. For a drug with pre-patent expiration annual sales of \$258 million in 1992 (approximately the typical large-revenue drug in the R&W sample), the first firm to gain FDA approval can earn between 19% and 27% of the total generic rents for that drug. Since our estimates indicate that there will be approximately 14 entrants in such a market, and the total rents earned by all 14 are

approximately \$6.2 million (see Section IV), the first entrant can expect to earn between \$1.3 and \$1.9 million, minus application costs.

Of course, each of the 14 firms would like to earn the first entrant's profit; each would like to get its ANDA approved as soon after patent expiration as possible. However, the time it takes the FDA to process applications can be both considerable and variable. According to Goldsmith (2002), between 1984 and 1999, only about 11% of all approved ANDAs were approved based on the initial submission. For the remaining applications, the initial ANDA was found deficient by the FDA, and the applicant was required to conduct additional tests. The median number of submissions required for approval was 3, and 10% required 5 or more submissions. For this reason, the time between the initial submission and FDA approval is not known to the applicant. Scott Morton (1996) calculates that between 1984 and 1994 the time between filing and approval of ANDAs averaged about 19 months, with considerable year-to-year variation. Because of this uncertainty, the timing of a particular ANDA's approval relative to other ANDAs for that drug is not known to the applicant at the time it begins to invest in the entry process.

In addition to the time it takes to get an ANDA approved, entering a generic market requires a period of time prior to making its FDA application to begin the production process, since an approved source of materials and adequate production facilities are required at the time of the application. In total, the applicant has to anticipate two to three years elapsing from the time it begins preparing to enter until it can begin selling a generic drug.

B. BRANDED GENERIC ENTRY

If the producer of a drug with a soon-to-expire patent decided to introduce an unbranded or "generic" version of its product, it would have three advantages over an independent generic firm in entering as a generic producer of that product. First, it has production experience with the drug, and to the extent learning-by-doing affects costs in this industry, the originator will have lower costs than a comparable independent firm. Second, as long as the generic version is produced on the same production lines as the branded product, the originator need not obtain FDA approval to enter the generic business. This not only saves the firm the cost of filing an ANDA, but also means that it knows with certainty that it can enter the generic segment as soon as it is profitable to do so. Third, because the generic version is introduced by the patent holder, there are no legal obstacles to launching at the preferred time, even prior to patent expiration.

Prior to the early 1990s, pharmaceutical firms tended to specialize either in innovator drugs or generic drugs. This is not to say that the two types of firms were mutually exclusive; even prior to 1990, several large innovator drug companies owned subsidiaries that produced generic drugs. In some cases, the subsidiary would produce a generic version of a drug for which its parent had held the patent.¹³ However, in the early 1990s, there were several significant changes in innovator firms' strategies. In 1993, Merck, the largest U.S. pharmaceutical manufacturer, established a new division to market generic versions of Merck products that had lost patent protection.¹⁴ This differed from other innovator firms with generic subsidiaries in that this division was focused on Merck products, whereas other subsidiaries were general generic

¹³ As a measure of the size of generic production by the initial patent holder, we note that in the data set used by Grabowski and Vernon (1992), for drugs whose patents expired between 1984 and 1988, the branded firm's generic had, on average, 11.3% of the generic market in that drug.

¹⁴ "Merck Sets Generic Drug Sales," New York Times, 9/8/92 at D1.

producers. At about the same time, several companies announced plans to market generic versions of their products shortly before patent expiration. These firms included Warner-Lambert, which brought out (through its subsidiary) a generic version of its cholesterol reducer Lopid (generic name ticlopidine HCL) in December 1992, one month before its patent expiration. The same strategy was pursued by Upjohn, which introduced a generic version of its anxiolytic, Xanax (alprazolam) in September 1993, one month before its patent expired. Other examples from that period include Naprosyn (Syntex's branded version of naproxen), Lopressor (Ciba's branded version of metoprolol), and Tagamet (SmithKline Beecham's branded version of cimetidine). These five drugs all had significant pre-patent expiration sales in the U.S. (annual sales between \$250 and \$600 million).¹⁵ Another change during this period was that several of the larger generic producers were acquired by innovator drug companies.

Acquisition of a generic drug company is not necessary in order for an innovator firm to bring a generic version of its product to market. A similar result has been obtained through contract, whereby the patent holder manufactures the generic version of its drug, but the generic version is marketed by another firm, and carries the marketer's label. This approach has been used by Lilly, who several months before its patent for the antibiotic Ceclor (cefaclor) expired, signed a long-term contract with Mylan for Mylan to sell the generic version. Like the other branded generic drugs discussed above, pre-patent expiration sales of Ceclor were significant; in excess of \$400 million annually.

¹⁵ By comparison, the average annual pre-patent expiration U.S. sales of the drugs in the R&W sample was about \$100 million.

More recently, in late 2003, Proctor and Gamble authorized Watson Labs to produce a generic version of its anti-infective, Macrochantin (nitrofurantoin), just prior to the first generic version entering the market.¹⁶ This contract greatly reduced the profits of the independent generic producer.¹⁷

The direct effect of the branded generic strategy is to give the branded firm a share of the generic profits. An indirect effect is to reduce the profits of independent generic producers, which can affect the long-run equilibrium in the generic segment. That is, as we explore more fully in Section III, patent holder entry into generic production may have the strategic motivation of discouraging independent generic entry.¹⁸

Changes in the profits from each segment can change a branded firm's incentive to introduce a generic version of its drug. As such, several factors may explain why such introductions became attractive to patent holders in the early 1990s. First, the effect of the Waxman-Hatch Act had been to erode the firm's post-patent expiration sales of the branded product. One way to mitigate the effect of easier generic entry on branded prices is to increase generic prices. By discouraging generic entry, the branded firm may be able to raise equilibrium generic prices, and in so doing, higher profits can be earned on its branded product.

Alternatively, branded firms' profits from entering the generic segment likely rose during this period. That is, even if the branded firm cannot influence generic prices, the firm knows that

¹⁶ See Forbes.com 8/29/04 (<http://www.forbes.com/feeds/ap/2004/08/29/ap1522386.html>).

¹⁷ As discussed in Section IV.D, the tactic has a particularly large effect on entrant's profits in "Paragraph IV" cases (such as nitrofurantoin) because the independent entrant would have otherwise had an 6-month period of exclusivity in producing the generic.

¹⁸ We use the word *strategic* to refer to behavior designed to influence other firms' actions.

because of Waxman-Hatch, significant generic sales will occur whether or not it enters that segment. Entry into generic production may simply be a way to capture some of the rents that it otherwise would lose to generic producers. That is, introducing a generic may not have been profitable in the absence of an independent generic segment, but becomes profitable if a generic segment will exist regardless of the firm's action.

Several other changes may have also prompted the branded drug maker to enter the generic market for non-strategic reasons. Specifically, there were several important demand-side changes in the market during the late 1980s that increased generic segment sales. Chief among these changes was the emergence of managed health care providers, such as health maintenance organizations (HMOs), since these organizations generally have drug formularies that tend to encourage the use of lower-priced drugs. The percentage of insureds enrolled in HMOs doubled between 1985 and 1993.¹⁹ By 1993, roughly 18% of insureds were covered by HMOs. Of these insureds, the majority obtained prescription coverage from their HMO (e.g., 95% by 1993)²⁰ Compared to traditional fee-for-service insureers (who typically paid a percentage of out-of-pocket expenses), HMOs tend to have policies that encourage the use of generics. For example, over 85% of these plans required that a prescription be filled with a generic, if available.²¹ Virtually all of the prescription plans that did not mandate generics required insureds to make an additional payment to obtain the branded version. As these types of health care providers have increased their share of insureds, the market for generic drugs has grown. In addition, even fee-

¹⁹ Quinn (1998) at 34 for non-Federal insureds, and at 42 for Federal Employee Health plan insureds.

²⁰ See Muirhead (1994).

²¹ CibaGeneva Pharmacy Benefit Report (1995).

for-service insurers have adapted in ways to promote generic substitution; for example, some of these insurers now charge a lower co-payment if the patient chooses the generic version. These changes have increased the size and profitability of the generic segment. Hence, demand-side changes may have induced innovator firms to enter as generic producers of their products.

These two motivations have different implications for the kinds of drugs for which we would expect to see branded firms attempt entry into generic production. The strategic motive is most effective for drugs for which the strategy increases generic prices most significantly. If, as we suspect, such drugs are those which would have relatively few entrants absent branded generic entry, then if the strategic motive were important, branded generic entry would be most common for drugs with relatively small pre-patent expiration sales. In contrast, if the motive were simply to obtain a share of the available rents, without regard to affecting generic prices, we would anticipate branded generic entry for drugs with large expected generic segment sales (i.e. those with large pre-patent expiration revenues).

III. The Effect of Branded Generic Entry on Market Equilibrium

The institutions described above suggest a means by which the presence of branded generic drugs can affect the nature of competition and consumer welfare. This section incorporates the above intuition into an equilibrium model of branded generic entry that explores the implications of such entry under alternative scenarios. Section IV provides empirical content to the model. That section describes how we use the structural estimates from R&W and CWH to determine the likely effects of branded generic entry on key measures of market performance including prices, profits, and welfare.

We begin by presenting a model of generic entry without branded generic drugs, and then adapt the model to incorporate branded generic entry. Our model represents a stylized version of the industry characteristics and economic intuition developed above. A central premise in our model is that earlier ANDA approval and entry by a generic firm implies greater quasi-rents for the generic firm. This could occur for several reasons. First, earlier entry means that a firm will be selling its product for a greater portion of the time period that the generic market is viable. Second, earlier entry may confer larger subsequent market shares because switching costs may make customers reluctant to buy from later entrants. Finally, since earlier entry means that a firm competes for a time in a market with fewer rivals, oligopolistic tendencies may lead to higher average realized prices for earlier entrants. For these reasons, firms prefer to be approved early and typically initiate the ANDA application process prior to patent expiration.

We assume that for any drug approaching patent expiration, there are a large number of potential generic producers, with ex-ante identical costs. A subset of these firms will choose to sink the costs of entry (prepare an ANDA application). Because initial applications are often found to be deficient by the FDA, firms typically conduct additional tests and resubmit their applications. This suggests that the order of entry to a generic drug market is stochastic, so that an individual firm does not know how many other generic firms will be approved before it gets its ANDA approved. This also implies that while firms are approved sequentially, they make entry decisions simultaneously. Free entry by potential entrants implies that the number of firms choosing to enter will equate the expected rents from entry with the expected costs.

To model this formally, we calculate the rents available to the industry. Let π_{it} represent the rents earned by all firms at time t when there are i firms, and let π_{it} represent the probability

that there are i firms at time t . Finally, let δ represent the discount factor and A represent the application costs. Then we have,

$$\text{Expected Profit} = \frac{1}{E[n]} \sum_{t=1}^{\infty} \delta^t \left(\sum_{i=1}^n \pi_{it} \right) - A = \frac{V}{E[n]} - A \quad (1)$$

where V is defined as the present value of the stream of rents available to all generic entrants.

Free entry implies that expected industry profits, $V - A E[n]$, are zero. We liken the entry decision to a mixed-strategy, simultaneous-move, Nash equilibrium. If there are M potential entrants, they independently chose a probability of entering, μ , such that the expected number of entrants, M , equals n . In equilibrium M will equal V/A , since if M is less (more) than V/A , then expected profits will be positive (negative), and it is profit improving for a firm to unilaterally deviate toward setting a higher (lower) μ . Such a deviation reduces (increases) V , moving towards $M = V/A$. Let n^* be the number of entrants associated with the equilibrium μ and V .

Note that the values of the available rents, π_{it} , will differ across generic drug markets. That is, different chemical entities have different demand and supply characteristics that will affect the value of the rents available. As such, the equilibrium number of firms producing each drug will vary with these exogenous market characteristics. The empirical approach of R&W takes advantage of this variation to determine the equilibrium relationships between rents and the number of entrants.

This enables us to calculate the number of entrants in a market in the benchmark case (i.e., without branded generic entry) as a function of market characteristics, and to examine the

effect of anticipated branded generic entry on the equilibrium.²² To model branded generic entry, we note that branded generic entry means that the first-mover rents $\pi_{1i} | i$ are no longer available to independent generic entrants. This means that if independent generic entrants anticipate branded generic entry, expected profits to each independent generic firm is,

$$\frac{1}{E[n]} \sum_{t=1}^{\infty} \delta^t \left(\sum_{i=1}^n \phi_{i-1,t} (\Pi_{1t} - (\pi_{1t} | i)) \right) - A = \frac{1}{E[n]} \sum_{t=1}^{\infty} \delta^t \left[\left(\sum_{i=1}^n \phi_{i-1,t} \Pi_{1t} \right) - \left(\sum_{i=1}^n \phi_{i-1,t} (\pi_{1t} | i) \right) \right] - A \equiv \frac{V'}{E[n]} - \frac{V_1}{E[n]} - A \quad (2)$$

Note that $\pi_{1i} = \pi_{1i} | i$, so that only the branded firm is making generic profits when $i = 1$.

Hence, determining the equilibrium with branded generic entry requires an estimate of $\pi_{1i} | i$, in addition to the structural estimates required for the benchmark case. As discussed below, because our information about the magnitudes required to estimate $\pi_{1i} | i$ is limited, we instead make assumptions that allow us to obtain upper and lower bounds on its magnitude.²³

²² That is, we assume that the branded firm credibly committed to entering generic sales of the drug. A branded firm that announces its intention to enter the generic segment, and thereby deters independent entry, may discover at the generic launch date that it is now not profitable to enter. Generic entry may not be profitable because, the holding the number of independent entrants constant, branded generic entry reduces generic price, thereby reducing branded profits. If introducing the branded product is not profitable at the time of patent expiration, the earlier announcement of its intention to enter would not be credible and strategies based on it are not sub-game perfect. Entry is profitable, and therefore the announcement is credible, when the branded firm's profits in the generic segment are large compared to the indirect effect of lower generic prices on its profits in the branded segment. As discussed below, profits from the generic segment are likely to dominate lost profits from cannibalization in the markets we examine.

²³ One simplifying assumption we make in regard to π_{1i} is that following entry by other generic firms, the branded generic firm behaves as though it was an independent firm. This assumption will overstate the effect of branded generic entry if the branded firm would, *ceteris parabus*, choose higher prices (or less aggressive marketing) than an independent generic firm would. The reason the branded firm might choose higher prices is that sales of the generic form of its product is likely to come at the expense of its higher-margin branded product. Alternatively, the branded firm may be more aggressive than a similarly-situated independent firm once there are rival producers (i.e., $i > 1$) if its goal in introducing the generic (continued...)

Comparing equations (1) and (2) shows that branded generic entry can reduce the aggregate number of generic producers. Recall that in equilibrium, the number of independent firms adjusts so that the expected profits are zero (e.g., the expected number of independent generic entrants, $E[n]$, equals V'/A). Since the branded firm's generic product captures more than $1/(E[n] + 1)$ of the total generic profits, we would expect that expected profits to each independent generic producer would decline, unless the total number of producers fell. For example, suppose the number of independent generic producers in the equilibrium with branded generic entry was $n^* - 1$, so that the total number of generic entrants was the same as the number in the equilibrium without branded generic entry. Then, if total generic rents are the same in the two equilibria, it follows that $V' = V - V_1$ and because $V_1 > V/n$, (that is, first entrant rents are larger than the average rents to other entrants), we know that $V' < V(1 - 1/n^*)$.²⁴ This in turn implies that a reduction of one in the number of independent generic firms is insufficient to replicate the average rent per entrant that would exist absent branded generic entry. Hence, the anticipated addition of one branded generic firm will crowd out more than one independent generic firm.

Determining the magnitude of the effect of a branded generic introduction on equilibrium in the generic market requires knowing several structural relationships. In addition to knowing the magnitude of the effect of the branded generic entry on independent generic rents, one needs to know the relationship between generic rents and the number of entrants, and the relationship

²³(...continued)
is to reduce the profits of independent generic firms.

²⁴ In general, we would expect total rents to all generic producers to fall if $n = n^* - 1$ (as our simulations suggest) although this conclusion depends in a complicated way on the entry probabilities.

between the number of generic producers and generic prices. These two relationships are estimated in R&W (the methodology is discussed in greater detail below). These estimates are based on a sample of 31 drugs that went off patent in the late 1980s/ early 1990s.

Thus, the R&W estimates are sufficient to allow us to calculate the impact of a branded generic introduction on equilibrium in the generic market segment, and in particular on generic prices. However, it does not provide any estimates regarding the impact of the introductions on profits from the branded drug. To calculate the effect on branded profits, we make use of estimates provided in Caves, Whinston and Hurwitz (1991). CWH estimate the equilibrium effects of the number of generic producers on branded price, generic-branded price ratios, branded market share and total quantity demanded. In a series of regressions, they use instrumental variables estimators that treat the number of generic producers as endogenous. Their sample includes drugs that went off-patent during the period 1976-1987. While this period overlaps somewhat with the sample period in the R&W data, the patent expirations for the drug in the CWH sample are generally earlier. In particular, it covers some drugs that went off-patent before the Waxman-Hatch Act of 1984 made generic entry substantially less difficult. However, there is no ex-ante reason to suspect that the degree of substitution between branded and generic drugs differed in the two samples²⁵

As such, we believe the results from the CWH analysis provides us with a reasonable means of estimating the effect of changes in the generic segment on profits on the branded

²⁵ While it is possible that the measured degree of substitution between branded and generic drugs differed because generic firms only entered very large markets prior to 1984, we view these drugs as sufficiently similar to those in R&W in terms of this substitution as to make their CWH measures meaningful.

product. That is, the changes in market conditions they document result from a change in the number of generic producers. The effects on branded prices are assumed to derive from branded firms' optimal unilateral response to generic price changes. The changes in branded and generic quantity reflect the substitution effects implied by these price changes. Our strategy is to calculate the effect of branded generics on generic prices from R&W and then to calculate the effect of this generic price change on the branded market segment using CWH.

IV. Results

A. CALIBRATING THE MODEL PARAMETERS

In Reiffen and Ward (2005), we estimate relationships that allow us to identify the structural model represented by equation (1) above. First, we estimate the effect of the number of competitors on prices that allows us to determine the point at which additional firms no longer lead to price reductions. We do this by regressing the ratio of the price with i firms present to the pre-patent expiration branded price (P_{bk}) against dummy variables for the number of competitors (D_i),

$$\frac{P_x}{P_{bk}} = \alpha_0 + \sum_{i=1}^{10} \alpha_i D_i + \sum \gamma_j X_j$$

where X_j represents other factors that could affect pricing.²⁶ We find that none of the dummy variables for ten or more firms are significant, indicating that no further price reductions are

²⁶ The relationship between generic prices and the number of generic competitors has been examined in several previous studies. All find a statistically significant negative relationship between generic price and the number of generic competitors. See, e.g., Caves, Whinston and Hurwitz (1991), Frank and Salkever (1997), and Wiggins and Maness (2004). For a discussion of these studies, and a comparison of the estimated price relationships, see R&W at 45.

associated with additional independent generic entry after that point. As such, we identify the price level when there are ten producers as long-run marginal cost, $(\alpha_0 + \sum_j \bar{X}_{kj})P_{b,k}$ where \bar{X}_{kj} is the mean value of the other explanatory variables. These estimates and this interpretation allow us to construct price-cost markups when fewer than ten generic competitors are present as $(P_{it} - MC)/P_{it} = (\alpha_i / (\alpha_0 + \alpha_i + \sum_j \bar{X}_{kj}))$.

R&W find that generic prices have the expected negative relationship to the number of producers. As depicted in Figure 1, the price-cost margin is roughly 25% when there is a single generic producer (with a standard error of about 5%). The margin declines monotonically with the number of firms, until there are 7 producers, at which point the margin is about 8%. The relationship is fairly flat between 7 and 9 competitors, and is statistically indistinguishable from 0 for 10 or more competitors. Of the other explanatory variables, we find statistically significant negative effects of time since patent expiration (i.e., price falls over time, holding the number of competitors fixed), and the number of new substitute drugs.

Next, R&W estimate how generic revenues vary over time. We find that the main determinants of generic revenues at time t (Rev_t) are the size of the branded firm's revenues prior to patent expiration and the time since patent expiration, although other factors contribute as well.²⁷ The predicted values derived from these two regressions are used to calculate the rents available with different numbers of firms and at different times as $\pi_{it} = (P_{it} - MC)/P_{it} Rev_t$.

²⁷ In R&W, generic revenue was shown to also be a function of the degree to which other chemicals substitute for this drug, the existence of multiple brands (pre-patent expiration), and the ease of switching between providers all affect the expected rents available.

Finally, R&W developed an iterative estimator that allowed us to estimate the probability of i firms at time t , π_{it} , that incorporates the simultaneity of the availability of rents on the probability of entry and the probability of entry on the available rents (as represented in equation (1)). We modeled the probabilities, π_{it} , as the product of a hazard function governing the speed of entry and a Poisson function governing the distribution of firms in the cross-section. For both the hazard and the Poisson estimations, the key determinant for the speed of entry and number of entrants was the amount of rents available V .²⁸ That is, markets with larger pre-patent expiration branded revenues experienced more entry and experienced it faster.

These estimates enable us to determine how an exogenous change in rents will affect the speed of entry and the number of entrants. Alternatively, one can use the estimates to simulate how an exogenous change, such as stricter FDA scrutiny of applications or branded generic entry, can affect equilibrium rents, entry, and pricing.

As noted above, estimating the effect of branded generic entry requires an estimate of the size of the difference between the rents available without branded generic entry, V , and those with branded generic entry, V' . The difference is the sum of first-mover rents ($\pi_{it}|i$) that are no longer available to independent entrants. While it is commonly recognized that these first-mover advantages exist and can be large, no precise estimates exist for our purposes.²⁹ Instead, we implement two alternative assumptions roughly corresponding to the severity of switching costs that serve to provide upper- and lower-bounds. As a lower-bound, we assume the first-mover

²⁸ In addition, we found evidence that, after the generic drug scandal of the late 1980s, the FDA was more restrictive in their approval procedures.

²⁹ See Cook (1998), Bond and Lean (1977) and Berndt et al. (1995).

obtains market share of $1/i$ where i represents the number of competing firms at a point in time. This assumption corresponds to the equilibrium of a Nash-Cournot game among homogeneous firms (i.e. no switching costs). Our alternative extreme assumption is that once a customer chooses a generic drug supplier, it cannot switch. New competitors now compete only for a share of new sales. We implement this by assuming that the first mover's quantity sold is its quantity in the previous period plus $1/i$ of any growth in the size of the market.

B. APPLYING THE R&W MODEL TO BRANDED GENERIC ENTRY

To calculate the effect of branded generic entry, we first generate the equilibrium outcomes without branded generic entry. We make this calculation for three different hypothetical market sizes, corresponding to the average drug from the R&W sample, and for a market in which the log of pre-patent innovator revenues were one standard deviation above and below the average. Next, we generate equilibrium outcomes assuming branded generic entry for our lower and upper-bound assumptions described above. Table 1 summarizes the results of these hypothetical situations.

Each calculation in Table 1 is based on determining the equilibrium number of independent generic entrants under the specified circumstances. That is, we determine how many independent generic firms can earn quasi-rents at least as high as the fixed costs of entering, given the characteristics of the drug (e.g., pre-patent expiration branded revenues), and the assumptions about the use of the branded generic strategy and switching costs. We use an

estimate of fixed entry costs of \$475 thousand, which is R&W's estimate of those costs for the drugs in our sample from (R&W, at p. 47).³⁰

Our calculations show that the branded generic strategy reduces the equilibrium number of entrants by roughly the same number in all three hypothetical markets; we estimate the change to be between 1.7 and 2.4 for all three markets. The effect of that change on branded profits and prices, however, is different for the three hypothetical markets. In the high switching-cost case, we estimate the branded firm earns rents of \$1.9 million from the generic segment in the large markets, compared to \$1.6 million in the medium market and \$1.4 million in the small market.

Conversely, the effect of prices is largest in small markets. This reflects the finding (portrayed in Figure 1) that a reduction of two in the number of entrants raises the generic price by more in a market that has fewer entrants in the benchmark case. Figure 2 displays the time paths of equilibrium price-cost ratios corresponding to these nine scenarios. The average lower and upper-bound percentage change in the prices, weighted by the number of units sold, are 1.1% and 1.8% for the small market, 0.4% and 1.2% for the average market and 0.3% and 0.7% for the large market.

C. APPLYING THE GENERIC PRICE CHANGES TO THE CWH MODEL

In addition to the profits earned from selling the generic product, the branded generic strategy allows the branded firm to earn higher profits on its branded product. CWH estimate the

³⁰ This estimate of \$475 thousand application costs in the late 1980/early 1990s is similar in real terms to Hollis's estimate of \$1 million Canadian (~ \$700 thousand in 1998 US dollars, or \$560 thousand in 1990 US dollars) in the late 1990s.

effects of the number of generic producers (N_i) on market “outcomes” (e.g., generic price or generic market share) with regression equations of the form:

$$\ln(\text{Outcome}_i) = \beta_0 + \beta_1 N_i + \beta_2 N_i^2 + \beta_3 X_i + \varepsilon_i. \quad (3)$$

Using these estimates from CWH, we calculate the percentage change in each outcome as:

$$\frac{\text{Outcome}_1}{\text{Outcome}_0} = \exp\left(\hat{\beta}_1(N_1 - N_0) + \hat{\beta}_2(N_1^2 - N_0^2)\right).$$

For example, in the branded price regressions, $\beta_1 = -0.0184$, $\beta_2 = .00048$, so that if $N_0 = 4.2$, and $N_1 = 2.3$, CWH predict a change in branded price of 2.95%.³¹

The effects of branded generic entry on the branded market segment are reported in Table 2. The model predicts that the branded firm’s unilateral response to higher generic prices is to raise its price. This indicates that some degree of substitution is implicit in the CWH estimates. However, the calculated average change in branded price over three years is quite small, never exceeding 0.3%. Because the branded generic strategy increases generic price by only a small amount in the hypothetical large market, the corresponding branded price change there is also quite small. The branded quantity rises because the substitution effect from the generic price change exceeds the direct effect from higher branded prices. We calculate the change in rents in the branded segment using the price cost margin estimates in R&W. The increase in rents range

³¹ The 2.95 estimate corresponds to the eventual equilibrium price difference between the benchmark and no switching cost estimates. Also note that the only outcome that is comparable between R&W and CWH concerns the estimates of the change in generic prices resulting from an exogenous change in the number of generic firms. The estimated effect is about six times larger using the CWH method. Rather than combine estimates from two analyses that would be inconsistent with each other, we instead generate estimates from CWH that would be consistent with the generic price change that results from R&W. This preserves the relative magnitudes of the structural parameters from CWH, but preserves the absolute magnitudes from R&W.

from less than 0.2% of branded revenues in the larger markets to 1.2% in the smaller markets. Because the larger markets already have so many generic firms, branded generic entry there has a small effect on generic prices, and an almost-negligible effect on branded rents in these markets.

For larger markets, the primary effect of the branded generic strategy is to increase the branded firm's profit through the sales it makes in the generic segment. Using the branded firm's profit estimates from tables 1 and 2, we find that its profit in the generic segment is always larger than its profit in the branded segment, more than twice as large in the no switching cost scenario. This occurs despite substantially more branded segment rents at risk to cannibalization in the larger markets. In this sense, the strategic motive is less important than the rent-seeking motive.

The "management" of branded cannibalization resulting from the generic strategy can be seen most dramatically by considering a market slightly smaller than the typical small market in our sample. For a drug with sales of less than \$2 million per month (roughly 2/3 the size of the small market in our simulations) and average values for the other exogenous variables, the branded generic entry eliminates all independent generic entry. In such a market, the branded firm can, under some circumstances, choose generic prices sufficiently high to drive generic sales towards zero, thereby minimizing the loss in branded profits. Specifically, if buyers' choices in period t are independent of prices in past periods, then the branded firm can choose high generic prices when it faces no generic competitors, and then lower them upon entry. This effectively prevents entry in markets with less than \$2 million per month in revenue. Alternatively, if buyers react slowly to price changes (high switching costs), then the branded firm may need to choose somewhat lower prices, even when it is the sole generic seller, in order to prevent entry. Since

five of the 31 drugs in the R&W sample had less than \$2 million per month in pre patent-expiration revenues, this case may apply for some important drugs.

The primary effect of branded generic strategy is to transfer rents from consumers to the patent holder. The transfer is roughly equal to the initial quantity times the price change in each segment. However, we estimate the social welfare effects are small, and potentially positive. This is because the price and quantity changes are so small that deadweight losses are typically less than two orders of magnitude smaller. In addition, production efficiencies will occur because fewer firms are incurring the fixed costs of entry. In equilibrium, independent firms' rents are completely dissipated on the fixed costs of entry, but branded generic firms' rents are not. Fewer firms implies less rent dissipation. We calculate the reduction in fixed costs as equal to the average fixed cost per firm times the reduction in the expected number of entrants as about \$0.8 million ($= 1.7 * \475) when there are no switching costs and \$1.1 million when they are high. This change in fixed costs assumes that the branded generic entrant incurs the same fixed costs as independent firms, which likely understates the cost savings..

A few generalizations seem clear. First, ignoring the effects on cannibalization of its branded sales, branded firms have a larger incentive to enter generic production in larger markets. Second, the effect of branded generic entry on generic prices is smaller in these larger markets. This would tend to reduce the additional profits from "managing" cannibalization. Third, even though the price increase is larger in smaller markets, because so few units are sold, the transfer from consumers to producers tends to be smaller. Fourth, a productive efficiency occurs from fewer firms sinking the costs of entry. Fifth, consumer losses from higher prices can

be comparable to the magnitude of the rents gained by the branded generic firm, even though deadweight losses are likely to be much smaller.

D. APPLICATION TO PARAGRAPH IV LITIGATION

The conclusion that branded generic entry will be more effective at raising prices in small and medium-sized markets results from two aspects of the equilibrium;

1. A given reduction in the number of independent generic firms has a larger effect in smaller markets,

2. The first mover profits are a larger percentage of total profits in such markets.

This second effect implies that branded generic entry can be particularly effective in maintaining incumbent profits in “Paragraph IV” cases. Paragraph IV of the Hatch-Waxman Act provides an incentive for generic firms to challenge the validity of patents on branded products. It stipulates that generic firms that prevail in court in patent litigation, and thereby demonstrate that an innovator firm’s drug patent is invalid, are given a 180 day period in which no other generic firm can produce the drug. Presumably, the 180 day period of exclusivity is the firm’s reward for demonstrating that the patent is not valid.

Under current regulations, the branded firm is not prohibited from producing a generic drug during the exclusivity period.³² As in the analysis above, the introduction of a branded generic will reduce the successful litigant’s profits significantly; creating a duopoly, rather than a monopoly during the 180 day period. Thus, branded generic entry in Paragraph IV cases can

³² In the case of nitrofurantoin discussed above, the judge described this feature as “a gaping black hole in the regulation.” See, *Forbes.com*, 8/29/04.

dramatically change the incentives of generic firms, perhaps eliminating the incentive to litigate the validity of patents in some cases.

It follows that the branded generic strategy can have a significant effect on prices for drugs which would otherwise have their patents challenged. Unlike the relatively small changes in prices we estimated above (where the drugs are not subject to patent uncertainty), the effect of branded generics on prices could be dramatic. That is, if the strategy allows a drug with an invalid patent to remain protected from competition for several years, it will result in significantly higher prices for those consumers who would have bought the generic. In addition, the price of the branded product would likely rise. Moreover, these effects can emerge in markets of any size. Specifically, unlike the estimates in Section B and C, the magnitude of the welfare and transfer effects can be especially large for large-revenue drugs.

V. Conclusion

This paper evaluates the potential for pharmaceutical patent holders to strategically introduce generic versions of their products just prior to patent expiration. It describes how such an introduction can change the incentives of independent generic firms to begin production of the generic drug. Specifically, we show that the long-run equilibrium may entail higher prices when a branded generic introduction is anticipated by independent generic producers, compared to the equilibrium when branded generic entry is precluded. Further, the paper provides estimates of the change in prices that can result from this strategy.

Our estimates show that generic price are higher in the equilibrium with branded generic entry. This in turn implies that the strategy increases the branded firm's profits. What we do not

consider is the cost of implementing the strategy. Chief among these is the branded firm's cost of credibly signaling that it will bring its generic product to market. Part of the signaling will likely involve introducing a generic drug into markets in which the branded generic product was *not* anticipated. In this "transitional" period, the number of independent generic producers is not affected by the branded generic introduction (since it was not anticipated), so that generic prices will actually be lower than they would have been in the initial "no branded generic" equilibrium. This provides one reason why the branded generic strategy has not been universally adopted by branded firms.

Comparing long-run equilibria, our estimates suggest that the price changes resulting from branded generic entry are largest in relatively small markets. Conversely, the estimates indicate that such introductions are least problematic (from the standpoint of social welfare), but most profitable in relatively large markets. As such, government policy targeting branded generic entry would be most appropriate if branded generic drugs were most often introduced in small markets.

As an factual matter, it is difficult to characterize the kinds of drugs for which branded generic entry has occurred. The examples cited in Section II from the popular press all represent large drugs, but one would expect that drugs with the greatest revenue are those that attract the most media coverage. Developing a systematic method of determining where branded generics have occurred in the past would therefore help determine whether branded generics should be a focus of government scrutiny.

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Table 1
The Equilibrium Effects of Branded Generic Entry:
Equilibrium Outcomes for Base Case (no Branded Generic) versus Branded Generic
Under Two Alternative First-mover advantage Assumptions, as a Function of Market Size

	Expected Number of Independent Generic Firms	Total Rents (\$ thousands)	Branded Generic Rents (\$ thousands)	Independent Generic Rents (\$ thousands)
Small Markets (\$2.9 million in pre-patent monthly sales)				
Base Case	4.2	\$1,888		
No Switching Costs	2.4	\$2,130	\$1,077	\$1,053
High Switching Costs	1.9	\$2,212	\$1,350	\$862
Average Markets (\$8.0 million in pre-patent monthly sales)				
Base Case	8.9	\$3,970		
No Switching Costs	7.2	\$4,210	\$1,010	\$3,200
High Switching Costs	6.5	\$4,500	\$1,600	\$2,900
Large Markets (\$21.5 million in pre-patent monthly sales)				
Base Case	13.9	\$6,220		
No Switching Costs	12.0	\$6,635	\$1,256	\$5,380
High Switching Costs	11.6	\$7,089	\$1,907	\$5,182

Table 2
The Effects of Branded Generic Entry on Branded Market Segment
Under Two Alternative First-mover advantage Assumptions, as a Function of Market Size

	Percent Change in Price	Percent Change in Quantity	Percent Change in Rents	Dollar Change in Rents (\$ thousands)
Small Markets (\$2.9 million in pre-patent monthly sales)				
No Switching Costs	0.2%	0.7%	0.5%	\$480
High Switching Costs	0.3%	1.2%	0.8%	\$806
Average Markets (\$8.0 million in pre-patent monthly sales)				
No Switching Costs	0.1%	0.3%	0.2%	\$449
High Switching Costs	0.2%	0.7%	0.4%	\$1,292
Large Markets (\$21.5 million in pre-patent monthly sales)				
No Switching Costs	0.0%	0.1%	0.1%	\$553
High Switching Costs	0.1%	0.3%	0.2%	\$1,246

Figure 1
Estimated Price-Cost Markups
Coef. Est. plus/minus 2 S.E.

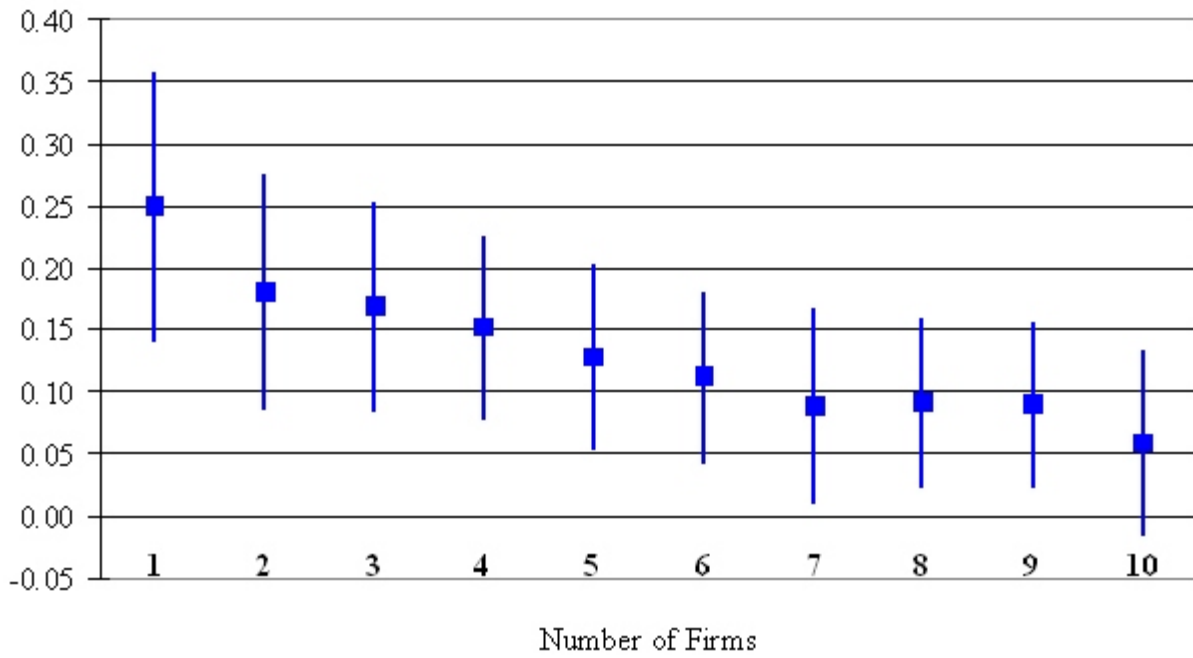


Figure2

Expected Prices Paths for Various Senarios

