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Jiangyun(Yunyun) Wan

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Hitotsubashi University
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Abstract

In the United States, brand-name drug manufacturers often pay generic companies to delay marketing of their generic products. In this paper we develop an analytical framework to examine the implications of banning reverse payment settlements. We first find that reverse payment settlements occur when generic firms face relatively high entry cost but do not when entry costs are sufficiently low. We next show cases in which reverse payment settlements are harmful to brands. We also consider the counterfactual case when 180-day marketing exclusivity rights are removed from Hatch-Waxman and find that the absence of marketing exclusivity rights encourages brands to proceed with reverse payment settlements.

Keywords: reverse payment settlements, generic entry competition, Hatch-Waxman, marketing exclusivity

JEL Classification Codes: I18, K23, L13

Institute of Innovation Research, Hitotsubashi University University, Kunitachi, Tokyo, Japan.
Email address: jiangyun.wan@gmail.com

[1] Institute of Innovation Research, Hitotsubashi University, Japan

1. Introduction

The Hatch-Waxman Act was enacted in 1984 to promote generic entry competition with an eye to slowing down the rising costs of medicines in the United States. To encourage generic entry, HW requires that generic drug manufacturers demonstrate only the bioequivalence of their generic products with the original brands, and also rewards the generic firm that successfully challenges the patent pertaining to the brand with the 180-day period of marketing exclusivity, during which no other generics are allowed to compete in the market.[1]

Brand-name manufacturers have responded to such entry-promoting measures by making arrangements for generic challengers to delay entry, usually in exchange for payments. Two features of Hatch-Waxman helps brands maintain monopolies. One is the fact when a generic challenges the brand's patent, the latter has the option of filing an infringement suit, which results in an automatic 30 month stay of FDA approval, prolonging the brand's monopoly. However, this is roughly how long a court takes before announcing its finding as to the validity of the brand's patent. Thus, as long as the FDA maintains the policy of not approving generics while they are litigated, removing this automatic stay has little effect on the monopoly. Thus, in our study we focus on the second feature, which is the 180-day marketing exclusivity right granted to the first challenger of the brand's patent. Before 2003, the brand and the generic could use this right to keep other generics from entering for additional 180 days to further prolong the brand's monopoly. The 2003 Amendments to Hatch-Waxman (so called the Medicare bill) addressed this abuse by making it a requirement that the marketing exclusivity right be forfeited if the generic fails to market the drug in question within 75 days since the granting of the exclusivity right.

The marketing exclusivity however is a rather controversial feature of Hatch-Waxman as it has both the pro-competitive (encourages entry competition among generics) and the anti-competitive (only one generic is allowed to market for the exclusivity period) effect so that its full effect on consumer welfare is not clear without further analysis. In this paper, we therefore explore

[1] See Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.

the implications of removing marketing exclusivity rights on incentives for brands to propose reverse payment settlements with generics.

It is time to outline our model. It is a multi-period model with one brand (incumbent) and two potential entrants (generics). 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 brand'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 explanation is that "data exclusivity" prohibits generic firms to use the innovation drug's test data to prove the safety and efficacy of the generic drugs.[2] Since preparing own test data is extremely costly, generic firms wait till data exclusivity expires to submit applications for marketing approval.

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 much emphasized in the economic and legal studies literature. 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 to strategically delay its entry. To model the time-consuming nature of litigation

[2] 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.

we assume that a court takes one period to deliver its verdict. Thus, the incumbent can delay generic entry for one period by filing infringement suit against a patent challenger. If the incumbent's patent is found invalid, generic entry is approved. Otherwise, generic entry occurs after patent expiration.[3]

Lastly, we assume that marketing exclusivity lasts for one period, to keep things simple. In reality, litigation lasts much longer than 180 days during which entry by other generics is checked.[4] Thus, with this assumption we may appear to be overstating the value of marketing exclusivity in our analysis. However, this overstatement is balanced, at least in part, by the fact that, contrary to our symmetry assumption, the first generic entrant in reality reaps greater profits relative to later entrants due to the presence of "substantial *switching costs* in pharmaceutical markets" (Crawford and Shum 2005).

In such a model environment we first present a model in which reverse payment settlements are ruled out. We then allow reverse payment settlements. A comparison of the results from these models gives us insight as to when reverse payment settlements are arranged and what their implications are on competition and social welfare. We next consider the counterfactual scenario in which marketing exclusivity is removed from hatch-Waxman provisions.

Our main findings are as follows. With marketing exclusivity, equilibria with reverse payment settlements occur when the generic entry costs are in the intermediate range. If the entry costs are too low there are no equilibria with reverse payment settlements because a forfeiture of the marketing exclusivity induces a second generic challenge, destroying the monopolistic equilibrium. If the entry costs are too high, of course, there is no generic entry before patent expiration. Even in such cases, there is a curious possibility that the prospect of a reverse payment settlement induces a generic to challenge the patent although generics have no incentive to do so when reverse payments are banned. In such cases brands and generics are better off when reverse payments are banned. As for the welfare effect, we find that banning reverse payment settlements improves social welfare

[3] We assume as in Choi (1998) that, when declared valid, the patent remains valid for the remainder of its life.
[4] An automatic 30-month stay will be given if infringement suit is filed against a patent challenger.

when the entry costs are in the intermediate range but otherwise has no effect on welfare. Finally, we show that removing marketing exclusivity rights results in more cases of reverse payment settlements.

The remainder of this paper is organized as follows. Section 2 describes the model environment. Section 3 presents the model without the possibility of reverse payment settlements, while section 4 examines the case with reverse payment settlements. Section 5 considers the counterfactual scenario when there is no granting of marketing exclusivity to the first generic patent challenger. The final section concludes.

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 an established branded drug manufacturer and the patent holder. Two potential entrants are generic drug manufacturers that must file for marketing approval before entering the market. Obtaining marketing approval requires the one-time fixed entry cost F (> 0). The incumbent's patent expires at the beginning of the third period, so entry occurring in period 3 or later does not entail patent infringement. In contrast, entry in period 1 or period 2 must begin with a patent challenge, which may result in infringement litigation.

With two potential generic entrants, there can be three market structures: monopoly (M), duopoly (D) and triopoly (T). Let Π^J denote the incumbent's (equilibrium) per-period profit when the market structure is J (= M, D, T). We assume that $\Pi^M > \Pi^D > \Pi^T$; the incumbent's profit decreases as generic competition intensifies. Similarly, let π^J be the profit to a generic firm when the market structure is J (= D, T). Naturally, we have that $\pi^D > \pi^T$. It is well known that even though the generics are known to be fully equivalent to the branded drug consumers tend to prefer the latter drug largely because of their familiarity with it through previous use.[5] In reflection of this fact we

[5] This is explored further in Wan (2016), who develops a two-period model to study brand loyalty in the pharmaceutical industry.

posit that $\Pi^D \geq \pi^D$ and $\Pi^T \geq \pi^T$. Finally, we suppose that $\pi^D/2 < \pi^T < 3\pi^D/4$. This assumption is more of a technical nature, which keeps the probability that the incumbent wins infringement suit between 0 and 1, and is satisfied in Cournot oligopoly with linear demand and constant marginal cost.

Let Ω denote the discounted sum of the triopoly profit for the incumbent; i.e., $\Omega \equiv \Pi^T/(1-\delta)$. Define $\omega = \pi^T/(1-\delta)$ for the generics similarly. For the remainder of the analysis, we assume that $\omega - F > 0$, implying that both generic firms enter after patent expiration, if they have not done so earlier. This assumption allows us to focus on the central question of this paper: generic entry competition before patent expiration.

If the generic firms challenge the patent, the incumbent decides whether to file patent infringement suit. We suppose that, if it chooses to file suit, a court takes one period to deliberate. Let $\alpha \in (0, 1)$ denote the probability that the patent is found valid. We further assume the following, as in Choi (1998). First, the probability α is exogenous.[6] Second, if one generic firm challenges and the patent is found invalid, then the other generic firm can also enter without infringing the patent. On the other hand, if the patent is found valid, the validity is respected for the rest of the patent life so generic entry occurs only after patent expiration. Third, when there are two simultaneous challengers, the court deliberates their cases jointly. Lastly, legal fees are negligibly small.

Consider next what happens if the incumbent accommodates entry in period 1. Then, FDA grants marketing approval in period 1, allowing the generic firm(s) to enter immediately.[7] In this case, however, the incumbent still 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 fully compensate the incumbent for all the losses it suffered from patent infringement.

3. Hatch-Waxman without reverse payment settlements

[6] 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.

[7] 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.

In this section we consider the model without possibilities of reverse payments. The game begins with two generic producers simultaneously deciding, in period 1, whether to challenge the incumbent's patent (action C) or not (action ~C). The generic firms' first-period actions gives rise to four subgames: two with symmetric actionss, (C, C) and (~C, ~C) and two more with asymmetric actions, (C, ~C) and (~C, C). Let v_{00} and v_{11} denote, respectively, the (symmetric) generic firm's profit from the subgames (~C, ~C) and (C, C). For the asymmetric subgames, let v_{10} denote the challenger's profit and v_{01} the non-challenger's profit. We **solve** each subgame first and then solve the whole game for the subgame-perfect Nash equilibrium.

3.1: Subgame (C, C): Two challengers in period 1

Suppose that two generic firms challenge the patent, both incurring the entry cost F in period 1. If the incumbent files suit and a court finds the patent invalid, only one generic firm enters in period 2; the other firm waits till period 3. Note that the second entrant need not incur the cost F in period 3 because FDA stayed marketing approval for it in period 1 but did not deny its application.

When both generic firms challenge the patent, filing suit is the dominant strategy for the incumbent. 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

$$\Pi^M + \delta[\alpha\Pi^M + (1-\alpha)\Pi^D] + \delta^2\Omega \tag{1}$$

where $\Omega \equiv \Pi^T/(1-\delta)$. On the other hand, if the incumbent does not file suit, FDA approves both generics but grants marketing exclusivity to only one firm. In period 2, marketing exclusivity expires and the other generic firm enters. However, the patent has not expired yet. At this point, the incumbent chooses to file suit because otherwise it would forgo the compensations for patent infringement (with probability α). As we assume full compensation when the patent is upheld, the incumbent's profit from accommodating entry in period 1 and then filing suit in period 2 is

$$\Pi^D + \delta\Pi^T + \delta^2\Omega + \alpha(\Pi^M + \delta\Pi^M - \Pi^D - \delta\Pi^T)$$
$$= \alpha\Pi^M (1+ \delta) + (1 - \alpha)(\Pi^D + \delta\Pi^T) + \delta^2\Omega.$$

Note that the term in parentheses on the left-hand side of the equality represents the compensation the incumbent receives when its patent is found infringed. However, the above profit is less than the profit (1), so the incumbent files suit against both challengers in period 1.

Given the incumbent's optimal response to challenging the patent, we calculate the generic firms' profits. In period 1, they earn zero profit because FDA does not generally grant marketing approval while there is litigation. In period 2, if the patent is found invalid one generic firm enters under marketing exclusivity while the other enters in period 3. If the patent is found valid, both generic firms wait till period 3 to enter. Assuming that each generic firm is equally likely to be granted marketing exclusivity, we obtain the following equilibrium profit for a generic firm

(2) $$v_{11} = - F + \delta(1- \alpha)\pi^D/2 + \delta^2\omega,$$

where $\omega \equiv \pi^T/(1- \delta)$. The incumbent's equilibrium profit is given by (1).

3.2. Subgames (C, ~C) and (~C, C): One challenger in period 1

As in the previous case, filing infringement suit guarantees the monopoly profit Π^M in period 1 for the incumbent. If the patent is found valid, the incumbent also earns Π^M in period 2. On the other hand, if the patent is found invalid, the challenger enters so the incumbent's profit is Π^D. Regardless of a court decision, the second generic firm does not enter till period 3. Therefore, the incumbent's expected profit is the same as the one in (1).

On the other hand, if the incumbent accommodates entry, 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, which delays entry of the second generic. The incumbent is also entitled to the compensations from the first entrant with probability α. Thus, accommodation in period 1 (followed by litigation against both generics in period 2, if the second enters) yields the expected profit to the incumbent:

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

where the last term in brackets represents the compensation. In contrast, also accommodating the second generic firm in period 2 yields $\Pi^D + \delta\,\Pi^T + \delta^2\Omega$. As this profit is clearly smaller than the one in (3). Thus, the incumbent files suit if the second generic firm enters in period 2. Therefore, in period 2's values, the second generic firm's expected profit will be $-F + \delta\omega$ if it enters and $\delta(\omega - F)$ if it waits till period 3. Clearly, the second firm chooses not to enter. However, the incumbent still files suit against the first entrant, because it yields the profit in (3) while filing suit against the first generic firm yields $\Pi^D(1+\delta) + \delta^2\Omega$, a smaller profit.

We have shown that the incumbent obtains the profit in (3) by accommodating a challenger in period 1 and then filing suit against that firm in period 2. However, this profit is still smaller than the one in (1). Thus, the incumbent files suit against the challenger in period 1. The incumbent's equilibrium profit is given in (1). The challenger's profit is

(4) $v_{10} = -F + \delta(1-\alpha)\pi^D + \delta^2\omega$

while that of the non-challenger is

(5) $v_{01} = \delta^2(\omega - F) > 0.$

3.3 (~C, ~C): No challengers in period 1

If the generic firms do not challenge the patent in period 1, then they again simultaneously decide whether to challenge the patent or not in period 2. We show, in Appendix A, that not to challenge the patent in period 2 is the dominant strategy. Therefore, the generic firms do not enter before patent expires, and hence the equilibrium profit is

$$v_{00} = \delta^2(\omega - F).$$

3.4 Equilibrium in period 1

Having solved all the subgames, we can move back to the first-period game, in which two generic firms simultaneously choose C or ~C. We present the equilibrium outcomes in the next

proposition while relegating the proof to Appendix B. We begin by defining the function $\Phi : (0,1) \to \mathbb{R}_+$:

$$\Phi(\alpha) \equiv \delta(1-\alpha)\Pi^D/(1-\delta^2).^8$$

From the preceding subsections, if only one generic firm enters in period 1, the other generic firm delays entry till period 3, earning the expected profit v_{01}. If instead the latter also enters in period 1, it pays the cost F upfront and faces the expected profit $(1 - \alpha)\pi^D/2$ in period 2, given equal chances of getting granted marketing exclusivity. Paying the cost F upfront as opposed to in period 3 costs the firm $(1 - \delta^2)F$ additionally. If this extra cost equals the firm's expected gain in profit, $\delta\pi^D(1 - \alpha)/2$, then the firm is indifferent between challenging the patent in period 1 and delaying entry till period 3, provided that the rival challenges the patent. Arranging the equality $(1 - \delta^2)F = \delta\pi^D(1 - \alpha)/2$, we obtain $F = \Phi(\alpha)/2$, which is equivalent to $v_{11} = v_{01}$. If $F = \Phi(\alpha)/2$, $v_{11} > v_{01}$ and hence the firm challenges the patent in period one.

Now consider the case in which neither firm challenges the patent in period 1. Then we can show that they both delay entry until period 3 (see Appendix B). In this case, if instead one firm decides to challenge the patent in period 1, its expected profit is raised by $(1 - \alpha)\delta\pi^D$, since it is the only challenger. Thus, when the rival does not challenge the patent in period 1, the firm is indifferent between challenging the patent and not doing so if $(1 - \delta^2)F = \delta\pi^D(1 - \alpha)$. Solving for F yields the other key condition $F = \Phi(\alpha)$, which is equivalent to the equality $v_{10} = v_{00}$.

Now, if the entry cost is low enough to satisfy $F < \Phi(\alpha)/2$, then $F < \Phi(\alpha)$. Thus, we have that $v_{11} > v_{01}$ and $v_{10} > v_{00}$; patent challenging is the dominant strategy. If F is higher so that $\Phi(\alpha)/2 < F < \Phi(\alpha)$, then $v_{11} < v_{01}$ and $v_{10} > v_{00}$, implying that a firm challenges the patent if and only if the rival does not. As a result, there is one challenger in this range of F. Finally, if F is so high that $F > \Phi(\alpha)$, not entering is the dominant strategy. We summarize these results in

Proposition 1: Fix α.

[8] $\Phi(\alpha)$ is the value of F that satisfies the equality $v_{10} = v_{00}$ $(= \delta^2(\omega - F))$; see Appendix B for details.

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

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

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

Proposition 1 is illustrated in figure 1. In region labeled 1, both generics challenge the patent; in region 2, only one generic does so, and there is no patent challenging in region 3.

As we saw in proposition 1 and figure 1, the equilibrium outcome crucially hinges on the entry cost F. 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).[9] Hatch-Waxman has introduced the Abbreviated New Drug Application (ANDA) process, which exempts generics from both pre-clinical and clinical trials and requires only the bioequivalence tests to be satisfied for FDA approval (Mossinghoff 1999). Furthermore, as noted earlier, test data of the branded drug, previously kept as trade secrets, are made available to generic drug manufacturers after five years of data exclusivity.[10] 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.[11]

We end this section with the welfare calculations. We first introduce notation and definitions. Social surplus is defined as the sum of consumer surplus and industry profits less entry costs in each period. Social welfare is the discounted sum of social surpluses evaluated at the beginning of period 1. CS^i (i = M, D, T) denotes the per-period consumer surpluses under monopoly, duoply and triopoly, respectively. S^i denotes the social surplus under the market

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

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

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

structures i = M, D, T. Social surplus is assumed to increase as the market becomes more competitive; i.e.,

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

Write $S^T / (1-\delta) \equiv \Sigma$.

We now 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 remains a monopoly. In period 2 there is duopoly with probability (1 – α) and monopoly otherwise. In period 3 there is triopoly. Thus, the equilibrium social welfare is given by:

(6) $$W(1) = S^M + \delta[\alpha S^M + (1-\alpha)S^D] + \delta^2\Sigma - 2F$$

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

$$W(2,3) = S^M + \delta[\alpha S^M + (1-\alpha)S^D] + \delta^2\Sigma - F - \delta^2 F .$$

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

(7) $$W(4) = (1+\delta)S^M + \delta^2(\Sigma - 2F) .$$

4. Reverse payment settlements

We now extend our baseline model to allow reverse payments and examine the implications. In the extension we assume that the incumbent cannot arrange for reverse payment settlements after the patent expires. This assumption rules out the possibility that the incumbent remains a monopoly forever by buying out all generic competitors and still earns a greater profit than when there is generic entry.

The extended model adds a new stage to the baseline game, in which the incumbent chooses whether to offer a reverse payment to the generic firm that has been granted marketing exclusivity. If such a proposal is made, the parties involved choose the amount of a reverse payment, which we denote by R. In the extended analysis, then the first period begins with two generic firms deciding whether to challenge the incumbent's patent or not. If the patent is

challenged and the notice is received that a paragraph IV certification was filed, the incumbent then chooses to file suit or not. If it files suit, the rest of the game proceeds as in the baseline model. On the other hand, if it chooses not to file suit so that a generic firm is granted marketing exclusivity, then the incumbent decides whether to accommodate entry in the manner described in section 3 or to proceed for a reverse payment settlement with the generic firm. In case of the latter choice the incumbent pays the generic firm the settlement payment R and the latter postpones entry until the patent expires.

Below we first solve the scenario in which the incumbent proceeds for a reverse payment settlement. We then move back to earlier stages to obtain the subgame-perfect Nash equilibrium of the extended model. We thus begin by examining the four period-one subgames that are initiated by the generic firms' decisions. Suppose that the first-period decision outcome is (C, C) but the incumbent does not file suit so that one firm is granted marketing exclusivity. If a reverse payment settlement agreement is reached, the generic firm chooses not to market its generic drug till period 3, which results in an automatic forfeiture of marketing exclusivity and the subsequent introduction of the other generic drug. Assume for now that the incumbent does not propose a reverse payment settlement with this firm, but instead files suit against the second generic firm, thereby delaying its entry till period 2, when the court decides whether the incumbent's patent is invalid. This means that the incumbent's expected profit equals $\Pi^M + \delta[\alpha\Pi^M + (1 - \alpha)\Pi^D] - R$. Since this profit is, for ant R, less than the profit in (1) the incumbent would receive if it filed suit in the first place, the incumbent never enters into a reverse payment settlement agreement when both generic firms challenge the patent in period 1. Thus, the expected profit to each generic firm is the same as in given in (2), that is, $v_{11}^R = v_{11} = -F + \delta(1-\alpha)\pi^D/2 + \delta^2\omega$.

In the preceding case we assumed that the incumbent does not consider a reverse payment settlement with the second generic firm. Suppose now that it does. Then, if this negotiation fails the incumbent's profit would as in the proceeding paragraph. A successful reverse payment settlement

with the second generic firm further reduces the incumbent's expected profit and hence the incumbent prefers to file suit in the first place.

Consider next the subgame in which only one firm challenges the patent in period 1. A reverse payment settlement with this firm makes the incumbent a monopoly in period 1 for sure. In period 2, if the other generic firm challenges the patent, the incumbent can file suit to delays its entry till period 3. Anticipating this reaction on the part of the incumbent, the second generic firm is better off waiting till period 3 to enter. Therefore, when there is one firm challenging the patent in period 1, the incumbent's expected profit from proceeding for a reverse payment settlement will be $\Pi^M (1 + \delta)\Pi^M - R$, which can exceed the profit in (1), depending on the value R.

In determining the amount of reverse payment, we suppose that the two firms determine R through Nash bargaining, that is, they choose R to maximize the Nash product $[\Pi^M (1 + \delta) - R - B](R - b)$, where B and b are the profits the incumbent and the generic firm would, respectively, receive in case bargaining fails. We compute B and b as follows. If negotiations fail, we suppose that the incumbent files suit against the generic firm immediately. If the patent is found invalid in period 2, the generic firm markets its produce under marketing exclusivity; otherwise, the incumbent remains a monopoly. Thus, the incumbent's profit would be

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

For the generic firm, the above action on the part of the incumbent implies that the generic firm gains only if the patent is found invalid; that is,

$$b = \delta(1 - \alpha)\pi^D.$$

Note that this expression does not contain F because it is sunk before the firms negotiate for a reverse payment settlement. Substituting these values, we can compute the equilibrium R:

$$\tilde{R} = \delta(1 - \alpha)(\Pi^M - \Pi^D + \pi^D)/2 > 0.$$

Substituting this value of R, we can compute the incumbent's expected profit:

$$\Pi^M (1 + \delta) - \delta(1 - \alpha)(\Pi^M - \Pi^D + \pi^D)/2,$$

This profit exceeds the profit in (1) by $\delta(1 - \alpha)(\Pi^M - \pi^D - \Pi^D)/2 > 0$, implying that the reverse payment settlement dominates litigation. The patent challenger's profit is

$$v_{10}^R = -F + \delta(1 - \alpha)(\Pi^M - \Pi^D + \pi^D)/2 .$$

Since the non-challenger enters in period 3, its profit in period 1 equals

$$v_{01}^R = \delta^2(\omega - F)$$

When neither generic firm enters in period 1, then as shown earlier, there is no introduction of generic drugs until period 3 and hence no reverse payment settlement. The generic firm's expected profit is symmetric and equals $v_{00}^R = v_{00} = \delta^2(\omega - F)$.

Now we can solve the first-stage game. Before proceeding, define

$$\Gamma(\alpha) \equiv \frac{\delta(1-\alpha)(\Pi^M - \Pi^D + \pi^D)}{1-\delta^2} .$$

We have (C, C) if $v_{10}^R \geq v_{00}^R$ and $v_{11}^R \geq v_{01}^R$. But the second inequality implies the first. Thus, we have (C, C) if $F \leq \Phi(\alpha)/2$ as in the baseline model. In this case, there are no reverse payment settlements. Next, we have (C, ~C) if $v_{10}^R \geq v_{00}^R$ and $v_{11}^R < v_{01}^R$, which translate into the inequalities: $F \leq \Gamma(\alpha)/2$ and $F > \Phi(\alpha)/2$. As we showed in this case there is a reverse payment settlement. Lastly, we have (~C, ~C) if $F > \Gamma(\alpha)/2$. In this case there are perforce no reverse payment settlements.

Proposition 2.

(A) The incumbent proceeds for a reverse payment settlement with a generic challenger if and only if $F \in (\Phi(\alpha)/2, \Gamma(\alpha)/2]$.

(B) For $F \in (\Phi(\alpha), \Gamma(\alpha)/2]$, the prospect of a reverse payment settlement prompts generic firms to challenge the patent although they would not without a reverse payment settlement.

Figure 2 illustrates thee above cases, where the broken line represents the function $\Gamma(\alpha)/2$. Reverse payment settlements occur only in the regions labeled 2 and 3A. In region 3A there was no generic

entry without reverse payments but now generics enter to take advantage of being party to reverse payment settlements. Note that $(\Pi^M - \Pi^D + \pi^D)/2 > \pi^D$, which implies that $\Gamma(\alpha)/2 > \Phi(\alpha)$ as shown in the figure. This fact also implies that the intervals $(\Phi(\alpha)/2, \Gamma(\alpha)/2]$ are not empty; that is, there is an F satisfying the condition in proposition 2. The welfare consequence of reverse payment settlements is straightforward. When low enough entry costs (i.e., $F \le \Phi(\alpha)/2$) induce both generic firms to challenge the patent, there are no reverse payment settlements, so the equilibrium welfare equals W(1) given in (6) Similarly, if $F > \Gamma(\alpha)/2$ there are no patent challenges so the welfare equals W(4) given in (7). In the complementary cases, i.e., $F \in (\Phi(\alpha)/2, \Gamma(\alpha)/2]$, reverse payment settlements occur and hence there is no generic entry in the first two periods. Since there is one patent challenger, the welfare level is given by

(8) $$W^R = (1+\delta)S^M + \delta^2\Sigma - F(1+\delta^2).$$

Note that this welfare level is lower than when there are no patent challengers, i.e., W(4), because here one firm incurs the entry cost F in period 1 instead of period 3 and yet there is no generic entry until period 3. Thus,

Proposition 3. Prohibiting reverse payment settlements increases social welfare for $F \in (\Phi(\alpha)/2, \Gamma(\alpha)/2]$, and has no welfare effects otherwise.

5. The effect of removing marketing exclusivity on reverse payments

Now we consider the counterfactual case: no marketing exclusivity in Hatch-Waxman. If both generic firms enter in period 1, we suppose that the incumbent enters into an agreement with both. To keep things simple, also assume that the three-party negotiations fail unless all three come to an agreement. Then the settlement payments R_j to firm j (= 1, 2) maximizes the Nash product $[\Pi^M (1 + \delta) - R_1 - R_2 - B](R_1 - b_1)(R_2 - b_2)$, where B and b_i are the expected profits to the

incumbent and to each generic firm i, respectively. If negotiations fail, the game reverts to the baseline model, where the incumbent chooses whether to file suit or not. Hence,

$$B = \Pi^M + \delta[\alpha\Pi^M + (1-\alpha)\Pi^T]$$

while

$$b = \delta(1-\alpha)\pi^T .$$

Thus, we have that $b_1 = b_2 = b$. Substituting these values, we can rewrite the Nash product as

$$[\delta(1-\alpha)(\Pi^M - \Pi^T) - R_1 - R_2][R_1 - \delta(1-\alpha)\pi^T]\,][R_2 - \delta(1-\alpha)\pi^T].$$

Maximization yields

$$\hat{R}_i = \hat{R} = \delta(1 - \alpha)(\Pi^M - \Pi^T + \pi^T)/3 .$$

The incumbent's profit is therefore equal to

$$(1+\delta)\Pi^M - 2\delta(1-\alpha)(\Pi^M - \Pi^T + \pi^T)/3.$$

This profit exceeds the profit in (6) by $\delta(1 - \alpha)(\Pi^M - 2\Pi^T + \pi^T)/3 > 0$, implying that a reverse payment settlement dominates litigation. The generic firm's profit is therefore

$$\hat{v}_{11}^R = \delta(1-\alpha)(\Pi^M - \Pi^T + \pi^T)/3 - F.$$

On the other hand, if one firm challenges the patent in period 1, the result is exactly the same as with marketing exclusivity. If there is no patent challenging, the outcome is the same as in the baseline model; there are no reverse payment settlements.

With all the subgames solved, we proceed to the first-stage game. To that end, first define

$$\Lambda(\alpha) \equiv \frac{\delta(1-\alpha)(\Pi^M - \Pi^T + \pi^T)}{1-\delta^2} .$$

We have (C, C) if $\hat{v}_{11}^R \geq v_{01}^R$ and $v_{10}^R \geq v_{00}^R$, which implies the bounds on F:

$$F \leq \text{Min}\{\Lambda(\alpha)/3\ ,\ \Gamma(\alpha)/2\}.$$

Since $(\Pi^M - \Pi^T + \pi^T)/3 < (\Pi^M - \Pi^D + \pi^D)/2$, we have

$$\Lambda(\alpha)/3 < \Gamma(\alpha)/2.$$

Hence, we have (C, C) if $F \leq \Lambda(\alpha)/3$. Next, we have (C, ~C) if $\hat{v}_{11}^R < v_{01}^R$ and $v_{10}^R \geq v_{00}^R$. These conditions implies that $\Lambda(\alpha)/3 < F \leq \Gamma(\alpha)/2$. Lastly, we have no patent challenges if $F > \Gamma(\alpha)/2$, as in the previous section. The next proposition puts together the above findings.

Proposition 4: (A) If $F \leq \Lambda(\alpha)/3$, both generic firms challenge the patent and the incumbent proceeds for a reverse payment settlement with both firms.

(B) If $\Lambda(\alpha)/3 < F \leq \Gamma(\alpha)/2$, one firm challenge the patent, with which the incumbent proceeds for a reverse payment settlement.

(C) If $F > \Gamma(\alpha)/2$, there is no patent challenging.

The relative location of $\Lambda(\alpha)$ and $\Phi(\alpha)$ depends on the difference $(\Pi^M - \Pi^T + \pi^T)/3 - \pi^D$. If the incumbent's product does not have much brand loyalty so that $\Pi^T \approx \pi^T$ and $\Pi^D \approx \pi^D$, then $(\Pi^M - \Pi^T + \pi^T)/3 - \pi^D < 0$, implying that $\Lambda(\alpha)/3 < \Phi(\alpha)$. We show this case in figure 4, where the dotted line represents $\Lambda(\alpha)/3$. In region 1 and region 2A both generics challenge the patent, resulting in reverse payment settlements. In regions 2B and 3A one generic challenges the patent, resulting in reverse payment settlements. Finally, if the incumbent's branded drug commands greater brand loyalty so that π^D is sufficiently small, then the above inequality *may* be reversed, i.e., $(\Pi^M - \Pi^T + \pi^T)/3 - \pi^D > 0$ so $\Lambda(\alpha)/3 > \Phi(\alpha)$.

A comparison between figures 2 and 3 yields the following results, which is independent of the relative magnitude between $\Lambda(\alpha)/3$ and $\Phi(\alpha)$. On the one hand, since $\Lambda(\alpha)/3 < \Gamma(\alpha)/2$, removing marketing exclusivity encourages both generic firms to challenge the patent even if the entry costs are higher. On the other hand, removing marketing exclusivity intensifies generic entry competition and as a result weakens generic firms' negotiation positions. Thus, with marketing exclusivity, when both generic firms challenge the patent, the incumbent does not offer a reverse payment settlement, whereas without marketing exclusivity a brand finds it more profitable to propose reverse payment settlements with both generics. In other words, removing marketing exclusivity facilitates reverse payment settlements.

Proposition 5. Removing of marketing exclusivity increases the incentive for reverse payment settlements, that is, without marketing exclusivity the incumbent proceeds for a reverse payment settlement whenever there is generic entry (which occurs for all $F \leq \Gamma(\alpha)/2$).

Proposition 5 has a dire welfare consequence. The equilibrium welfare is

$$\hat{W}_{11}^{R} = (1+\delta)S^{M} + \delta^{2}\Sigma - 2F$$

when both generic firms challenge and W^R given in (8) when one firm challenges. Clearly $\hat{W}_{11}^{R}$ is the worse since entry costs are incurred upfront in period 1 without generic penetration into the market. We thus conclude that in the presence of reverse payment settlements, removing marketing exclusivity from Hatch-Waxman reduces social welfare.

6. Concluding remarks

In this paper we develop a formal analytical framework to examine the implications of banning reverse payment settlements. We find that reverse payment settlements occur when generic firms face relatively high entry costs while reverse payments are not profitable when entry costs are sufficiently low. We also identify cases in which reverse payment settlements are harmful to brands. Such cases occur when generic firms have no incentives to challenge brands' patents without reverse payment possibilities, but generics are induced to challenge the brands' patents by the prospect of sharing the monopoly profits through reverse payments.

We also consider the counterfactual case when marketing exclusivity rights are removed from Hatch-Waxman and find that the absence of marketing exclusivity rights encourages brands to proceed with reverse payment settlements. This marketing exclusivity rights serve as checks to spreading of reverse payment settlements.

Appendices

Appendix A: We analyze the period-2 subgames with marketing exclusivity, when there are no challengers in period 1. We consider each subgame.

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 there is no longer granting of marketing exclusivity. Therefore, regardless of what court determines, both generic firms enter, yielding Π^T to the incumbent. Thus, if the incumbent files suit, its expected profit (evaluated at the beginning of period 2 and exclusive of the first-period profit) equals

(A1) $\Pi^M + \delta\Pi^T + \delta^2\Omega$.[12]

In contrast, with accommodation, only one generic firm enters in period 2 under marketing exclusivity, yielding to the incumbent

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

This is less than the profit in (A1) and hence the incumbent files suit against both challengers. Given the preceding discussion, each challenger's expected profit in period 2 is $e_{11} = -F + \delta\omega$.

A2. One challenger in period 2

This case is similar to the previous subcase. By filing suit, the incumbent receives the same profit as in (A1). By accommodating, the incumbent receives Π^D in period 2 and Π^T in all later periods, so its profit is given by (A2). Thus, the incumbent files suit against the challenger in period 2. The challenger's profit is $e_{10} = -F + \delta\omega$ while the non-challenger's profit is $e_{01} = \delta(\omega - F) > e_{10}$.

A3. No challenger in period 2

If both generic firms wait till period 3 to enter, each firm expects the profit $e_{00} = \delta(\omega - F)$.

[12] Originally, market exclusivity was not forfeited by patent expiration. In such a case, the incumbent's profit from filing suit is greater and equals $\Pi^D + \delta[\alpha\Pi^T + (1-\alpha)\Pi^D] + \delta^2\Omega$.. This therefore does not change the remainder of the analysis.

These profits to the generic firms imply that not challenging is the strictly dominant strategy. Hence, the generic firm's equilibrium profit is

$$v_{00} = \delta^2(\omega - F)$$

and the incumbent's equilibrium profit is $\Pi^M(1+\delta\Pi) + \delta^2\Omega$.

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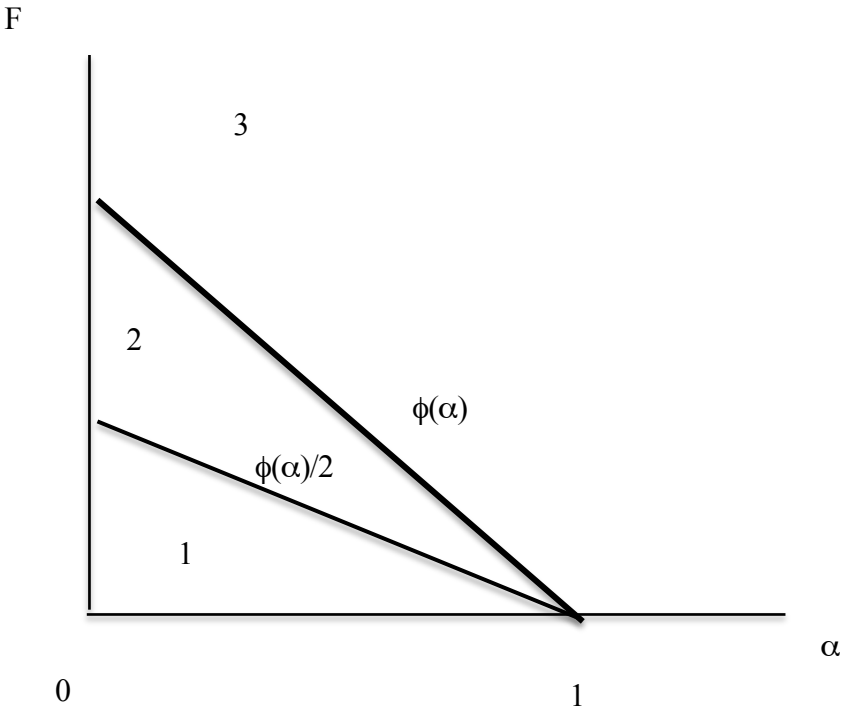

Figure 1: Generic entry without reverse payment

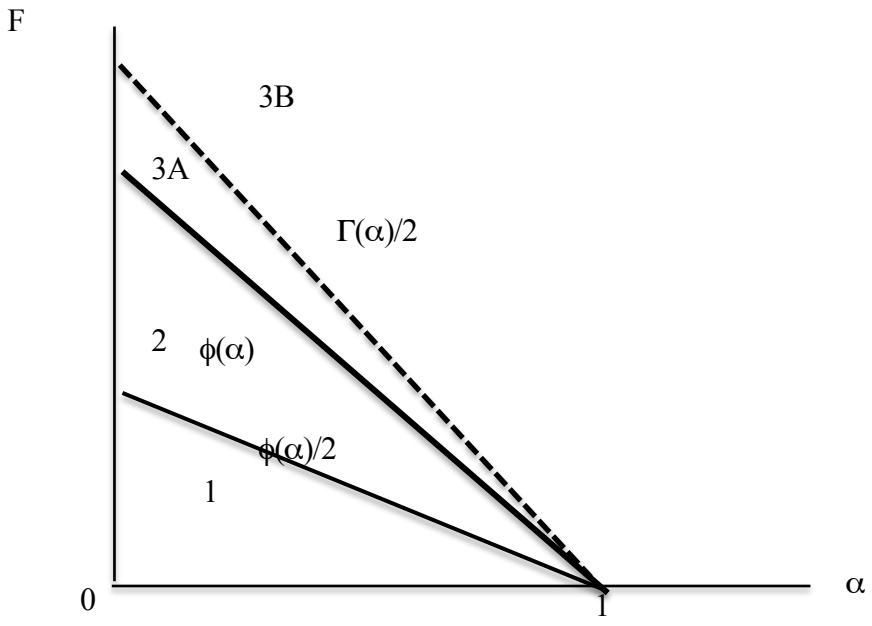

Figure 2: Generic entry with reverse payment

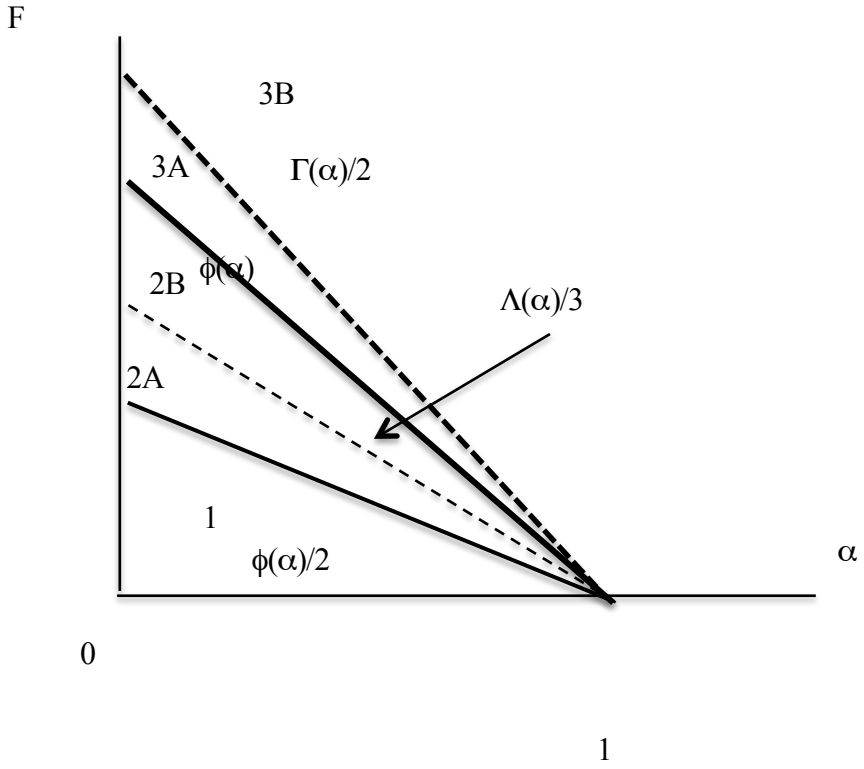

Figure 3: Generic entry without marketing exclusivity