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Brand Royalty and Generic Competition

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Abstract

Facing generic competition, a brand-name drug company sometimes launches its own generic called an "authorized generic" (AG) through a third-party entity. If an authorized party transfers a substantial part of its profits to the brand-name drug company, the latter's total profit increases as a result and every branded drug that comes off the patent should have its AG version. However, in actual fact only a small proportion of branded drugs have AGs. To explain this puzzle, I develop a model that features switching costs due to the customer base a brand-name drug develops prior to generic entry. The model predicts that AGs are launched when switching costs to the generics are sufficiently low. I test this hypothess using prescription drug data and find strong support for it.

1 Introduction

When facing generic competition, brand-name drug companies sometimes launch their own generic drugs. Such generics, to be distinguished from ordinary generics, are called "authorized generics" (AGs). Authorized generics contain exactly the same ingredients as the brand-name drugs and even come off the same production lines. However, they are sold by third-party entities in the

generic category and hence they directly compete with the brand-name drugs like any other generics. This gives rise to the puzzle: why brand-name drug companies use such a strategy? One popular answer is product differentiation. But product differentiation is considered a strategy for entry deterrence whereas AGs are launched almost simultaneously with generic entry.

Another possible explanation is in terms of divisionalization due to Baye, Crocker and Ju (1996), who show that in Cournot oligopoly a firm can always increase total profit by splitting itself into two autonomous entities. Thus, a launch of an authorized drug makes business sense if the authorized generic distributer acts as an autonomous entity but agrees to transfer a large part of its profit to the brand-name drug manufacturer. But if such a "divisionalization" strategy is profitable, we should observe brand-name drug companies launching AGs without fail whenever they face generic competition. In actual fact, however, only a small number of off-patent brand-name drugs have ever had AGs. [1]This fact gives rise to the second puzzle: if divisionalization is profitable, why don't brand-name drug companies launch authorized generics against every generic entry?

In this paper I intend to explain these puzzles. In doing so, I maintain the assumption that consumers are well aware that generics are bioequivalent to (i.e., just as effective and safe as) the branded drug. However, the same drug never treats every patient equally well because the same illness affects individuals differently and make them react differently to the same drug. In such cases patients learn the efficacy of a drug through experiences; that is, as they keep using the drug, they continuously Baysian-update their beliefs in the efficacy of the drug. Thus, although all drugs, the brand-name and generics, are

[1] This is according to the AG list prepared by FDA (U. S. Food and Drug Administration),

equally efficacious on average, personal experiences determine the actual efficacy for each patient and therefore his or her preferences for the drug. In such cases, the brand-name drug is distinguishable from generics in that patients have used the former long before the generics are introduced. That is, the brand-name drug enjoys a customer base at the time of generic entry.

In this paper, I place the customer base at center stage of my analysis and analyze its implications using the notion of switching costs popularized by a series of papers by Klemperer.[5] More specifically, I first build an analytical model, which predicts that the brand-name drug company launches an authorized generic when consumers face sufficiently low switching cost to the generic. I then develop an econometric model to find strong support for my hypothesis.

My analytical model has two periods and two firms; the brand-name company and the generic drug company. In the first period the brand-name drug company acts as a monopoly. In the second period, the generic drug producer enters the market and the two firms compete in a quantity-setting (Cournot) game. The Cournot assumption simplifies the analysis by eschewing mixed-strategy equilibria. As explicated above, customers who buy the brand-name drug in the first period develop certain affinities towards it, thereby forming the customer base for the incumbent. I assume that the brand-name company can influence the size of its customer base but cannot affect the switching cost per se, which comes to patients through experiences. In other words, I treat the switching cost as a key parameter of this model.

I next extend the model to allow the brand-name company to launch an authorized generic in period 2. As is the case, it is assumed that the authorized drug is marketed by a third party,which competes as an autonomous entity. Consumers regard all three drugs (brand-name, generic and authorized generic) as homogeneous. However, consumers constituting the customer base incur the

switching cost when switch to either kind of generics. Finally, I assume that there are more than one firm which want to market the authorized generic so that the brand-name drug manufacturer can make a take-it-or-leave-it offer to capture all the profit from AG sales.

A comparison of the two versions of the model yields two results. My principal result is that the brand-name drug manufacturer is more likely to launch an authorized generic, the smaller the switching cost from its brand-name drug to the generics. This has the following intuitive explanation. In the standard Cournot game, a launch of an AG has only the divisionalization effect, which is profitable to the brand-name drug company as shown by Baye et al. (1996).[6] However, in the presence of a customer base, a launch of an AG lowers the generic prices and lures consumers from the customer base to the generics. I call this potential erosion to the customer bases the cannibalization effect. In short, then, a decision whether to launch an AG hinges on the balance between the divisionalization effect which is beneficial to the brand-name drug, and the cannibalization effect, which proves harmful to the firm.

When the switching cost is sufficiently high, consumers do not switch so easily, so the incumbent can create a larger customer base to better position itself against generic entry. However, a large customer base exacerbates the cannibalization effect so it is to the interest of the brand-name drug company to guard the customer base. As a result, it is better off not launching an AG. Even if the switching cost is somewhat smaller so that some consumer base erosion is inevitable, the brand-name drug company may still refrain from launching an AG to avoid further customer base erosion. However, if the switching cost is sufficiently smaller so that generic entry causes an extensive customer base erosion, then an AG can give rise to only a small cannibalization effect, so the brand-name drug company launches one.

My second finding is that for a given switching cost, the incumbent is more likely to launch an AG if the market is larger. The intuition is that an increase in demand (intercept) expands the divisionalization effect relative to the cannibalization effect; more specifically, it raises the combined profit from the brand-name drug and the AG by a greater magnitude than the profit from brand-name drug sale alone.

My model thus yields two empirically testable hypotheses: a launch of an AG is more likely, the smaller the switching cost, and the larger the market demand level. In the second half of this paper, I test these hypotheses using the data collected from the FDA website and find strong support.

In the empirical extension of the present model it is of utmost importance to specify what constitutes the switching costs in the present context. To that end, note first that most drugs do not miraculously cure fatal illnesses. Rather, they reduce probabilities of death by relieving symptoms such as pain or anxiety or by altering clinical measurements - reducing cholesterol or blood pressure, for example. The point is that the true efficacy of drugs is difficult to ascertain even for scientists. In a word, drugs are credence goods. As such, consumers tend to rely on personal experiences to gain confidence in the drugs they take. Such confidence - or aversion to alternative drugs - grows if they use the same drugs repeatedly. In this respect, brand-name drug manufacturers have the first-mover advantage over generic entrants simply because consumers have always been using the brand-name drugs before the generics enter. This confidence in the brand-name drugs consumers have developed serves as the switching cost, i.e., the benefit a consumer must give up when switching to the generics.

I now relate my work to the literature. Some papers examine the effects of AGs on non-authorized generic entry. For example, FTC's 2009 report shows that a launch of an AG lowers generic prices and revenues, and it goes on to spec-

ulate that threats of AGs may even prompt a collusive agreement between the generic and the brand-name drug manufacturer, delivering a double whammy to consumers in the form of deferment of generic entry and non-marketing of AGs.[2] Ward (2005) finds a similar result; a launch of an AG reduces the number of potential generic entrants in the future.[3] In contrast, however, Berndt and Mortimer (2007) show that despite reduced expected gains due to a launch of an AG , there remain sufficient incentives for generic entry. Studying German data, Appelt (2010) even goes further to claim that introduction of AGs has no effect on the number of generic entrants, and concludes that entry deterrence is not a rationale for launching of AGs.[4][3]

In contrast to all these papers focusing on the effects of AGs on generic entry, there is only a scanty literature examining the incentives to launch AGs. My paper is an attempt to fill this lacunae in the literature. Further, my findings can shed light on some recent empirical findings. For example, Appelt (2010) empirically identifies earning generic profits as the primary motive for introduction of AGs.[4] My analysis interprets this as the divisionalization effect. My result may also explain the empirical finding of Berndt and Mortimer (2007) that drugs with higher pre-generic revenues are more likely to have AGs.[1] If the pre-generic revenues are interpreted as a proxy of the market size, my second result provides an explanation for their finding.

The remainder of this paper is organized in 5 sections. Section 2 presents a two-period model of Cournot oligopoly, in which a launch of an AG is ruled out. Section 3 extends the above model to allow for a launch of an AG through a third party. Section 4 I compares the two models and shows that a launch of

[2]Authorized Generics: An Interim Report of the Federal Trade Commission, 2009. http://www.ftc.gov/reports/authorized-generics-interim-report-federal-trade-commission

[3] Chen (2007) examines the legal issues arising from AGs, and calls for a legislative reform of the Hatch-Waxman Act.[2]

an AG is profitable to the incumbent only when the switching cost is relatively small. Section 5 presents an empirical model to test the hypotheses and discuss my empirical findings. Section 6 concludes the paper.

2 Competition without an authorized drug

This section presents a two-period model of entry and competition without the AG. The model has the following game structure. On the demand side I assume that consumers consider the brand-name drug and its generics equally effective (i.e., homogeneous). Each consumer buys at most one unit of either drug per period. Consumers however have varied needs for the drugs, generating the downward-sloping market demand function. I assume that demand is constant over time. Further, to keep things simple, I assume linear demand and write it as p = m - Q, where m is demand intercept and Q is total industry supply. In period 1 only the brand-name drug is marketed; the generic substitute is brought to the market only in period 2. Although the drugs are considered homogeneous, as explicated in the introduction, those who buy the brand-name drug develop affinities towards it, which define the switching cost consumers must incur if they buy the generic substitute in period 2, because although it is as efficacious on average, they are not sure if they work as well as the brand-name drug they have been using since period 1.

I next describe the strategic interactions between the brand-name company and the generic firm. In period 1, a brand-name company, an incumbent monopoly, chooses quantity B of sales of its drug. Since each consumer buys at most one unit of it, B also equals the number of customers who buy the branded drug in period 1, i. e., the size of the brand-name drug's customer base. In period 2, a generic firm enters and the two firms play a Cournot game. I assume that they produce their products at a common constant marginal cost,

which I set equal to zero without loss of generality under linear demand.

I solve the model for subgame-perfect Nash equilibrium. Thus consider the second period, where the customer base B is given. Let b and g, respectively, denote the quantity of output supplied by the incumbent and the generic firm so that $Q = b + g$. The entrant maximizes the profit $\pi_g = (m - b - g)g$. yielding the standard best-response function $g(b) = (m - b)/2$. To derive the incumbent's best-response function, note that the incumbent faces the inverse demand function :

$$p_2 = \begin{cases} m + s - b - g & (b \leq B), \\ m - b - g & (b > B). \end{cases}$$

which is discontinuous at output b = B. This shows that, if the incumbent serves its customer base only, it can keep the price above the generic price due to the switching cost (s), but if wants to attract new customers, then it has to lower the price to match the generic price. Therefore, the incumbent's profit is also discontinuous at b = B and given by

$$\pi_b = \begin{cases} (m + s - b - g)b & (b < B), \\ (m + s - B - g)B & (b = B), \\ (m - b - g)b & (b > B). \end{cases}$$

In Figure 1 the curve to the left of point B displays the profit from the customer base only

$$\pi(b, s, g) = (m + s - b - g)b,$$

while the one to the right of B corresponds to the profit

$$\pi(b, g) = (m - b - g)b.$$

Now, to obtain the incumbent's best-response function, define these key quantities:

$$\overline{b}(g) = argmax\{(m + s - b - g)b\}$$

and

$$\underline{b}(g) = argmax\{(m - b - g)b\}.$$

Write the corresponding maximum profits as $\overline{\pi}(\overline{b}, s, g)$ and $\underline{\pi}(\underline{b}, g)$. Define the quantity $\widehat{b}(g)$ implicitly by

$$\pi(\hat{b}, s, g) = (m + s - \hat{b} - g)\hat{b} = \underline{\pi}(\underline{b}, g).$$

It is obvious that for given g

$$\widehat{b}(g) < \underline{b}(g) < \overline{b}(g).$$

In the linear case we have,

$$\overline{b}(g) = \frac{m + s - g}{2}$$

$$\underline{b}(g) = \frac{m - g}{2}$$

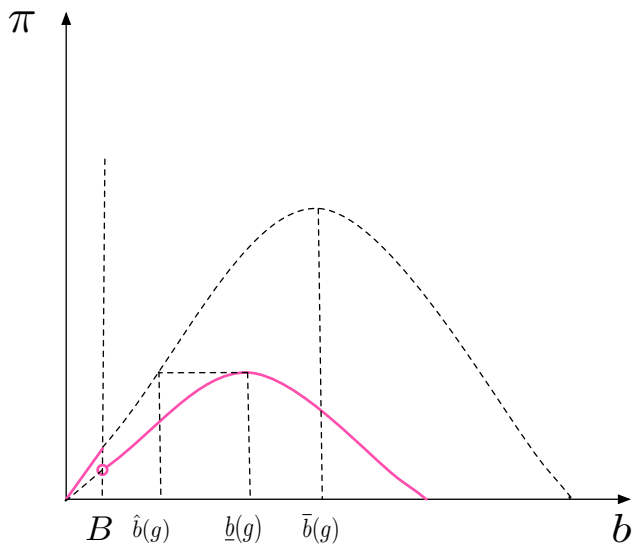
$$\widehat{b}(g) = \frac{m + s - g - \sqrt{s(2m + s - 2g)}}{2}$$

Now, as g increases, the profit functions $\pi(b, s)$ and $\pi(b)$ shift down, giving rise to the following three cases, depending on the location of point B.

Case 1. g is relatively small such that $B \leq \widehat{b}(\text{g})$. Then $\underline{b}(g)$ is the incumbent's best response to g

Case 2: g takes on an intermediate value so that $\widehat{b}(g) < B < \overline{b}(g)$. Then the incumbent's best response is B.

Figure 1: $B \leq \widehat{b}(g)$



Case 3: g is large so that $\bar{b}(g) \geq B$. In this case its best response is $\bar{b}(g)$.

These three cases are displayed in Figures 1 - 3.

Accordingly, the incumbent's best-respond function has three segments

$$b(g) = \begin{cases} \dfrac{m-g}{2} & g \leq m - 2B - 2\sqrt{sB}, \\ B & g \in (m - 2B - 2\sqrt{sB}, m - 2B + s), \\ \dfrac{m+s-g}{2} & g \geq m - 2B + s. \end{cases}$$

Figure 4 depicts the incumbent's best-response function. Note that it is discontinuous at b = B.

Accordingly, we can write the incumbent's equilibrium second-period profit

Figure 2: $\widehat{b}(g) < B < \overline{b}(g)$

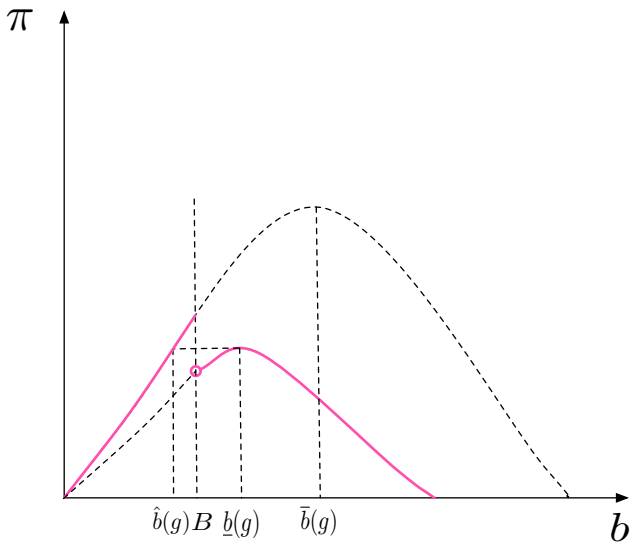


Figure 3: $\overline{b}(g) \geq B$

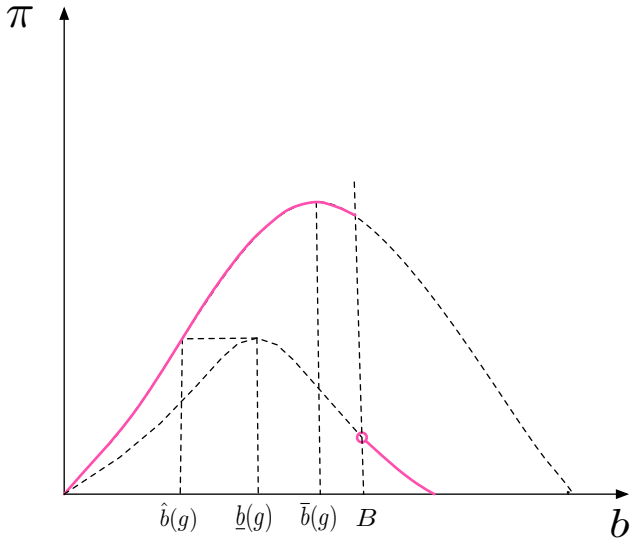
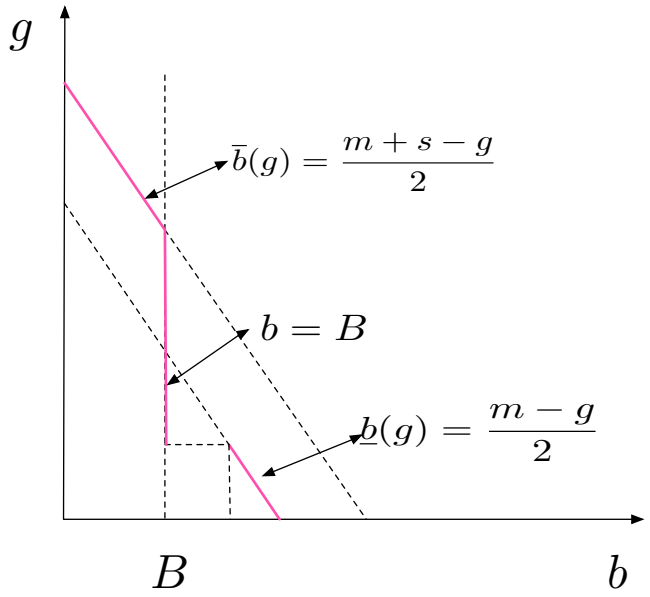


Figure 4: Best response function of the incumbent



as

$$\pi_b = \begin{cases} \frac{m^2}{9} & B \in (0, \hat{B}_2], \\ \frac{(m-B+2s)B}{2} & B \in [\hat{B}_1, \frac{m+2s}{3}), \\ \frac{(m+2s)^2}{9} & B \in [\frac{m+2s}{3}, \infty), \end{cases}$$

where $\hat{B}_1 \equiv \frac{3m+8s-4\sqrt{4s^2+3ms}}{9}$ and$\hat{B}_2 \equiv \frac{2m+3s-\sqrt{9s^2+12ms}}{6}$. As $\hat{B}_1 < \hat{B}_2$, if $B \in [\hat{B}_1, \hat{B}_2]$, there are two equilibria, one on the vertical section, the other on the lower section. So what equilibrium will the chosen? Since here we are actually looking for sub-game perfect equilibrium, we can let incumbent try out both equilibria to see which one will yield greater total profit.

Having computed the equilibrium profits in period 1, I am ready to move to period 1, in which the incumbent chooses output B to maximize the sum of

profits in both periods (we ignore discounting):

$$\Pi = \begin{cases} (m-B)B + \dfrac{m^2}{9} & B \in (0, \hat{B}_2], \\ (m-B)B + \dfrac{(m-B+2s)B}{2} & B \in [\hat{B}_1, \dfrac{m+2s}{3}), \\ (m-B)B + \dfrac{(m+2s)^2}{9} & B \in [\dfrac{m+2s}{3}, \infty). \end{cases}$$

Since the total profit function is not continuous, I first derive the optimal B in each case and then determine the global optimum.

Case 1: $B \in (0, \hat{B}_2]$.

In this case, B has no effect on the incumbent's period 2 profit. In the appendix I show that the constraint on B is binding. Therefore, the optimal B is $\hat{B}_2$, and the maximum profit is $\Pi(\hat{B}_2)$.

Case 2: $B \in [\hat{B}_1, \dfrac{m+2s}{3})$.

The unconstrained optimum occurs at $B_2 = \dfrac{3m+2s}{6}$, which is greater than $\hat{B}_1$. If $s > m/2$, then $B_2 < (m+2s)/3$, and hence B_2 is the interior solution, with the maximum profit $\Pi(\frac{3m+2s}{6})$; On the other hand, if $s \leq m/2$, B_2 exceeds the upper limit of the range of B so there is no optimum ($B = (m+2s)/3$ is the supremum).[4]

Case 3: $B \in [\dfrac{m+2s}{3}, \infty)$.

The unconstrained optimum occurs at $B_3 = \dfrac{m}{2}$. To find out if B_3 is an interior solution, I compare B_3 with the lower bound, $\dfrac{m+2s}{3}$. If $s \leq m/4$, $B_3 \geq$

[4]If the incumbent chooses B to maximize its total profit so that the second period equilibrium will appear on the vertical section, $B \in [\hat{B}_1, \hat{B}_2]$ will not be chosen.

$(m+2s)/3$, and so B_3 is the interior solution, with the maximum profit $\Pi(m/2)$. If $s > m/4$, $B_3 < (m+2s)/3$, and therefore B_3 is not an interior solution. Therefore, the maximum profit is $\Pi((m+2s)/3)$.

The next lemma summarizes the main findings:

Lemma 1:

1. When $B \in (0, \hat{B}_2]$, the local maxima is $\Pi(\hat{B}_2)$.
2. When $B \in [\hat{B}_1, \frac{m+2s}{3})$, the local maximum is $\Pi(\frac{3m+2s}{6})$ if $s > m/2$; otherwise, there is no maximum.
3. When $B \in [\frac{m+2s}{3}, \infty)$, the local maximum is $\Pi(m/2)$ if $s \leq m/4$ or $\Pi((m+2s)/3)$ otherwise.

2.1 Global maxima

So far we identified the local maxima in the three disjoint intervals of the incumbent's feasible set. We now turn to the global maxima for the incumbent.

1. If $s \leq \frac{m}{4}$, the local maxima are $\Pi(\hat{B}_2)$ and $\Pi(m/2)$. Computation shows that $\Pi(\hat{B}_2) < \Pi(\frac{m}{2})$ so the global optimum occurs at $B = \frac{m}{2}$ and $b = \frac{m+2s}{3}$. The incumbent's equilibrium total profit is $\Pi(\frac{m}{2})$.
2. If $s \in (\frac{m}{4}, \frac{m}{2}]$, the local maxima are $\Pi(\hat{B}_2)$ and $\Pi((m+2s)/3)$. A calculation establishes that $\Pi(\hat{B}_2) < \Pi(\frac{m+2s}{3})$ so the global maximum occurs at $B = \frac{m+2s}{3}$ and $b = \frac{m+2s}{3}$. The equilibrium total profit is $\Pi(\frac{m+2s}{3})$.
3. If $s \in (\frac{m}{2}, m)$, the local maxima are $\Pi(\hat{B}_2)$, $\Pi(\frac{3m+2s}{6})$ and $\Pi((m+2s)/3)$. Computation shows that $\Pi(\frac{3m+2s}{6})$ exceeds the other two. Hence, the equilibrium outputs are $B = \frac{3m+2s}{6}$ and $b = \frac{3m+2s}{6}$, and its total profit is $\Pi(\frac{3m+2s}{6})$

These results are summarized in

Proposition 1: The equilibrium customer base is given by

$$B = \begin{cases} m/2 & s \in (0, m/4], \\ (m+2s)/3 & s \in (m/4, m/2], \\ (3m+2s)/6 & s \in (m/2, m). \end{cases}$$

The following results are immediate consequences of Proposition 1

Proposition 2:

A) when $s \in (0, m/4]$, the brand-name firm sells less than its customer base in the second period;

B) when $s \in (m/4, m)$, the brand-name firm holds on to its customer base in the second period;

From Proposition 2, we can see that the brand-name drug is never sold to new customers in the second period. This implies that those who bought the brand-name drug in the first period are willing to pay the premium over the generic, which reflects the switching cost. This is consistent with the fact that in the real world the brand-name drugs are always priced higher than their generic counterparts.

3 Competition with the authorized generic

In this section we allow the incumbent to launch an AG through a third party in period 2. The firm distributing the AG is autonomous and competes fully with the brand-name drug company and the generic firm. I assume that the incumbent makes a take-it-or-leave-it offer to the management of the AG firm and receives all the profit from AG sales through a contractual agreement with the AG supplier. This increases the total profit in the standard Cournot

model and is called the divisionalization effect as noted earlier.

The model is similar to the one developed in the preceding section. In the first period the incumbent chooses the quantity B. In the second period, it competes now with two generic firms. Let a denote the quantity of the authorized generic supplied, and b and g the quantities of the brand-name drug and the generic drug supplied in the second period, respectively. With this notation the brand-name company faces the inverse demand function :

$$p_2 = \begin{cases} m + s - b - a - g & (b \leq B), \\ m - b - a - g & (b > B). \end{cases}$$

Note that the demand function is discontinuous at output b = B. Therefore, the incumbent's profit is also discontinuous at b = B:

$$\pi_b = \begin{cases} (m + s - b - a - g)b & (b < B), \\ (m + s - B - a - g)B & (b = B), \\ (m - b - a - g)b & (b > B). \end{cases}$$

The incumbent's best response function can be written as

$$b(a, g) = \begin{cases} \dfrac{m - a - g}{2} & a + g \leq m - 2B - 2\sqrt{sB}, \\ B & a + g \in (m - 2B - 2\sqrt{sB}, m - 2B + s), \\ \dfrac{m + s - a - g}{2} & a + g \geq m - 2B + s. \end{cases}$$

Without the customer base, the generic faces the demand

$$p_2 = m - b - a - g$$

and maximizes the profit $\pi_g = (m - b - a - g)g$. The best response function is

given by

$$g(b,a) = \frac{m-b-a}{2}$$

Similarly, the authorized generic faces the symmetric demand

$$p_2 = m - b - a - g$$

and maximizes the profit $\pi_a = (m-b-a-g)a$, obtaining the best response

$$a(b,g) = \frac{m-b-g}{2}$$

As in the previous case without the AG, the incumbent has three distinct best-response functions, depending on B, and hence there are three possible equilibria. Below I calculate, the incumbent's equilibrium profits for each possibility.

$$\pi_b = \begin{cases} \frac{m^2}{16} & B \in (0, \tilde{B}_2], \\ \frac{B(m-B+3s)}{3} & B \in [\tilde{B}_1, \frac{m+3s}{4}), \\ \frac{(m+3s)^2}{16} & B \in [\frac{m+3s}{4}, \infty). \end{cases}$$

Calculation shows that if

$$1/8\left(2m+9s-3\sqrt{s(4m+9s)}\right) \leq B \leq 1/4\left(m+2s-2\sqrt{s(m+s)}\right),$$

there are two equilibria, one is $(B, 1/3(m-B), 1/3(m-B))$, the other is $(m/4, m/4, m/4)$. Let $\tilde{B}_1 \equiv 1/8\left(2m+9s-3\sqrt{s(4m+9s)}\right)$ and $\tilde{B}_2 \equiv 1/4\left(m+2s-2\sqrt{s(m+s)}\right)$.

With the AG the equilibrium profits for the authorized drug manufacturer are:

$$\pi_a = \begin{cases} \frac{m^2}{16} & B \in (0, \tilde{B}_2], \\ \frac{(m-B)^2}{9} & B \in [\tilde{B}_1, \frac{m+3s}{4}), \\ \frac{(m-s)^2}{16} & B \in [\frac{m+3s}{4}, \infty). \end{cases}$$

In the first period, the brand-name firm's profit is $(m - B)B$ so the incumbent's total profits (including the profit for AG sales) are :

$$\Pi_{AG} = \begin{cases} (m-B)B + \frac{m^2}{8} & B \in (0, \tilde{B}_2], \\ (m-B)B + \frac{B(m-B+3s)}{3} + \frac{(m-B)^2}{9} & B \in [\tilde{B}_1, \frac{m+3s}{4}), \\ (m-B)B + \frac{(m-s)^2}{16} + \frac{(m+3s)^2}{16} & B \in [\frac{m+3s}{4}, \infty). \end{cases}$$

The incumbent chooses B to maximize Π_{AG} I consider the three cases seriatim.

Case 1 : $B \in (0, \tilde{B}_2]$

In this case, since the choice of B will not affect the incumbent's profit in the second period, the unconstrained optimum is B = m/2. However, since m/2 $> \tilde{B}_2$, the constraint on B is binding. Hence, $\tilde{B}_2$ maximize the total profit, yielding the maximized profit $\Pi_{AG}(\tilde{B}_2)$.

Case 2: $B \in [\tilde{B}_1, \frac{m+3s}{4})$

In this case the unconstrained optimum is $B_2 = \dfrac{10m + 9s}{22} > \tilde{B}_1$. Further, if $s \leq \dfrac{3m}{5}$, B_2 exceeds the upper bound on B and hence there is no optimum (the supremum is $B = (m + 3s)/4$. If $s > \dfrac{3m}{5}$, $B_2 < \dfrac{m + 3s}{4}$, and hence the incumbent choose B_2 ,with the maximum profit $\Pi_{AG}(\frac{10m+9s}{22})$

Case 3: $B \in [\frac{m+3s}{4}, \infty)$

In this case the unconstrained optimum is $B = \dfrac{m}{2}$. However, $m/2 \geq (m + 3s)/4$ if and only if $s \leq m/3$. Hence, when $s \leq \dfrac{m}{3}$, the constraint is not binding, and the maximized profit is $\Pi_{AG}(\frac{m}{2})$; otherwise, the constraint is binding and

the maximized profit is $\Pi_{AG}(\frac{m+3s}{4})$.

3.1 Global Maxima

The results from the preceding section are the following:

1. When $B \in (0, \tilde{B}_2]$, the local maximum equals $\Pi_{AG}(\tilde{B}_2)$.
2. When $B \in [\tilde{B}_1, \frac{m+3s}{4})$, there is a local maximum, $\Pi_{AG}(\frac{10m+9s}{22})$, if $s > 3m/5$
3. When $B \in [\frac{m+3s}{4}, \infty)$, there is a local maximum, $\Pi_{AG}(\frac{m}{2})$, if $s \leq \frac{m}{3}$; there is a local maximum, $\Pi_{AG}(\frac{m+3s}{4})$, if $s \in (\frac{m}{3}, m]$.

As we can see, the local maxima depend on the switching cost, and hence so does the global maximum. I compute the following:

1. When $s \leq \frac{m}{3}$, the local maxima are $\Pi_{AG}(\tilde{B}_2)$ and $\Pi_{AG}(\frac{m}{2})$. Computation shows that $\Pi_{AG}(\frac{m}{2}) > \Pi_{AG}(\tilde{B}_2)$, so the global optimum occurs at $B = \frac{m}{2}$ and $b = \frac{m+3s}{3}$. The incumbent's equilibrium total profit is $\Pi_{AG}(\frac{m}{2})$.
2. When $s \in (\frac{m}{3}, \frac{3m}{5}]$, the incumbent will compare $\Pi_{AG}(\tilde{B}_2)$ and $\Pi_{AG}(\frac{m+3s}{4})$. A calculation shows that $\Pi_{AG}((m+3s)/4) > \Pi_{AG}(\tilde{B}_2)$ so the global maximum occurs at $B = \frac{m+3s}{4}$ and $b = \frac{m+3s}{4}$. The equilibrium total profit is $\Pi_{AG}(\frac{m+3s}{4})$.
3. When $s \in (\frac{3m}{5}, m]$, the incumbent will compare $\Pi_{AG}(\tilde{B}_2)$, $\Pi_{AG}(\frac{10m+9s}{22})$ and $\Pi_{AG}(\frac{m+3s}{4})$. A calculation shows that $\Pi_{AG}(\frac{10m+9s}{22})$ is greater than the other two. Hence, the equilibrium outputs are $B = \frac{10m+9s}{22}$ and $b = \frac{10m+9s}{22}$, and the total profit is $\Pi_{AG}(\frac{10m+9s}{22})$.

Proposition 3: If the incumbent launches an AG, the equilibrium customer

base is given by

$$B = \begin{cases} m/2 & s \in (0, m/3], \\ (m+3s)/4 & s \in (m/3, 3m/5], \\ (10m+9s)/22 & s \in (3m/5, m). \end{cases}$$

4 Comparison

In this section we compare the incumbent's profit in two regimes at various values of s. First, for $s \in (0, \frac{m}{4}]$, the incumbent's profit is $\Pi(\frac{m}{2})$ without an AG and $\Pi_{AG}(\frac{m}{2})$ with an AG. Calculations show that when $s \in (0, 0.077m)$, $\Pi(\frac{m}{2}) < \Pi_{AG}(\frac{m}{2})$, meaning that launching an AG will be more profitable for the incumbent. However, when $s \in [0.077m, \frac{m}{4}]$, $\Pi(\frac{m}{2}) \geq \Pi_{AG}(\frac{m}{2})$, so launching a AG is less profitable.

When $s \in (\frac{m}{4}, \frac{m}{3}]$, the incumbent's profits are $\Pi(\frac{m+2s}{3})$ without an AG, and $\Pi_{AG}(\frac{m}{2})$ with an AG. It can be shown that $\Pi(\frac{m+2s}{3})$ is the greater and hence the incumbent will not launch AG if the switching cost is within this range. In all other values of s the incumbent receives greater profits if it does not launch an AG. To conclude, the incumbent launches an AG only when the switching cost is sufficiently small, namely, if $s < 0.077m$.

Proposition 4. The incumbent launches an AG only when $s < 0.077m$.

This result contrasts sharply with the standard result from Cournot oligopoly. There, an oligopolist can increase total profits by setting up an autonomous company that competes with the parent company; see Baye. Crocker and Ju (1996).[6] This fact also lies at the heart of the so-called horizontal merger puzzle; see first formulated by Salant, Switzer and Reynolds (1983).[7]

Proposition 4 leads to the following empirically testable hypothesis.

Hypothesis. The brand-name company is more likely to launch an AG

when the switching cost is relatively low.

In the next section we test this hypothesis.

5 Empirical investigations

5.1 Data

In this section we empirically test the hypotheses presented at the end of the preceding section. To that end, I use the dataset I collected on all the brand-name drugs that have experienced generic penetration from the beginning of 2001 till the beginning of 2003.

This data set was constructed by combining information from three different resources on the FDA website. The first resource is the First Generics list[5]. First Generics are "those drug products that have never been approved before as generic drug products and are new generic products to the marketplace." From this list, I obtained the information about all the first generics approved from 2001 to 2003, including the generic names and the dates of marketing approval. Then I used the name of the generics to find out the corresponding brand-name drugs in the Orange Book, which contains all the brand-name drugs and their generic counterparts, including the names, the dosage and dosage forms, and the marketing approval dates.[6]. After the corresponding brand-name drugs are determined, I used the Authorized Generics List[7] to find out if these brand-name drug companies had ever launched authorized generics.

I conjecture that the switching cost from the brand-name drugs to the generics mainly comes from two factors, "unwilling to switch" and "unable to switch". "Unwillingness to switch" to a generic means that a consumer feels a mental and psychological attachment to the brand-name drug. I measure the degrees of

[5]website
[6]website.
[7]website.

consumer "attachment" by the length of time during which there were no other drugs than the brand-name drugs on the markets, that is, the length of time between the date a brand-name drug was approved and the date its first generic was approved. As is mentioned in the introduction, drugs are credence goods. It takes time for consumers to develop affinities to drugs. Drugs for acute conditions may have immediate curing effects. However, the same conditions often recur over time, requiring the consumer to take the same drug (since the brand-name drug is the only drug available of its kind before generic entry) repeatedly. Each additional use can make the consumer feel more confident about the the drug's efficacy. Similarly, for chronic illnesses, a longer-term continual use of a brand-name drug may give a consumer a better understanding of its effects on her health. As these cases imply, the longer the brand-name drug has been marketed, the greater the degree of confidence a consumer has in its efficacy. As a consequence, the length of time the brand-name drug has been marketed can serve as a proxy for the consumer switching costs.

Unfortunately, however, the time before generic entry cannot be used to measure the "mental and psychological attachment" to OTC drugs, which are previous prescription drugs that have been made available over the counter after long marketing periods with established safety records. From the pre-generic marketing time, we only know how long the OTC version had been on the market before the first generic OTC enters., We do not know, however, how long the prescription version had existed on the market, at home or abroad, before the OTC version first appeared. For this reason, my data set comprises only the data for prescription drugs.

The other factor defining a consumer switching cost is the consumer's "inability to switch." Inability to switch means that a consumer has limited freedom to choose among different versions (the brand-name version or the generic

substitutes) of the drug. I consider that all the drugs fall into two categories: "Hospital Use" and "Home use". "Hospital Use" drugs are used administered in hospitals, mainly provided by caregivers, during surgery or medical tests. On the other hand, "Home Use" drugs are those patients administer themselves at home, for example, tablets to be taken orally, and cream to be applied on the skin. Usually patients who take "Hospital Use" drugs face less choice. First, those who receive hospital treatments are more likely to be in emergency, and therefore take whatever drugs they are given. Second, their choices are limited by the hospital's pharmacy: it is possible that the hospital does not carry the drugs they want to switch to. Third, treatments provided by a caregiver usually involve fairly complex procedures and hence, given the limited knowledge, patients are more likely to leave the choice of drugs up to their doctors. In contrast, patients who take "Home Use" drugs have more options. With prescriptions, they can go to pharmacies they like best or even to online pharmacies, and can choose between the brand-name drug and the generic substitute. For this reason, "Home Use" drugs should have lower switching costs relative to "Hospital Use" drugs.

To decide which drugs are for "Hospital Use" and which are for "Home Use" is not an easy task, however. To do that, I looked up each drug online to determine its uses, and I then used the following criteria for classifications. Drugs used in surgery, or for other treatments mainly practiced by caregivers, injection, for example, are considered "Hospital Use" drugs; otherwise they are considered for "Home Use". For example, Ultane (inhalation liquid) is an anesthesia used before surgery. Therefore it is classified as a "Hospital Use" drug. Similarly, Rimso-50 (intraversical solution) is used for bladder instillation, which I classify as a "Hospital Use" drug, though some patients might practice bladder instillation at home. Sometimes, the "dosage forms" can be useful

to determine drugs' uses. For example, Amicar is used to control bleeding during or after a surgery. While Amicar Injection is grouped as "Hospital Use", Amicar Tablet is grouped as "Home Use". Compared to injections, tablets are taken orally and require a longer time before taking effect, so they should not be used to treat serious bleeding problems or used in emergencies, like during a surgery. Also the "How to Use" instruction[8] further implies that Amicar Tablets should only be used to treat mild bleeding problems after a small surgery, like dental surgery, which can be practiced by patients on their own in a less urgent situation.

Table 1 below summaries the characteristics of the three variables in my dataset.

Table 1

	count	mean	sd	min	max
ag	202	.282	.451	0	1
inp	202	.198	.399	0	1
mono_month	202	141.018	70.564	21.767	256.433

The dataset has 202 observations. "ag", a dummy variable, denotes brand-name firm's decision on launching AG, with 1 for "launch" and 0 for "not launch". "ag" has mean 0.282, implying that out of the 202 brand-name drugs, about 28.2% has launched AG. "inp", another dummy variable, with 1 for "Hospital Use" and 0 for "Home Use", denotes whether a drug is taken in treatments mainly in the hospitals . This variable is intended to represent the degree of consumers' "freedom to switch". The mean of "inp" shows that, out of the 202 drugs, 19.8% are made mainly for "Hospital Use". "mono_month", measured in months, denotes the length of brand-name drug marketing periods before generic entry. This variable captures consumers' "unwillingness to switch" (brand loy-

[8] "once every hour, for up to 8 hours, or until bleeding is controlled..." website

alty). The mean of "mono_month" is about 12 years (141 months), which is consistent with the fact that the average brand-name marketing time before generic entry is 13 years[9]. Note this variable implies substantial variations in the length of pre-generic marketing time across different brand-name drugs[10].

5.2 Methodology

I assume whether or not a brand-name company launches an authorized generic is related to the switching cost its consumers has to pay to switch to a new drug. I treat the decision to launch an authorized generic as a binary variable, Y_i, which equals 1 if brand-name drug i launches an authorized generic, and 0 if it does not. A probit model is built to analyze the determinants of such decisions. The probability of launching an authorized generic is defined as:

$$\Pr(Y_i = 1 \mid X_i, \varepsilon_i) = \Phi(X_i\beta + \varepsilon_i)$$

where X_i, a vector of regressors, contains observed factors that explain the decision of launching authorized generics, while ε_i, with $\varepsilon \sim N(0, 1)$, is an error term, which captures the effect of unobserved factors on such decisions, and β is a vector of coefficients to be estimated. Φ is the CDF of the standard normal distribution.

5.3 Results

In my probit regressions, the dependent variable, "ag", is 1 whenever an authorized generic is launched for brand-name drug i. The independent variables are "lnmono_month" (log-linearized "mono_month") and "inp". As I have mentioned in section 5.1, "mono_month", denoting the length of pre-generic marketing period of brand-name drug i, is a continuous variable, and hence so is its log-linearized version "lnmono_month". "inp" is a dummy variable, which

[9] quote
[10] explain why

equals 1 when drug i is made mainly for "Hospital Use" and 0 otherwise. Table 2 shows the regression results:

Table 2

ag	Coef.	Std. Err.	P>z
inp	-0.796	0.293	0.007
lnmono_month	-0.341	0.139	0.015

The coefficient of the variable "inp" is negative, which means that, if a drug is made mainly for "Hospital Use", the brand-name company would be less likely to launch an authorized generic. The coefficient of the variable "lnmono_month" is negative, implying that, if a brand-name drug has a longer pre-generic marketing period, the brand-name company would be less likely to launch an authorized generic. The results are significant as the p-values are less than the cutting value 0.05.

A brand-name drug company launches an authorized generic at a lower price to to attract consumers who would not buy brand-name drugs. For "Hospital Use" drugs, consumers do not have much freedom to choose as their choices are usually made by the doctors. It is reasonable to assume that doctors are relatively less sensitive to price changes than patients. Therefore for hospital-use drugs, brand-name firms are more likely to influence the doctors to stay with their brand-name drugs instead of lowering prices to compete with generics.

In contrast, for "Home Use" drugs, consumers have more freedom to choose from, and therefore the strategy to launch an AG is more important in competition with generics. However, launching an AG leads erodes the brand-name drug's customer base as a lower price tempts some customers in the base to switch to the generics. This dilemma can be resolved if the brand-name companies can figure out how much more the higher-end customers would like to pay for the brand-name drugs. The results of my test show that the length

of the pre-generic marketing periods of the brand-name drugs may serve as a good proxy for the "how much more". If consumers have longer experiences with the brand-name drugs, they would value them considerably more (than generic substitutes). In this situation, the brand-name firm might find it more profitable to exploit the higher end customers, and hence is less likely to launch an AG. In contrast, if consumers have relatively short experiences with the brand name drug, they would not value the brand-name drugs as much (more than the generic substitutes), and hence a brand-name firm is more likely to launch an AG to compete for the lower-end customers with the generic firm. Concluding remarks

When there is generic competition the brand-name company sometimes (but not always) launches an generic version of its brand-name drug, called an authorized generic, through a third party. A launch of an AG is justifiable in terms of "divisionalization" but then AGs should be launched virtually for all brand-name drugs that come off the patent. In actual fact, however, only a small percentage of such drugs have the AGs. In this paper I address this puzzle. To that end, I develop a two-period model in which the incumbent develops a customer base as a monopoly in the first period and readies itself for generic competition in the second period.

My main finding is that a brand-name company launches an authorized generic only when users of the branded drug have sufficnetly low switching cost. . When the switching cost is high, the incumbent sells more than the the profit-maximizing quantity to develop a larger customer base.. If the switching cost is low, however, the customer bases is more vulnerable to price competition and hence instead of building a large customer base and defending it, the brand-name company launches an AG and resorts to the divisionalization tactic to steal lower end customers from the generic entrant. . makes more sense to

compete with the generic entrant in the lower end market with a authorized generic. To test my main finding econometrically I then build a probit model. The regression result gives significant support for my hypothesis.

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