Pharmaceutical patents and generic entry competition: the role of marketing exclusivity

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Abstract

Extensive tests required by FDA severely curtail effective patent length for innovation drugs, raising concern that incentives to develop new drugs are insufficient in the U.S. The Hatch-Waxman Act addresses this issue with a five-year patent extension. At the same time, Hatch-Waxman promotes generic entry by reducing the entry cost for generics and by granting 180-day marketing exclusivity to a first challenger of the patent. While these two objectives seem at odds with other, we show that if the entry cost reduction is substantial, granting the marketing exclusivity also contributes to restoration of incentives to innovate. However, market exclusivity most likely decreases social welfare.

Keywords: innovation, generic entry competition, patent, pharmaceuticals

JEL Classification Codes: I18, K23, L13

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1. Introduction

The patent grants the inventor exclusive rights to the innovation for 20 years. For innovation drugs, however, effective patent length is severely curtailed by FDA (U.S. Food and Drug Administration) requirements that new drugs undergo preclinical (laboratory and animal) and clinical (human) trials for efficacy, safety, side effects and reactions from long-time use for sinning marketing approval. Completion of such trials takes 10 to 12 years, raising concern that incentives to develop new drugs are insufficient in the United States.[1]

Enacted in 1984, the Hatch-Waxman Act addresses this problem with a five-year patent extension for innovation drugs.[2,3] However, an extended patent life delays arrivals of generic drugs and keeps the costs of medicine high.[4] Hatch-Waxman counters this problem by promoting generic entry before patent expiration. Generic entry promotion takes a two-pronged approach. First, streamlining the FDA test requirements for marketing approval reduces entry cost for generics. Secondly, the first generic firm that successfully challenges the patent is granted 180-day marketing exclusivity, during which no other generics are allowed to compete.[5]

In this paper we investigate the role of marketing exclusivity in Hatch-Waxman. We address these two questions. First, marketing exclusivity intensifies generic entry competition and causes a generic to be brought to the marketplace sooner, hurting the innovation drug manufacturer. On the other hand, during the 180 days the branded drug competes with only one generic instead of multiple generics, so marketing exclusivity benefits the innovation drug manufacturer. This shows that marketing exclusivity has both pro-competitive and anti-competitive effects on the profit of the innovation drug, making its effect on the incentive to develop a new drug ambiguous. Second, if the entry-cost reduction measures of Hatch-Waxman stimulate early generic entry, could the marketing exclusivity be redundant, and even harmful as it retards arrivals of other generic on the market?

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[1] See Mossinghoff (1999) for the timeline of the patent and the FDA review process.
[2] Formally, Hatch-Waxman is short for the1984 Drug Price Competition and Patent Term Restoration Act.
[3] To be specific, 5 years are the maximum.
[4] Iizuka (2012) uses micro panel data from the Japanese pharmaceutical markets to demonstrate the sensitivity of generic entry to the prescription pattern, especially, to physicians' failure to internalize cost differences offered by generics.
[5] See Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.

Our formal analysis utilizes a multi-period model with three firms: one incumbent and two entrants. The incumbent is an innovation drug company that produces the branded drug with the patent. Two entrants are generic drug manufacturers that must win marketing approval before entering the market. To make the multi-period model analytically tractable, some simplifying assumptions are made. One such assumption is that the innovation drug's patent expires at the end of period 3. This is a simple way to capture the fact that generic entry usually occurs towards the end of the branded drug's patent life. One reason is that "data exclusivity" prohibits use of the innovation drug's test data by generic firms to prove the safety and efficacy of the generic drugs.[6] Since preparing own test data is extremely costly, generic firms opt to submit applications for marketing approval after the data exclusivity expires. This implies that the early years of the patent life are irrelevant for our purpose.

If generic firms challenge the patent, they are likely to be embroiled in patent infringement litigation. In fact, patent infringement litigation is a key ingredient of our analysis. We highlight two features of litigation. First, litigation is stochastic. This is the current view among economists and legal scholars. For example, as Lemley and Shapiro (2005) put it, "When the patent holder asserts the patent against an alleged infringer, the patent holder is throwing the dice. If the patent has been found invalid, the property right has been evaporated" (p. 75). To model this feature of litigation, we follow Choi (1998) and assume that with exogenous probability the court finds the patent valid.

The other feature of litigation we highlight is its length. Lengthy litigation is a fact of life and especially pertinent to the pharmaceutical industry. Since FDA does not approve generic drugs while infringement is disputed, the branded drug manufacturer has the incentive to take the challenger to court for the purpose of delay its entry. To model the time-consuming nature of litigation we assume that a court takes one period to settle litigation. Thus, the incumbent can delay generic entry for one period by filing infringement suit. If the incumbent's patent is found invalid,

[6] Data exclusivity refers to protection of the clinical test data of a new drug submitted to FDA. It prevents generic drug manufactures from relying on this data in their own applications. Data exclusivity is granted for 5 years for new chemical entities but in cases can be extended for three additional years. For more details, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm.

FDA immediately approves generic entry. Otherwise, generic entry occurs after the patent has expired.[7]

Our main results can now be summarized. Firstly, at sufficiently low entry costs for generics, marketing exclusivity increases profit for the incumbent and decreases profit for the generic manufacturers. At sufficiently high costs, these results are reversed. Interestingly enough, when entry cost is in the intermediate range, marketing exclusivity may benefit all firms. Secondly, the welfare effect of marketing exclusivity may not be monotonic. While it lowers social welfare at all entry cost, market exclusivity may be welfare-increasing when entry cost is in the intermediate range.

These findings have the following implications. First, marketing exclusivity benefits the innovation drug manufacturer only when the entry cost is sufficiently low for generics. Thus, if there is a sufficient entry cost reduction for generics, marketing exclusivity contributes to restore incentives for new drug development. If the entry cost is high, removing the marketing exclusivity from Hatch-Waxman increases profit for the incumbent and restores the incentive to innovate. Secondly, although marketing exclusivity is likely to have a negative welfare effect at all entry costs, this finding is predicated on the branded drug having already been discovered. For an undeveloped drug, the prospect of a greater profit prompts the incumbent to discover a new drug sooner. An earlier discovery of a new drug benefits both consumers and generic firms and may improve social welfare.

The remainder of this paper is organized as follows. Section 2 describes the model environment. Section 3 presents the model with marketing exclusivity. Section 4 examines the counterfactual scenario, in which marketing exclusivity is removed from Hatch-Waxman. Section 5 compares the results obtained in sections 3 and 4. Section 6 examines the welfare effect of marketing exclusivity. The final section concludes.

[7] We assume as in Choi (1998) that, when declared valid, the patent remains valid for the remainder of its life.

2. Model environment

We consider a multi-period model with three firms: an incumbent and two potential entrants. Periods run from 1 to infinity. All actions take place at the beginning of periods. Let δ (< 1) denote the common discount factor. The incumbent is a well-established branded drug manufacturer and the patent holder. The potential entrants are generic drug manufacturers that must file for marketing approval before entering the market. Winning marketing approval and bringing a generic drug to the marketplace requires the one-time entry cost $F > 0$. The incumbent's patent is assumed to expire at the beginning of the third period. Thus, generic firms can enter in period 3 or later without infringing the patent. In contrast, to enter in period 1 or period 2 they must first challenge the patent.

All three firms use identical technologies to manufacture their drugs. Consumers regard the branded drug and its generic versions as homogenous. Therefore, all active firms receive identical per-period profits, denoted by Π^D in duopoly and by Π^T in triopoly. When there is generic competition the incumbent earns the monopoly profit Π^M. It is assumed that these profits satisfy

Assumption 1: (A) $\Pi^M > \Pi^D > \Pi^T$; (B) $(1/2)\Pi^D < \Pi^T < (3/4)\Pi^D$,

Assumption 1.A says that the profit per firm as more firms complete. Assumption 1.B is more of a technical nature and keeps the probability that the incumbent wins infringement suit between 0 and 1. Both assumptions are satisfied in standard Cournot oligopoly.

Let Δ denote the discounted sum of profit under triopoly; i.e., $\Delta \equiv \Pi^T/(1-\delta)$. Assume that $\Delta - F > 0$, meaning that entry is profitable for both generic firms after patent expiration. This assumption focuses attention on the central question of this paper: whether there is generic entry before patent expiration.

If the generic firms challenge the patent in period 1 or in period 2, the incumbent decides whether to file patent infringement suit or to accommodate entry. If the incumbent files suit, a court takes one period to deliberate, and finds the patent to be valid with probability $\alpha \in (0, 1)$.[8] We follow Choi (1998) to assume the following. First, α is exogenous. Second, when the patent is found invalid, the other generic firm can enter without infringing the patent. Third, when the patent is found valid, the patent remains valid for the rest of its life. Fourth, when there are two simultaneous challengers; the generic firms win suit jointly with probabilities $(1 - \alpha)$. Lastly, we assume legal fees to be negligible.

If the incumbent accommodates entry in period 1, FDA grants marketing approval, allowing the generic firm(s) to enter in that period.[9] In this case, the incumbent reserves the right to file infringement suit later. If the incumbent files suit later and the patent is found infringed, the infringers are ordered to pay the incumbent compensations equal to the discounted sum of the profits they have earned while infringing the patent.

3. Hatch-Waxman with marketing exclusivity

The game begins with two generic producers simultaneously deciding, in period 1, whether to challenge the incumbent's patent. Let C denote the action "challenge the patent" and ~C the action "do not challenge the patent. Depending on the number of challengers, there are three types of subgames. Let E_{00} denote a (symmetric) generic firm's discounted sum of profits when the outcome is (~C, ~C). If the outcome is (C, ~C) or (~C, C), let E_{10} denote the challenger's profit and E_{01} denote the non-challenger's profit. If the outcome is (C, C), denote each challenger's profit by E_{11}. We first solve each subgame that follows from the generic firms' first-period actions.

3.1: Two challengers in period 1

[8] According to a 2002 FTC study entitled *Generic Drug entry Prior to Patent Expiration*, generic applicants prevailed 73 per cent of the cases in which a court has resolved the patent dispute. This suggests a relatively small value for α.

[9] In reality, FDA takes about two years to review and approve a generic drug application; Mossinghoff (1999). To focus on patent challenges, however, we assume immediate FDA approval.

Suppose that in period 1 both generic firms file applications for marketing approval, incurring the entry cost F. If the incumbent files suit against them and a court finds the patent invalid, only one generic firm enters with the marketing exclusivity. The second generic firm enters when the marketing exclusivity expires the next period. Note that in this case the second entrant need not incur the cost F again because, when it previously filed application for marketing approval, FDA stayed approval but did not deny it.

When both generic firms challenge the patent, it is the dominant strategy for the incumbent to file suit against both. To see this, observe that filing suit delays generic entry for one period due to lengthy litigation. Thus, the incumbent receives the monopoly profit Π^M in period 1 and either Π^M with probability α or Π^D with probability $1 - \alpha$ in period 2. In period 3 the other generic firm enters, regardless of a court decision. Thus, the incumbent's expected profit from filing suit is

(1) $$\Pi^M + \delta[\alpha\Pi^M + (1 - \alpha)\Pi^D] + \delta^2\Delta.$$

If the incumbent does not file suit, FDA approves both generics but only one firm enters in period 1 with the marketing exclusivity. In period 2, the marketing exclusivity ends and the other generic firm also enters. However, the patent has not expired yet so it is the dominant strategy for the incumbent to file suit in period 2; not doing so makes the incumbent forgo the compensations for patent infringement (with probability α). Thus, the incumbent's profit from not filing suit (i.e., accommodating entry) in period 1 and filing suit in period 2 is

$$\Pi^D + \delta\Pi^T + \delta^2\Delta + \alpha(\Pi^D + 2\delta\Pi^T),$$

where the last term represents the (probability-weighted) compensations. This profit is less than the profit (1) under Assumption 1, so the incumbent always files suit in period 1.

Given the incumbent's optimal response, we calculate the generic firms' profits. In period 1 they earn zero profit while there is litigation. In period 2, if the patent is found invalid one generic firm enters. In period 3 both generic firms enter. If the patent is found valid, they both enter in period 3. If we assume that each generic firm is equally likely to be granted marketing exclusivity, we obtain the following equilibrium profit for a generic firm

$$E_{11} = - F + \delta(1- \alpha)\Pi^D/2 + \delta^2\Delta .$$

The incumbent's equilibrium profit is given by (1).

3.2. One challenger in period 1

In this case, filing suit guarantees the monopoly profit Π^M in period 1 to the incumbent. If the patent is found valid, the incumbent earns Π^M in period 2, whereas if the patent is found invalid it earns Π^D. In either case, the second generic firm does not enter till period 3. Therefore, the incumbent's expected profit is the same as in (1).

Accommodation of the single challenger is slightly more complicated than when there are two challengers. If the incumbent accommodates, there is duopoly in period 1. In period 2 the market exclusivity expires but the patent does not. If the second generic firm challenges the patent in period 2, the incumbent files suit against both generic firms to delay entry by the second generic firm and also to collect the compensations $\Pi^D(1 + \delta)$ with probability α. Thus, accommodation in period 1 (and litigation against both in period 2, if the second enters) yields the expected profit

(2) $$\Pi^D (1 + \delta) + \delta^2\Delta + \alpha\Pi^D(1 + \delta).$$

Accommodating the second generic firm in period 2 yields $\Pi^D + \delta \Pi^T + \delta^2\Delta$, a smaller profit than the one in (2). Hence, in period 2's values, the second generic firm's expected profit equals $– F + \delta\Delta$ from entry and $\delta(\Delta - F)$ from non-entry. Clearly, the second firm has no incentive to enter in period 2. Even if there is no entry by the second firm, the incumbent still files suit against the first, because filing suit yields the profit in (2) while not doing so yields $\Pi^D + \delta\Pi^D + \delta^2\Delta$, a smaller profit.

We have shown that, if it accommodates the first challenger in period 1, the incumbent files suit against that firm in period 2 and the second firm enters in period 3. The incumbent's profit given in (2) is smaller than the one in (1). Thus, in equilibrium the incumbent files suit against the challenger in period 1. Thus, the equilibrium profit for the incumbent is given in (1). The challenger receives

$$E_{10} = - F + \delta(1 - \alpha)\Pi^D + \delta^2\Delta$$

while the non-challenger receives

$$E_{01} = \delta^2(\Delta - F).$$

3.3 No challengers in period 1

If there are no challengers in period 1, the incumbent is a monopoly in period 1. In period 2, two generic firms simultaneously decide whether to challenge the patent or not, which results in multiple subcases. This analysis is relegated to Appendix A.

3.4 Equilibrium in period 1

Having solved all the subgames, we move back to the first-period game, in which two generic firms simultaneously choose C or ~C. We relegate the details to Appendix B and discuss the equilibrium outcome here. Define the two equations: $F = \Phi/2$ and $F = \Phi$, where

$$\Phi \equiv \delta(1- \alpha)\Pi^D/(1- \delta^2).$$

Then, the next proposition gives the equilibrium outcomes of the game.

Proposition 1:

(A) If $F \in (0, \Phi / 2)$, both generic firms challenge the patent in period 1.

(B) If $F \in (\Phi / 2, \Phi)$, only one generic firm challenges the patent in period 1.

(C) If $F \in (\Phi, \infty)$, neither firm challenges the patent in period 1.

We illustrate Proposition 1 in Figure 1. The next result follows immediately from Proposition 1.

Corollary 1: If $F < \Phi$, with probability $(1 - \alpha)$ one generic drug is brought to the market in period 2. If $F \geq \Phi$, there are no generics available until period 3.

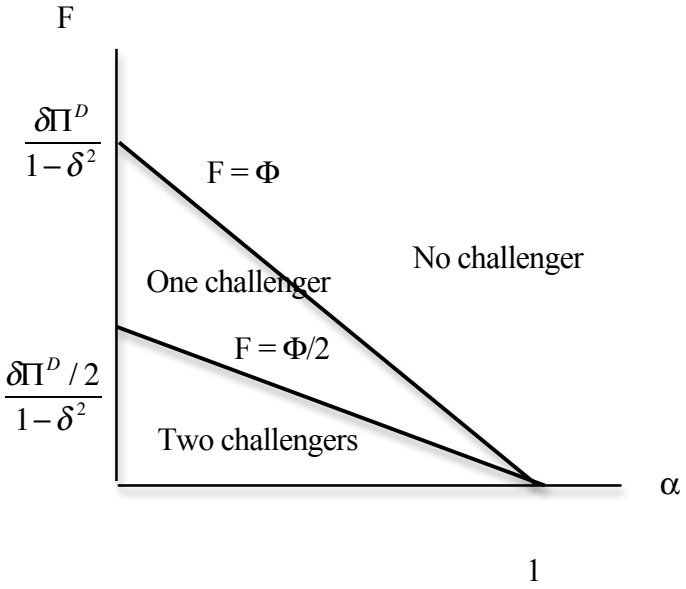

Figure 1

We end this section with the following remark. As we saw, the equilibrium outcome crucially hinges on the entry cost for generics. Prior to Hatch-Waxman, entry costs were probably very high because "there were 150 drugs that went off-patent (after 1962), but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to the market" (Mossinghoff 1999).[10] Hatch-Waxman has introduced the Abbreviated New Drug Application (ANDA), exempting generics from both pre-clinical and clinical trials, requiring that they satisfy only the bioequivalence tests for FDA approval (Mossinghoff 1999). Furthermore, test data of the branded drug, previously kept as trade secrets, are made available to generic drug manufacturers after five years of data exclusivity.[11] The fact that there are many generic versions of the branded drugs today implies that Hatch-Waxman has been quite successful in reducing entry costs for generics.[12]

[10] DiMasi et al. (1991) estimated the average cost to develop and win marketing approval for a new drug was $231 million (in 1987 dollars).

[11] Refer to Footnote 5 for the definition of data exclusivity.

[12] Empirical work shows remarkable growth of generic sales in the U.S. pharmaceutical markets since the 1980s; see, for example, Frank and Salkever (2004).

4. A counterfactual: Hatch-Waxman without marketing exclusivity

In this section we examine the counterfactual scenario: Hatch-Waxman without marketing exclusivity. The analysis here closely follows that of the preceding section. Start by solving all the subgames that follow the generic firms' decisions in period 1.

4.1. Two challengers in period 1

When both generic firms choose C in period 1, filing suit against both firms yields Π^M in period 1, and Π^M with probability α and Π^T with probability $(1 - \alpha)$, giving the incumbent the expected profit

(3) $$\Pi^M + \delta[\alpha\Pi^M + (1 - \alpha)\Pi^T] + \delta^2\Delta.$$

In contrast, accommodation yields Π^T in period 1. In period 2 the incumbent again earns Π^T, whether it files suit or not in that period, because generic sales cannot be blocked by litigation. The only motive for filing suit in period 2 is the possible compensations from patent infringement. Thus, accommodating both firms in period 1 (and then suing them in period 2) yields the following profit for the incumbent:

(4) $$\Pi^T(1 + \delta) + \delta^2\Delta + 2\alpha\Pi^T(1 + \delta),$$

where the last term represents the expected compensations. Since $\Pi^M > 3\Pi^T$, this profit is smaller than the one in (3), and hence the incumbent files suit against both challengers in period 1. The incumbent's equilibrium profit is given in (3). Each challenger's equilibrium profit equals

(5) $$\hat{E}_{11} = -F + \delta(1 - \alpha)\Pi^T + \delta^2\Delta .$$

4.2. One challenger in period 1

In this case, filing infringement suit yields Π^M in period 1. In period 2, both generic firms enter if the patent is invalid, so the incumbent's period-2 profit is Π^M with probability α and Π^T with probability $(1 - \alpha)$. Filing suit yields the profit in (3). In contrast, accommodation yields Π^D in

period 1. In period 2, if the second generic firm challenges the patent, filing suit has FDA stay marketing approval for the second challenger and yields the duopoly Π^D to the incumbent. In period 3 there is triopoly, regardless of litigation outcomes. The incumbent receives compensations from the first entrant (with probability α). Thus, the incumbent's profit from accommodating the first challenger in period 1 is

(6) $$(1 + \delta)\Pi^D + \delta^2\Delta + \alpha\Pi^D(1 + \delta).$$

Since filing suit in period 2 is the dominant strategy for the incumbent, the second generic firm chooses not to challenge the patent in period 2 to save the entry cost F. Even so, the incumbent still files suit against the first challenger in period 2. It earns the profit given by (6), which is less than the profit in (3).

To sum, the incumbent files suit against the single challenger in period 1 and receives the profit given in (3). The first challenger's equilibrium profit equals

(7) $$\hat{E}_{10} = - F + \delta(1 - \alpha)\Pi^T + \delta^2\Delta.$$

The non-challenger enters in period 2 only if the patent is invalid and waits till period 3 otherwise. Hence the non-challenger's profit is

(8) $$\hat{E}_{01} = \delta(1- \alpha)(\Delta - F) + \alpha\delta^2(\Delta - F).$$

4.3. No challengers in period 1

In this case, consider the subgame beginning in period 2. If both generic manufacturers challenge the patent, filing suit makes FDA stay approval till period 3. Thus, filing suit in period 2 yields

(9) $$(1+ \delta)\Pi^M + \delta^2\Delta.$$

Accommodation yields a smaller profit, $\Pi^M + \delta\Pi^T + \delta^2\Delta$. Thus, filing suit is dominant. The result is the same if there is one challenger in period 2. Hence, the incumbent's equilibrium profit is given in (9). Each generic firm's equilibrium profit equals

(10) $$\hat{E}_{00} = \delta^2(\Delta - F) > 0.$$

4.4 Equilibrium in period 1

Having solved all the subgames, we turn to the first-stage game, where two generic firms simultaneously chooses C or ~C. This game is summarized in the table below, where the generic firms' payoffs $\hat{E}_{ij}$ (i, j = 1, 0) are given in (5), (7), (8) and (10).

	C	~C
C	$\hat{E}_{11}$, $\hat{E}_{11}$	$\hat{E}_{10}$, $\hat{E}_{01}$
~C	$\hat{E}_{01}$, $\hat{E}_{10}$	$\hat{E}_{00}$, $\hat{E}_{00}$

It is easy to show that $\hat{E}_{11} < \hat{E}_{01}$ thereby ruling out the simultaneous challenges. It is also verified that $\hat{E}_{00} > \hat{E}_{10}$ if and only if

$$F > \Psi \equiv (1-\alpha)\delta\Pi^T / (1-\delta^2).$$

Thus, if $F > \Psi$, the unique equilibrium has no challenging of the patent in periods 1 and 2. If $F \leq \Psi$, there are two pure-strategy Nash equilibria, in which only one firm challenges in period 1. We focus on them to keep analysis simple.[13]

We now summarize the main finding of this section.

Proposition 2: Suppose there is no marketing exclusivity in Hatch-Waxman. In the pure-strategy equilibrium, if $F \leq \Psi$, one generic firm challenges the patent in period 1; if $F > \Psi$, there are no challengers in periods 1 and 2.

[13] There is also a mixed strategy equilibrium, in which each firm challenges the patent with probability $k = [\delta(1-\alpha)\Pi^T - F(1 - \delta^2)]/[\delta(1-\alpha)(1-\delta)(\Delta - F)]$. In this case, two firms enter with probability k^2. But this equilibrium is payoff-dominated by the decision vector (~C, ~C) for $\delta \geq (1 - \alpha)/(2 - \alpha)$.

Figure 2 illustrates proposition 2. A patent challenge occurs if $F \leq \Psi$, i.e., the entry cost is sufficiently low and/or the likelihood of patent invalidation is sufficiently high (α is sufficiently small). Since a second generic firm enters only if the patent is invalid, two generic drugs are brought to the market in period 2 with probability $(1 - \alpha)$.

Corollary 2: If $F \leq \Psi$, with probability $(1 - \alpha)$ two generics are brought to the market in period 2. If $F > \Psi$, two generic drugs are available only after the patent expires.

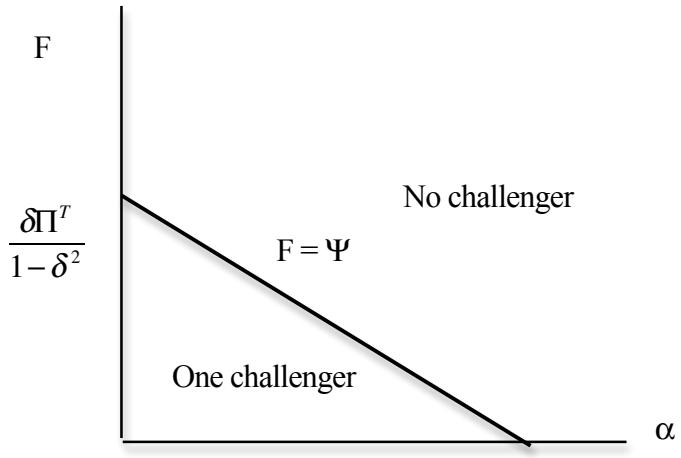

Figure 2

In the present model, only one firm challenges in period 1 because of time-consuming litigation. If litigation settlement is immediate as is commonly assumed in the literature, there is a range of parameter values in which there are two challengers in period 1 in pure-strategy equilibrium. Thus, the assumption of time-consuming litigation makes differences in our analysis.

5. The effect of marketing exclusivity

We are now ready to evaluate the effect of marketing exclusivity. Figure 3 combines Figures 1 and 2. The three lines represent the three values Φ /2, Ψ and Φ. By assumption 1, Φ /2 < Ψ < Φ. They define the four regimes, labeled by 1 through 4. We examine them seriatim.

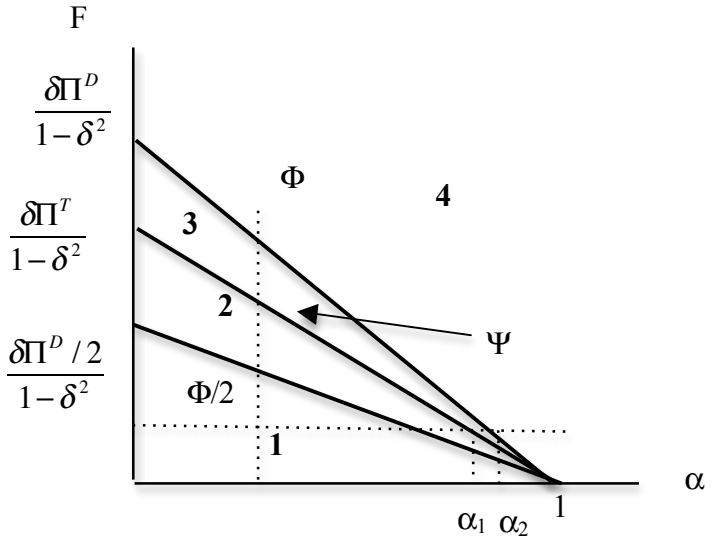

Figure 3

Regime 1: F < Φ /2

In this region, when there is marketing exclusivity both generic firms challenge the patent in period 1 and the incumbent files suit. From Section 3, the equilibrium profit for the incumbent is given by (1). The profit for each generic firm is given by

(11) $\delta(1-\alpha)\Pi^D/2 + \delta^2\Delta - F.$

Without marketing exclusivity one generic challenges the patent in period 1, while the other enters in period 2 only if the patent is found invalid. The incumbent's profit is given by (3). Given symmetry, averaging the profits in (7) and (8) yields each generic firm's equilibrium profit.

(12) $\delta(1-\alpha)\Pi^T + \delta^2\Delta - [1 + (1-\alpha)\delta + \alpha\delta^2](F/2).$

The profit in (11) exceeds the profit in (12), while the profit in (1) exceeds the profit in (3). Thus,

Claim 1: In regime 1 market exclusivity increases the incumbent's expected profit and reduces the generic firm's expected profit.

Regime 2: $F \in (\Phi/2, \Psi]$

With marketing exclusivity there is only one generic challenger in period 1. Hence, the incumbent's equilibrium profit is the same as in regime 1 and given in (1). Calculations show that the expected profit for a challenger is $\delta(1- \alpha)\Pi^D - F + \delta^2\Delta$ and that for a non-challenger is $\delta^2(\Delta - F)$. Thus, a generic firm's average profit is given by

(13) $$\delta(1- \alpha)\Pi^D/2 + \delta^2\Delta - F(1 + \delta^2)/2.$$

Without marketing exclusivity, there is only one challenger in period 1, as well. The incumbent's equilibrium profit is given in (1). Each generic firm's expected profit equals the profit in (11). Comparing the profits in (1) and (3) yields the first result of the next claim. Comparing the profits in (11) and (13) yields the second.

Claim 2. In regime 2:

(A) Marketing exclusivity increases the incumbent's profit;

(B) Marketing exclusivity increases a generic firm's profit if $F > (2\Pi^T - \Pi^D)/(1- \delta)$ and decreases a generic firm's profit if the preceding inequality is reversed.

The condition $F > (2\Pi^T - \Pi^D)/(1- \delta)$ is more likely to be met when α is higher (when the patent is found valid with higher probability). Then

Corollary 3: In regime 2 (entry cost in the intermediate range), if the condition $F > (2\Pi^T - \Pi^D)/(1- \delta)$ holds, marketing exclusivity raises the expected profits for all three firms.

Regime 3: $F \in (\Psi, \Phi]$

With marketing exclusivity, this regime yields the same equilibrium outcome as regime 2. The equilibrium profits for the incumbent and for each generic firm are given, respectively, by (1) and (13). Without marketing exclusivity no generic firm challenges the patent. Each generic firm's profit is $\delta^2(\Delta - F)$ and the incumbent's profit is $\Pi^M(1+ \delta) + \delta^2\Delta$. Obviously, the incumbent makes a greater profit without marketing exclusivity, whereas the generic firm's profit, given in (13), exceeds $\delta^2(\Delta - F)$ if and only if $F \leq \Phi \equiv \delta(1- \alpha)\Pi^D/(1 - \delta^2)$. This condition is satisfied in regime 3. Thus:

Claim 3: In regime 3 marketing exclusivity reduces the incumbent's profit and increases a generic firm's profit.

Regime 4: $F > \Phi$

With or without exclusivity there are no challengers. The generic firm's expected profit equals $\delta^2(\Delta - F)$ and the incumbent's profit equals $\Pi^M(1 + \delta) + \delta^2\Delta$.

Claims 1 – 3 lead to the next proposition:

Proposition 3:

(A) Marketing exclusivity increases the incumbent's expected profit when entry cost is low (regime 1) or in the intermediate range (region 2), but decreases it when entry cost is high (regime 3).

(B) Marketing exclusivity decreases a generic firm's expected profit when entry cost is low (regime 1) but increases its profit when entry cost is high (regime 2).

(C) When entry cost is in the intermediate range (regime 2), marketing exclusivity raises the generic firm's expected profit if and only if $F > (2\Pi^T - \Pi^D)/(1- \delta)$.

We now summarize the effect of marketing exclusivity on the incentives to develop a new drug. At sufficiently low entry costs marketing exclusivity raises the incumbent's expected profit and hence the incentives to develop a new drug. When the entry cost is relatively high, the results are reversed. Thus, if there is a sufficient entry cost reduction for generics, marketing exclusivity not only promotes early generic entry but contributes towards restoration of incentives to develop new drugs.

6. The welfare effect of marketing exclusivity

In this section we evaluate the welfare impact of market exclusivity. We begin with some definitions and notation. Social surplus is the sum of consumer surplus and industry profits less entry costs. Social welfare is defined by the discounted sum of social surpluses evaluated at the beginning of period 1. Denote the per-period consumer surplus under monopoly, duoply and trioply by CS^i (i = M, D, T), respectively. Let S^i denote the social surplus under the market structures i = M, D, T. Assume that social surplus increases as the market becomes more competitive; i.e.,

$$S^M (= \Pi^M + CS^M) < S^D (= 2\Pi^D + CS^D) < S^T (= 3\Pi^T + CS^T).$$

6.1 Marketing exclusivity

We first compute the equilibrium social welfare in the four regimes under marketing exclusivity.

In regime 1, there are two challengers in period 1. The incumbent files suit and is a monopoly. In period 2 there is duopoly with probability $(1 - \alpha)$ and monopoly otherwise. In period 3 there is triopoly. Thus, the equilibrium social welfare is given by:

$$\tilde{W}(1) = S^M - 2F + \alpha\delta S^M + (1-\alpha)\delta S^D + \delta^2 S^T / (1-\delta)$$

In regimes 2 and 3, there is only one challenger in period 1. In period 2, there is duopoly with probability $(1 - \alpha)$ and monopoly otherwise. The equilibrium social welfare is given by:

$$\tilde{W}(2,3) = S^M - F + \alpha\delta S^M + (1-\alpha)\delta S^D + \delta^2 [S^T / (1-\delta) - F].$$

In regime 4 there is no entry until period 3. The social welfare equals

$$\tilde{W}(4) = (1+\delta)S^M + \delta^2[S^T/(1-\delta) - 2F].$$

6.2. No marketing exclusivity

We next compute the equilibrium social welfare without marketing exclusivity. In regimes 1 and 2, only one generic firm challenges in period 1. In period 2, if the patent is invalid, both generic firms enter. Otherwise, there is monopoly until period 3. Therefore, the welfare is

$$\hat{W}(1,2) = S^M - F + \alpha\delta S^M + (1-\alpha)\delta S^T + \delta^2 S^T/(1-\delta) - \delta F[(1-\alpha)+\alpha\delta]$$

In regimes 3 and 4, there is no entry until period 3. Therefore,

(14) $$\hat{W}(3,4) = (1+\delta)S^M + \delta^2[S^T/(1-\delta) - 2F] = \tilde{W}(4)$$

6.3 The welfare impact of marketing exclusivity

With the above calculations we make the following welfare comparisons.

Regime 1:

$$\tilde{W}(1) - \hat{W}(1,2) = -F + (1-\alpha)\delta(S^D - S^T) - \delta F[(1-\alpha)-\alpha\delta]$$
$$< F[(1-\alpha)\delta + \alpha\delta^2 - 1] = -(1-\delta)(1+\alpha\delta)F < 0.$$

Therefore, *marketing exclusivity decreases social welfare.*

Regime 2:

$$\tilde{W}(2,3) - \hat{W}(1,2) = (1-\alpha)\delta(S^D - S^T) - F[\delta^2 - \delta(1-\alpha) - \alpha\delta^2]$$
$$< -\delta(1-\delta)(1-\alpha)F < 0.$$

Again, *marketing exclusivity decreases social welfare.*

Regime 3:

$$\tilde{W}(2,3) - \hat{W}(3,4) = (1-\alpha)\delta(S^D - S^M) + (\delta^2 - 1)F.$$

The first term on the right is positive while the second is negative. To sign the right-hand side expression define $\bar{F}$ by

$$\tilde{W}(2,3) - \hat{W}(3,4) = (1-\alpha)\delta(S^D - S^M) + (\delta^2 - 1)\bar{F} = 0;$$

i.e.,

$$\bar{F} = (1-\alpha)\delta(S^D - S^M)/(1-\delta^2).$$

Then, $\tilde{W}(2,3) - \hat{W}(3,4) > 0$ if and only if $F < \bar{F}$. Thus, marketing exclusivity increases social welfare if and only if $F < \bar{F}$. Since $\bar{F}$ depends on α, we can use Claim 3 to derive

Claim 4: In regime 3:

(A) If $S^D - S^M < \Pi^T$, then $F > \bar{F}$ for all α; i.e., marketing exclusivity decreases social welfare.

(B) If $S^D - S^M > \Pi^D$, then $F < \bar{F}$ for all α; i.e., marketing exclusivity increases social welfare.

If $\Pi^T \leq S^D - S^M \leq \Pi^D$, the welfare effect is indeterminate without knowledge about demand and cost functions.

We summarize the main results of this section in

Proposition 4: Marketing exclusivity reduces social welfare unless both of the following conditions are met:

(A) $F \in (\Psi, \Phi]$; i.e., we are in regime 3,

(B) $F < \bar{F} = (1-\alpha)\delta(S^D - S^M)/(1-\delta^2)$.

A final remark is this. Proposition 4 is predicated on the branded drug having already been discovered. For drugs yet to be discovered, the prospect of higher profits stimulates incentives to discover them sooner. Earlier arrivals of new drugs benefit both consumers and generic drug manufacturers. If these additional effects are taken into account, marketing exclusivity may increase social welfare in the long run.

7. Concluding remarks

The 1984 Hatch-Waxman Act has two objectives: restoration of the incentives to develop new drugs and promotion of generic entry before patent expiration. To restore incentives it extends the patent for innovation drugs by 5 years (maximum). To promote generic entry it reduces entry costs for generic drugs and also grants 180-day marketing exclusivity to a first generic firm that successfully challenges the branded drug's patent.

Although these objectives appear incompatible, we show that if there is a sufficient entry cost reduction for generics, marketing exclusivity can contribute to restoration of incentives to develop new drugs. However, if the entry cost reduction is insufficient, marketing exclusivity decreases the profit of an innovation drug, and hence discourages discovery of new drugs.

We also find, however, that marketing exclusivity tends to decrease social welfare. However, this result is conditional on the innovation drug having already been discovered. For innovation drugs yet to be discovered, it is quite possible that the prospect of greater profitability prompts early development of new drugs, which benefit consumers and generic drug manufacturers alike. If these dynamic effects are taken into account, the marketing exclusivity at a sufficiently low entry cost for generics may have a welfare-enhancing effect in the long run. Competition among several innovators can further increase social welfare. We leave those extensions for future research.

Appendices

Appendix A: We analyze the period-2 subgames, when there are no challengers in period 1 under marketing exclusivity. We need to consider three types of subgames in period 2.

A1. Two challengers in period 2

In this subgame, filing suit in period 2 delays entry till period 3. In period 3, the patent expires so both generic firms enter, regardless of a court decision. Thus, the incumbent's profit in period 3 is Π^T. If the incumbent files suit, its expected profit equals

(A1) $$\Pi^M + \delta [\alpha\Pi^T + (1 - \alpha)\Pi^D] + \delta^2\Delta.$$

In contrast, with accommodating, only one generic firm enters in period 2, yielding the following profit to the incumbent

(A2) $$\Pi^D + \delta\Pi^T + \delta^2\Delta.$$

The profit in (A1) is greater than the profit in (A2) and hence the incumbent files suit against both challengers. Therefore, each challenger's expected profit in period 2 is

$$e_{11} = - F + \delta[\alpha\Pi^T + (1 - \alpha)\Pi^D/2] + \delta^2\Delta.$$

A2. One challenger in period 2

This case is similar to the previous subcase. If the incumbent files infringement suit, there is no entry until period 3. Further, if the patent is invalid, the challenger is granted marketing exclusivity in period 3. Thus, the incumbent receives the same profit as in (A1). Accommodating yields Π^D in period 2 and Π^T in all later periods, so the incumbent's profit is given by (A2). A comparison shows that, the incumbent files suit against the challenger in period 2. The challenger's profit is

$$e_{10} = - F + \delta[\alpha\Pi^T + (1 - \alpha)\Pi^D] + \delta^2\Delta.$$

and the non-challenger's profit is

$$e_{01} = \delta\alpha(\Pi^T - F) + \delta^2\Delta – \delta^2(1 - \alpha)F.$$

A3. No challenger in period 2

If both generic firms wait till period 3 to enter, each of them expects the profit

$$e_{00} = \delta(\Delta - F).$$

Now, we can present the period-2 subgame in the matrix below.

	C	~C
C	e_{11}, e_{11}	e_{10}, e_{01}
~C	e_{01}, e_{10}	e_{00}, e_{00}

To find the equilibrium of this game, define F_X implicitly by the equation $e_{11} - e_{01} = 0$ and F_Y by $e_{10} - e_{00} = 0$. Substitution into e_{ij} yields:

$$F_X \equiv \frac{\delta(1-\alpha)\Pi^D / 2}{(1-\delta)[1+\delta(1-\alpha)]} \text{ and } F_Y \equiv \frac{\delta(1-\alpha)(\Pi^D - \Pi^T)}{1-\delta}.$$

F_X and F_Y decline toward zero as α goes to one. The next result presents the equilibrium outcomes of this subgame (proof is immediate from the above table).

Lemma 1. Suppose that there are no challengers in period 1. Then,

(A) If $F < \min \{F_X, F_Y\}$, (C, C) is the equilibrium outcome in period 2. Each generic firm's profit equals

$$\delta^2[\alpha\Pi^T + (1 - \alpha)\Pi^D/2] + \delta^3\Delta - \delta F$$

(B) If $F > \max \{F_X, F_Y\}$, (~C, ~C) is the equilibrium outcome. Each generic firm's profit is

$$\delta^2(\Delta - F).$$

(C) If $F \in | F_X - F_Y |$, (C, ~C) or (~C, C) is the equilibrium outcome. A generic firm's expected profit is

$$\delta^2\alpha\,\Pi^T + \delta^2(1 - \alpha)\Pi^D/2 + \delta^3\Delta - [\delta + \delta^2\alpha + \delta^3(1 - \alpha)]F/2.$$

The next lemma relates F_X and F_Y to the key parameters of the model.

Lemma 2

$F_X > F_Y$ if and only if $\delta(1-\alpha) < \dfrac{\Pi^T - \Pi^D/2}{\Pi^D - \Pi^T}$.

Proof. The conclusion follows from

$$F_X - F_Y = \{\Pi^D/2 - (\Pi^D - \Pi^T)[1 + \delta(1-\alpha)]\}\delta(1-\alpha)/\{(1-\delta)[1+\delta(1-\alpha)]\}.$$

Note that $(\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T) \in (0,1)$ under assumption 1. The next lemma follows immediately from Lemma 1.

Lemma 3:

(A) If $\delta > (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$, there is

$$\hat{\alpha} \equiv 1 - \frac{\Pi^T - \Pi^D/2}{\delta(\Pi^D - \Pi^T)} \in (0,1)$$

so that (i) $F_X < F_Y$ for $\alpha < \hat{\alpha}$; (ii) $F_X = F_Y$ for $\alpha = \hat{\alpha}$; (iii) $F_X > F_Y$ for $\alpha > \hat{\alpha}$

(B) If $\delta \leq (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$, $F_X > F_Y$ for all $\alpha \in (0,1)$.

Lemma 3A and 3B are illustrated in Figures A2 and A1, respectively.

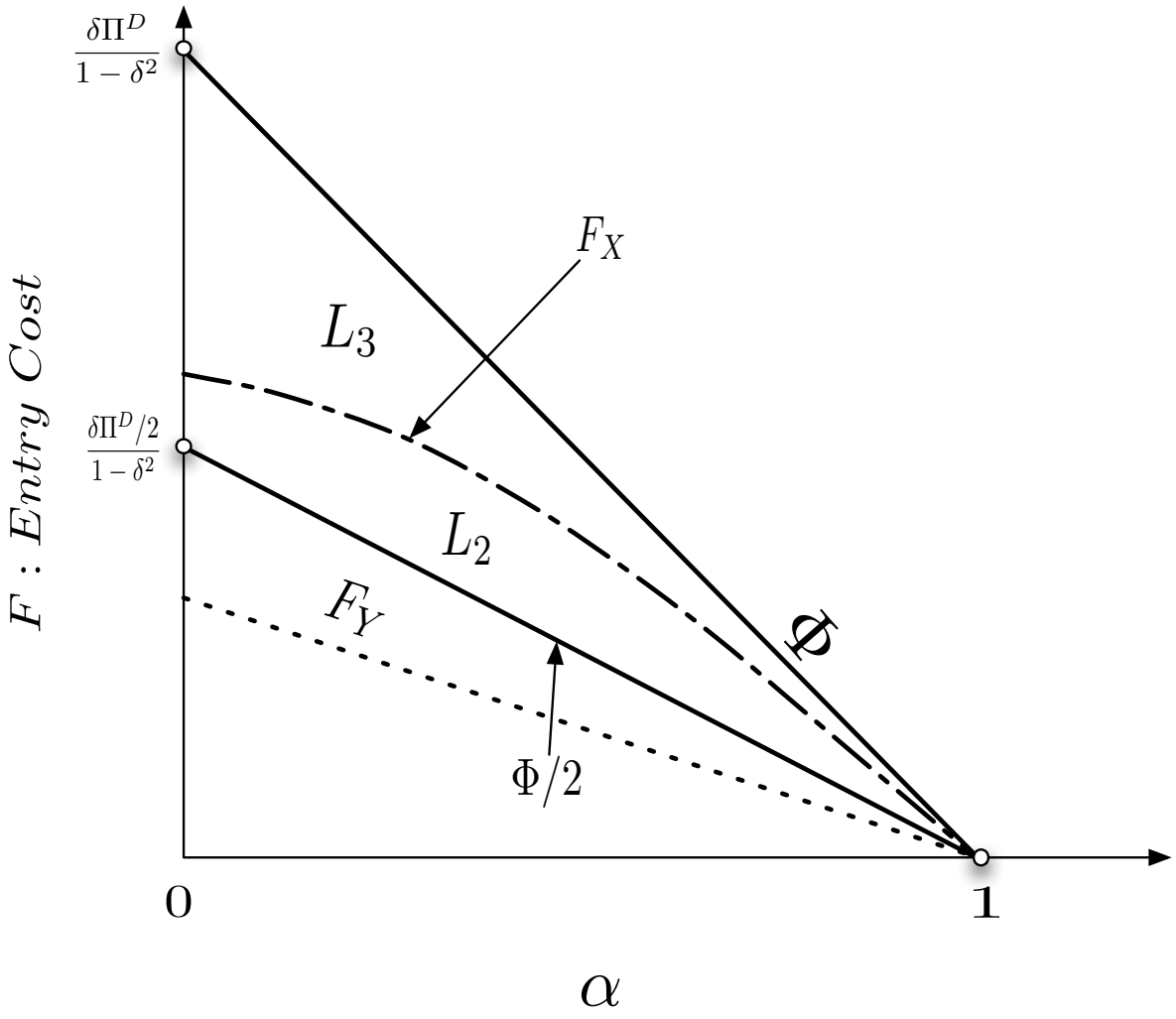
$\frac{\delta\Pi^D}{1-\delta^2}$
$\frac{\delta\Pi^D/2}{1-\delta^2}$
$F : Entry\ Cost$
F_X
L_3
L_2
F_Y
Φ
$\Phi/2$
0
1
α

Figure A1

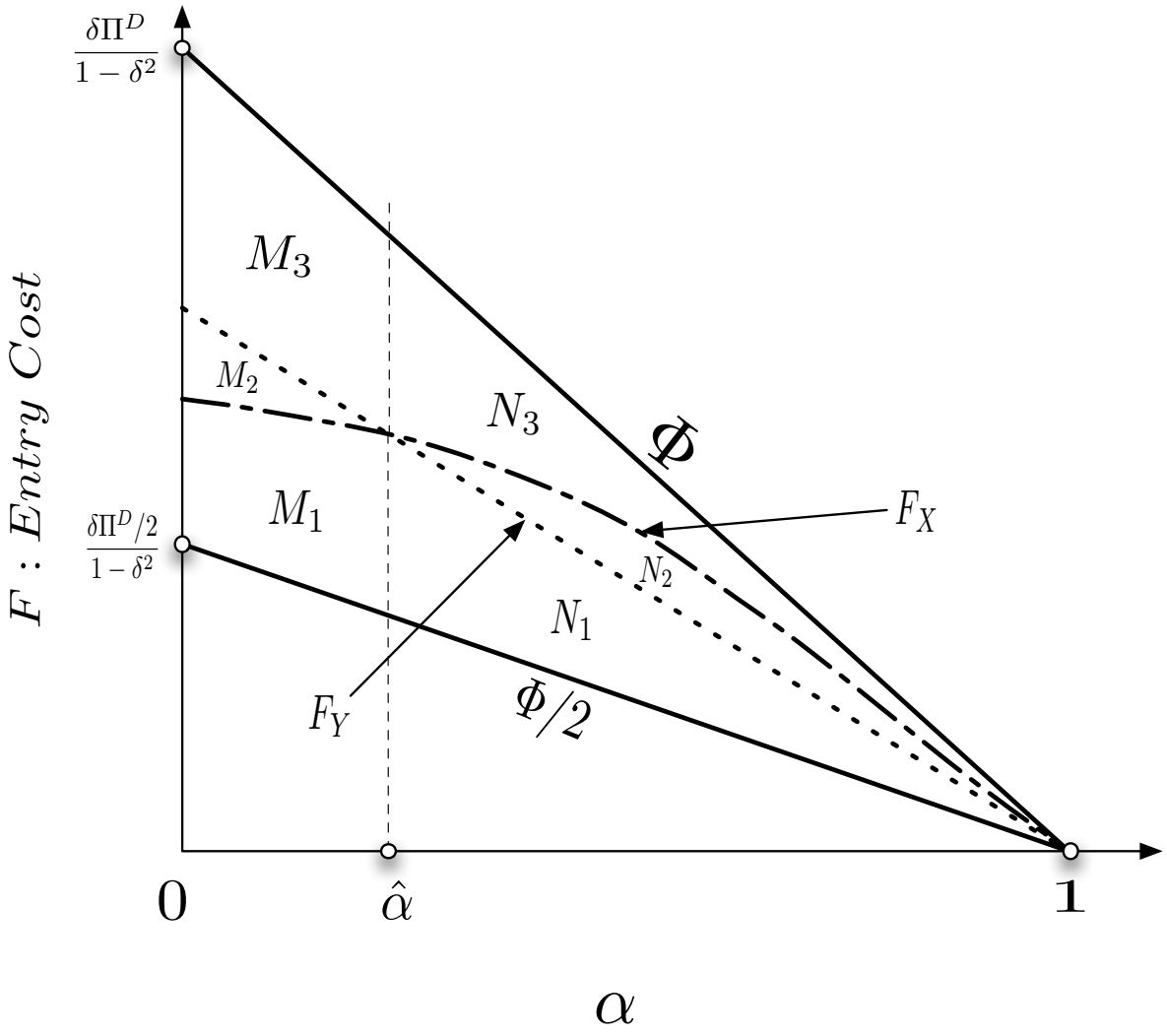
$\frac{\delta\Pi^D}{1-\delta^2}$
$\frac{\delta\Pi^D/2}{1-\delta^2}$
$F: Entry\ Cost$
M_3
M_2
M_1
N_3
N_2
N_1
Φ
$\Phi/2$
F_X
F_Y
0
$\hat{\alpha}$
1
α

Figure A2

Appendix B: Proof of Proposition 1

The table below summarizes the first-stage game with marketing exclusivity, where

$$E_{11} \equiv -F + \delta(1-\alpha)\Pi^D/2 + \delta^2\Delta$$

$$E_{10} \equiv -F + \delta(1-\alpha)\Pi^D + \delta^2\Delta$$

$$E_{01} \equiv \delta^2(\Delta - F),$$

as derived in the text, whereas E_{00} takes on these three separate values, derived in Lemma 3 in Appendix A:

Case 1: $F < \min\{F_X, F_Y\}$: $\quad E_{00} \equiv \delta^2[\alpha\Pi^T + (1-\alpha)\Pi^D/2] + \delta^3\Delta - \delta F$

Case 2: $\min\{F_X, F_Y\} < F < \max\{F_X, F_Y\}$.

$$E_{00} \equiv \delta^2[\alpha\Pi^T + (1-\alpha)\Pi^D/2] + \delta^3\Delta - (\delta F)[1 + \delta\alpha + \delta^2(1-\alpha)]/2$$

Case 3: $F > \max\{F_X, F_Y\}$: $\quad E_{00} \equiv \delta^2(\Delta - F)$.

	C	~C
C	E_{11}, E_{11}	E_{10}, E_{01}
~C	E_{01}, E_{10}	E_{00}, E_{00}

Proof of Proposition 1 has three parts:

Part I: (C, C) is the Nash equilibrium outcome of the above game if $E_{11} - E_{01} \geq 0$. Letting $E_{11} - E_{01} = 0$ and solving for the value of F, we can express the above condition as $F \leq \Phi/2$, where

$$\Phi/2 \equiv \delta(1-\alpha)(\Pi^D/2)/(1-\delta^2).$$

Part II: For either (C, ~C) and (~C, C) to be an equilibrium outcome, we must have $E_{10} - E_{00} > 0$ and $E_{01} - E_{11} > 0$. The latter inequality is written as $F > \Phi/2$ from the preceding discussion. The former involves the term E_{00} and hence there are three cases from Appendix A. The results also depend on the sign of $F_X - F_Y$. Calculations show that for a given $\alpha < 1$

$$\Phi > F_X = \frac{\delta(1-\alpha)\Pi^D/2}{(1-\delta)[1+\delta(1-\alpha)]} > \Phi/2$$

Suppose first that $\delta < (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$, so $F_X > F_Y$ all $\alpha \in (0,1)$ by Lemma 3. Substituting the expressions from the above, we can write the condition $E_{10} - E_{00} > 0$ as follows

Case 1: $F < F_Y$

$$F < \hat{F}_1 \equiv \delta(1-\alpha)[\Pi^D(1-\delta/2)+\delta\Pi^T]/(1-\delta).$$

Case 2: $F_Y < F < F_X$.

$$F < \hat{F}_2 \equiv \frac{\delta(1-\alpha)[\Pi^D(1-\delta/2)+\delta\Pi^T]/(1-\delta)}{\{2-\delta[1+\delta\alpha+\delta^2(1-\alpha)\}/2} = \frac{2(1-\delta)\hat{F}_1}{2-\delta[1+\delta\alpha+\delta^2(1-\alpha)]}$$

Case 3: $F > F_X$

$$F < \Phi \equiv \delta(1-\alpha)\Pi^D/(1-\delta^2).$$

Define the sets that correspond to the three cases

$$L_1 = \{(\alpha, F): F > \Phi/2 \text{ , } F < F_Y \text{ and } F < \hat{F}_1\},$$

$$L_2 = \{(\alpha, F): F > \Phi/2, F_Y < F < F_X \text{ and } F < \hat{F}_2\}$$

$$L_3 = \{(\alpha, F): F > \Phi/2, F_X < F \text{ and } F < \Phi\}$$

and $L = L_1 \cup L_2 \cup L_3$. We can show that, given the restriction on $\delta < (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$, $F_Y < \Phi/2$ and hence $L_1 = \varnothing$. Next, we have $F_X < \hat{F}_2$ so that $L_2 = \{(\alpha, F): \Phi/2 < F < F_X\}$. Finally, since $F > \Phi/2$, we have $L_3 = \{(\alpha, F): F_X < F < \Phi\}$. Therefore, there is one challenger in the set $L = \{(\alpha, F): \Phi/2 < F < \Phi\}$. This is illustrated in Figure A1 above.

Consider the complementary case, where $\delta \geq (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$. Then, $F_X < F_Y$ for $\alpha < \hat{\alpha}$, $F_X = F_Y$ for $\alpha = \hat{\alpha}$ and $F_X > F_Y$ for $\alpha > \hat{\alpha}$ by Lemma 3. First, consider the subcase in which $\alpha < \hat{\alpha}$. Corresponding to the three cases above, define the three sets as follows:

$$M_1 = \{(\alpha, F)| F > \Phi/2, F < F_X \text{ and } F < \hat{F}_1; \alpha < \hat{\alpha}\},$$

$$M_2 = \{(\alpha, F)| F > \Phi/2, F_X < F < F_Y \text{ and } F < \hat{F}_2; \alpha < \hat{\alpha}\} \text{ and}$$

$$M_3 = \{(\alpha, F)| F > \Phi/2, F_Y < F \text{ and } F < \Phi; \alpha < \hat{\alpha}\}$$

and $M = M_1 \cup M_2 \cup M_3$. Given $\delta \geq (\Pi^T - \Pi^D/2)/(\Pi^D - \Pi^T)$, we have $F_Y > \Phi/2$. Also, $\hat{F}_1 > F_Y$. The proof is as follows: $(1-\delta)\hat{F}_1 > \delta(1-\alpha)\Pi^D > \delta(1-\alpha)(\Pi^D - \Pi^T) = (1-\delta)F_Y$). Thus, $M_1 = \{(\alpha, F)|\Phi/2 < F < F_X; \alpha < \hat{\alpha}\}$. Next, we want to show that $\hat{F}_2 > F_Y$. Since the denominator of $\hat{F}_2$ is

greater than that of F_Y, we only need to show that the numerator of $\hat{F}_2$ exceeds that of F_Y, which is true since

$$\Pi^D + \delta(\Pi^T - \Pi^D/2) > \Pi^D - \Pi^T .$$

Therefore, $M_2 = \{(\alpha, F)| F_X < F < F_Y; \alpha < \hat{\alpha}\}$. Finally, since $F_Y < \Phi$, we have $M_3 = \{(\alpha, F)| F_Y < F < \Phi; \alpha < \hat{\alpha}\}$. In conclusion, $M = \{(\alpha, F): \Phi/2 < F < \Phi; \alpha < \hat{\alpha}\}$.

Consider next the subcase in which $\alpha > \hat{\alpha}$. Corresponding to the three cases above, define the three sets:

$N_1 = \{(\alpha, F)| F > \Phi/2, F < F_Y \text{ and } F < \hat{F}_1; \alpha > \hat{\alpha}\}$,

$N_2 = \{(\alpha, F)| F > \Phi/2, F_Y < F < F_X \text{ and } F < \hat{F}_2; \alpha > \hat{\alpha}\}$ and

$N_3 = \{(\alpha, F)| F > \Phi/2, F_X < F \text{ and } F < \Phi; \alpha > \hat{\alpha}\}$

and $N \equiv N_1 \cup N_2 \cup N_3$. For N_1, we have $F_Y > \Phi/2$. We also have $F_Y < \hat{F}_1$. Hence, $N_1 = \{(\alpha, F)| \Phi/2 < F < F_Y; \alpha > \hat{\alpha}\}$. Next, $\hat{F}_2 > F_X$. Therefore, $N_2 = \{(\alpha, F)| F_Y < F < F_X; \alpha > \hat{\alpha}\}$. Finally, since $F_X > \Phi/2$, $N_3 = \{(\alpha, F)| F_X < F < \Phi; \alpha > \hat{\alpha}\}$. Hence, $N = \{(\alpha, F)| \Phi/2 < F < \Phi; \alpha > \hat{\alpha}\}$. Finally, suppose $\alpha = \hat{\alpha}$ so that $F_X = F_Y$ by Lemma 3. By continuity of F_X and F_Y, we can show that there is one challenger in the set $N' = \{(\alpha, F)| \Phi/2 < F < \Phi; \alpha = \hat{\alpha}\}$. Thus, $M \cup N \cup N' = \{(\alpha, F)| \Phi/2 < F < \Phi; \alpha \in (0,1)\}$. This is illustrated in Figure A2 above.

Part III: (~C, ~C) is the Nash equilibrium outcome if and only if $E_{10} - E_{00} < 0$ and $E_{11} - E_{01} < 0$. These are complementary to the conditions under which the other equilibrium outcomes considered above do not occur, and hence is represented by the area above the line $F = \Phi$. Furthermore, Lemma 1B shows that there are no challengers in period 2, either. Q.E.D.

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