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REVERSE PAYMENTS AND RISK OF BANKRUPTCY UNDER PRIVATE INFORMATION *

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Reverse Payments and Risk of Bankruptcy under Private Information *

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Abstract

In the pharmaceutical industry, a reverse payment is a payment from an originator to a generic producer to delay her entry. In some recent cases, the US and the EU Antitrust Authorities have banned these agreements *per se*. This paper analyzes their dynamic effects and shows that a ban *per se* is not optimal when the generic may go bankrupt and her financial situation is private information. Reverse payments may allow the generic to remain on of the market and increase competition before and after patent expiry. Reverse payments are more beneficial when competition among few players is soft, the economy is in a downturn, the period of drug usage after patent expiry is long or the entrant has a disadvantage with respect to the originator. Results suggest that a rule of reason is more suited than a ban *per se*.

JEL Classification: K21, L12, L41.

Keywords: reverse payments, pay-for-delay, cartel, pharmaceutical industry, litigation, settlement, asymmetric information, financial problems.

1 Introduction

In the pharmaceutical industry, patents are the main assets of firms. Originators have the right to enforce them by litigating against potential infringers, in order to prevent them from exploiting their own inventive activities. Litigations, however, are costly and their outcome

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is uncertain. As an alternative to litigation, the parties can settle the potential dispute. Patent settlements, however, could cover cartel-like agreements where an originator with a weak patent may agree to share his monopoly profits with a rival. A simple way to do that is a payment from the originator to the entrant in exchange of a delay in her entry – a so-called reverse payment (or *pay-for-delay*).

In *FTC v Actavis*, 17 June 2013, the Supreme Court in the US found that “reverse payment” agreements are not immune from antitrust scrutiny, ending a period of inconsistent treatments by different US Circuit Courts.¹ The Supreme Court ruled that reverse payment settlements within the scope of a patent could be assessed by competition law; it also found that such settlements are not *per se* legal, nor are they *per se* illegal, but must instead be assessed on a “rule of reason” basis.² In contrast, the Canadian Competition Bureau has stated that it will adopt a harsher line against reverse payment settlements than in the US.³

In Europe, reverse payments are under the spotlight as well. In 2008, the European Commission launched an inquiry into the pharmaceutical sector with dawn raids at the premises of several originator and generic companies, with particular attention to settlement agreements involving reverse payments. In June 2013, in the *Lundbeck*⁴ case, the (at the time) Commission Vice-President Joaquín Almunia, in charge of competition policy, said: “*It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices*”.⁵ This suggests a presumption that reverse payments are harmful. More recently, while the Commission has indicated that settlement agreements with reverse payments are likely to attract “the highest degree of antitrust scrutiny”, it has also indicated that agreements falling into this category would not always be incompatible with EU competition law – an assessment on the basis of the circumstances of each individual case being required.⁶ The European Commission eventually fined Lundbeck and other

¹http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

In 2003, in the *Bristol-Myers* case, the *Cardizem* case and the *Valley Drug-Geneva Pharmaceuticals* case, and in 2006 in the *Tamoxifen* case, the incumbent paid a potential generic competitor to avoid litigating over the patent and to stay out of the market until patent expiry. The FTC found these agreements anticompetitive.

At the appeal level, however, some of these decisions have been overturned. In the appeal of the *Tamoxifen* and *Valley Drug-Geneva Pharmaceuticals* cases, respectively the Sixth and the Eleventh Circuit reversed the initial judgement of the FTC and found the agreements not illegal, as they did not extend beyond the original patent terms.

²The Supreme Court defined a “reverse payment” as a case where a party with no claim for damages walks away with money simply so it will stay away from the patentee’s market. The Supreme Court contrasted that with settlements where a party (e.g. an enjoined party) receives a payment reflecting the potential liability for the originator to pay damages for lost sales during the enjoined period.

³<http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03817.html>.

⁴http://europa.eu/rapid/press-release_IP-13-563_en.htm.

⁵European Commission Press Release 19 June 2013, Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines.

⁶See paragraph 17 of the European Commission’s 5th Report on the Monitoring of Patent Settlements (pe-

companies for delaying generic entry through the use of reverse payments. In July 2014 the same happened with Servier and some generic firms.⁷

Proponents of the view that settlements with (large) reverse payments should be presumed anti-competitive typically rely on the argument that, by expanding contractual space, the reverse payment allows the originator scope to compensate the generic would-be entrant with a payment for delaying entry; such a payment is profitable for both parties because it allows the originator to earn monopoly profits during a longer period and because monopoly profits exceed the sum of duopoly profits – so there is scope to compensate the generic entrant. They go on to argue that absent a reverse payment, earlier entry would occur either as a result of settlement or, in the event of litigation, because the expected outcome of litigation would be earlier. These papers reflect the view that patents should be considered as probabilistic property rights (Shapiro 2003, Lemley and Shapiro 2005), as a patent may later be found invalid – or the entrant’s product may be found not to infringe a valid patent.⁸ In other words, the patent-holder should not have the right to exclude a party from using its own patent, but only to try to exclude it. This makes entry possible, if parties litigate. Shapiro (2003) suggests to allow settlements that leave consumers, in expectations, at least with the same surplus as under litigation. He concludes that reverse payments are a sign of anticompetitive settlement. Lemley and Shapiro (2005) state that reverse payments should be presumed anticompetitive, as they delay entry relative to continued litigation and settlements not involving reverse payments. Willig and Bigelow (2004), on the other hand, demonstrate that in some cases a settlement with reverse payments can be beneficial to consumers. This occurs when there are differences in (i) the information about the future states of the market, (ii) the expectation of success in the litigation, and (iii) the impact that entry of another firm has on the incumbent and the entrant. Gratz (2012) compares *per se* legality, illegality and rule of reason. She finds that *per se* legality induces maximal collusion, *per se* illegality entirely prevents it and the rule of reason induces limited collusion when antitrust enforcement is subject to error. This limited collusion can be welfare enhancing, as it increases the expected settlement profits, thus fostering generic entry. Dickey & Rubinfeld (2012) also present an informal discussion of how permitting reverse payments may increase generic entry.

The aim of this paper is to contribute to the literature on reverse payments by analyzing their dynamic effects. We use the analytical framework of the literature of litigations and settlements.⁹ We deliberately adopt a framework consistent with a skeptical view over the

riod: January-December 2013), 5 December 2014, available at http://www.mlex.com/EU/Attachments/2014-12-05_587L6F26816B614Y/patent_settlements_report5_en.pdf The EU Commission defines reverse payment settlements as those which foresee a value transfer from the originator to the generic company.

⁷http://europa.eu/rapid/press-release_IP-14-799_en.htm.

⁸Leonard and Mortimer (2005) argue for a rule of reason approach but consider that pro-competitive reverse payments are likely to be small in most cases. See also Elhauge & Krueger (2012), who argue that reverse payments in excess of the originator’s anticipated litigation costs are anti-competitive.

⁹Litigations and settlements have been studied by, among others, Salant and Rest (1982), P’Ng (1983), Bebchuk (1984), Salant (1984), Reinganum and Wilde (1986), Schweitzer (1989) and Daughety and Rein-

pro-competitive effects of reverse payments, i.e. if the generic entrant would remain on the market in any case, then allowing for reverse payments necessarily delays entry (where the entry date in the latter regime is either that which would arise in the event of settlement or the expected entry date in the event of litigation).

We include in the setting the possibility that the entrant has financial problems, which are her private information. There is evidence that pharmaceutical firms, especially the small ones, have frequent financial problems. Hall (2002) shows that small and new pharmaceutical firms experience high costs of capital, which can create and worsen financial problems. Pisano (2006) shows that new biotechnology firms are financially constrained and some drug development failures can lead to bankruptcy.¹⁰ In this paper we show that banning reverse payments reduces the entrant's expected profits, which forces the financially weak entrants out of the market. This reduces consumer surplus both before and after patent expiry through the reduction of the number of competitors. In some parameter sets this effect offsets the positive effect of banning reverse payments, which consists of early entry provided that the entrant does not have financial problems. An important condition for this to occur is that competition among few players is soft and, when there is a sufficient number of competitors, it becomes harsher. Reiffen and Ward (2005) analyze the relationship between the price and the number of generic competitors in 31 drugs and report that the average wholesale price when only one generic competitor is present is very close to the pre-expiry branded price, while when generics are two or more the average wholesale price decreases considerably. They also analyze the first wholesale price, the average ratio revenue/quantity and the first ratio revenue/quantity and find that when generic competitors are up to four prices remain relatively stable, but when the fifth generic enters prices decrease dramatically.¹¹ Other papers study the relationship between price and number of generic sellers m but, differently from Reiffen and Ward (2005), they assume a specific type of relationship in the econometric model. For example, Caves et al. (1991) assume that price varies with m and m^2 and Wiggins and Maness (2004) assume that it varies with m and $1/m$. Both papers show a dramatic decrease in prices as the number of competitors increase.¹² The Food and Drug Administration analyzed the

ganum (1994). Almost all of these models assume that the bargaining process occurs sequentially, where one part makes a take-it-or-leave-it offer and the other one accepts or rejects it. If the responder accepts, the terms of the offer are enforced, while, if he rejects, parties litigate. Except for Schweitzer (1989) and Daughety and Reinganum (1994), incomplete information is one-sided. Some models assume that the party making the offer is the informed one (P'Ng, Salant and Rest, Salant), in which case, due to the transmission of private information through the offer, equilibria are typically very numerous (a well known feature of signalling games), while Bebchuk assumes the opposite - which makes the equilibrium unique. Other models of bargaining assume that the identity of the proposer is determined by a coin flip, like Rubinstein and Wolinsky (1985, 1990), Gale (1986a, 1986b, 1987) and Binmore and Herrero (1988a, 1988b), or that both parties make simultaneous announcements (Wolinsky 1990).

¹⁰From a policy oriented perspective, Arve (2014), in the context of a public procurement auction, provides a rationale for policies that help financially weak players.

¹¹In all of these cases they control for time since market opening.

¹²Also Frank and Salkever (1997) analyze the relationship between price and number of generic competitors,

impact of the number of generic competitors on average prices for generics as a percentage of the price of the branded drug. They found that the first generic entrant had a very small impact on prices but subsequent entrants dramatically reduced the ratio of the generic price over the branded one.¹³ These results suggest that prices depend in a non-linear way on the number of competitors and that one or few additional competitors may make prices decrease considerably. This is the case, for example, when few players can sustain a collusive outcome which becomes unsustainable when more players enter the market.¹⁴

In the following analysis we also find that reverse payments are more beneficial when the economy is in a downturn, the period of drug usage after patent expiry is long or the entrant has a disadvantage, in terms of cost or perceived quality, with respect to the originator.

The optimal policy dictates that when the generic producer has a negligible risk of going bankrupt, a ban on reverse payments is optimal. Otherwise, it is optimal to permit reverse payments and the cap must be set at the minimum consistent with allowing the entrant to remain on the market and making her enter as soon as possible. Moreover, under several parameter sets even a "laissez-faire" policy that sets no cap on reverse payments yields higher consumer surplus than a ban *per se*. This suggests that a rule of reason is more suited than a ban *per se*.¹⁵

In order to show the intuitions set out above, we present the theoretical framework (Section 2) and some simulations of hypothetical scenarios (Section 3). Specifically, these simulations allow a number of key parameters to vary such as the entrant's marginal cost, the probability that the entrant has financial problems, the discount factor and the intensity of competition between the originator and the entrant (modelled by a conjectural variation parameter).¹⁶

but they assume that generic price varies linearly with m , so they cannot draw conclusions over the change of the relationship as the number of generic competitors increases.

¹³They found that the first entrant only reduces price by 6%, while it was sufficient to have just two generic competitors to have a reduction of 48%. See <https://aspe.hhs.gov/basic-report/expanding-use-generic-drugs#f13>.

¹⁴Cases of *explicit* collusion are not rare either. In 2014 the Italian competition authority fined Roche and Novartis for agreeing not to use Roche's cheap drug Avastin to treat senile macular degeneration in favour of the much more expensive Lucentis of Novartis. Roche earned profits from the sales of Lucentis because its subsidiary Genentech - which developed both drugs - gets relevant royalties from Novartis. The latter, for its part, in addition to gaining from increased sales of Lucentis, holds a 30% stake in Roche. See <http://www.agcm.it/en/newsroom/press-releases/2139-i760-drugs-antitrust-applies-sanctions-to-roche-and-novartis-for-a-sign-that-has-conditioned-sales-of-main-products-intended-for-the-care-of-sight-avastin-and-lucentis-with-fines-of-more-than-180-million.html>.

In 2008 four South African drug manufacturers have been found guilty of colluding in fixing bids for the supply of products to hospitals and healthcare services of the State. See <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2249668/>.

¹⁵This argument resembles to a "failing firm" defense. The EC recently opened the door to this type of defense in a case of merger between the two airways Aegean and Olympic (http://europa.eu/rapid/press-release_IP-13-927_en.htm).

¹⁶The conjectural variation is the belief a firm has over the reaction of the other firms in response to a change in its output or price. It is a way to model the intensity of competition in a market. In a two-player

We find that the relationship between consumer surplus and the cap on reverse payments is highly non-monotonic. A positive cap on reverse payments increases consumer surplus under several situations, namely when competition among few players is soft, the economy is in a downturn, the period after patent expiry in which the drug is expected to be used is long or the entrant has a disadvantage with respect to the originator. When few players are able to tacitly collude or compete softly, reverse payments are more useful in that they allow financially weak players to remain on the market before and after patent expiry, possibly destabilizing the sustainability of collusion. When the economy is in a downturn, the probability that a generic producer has financial problem is higher, which in turn increases the utility of allowing reverse payments. When the drug is expected to be used during a long period after patent expiry, it becomes more useful to have strong competition after patent expiry and therefore to allow reverse payments, as the potential consumer surplus loss before patent expiry (due to the later entry of the financially strong entrant) is more easily compensated by the consumer surplus gains after patent expiry. When the entrant has a cost disadvantage or is perceived as of lower quality with respect to the originator, the cost of allowing reverse payments is smaller, as the strong generic producer whose entry is delayed exerts a weaker constraint on the originator's behavior, while the benefit of having more players on the market, thus making competition more fierce, is unchanged.

All of these features work in favor of allowing at least some amount of reverse payments and point towards a rule of reason in assessing the competitiveness of reverse payments instead of a ban *per se*.

The paper is organized as follows. Section 2 presents the model, Section 3 shows some simulations and Section 4 concludes.

2 The model

There are three players: an Antitrust Authority (AA), an originator and a generic manufacturer (the entrant). Normalize patent length to 1 and current date to 0.¹⁷ In the first stage, the AA sets the maximal allowed reverse payment \hat{R} . In the second stage, the entrant learns his type, which can be *weak* or *strong*. It is weak with probability $\mu \in [0, 1]$. When the entrant is *weak*, if the originator and the entrant do not settle with a reverse payment at least equal to a threshold k , the entrant is not able to compete and exits the market;¹⁸

game, it takes a value between -1 and 1. For example, in a Cournot game where firms choose quantities, Nash equilibrium means a conjectural variation of 0. A conjecture of -1 makes this game equal to a Bertrand game: each firm thinks that raising its own quantity makes the other firms reduce their quantity in such a way that total quantity remains the same. A conjecture of +1 is equal to the monopoly problem, as each firm believes that its choices will be imitated by the others.

¹⁷Date 0 is the date when the entrant is ready to enter, which is the same as the one when the parties decide whether to litigate or to settle. The intuition is that the entrant has no reason to wait, as this reduces the profits he can ask to the originator.

¹⁸This represents a situation where the entrant goes bankrupt or simply prefers to abandon that market.

if the entrant is *strong*, he can remain on the market in any case.¹⁹ In the third and fourth stage, the originator and the entrant litigate or settle their dispute. The bargaining process is sequential: in the third stage the entrant makes a take-it-or-leave-it offer and, in the fourth stage, the originator accepts or rejects it.²⁰ The offer consists of an entry date $0 \leq D \leq 1$ and a payment $R \leq \hat{R}$ from the originator to the entrant. If the originator accepts the offer D and R are enforced, while if he rejects it parties litigate. If the parties litigate *or* if the reverse payment is below k , the weak entrant exits the market.

The timing is then the following:

1. **Policy choice.** The Antitrust Authority chooses a cap \hat{R} .
2. **Entrant's type.** The entrant learns his type.
3. **Entrant's offer.** The entrant makes a settlement offer.
4. **Originator's response.** The originator accept or rejects it.

In case of litigation, the originator and the entrant bear, respectively, litigation costs C_O and C_E .²¹ The originator's patent strength – the probability that he wins in a trial – is θ . In the pre-expiry period let H be the originator's profits if he is the sole supplier for the entire patent period, L if entry occurs immediately and E the entrant's profits if she enters immediately. Hence, $L + E$ are the joint profits of the originator and entrant if entry occurs immediately. We assume that $H > L + E$. In the post-expiry period, denote h the originator's profits if the entrant has exited the market, l the originator's profits if the entrant is still present and e the entrant's profits if she is still on the market. \underline{S} is the consumer surplus (CS) in the pre-expiry period when only the originator is active and \bar{S} the pre-expiry CS when also the entrant is on the market; moreover, denote \underline{s} the post-expiry CS when the entrant has exited the market and \bar{s} when the entrant is on the market. Of course we assume $\bar{S} \geq \underline{S}$ and $\bar{s} \geq \underline{s}$. The weight of the post-expiry period, in both the parties' profits and CS, is δ . Note that δ may be higher than 1, as the post-expiry period of the drug can be much longer

¹⁹We assume that the weak entrant needs a sufficiently high reverse payment to avoid bankruptcy - an early entry date is not sufficient. This assumption simplifies the analysis but does not change the main conclusions. The only necessary feature for the result is that a settlement with reverse payment yields higher profits for the entrant than a settlement without it, which is always the case.

²⁰The fact that the entrant makes the offer is not necessary for the result. Any form of bargaining that can leave the entrant with *some* additional surplus from the settlement with respect to his threat point (the litigation payoff) gives our result. For the framework in the main text, any form of bargaining that can make the equilibrium reverse payment equal to or bigger than k gives our result. In other words, the only bargaining solution that is not compatible with our claim is the originator making the take-it-or-leave-it offer.

²¹They can be seen as the incremental legal costs of litigation (i.e. those in excess of any legal costs associated with settlement).

than the pre-expiry one.²²

The following subsection computes the litigation and settlement profits in the pooling equilibrium where both entrant's types use the same strategy.²³

2.1 Litigation-Settlement stage

If the parties *litigate*, they expect to obtain:

$$\text{Originator: } \mu(H + \delta h) + (1 - \mu)[\theta H + (1 - \theta)L - C_O + \delta l]$$

$$\text{Entrant: } [(1 - \theta)E - C_E] + \delta e \text{ if she is strong, } 0 \text{ otherwise.}$$

By litigating, the originator knows that with probability μ the entrant is weak, in which case refusing to settle drives her out of the market. In this case, the originator enjoys full monopoly profits in the pre-expiry period, H , plus the post-expiry profits with one competitor less, h . If the entrant is strong, which occurs with probability $(1 - \mu)$, she remains on the market: the originator has a probability θ of winning the case, in which case he gets H , and probability $1 - \theta$ of losing it and get L ; in both cases, he pays C_O for the litigation costs and gets l in the post-expiry period. The strong entrant, instead, knows that she has a probability $(1 - \theta)$ of winning, in which case she gets E , and a probability of θ of losing and earning nothing. Her litigation costs are C_E . The weak entrant, on the other hand, knows that she would not be able to stay on the market if they litigate, so her litigation payoff is 0.

If parties *settle* with a null or small reverse payment ($0 \leq R < k$), their expected payoff is:

$$\text{Originator: } \mu(H + \delta h) + (1 - \mu)[DH + (1 - D)L + \delta l] - R$$

$$\text{Entrant: } (1 - D)E + R + \delta e \text{ if she is strong, } R \text{ otherwise.}$$

If the parties *settle* with a sufficiently high ($R \geq k$) *reverse payment*, they obtain:

$$\text{Originator: } DH + (1 - D)L - R + \delta l$$

²²For example, the patent could expire in two years from the settlement offer, while the drug is not expected to be replaced by better drugs in the following ten years. The post expiry period can therefore have a much higher importance than the present.

²³In the pooling equilibrium, by definition, the strong and the weak entrant use the same strategies. In a separating equilibrium, on the other hand, the originator perfectly knows what type of entrant he is facing. This makes him accept a settlement if and only if the entrant is strong, because refusing to settle with a weak entrant gives him the full monopoly profits. Therefore, the weak entrant always gets 0, because no settlement offer involving a reverse payment would ever be accepted by the originator. Therefore, if the strong entrant asks for a reverse payment, the weak entrant has an incentive to deviate from this candidate equilibrium and to mimick the strong entrant's strategy, to get some positive reverse payment and, therefore, some positive payoff. Therefore, no separating equilibrium with positive reverse payment can exist. There can only be a separating equilibrium without reverse payment. In such an equilibrium, the weak entrant still receives 0, but has no incentive to mimick the strong entrant's strategy, as she would receive 0 in that case too (as no reverse payment is involved and she will have to exit the market). Given that reverse payments are not used in this type of equilibrium, the policy of the AA has no impact on CS.

Entrant: $(1 - D)E + R + \delta e$ independently from her type.

By settling, the originator enjoys DH in the period before the agreed entry date and $(1 - D)L$ in the period until patent expiry. He pays R to the entrant and, finally, obtains δl from the post-expiry period. The entrant earns $(1 - D)E$ if she enters at date D , receives the payment R and obtains δe after patent expiry. The same occurs when the reverse payment is smaller than k , provided that the entrant is strong - otherwise, she only gets R and exits the market.

When the entrant's settlement offer includes a reverse payment smaller than k , the originator accepts it as long as $\mu(H + \delta h) + (1 - \mu)[DH + (1 - D)L + \delta l] - R \geq \mu(H + \delta h) + (1 - \mu)[\theta H + (1 - \theta)L - C_O + \delta l]$, which yields

$$D \geq D^{R < k} = \theta - \frac{C_O}{H - L} + \frac{R}{(1 - \mu)(H - L)}. \quad (1)$$

When the reverse payment required by the entrant is at least equal to k , the originator knows that, by accepting, he is making the weak entrant stay on the market. Therefore he will accept the settlement offer if and only if $DH + (1 - D)L - R + \delta l \geq \mu(H + \delta h) + (1 - \mu)[\theta H + (1 - \theta)L + \delta l - C_O]$, which yields

$$D \geq D^{R \geq k} = \theta + \frac{R - C_O}{H - L} + \mu(1 - \theta + \frac{C_O + \delta(h - l)}{H - L}). \quad (2)$$

The minimal entry date acceptable for the originator is increasing in R and θ and decreasing in C_O and $(H - L)$, as long as $R > C_O$. It is also increasing in the probability μ that the entrant is weak: the higher this probability, the less the originator is willing to pay a reverse payment that keeps her on the market. To simplify the exposition, that $\mu < \frac{H - L - E}{H - L}$ and that both $D^{R < k}$ and $D^{R \geq k}$ are not greater than 1.^{24,25}

Lemma 1 *The entrant asks for the maximal possible payment, which is \hat{R} or the one such that entry occurs at patent expiry ($D^{R \geq k} = 1$).*

Proof. The intuition is that a larger reverse payment more than compensates the entrant's profit loss due to the later entry needed to keep the originator willing to settle. Consider the two cases: (i) $R < k$ and (ii) $R \geq k$. In the first case, a marginally later entry d by the generic

²⁴The assumption $\mu < \frac{H - L - E}{H - L}$ makes the entrant ask for the maximal reverse payment also when the maximal allowed one is below k . This condition comes from the originator's settlement profits when $0 \leq R < k$ – see Lemma 1. Note that this assumption is conservative with respect to the result that reverse payments may increase consumer surplus, as it sets a cap on the benefit of using reverse payments.

²⁵If any of $D^{R < k}$ or $D^{R \geq k}$ were higher than 1, the entrant would just reduce the reverse payment she asks for (with respect to $k - \varepsilon$ when he asks for $D^{R < k}$ and with respect to \hat{R} when he asks for $D^{R \geq k}$) in order to keep the originator indifferent between accepting and litigating with $D = 1$. This would complicate the exposition without changing the qualitative results.

makes the originator earn $d(1 - u)(H - L)$, higher than the gain by the generic dE as long as $\mu < \frac{H-L-E}{H-L}$. In this case the entrant will ask for the maximal allowed reverse payment \hat{R} , which is also the optimal one from the industry perspective. In the second case, a marginally later entry d by the generic makes the originator earn $d(H - L)$, higher than the gain by the generic dE . The second part of the lemma comes from the fact that the parties cannot agree on an entry date after patent expiry $D > 1$. Therefore, $D = 1$ constrains the maximal reverse payment. $D^{R \geq k}$ is greater than 1 when $\hat{R} > R^{D=1}$, where

$$R^{D=1} = (1 - \mu)[(1 - \theta)(H - L) + C_O] - \mu\delta \frac{(h - l)}{(H - L)}. \quad (3)$$

Any cap larger than this threshold, therefore, is equivalent to $\hat{R} = (1 - \mu)[(1 - \theta)(H - L) + C_O] - \mu\delta \frac{(h - l)}{(H - L)}$.

Note also the duality between the imposition of a latest entry date \hat{D} and the maximal reverse payment \hat{R} .

Lemma 2 *The choice of the maximal reverse payment \hat{R} is a perfect substitute for the choice of the latest entry date \hat{D} .*

Proof. See (1) and (2). There is a bi-univocal correspondence between R and D^* , so setting a cap on R or on D is equivalent.

We can therefore restrict our attention to a cap on R . This Lemma implies that capping the reverse payment is equivalent to capping the latest entry date.

Consider now the *strong* entrant's incentives. By comparing her settlement profits under $R \geq k$ and under $R < k$, given the originator's minimal required entry dates $D^{R < k}$ and $D^{R \geq k}$, the strong entrant will propose a settlement with a reverse payment larger or equal to k if and only if $(1 - D^{R \geq k})E + \hat{R} + \delta e \geq (1 - D^{R < k})E + k + \delta e$, which yields

$$\hat{R} \geq R^* = \frac{(1 - \mu)(H - L)}{(1 - \mu)(H - L) + \mu E} \left\{ k + \mu \left[1 - \theta + \frac{C_O + \delta(h - l)}{H - L} \right] E \right\}. \quad (4)$$

If $\hat{R} < R^*$, then the strong entrant prefers to ask for $k - \varepsilon$ in order to reduce the originator's expected cost of settling – by making an offer that pushes the weak entrant out of the market. The higher the probability μ that the entrant is weak, the more likely it is that the strong entrant asks for $k - \varepsilon$, as a high μ increases the cost of accepting a high reverse payment for the originator and therefore reduces the settlement profits the entrant can obtain.

Consider now the *weak* entrant's incentives. She gets positive profits only through R before patent expiry and remains on the market after patent expiry only if R is at least equal to k . Therefore her incentives to ask for a reverse payment higher than k are stronger than for the strong entrant. But the originator knows that, if $\hat{R} < R^*$, the strong entrant prefers to ask for $k - \varepsilon$, so the originator would understand that the entrant is weak if she asked for $R \geq k$. The originator knows that, by litigating against a weak type, he gets the full monopoly profits $H + \delta h$, so no settlement could ever take place. In other words, if the weak

entrant asks for a reverse payment larger or equal to k when the strong type would not, she is revealing that she is weak - therefore the originator will always litigate, driving her out of the market. The weak entrant has, therefore, no better option than just mimicking the strong entrant's strategy. That is why we just refer to the "entrant", regardless of her type, in the following analysis.²⁶

When $R^* > k$, we have three possible outcomes depending on the maximal reverse payment \hat{R} : (1) $\hat{R} < k$: the entrant asks for \hat{R} and the weak type exits the market; (2) $k \leq \hat{R} < R^*$: the entrant asks for $k - \varepsilon$ and the weak type exits the market; (3) $\hat{R} \geq R^*$: the entrant asks for \hat{R} and the weak type survives.²⁷

This leads to the following Lemma.

Lemma 3 *Any policy $\hat{R} < R^*$ makes the weak entrant exit the market.*

This Lemma states that such a low reverse payment cannot increase consumer surplus. Next section analyzes consumer surplus in general under different policies.

2.2 Consumer surplus and optimal policies

Recall that \underline{S} is the CS in the pre-expiry period when only the originator supplies the product, \bar{S} the pre-expiry CS when also the entrant is on the market, \underline{s} the post-expiry CS when the entrant has gone bankrupt and \bar{s} when the entrant is on the market. We have $\bar{S} \geq \underline{S}$ and $\bar{s} \geq \underline{s}$.

Therefore, when the parties settle with $R < k$, we have

$$CS^{R < k} = \mu(\underline{S} + \delta \underline{s}) + (1 - \mu)[D^{R < k} \underline{S} + (1 - D^{R < k}) \bar{S} + \delta \bar{s}]. \quad (5)$$

With probability μ the generic is weak and exits the market, leaving the monopoly to the originator until patent expiry, after which competition - with one competitor less - takes place. With probability $(1 - \mu)$ the generic is strong and, therefore, remains on the market,

²⁶Here we are discussing the pooling equilibrium where the strong and the weak entrant, by definition, use the same strategies. In a separating equilibrium, by definition, the originator perfectly knows what type of entrant he is facing. This makes him accept a settlement if and only if the entrant is strong, because refusing to settle with a weak entrant gives him the full monopoly profits. Therefore, the weak entrant always gets 0, because no settlement offer would ever be accepted by the originator. Therefore, if the strong entrant asks for a reverse payment, the weak entrant has an incentive to deviate from his candidate equilibrium strategy and to mimic the strong entrant's strategy, to get some positive reverse payment and, therefore, some positive payoff. Therefore, no separating equilibrium with positive reverse payment exist. There can only be a separating equilibrium without a reverse payment. In such an equilibrium, the weak entrant still receives 0, but has no incentive to mimic the strong entrant's strategy, as he would receive 0 in that case too. Given that reverse payments are not used in this type of equilibrium, the policy of the AA has no impact on CS.

²⁷When $R^* \leq k$, case (2) disappears. In the following, to make the analysis more complete, assume that $R^* > k$.

so CS is equal to the monopoly consumer surplus \underline{S} until $D^{R < k}$, to the duopoly consumer surplus \bar{S} after $D^{R < k}$ before patent expiry and to the competitive consumer surplus with the entrant active \bar{s} after it.

When the parties settle with $R \geq k$, which occurs when $\hat{R} \geq R^*$, we have

$$CS^{R \geq k} = D^{R \geq k} \underline{S} + (1 - D^{R \geq k}) \bar{S} + \delta \bar{s}. \quad (6)$$

This is the sum of the monopoly consumer surplus \underline{S} until $D^{R \geq k}$, the duopoly consumer surplus \bar{S} after $D^{R \geq k}$ until patent expiry and the competitive consumer surplus with the entrant active, \bar{s} , after patent expiry.

By analyzing $CS^{R < k}$ we have the following Lemma.

Lemma 4 $CS^{R < k}$ decreases with \hat{R} .

For any settlement with $0 < R < k$, entry is delayed compared to a settlement without a reverse payment. Moreover, given that $R < k$, if the entrant is weak she will exit the market anyway, so the advantage of getting her on board is lost. Therefore, a policy that makes the parties settle with $0 < R < k$ is never optimal. The basic trade-off for the AA is between (i) making the weak entrant not go bankrupt, and (ii) early entry. It is, therefore, useless to set a policy such that reverse payments are used but they are too small to keep the weak entrant on the market. Therefore, disregarding the entrant's bankruptcy problem, it is easy to see that consumer surplus is higher under $\hat{R} = 0$. A "laissez faire" policy makes firms choose a later entry date (equal to $D^{R < k}$ or 1, depending on the choice that grants more profits to the entrant), while banning them makes the entrant propose $D^{R=0} = \theta - \frac{C_O}{(H-L)}$, that is strictly smaller than $D^{R < k}$ for any positive reverse payment. Being consumer surplus decreasing in the generic producer's entry date, it is clear that consumer surplus is higher under a ban on reverse payments. This supports the FTC and EC's opinion that reverse payments should be banned *per se*. However, banning reverse payments can reduce consumer surplus when we consider the entrant's bankruptcy problem. A ban on reverse payments, indeed, can force the weak entrant out of the market, which makes the originator enjoy full monopoly profits until patent expiry and competition with one competitor less afterwards. Consumer surplus, both before and after patent expiry, is reduced. For several parameter sets, this effect overwhelms the negative effect of inducing a later entry, making consumer surplus lower than if reverse payments had been allowed.

This leads to the following Proposition.

Proposition 1 *There exist parameter sets where banning reverse payments reduces consumer surplus.*

Proof. Given Lemmas 3 and 4, we can disregard the policies $0 < \hat{R} < R^*$, because they do not allow the weak entrant to remain on the market and entry is delayed compared to a ban scenario. We can, therefore, just focus on a policy $\hat{R} = 0$ and on the policies $\hat{R} \geq R^*$.

From (5) and (6), the former with $\hat{R} = 0$, we get that allowing reverse payments increases consumer surplus when

$$\hat{R} < \tilde{R} = \mu(H - L)\delta\left[\frac{(\bar{s} - \underline{s})}{(\bar{S} - \underline{S})} - \frac{(h - l)}{(H - L)}\right]. \quad (7)$$

as long as the chosen reverse payment is higher than k (4) and the entry date is no larger than 1 (3). Therefore, allowing reverse payments increases consumer surplus when $R^* < \hat{R} < \min\{R^{D=1}, \tilde{R}\}$. In particular, consumer surplus is maximal when $\hat{R} = R^*$ if $R^* < \tilde{R}$ and when $\hat{R} = 0$ otherwise.

This yields the following policy implications.

Corollary 1 *If the ratio of the increase in future CS over the increase of current CS from having an additional competitor $\frac{(\bar{s} - \underline{s})}{(\bar{S} - \underline{S})}$ is lower than the ratio of the increase in future profits over current profits from having a competitor less $\frac{(h - l)}{(H - L)}$, reverse payments do not increase consumer surplus.*

Proof. When $\frac{(\bar{s} - \underline{s})}{(\bar{S} - \underline{S})} < \frac{(h - l)}{(H - L)}$, we have $\tilde{R} < 0$, so no reverse payment can increase CS.

When $\frac{(\bar{s} - \underline{s})}{(\bar{S} - \underline{S})} > \frac{(h - l)}{(H - L)}$, we have the following corollaries.

Corollary 2 *The higher the probability μ that the entrant is weak, the smaller the parameter set in which reverse payments are used and, when used, the larger the parameter set where allowing them increases consumer surplus.*

Proof. The first part comes from (3), where a higher μ reduces the maximal reverse payment compatible with entry prior to patent expiry, and the second one comes from (4) and (7), where a higher μ makes the inequalities easier to fulfill.

A consequence is that during an economic downturn (higher μ) it is better to be more lenient towards reverse payments. An economic downturn means lower profitability and worse credit crunch - conditions that negatively impact the survival rate of small firms. It becomes, therefore, more important that the AA be more lenient in this case, as a strict ban on reverse payments can force a number of generic firms out of the market, reducing competition both before and after patent expiry.

Corollary 3 *(i) The higher the difference in future CS $(\bar{s} - \underline{s})$ from having one additional competitor and (ii) the lower the difference in present CS $(\bar{S} - \underline{S})$ from having one additional competitor, the larger the parameter set where it is optimal to allow for reverse payments.*

These two apparently contrasting points can be linked if some collusion or soft competition is possible as long as the number of firms is sufficiently low. The idea is that one additional competitor, in addition to the traditional pro-competitive effect, could also make it impossible

for the firms to tacitly collude. If that additional competitor makes the firms switch to a more competitive equilibrium, $(\bar{s} - \underline{s})$ can be substantial. This makes $(\bar{s} - \underline{s})$ higher when passing from, say, three competitors to four, rather than from two to three. For the same reason, the difference $(\bar{S} - \underline{S})$ can be small if the originator and the entrant can achieve some form of collusion. If competition among few players is not fierce, allowing weak generic firms to stay on the market reduces the sustainability of collusion and can increase consumer surplus.

Finally, note that even a “laissez-faire” policy of no cap to reverse payments may increase consumer surplus compared to a ban scenario.

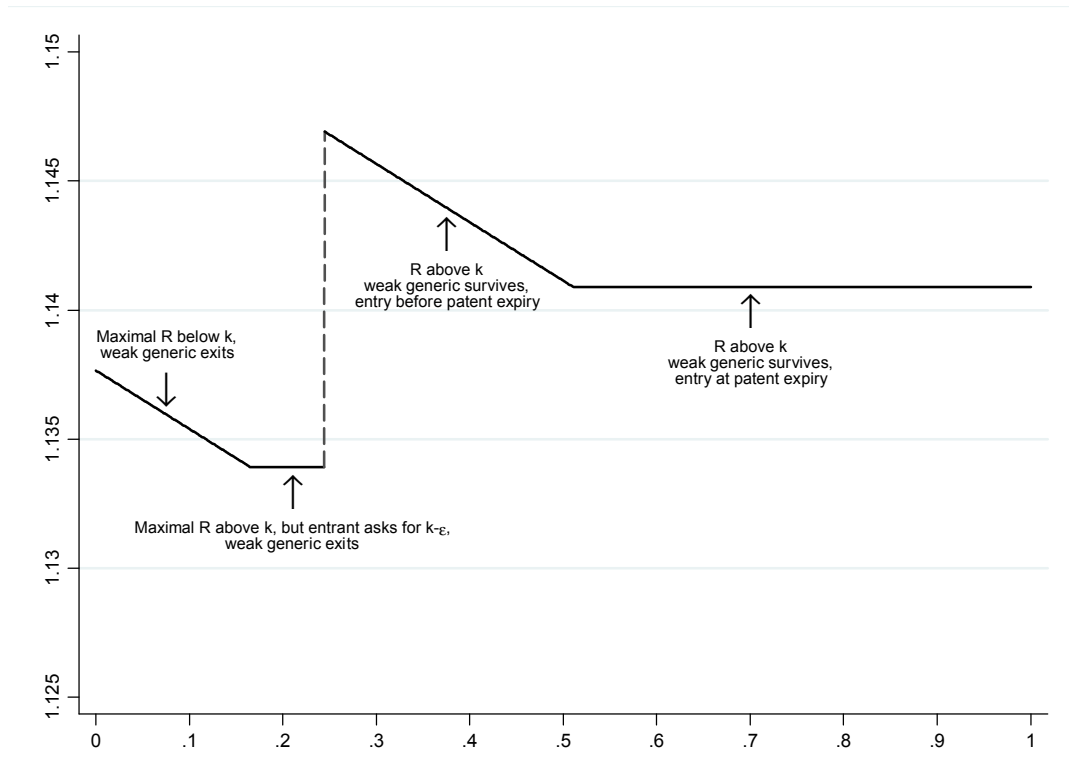
Corollary 4 *A “laissez-faire” policy yields higher consumer surplus than $\hat{R} = 0$ if and only if $(1 - \mu)[(1 - \theta)(H - L) + C_O] - \mu\delta(h - l) < \mu(H - L)\delta[\frac{(\bar{s} - \underline{s})}{(\bar{S} - \underline{S})} - \frac{(h - l)}{(H - L)}]$.*

Proof. When no cap is set on reverse payments, the parties agree on the one such that the entry is upon patent expiry $R^{D=1}$ (3). By plugging it into (7) we get the result.

The next section provides some simulations.

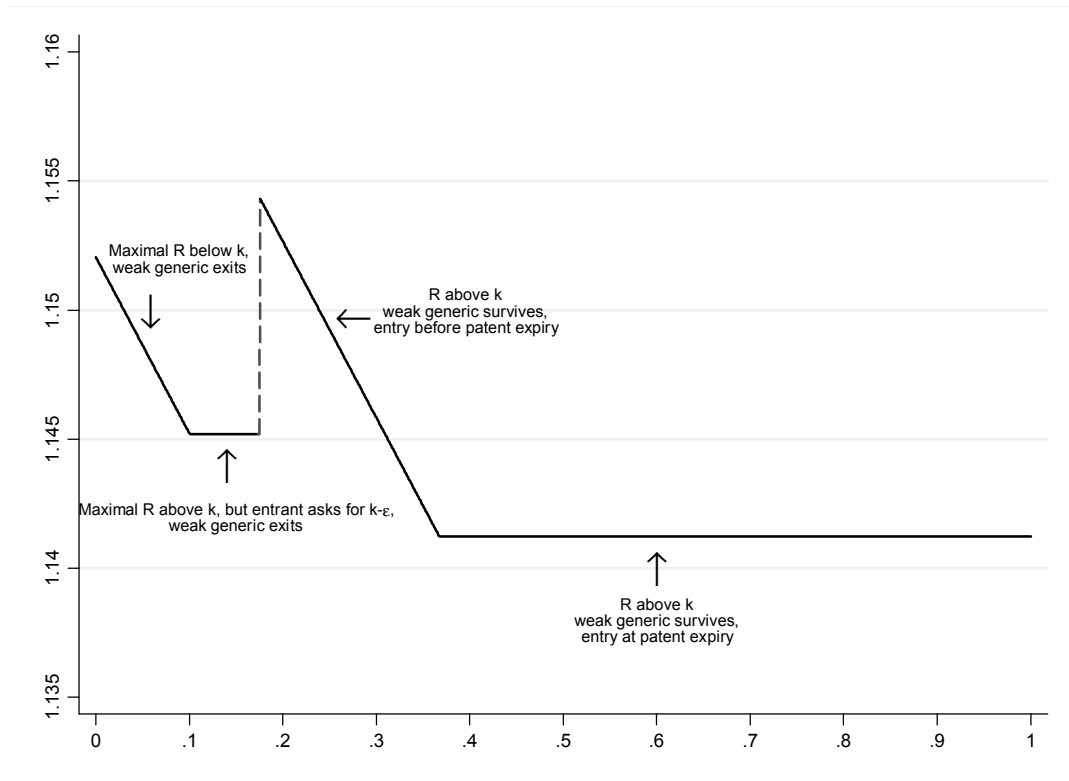
3 Simulations

In order to test the intuitions presented above, we run a number of hypothetical scenarios. Specifically, we assume demand is linear of the form $P = 2 - Q$, the patent strength θ is equal to 0.5 and the originator’s marginal cost is normalized to zero. We then allow a number of key parameters to vary such as the intensity of competition between the originator and the entrant (modelled by a conjectural variation parameter), the probability that the entrant is weak, the degree of symmetry between the originator and the entrant (modelled by variations in the entrant’s marginal cost), the discount factor, the amount needed by the entrant to remain on the market and the number of generic competitors after patent expiry. While this set up is simple, it is nonetheless a helpful way to test our earlier intuitions. For each case we consider, we identify expected consumer surplus (which we refer to as “consumer surplus” for convenience). The baseline scenario has a conjectural variation parameter of 0.75 when there are two competitors, a conjectural variation parameter of 0 when competitors are more than two, the entrant’s marginal cost equal to 0.3, the probability that the entrant is weak equal to 0.2, a discount factor equal to 0.5 and the amount needed to remain on the market equal to 0.05. Litigation costs are assumed to be 0. These parameters make consumer surplus under monopoly equal to 0.5. The conjectural variation parameter of 0.75 represents a situation of less-than-perfect tacit collusion (recall that a value of 1 is equivalent to full collusion), while a parameter of 0 represents Cournot competition. Note that, with such a demand function and such conjectural variation parameters, we get $H = 1$, $L = 0.56$, $E = 0.303$. Given these parameters, the amount k needed to remain on the market represents 16.5% of the entrant’s pre-expiry profits. We evaluate consumer surplus (y-axis) as a function of the allowed reverse payment (x-axis), considered as a fraction of the entrant’s pre-expiry profits E . This baseline simulation yields the following graph.



This scenario shows that when reverse payments are banned, or too low (below 25% of the entrant's profits), the entrant will ask for a reverse payment smaller than k . This can be simply because the maximal allowed reverse payment \hat{R} is below k or because the strong entrant prefers to ask for a smaller payment (equal to $k - \epsilon$) in order to make the originator willing to accept an early entry date. The originator in turn accepts it because, with such a low reverse payment, he makes sure that the weak generic producer will exit the market. When the maximal reverse payment \hat{R} is below k , consumer surplus decreases with \hat{R} , because a larger allowed reverse payment delays the entry of the strong entrant. When the maximal payment is such that the entrant asks for $k - \epsilon$, consumer surplus does not vary with \hat{R} , as the entry date remains the one resulting from a reverse payment equal to $k - \epsilon$. When \hat{R} is greater than 25% of the entrant's pre-expiry profits, the reverse payment actually used allows the weak entrant to remain on the market. This makes consumer surplus have a discrete increase and get to its maximum when the cap \hat{R} is the minimum reverse payment compatible with the weak entrant remaining on the market. Higher values of \hat{R} yield a lower consumer surplus but still higher than a ban scenario. This happens both when \hat{R} is below 52% of E , in which case entry by the strong generic occurs before patent expiry, and when \hat{R} is above 52%, in which case the strong generic enters at patent expiry.

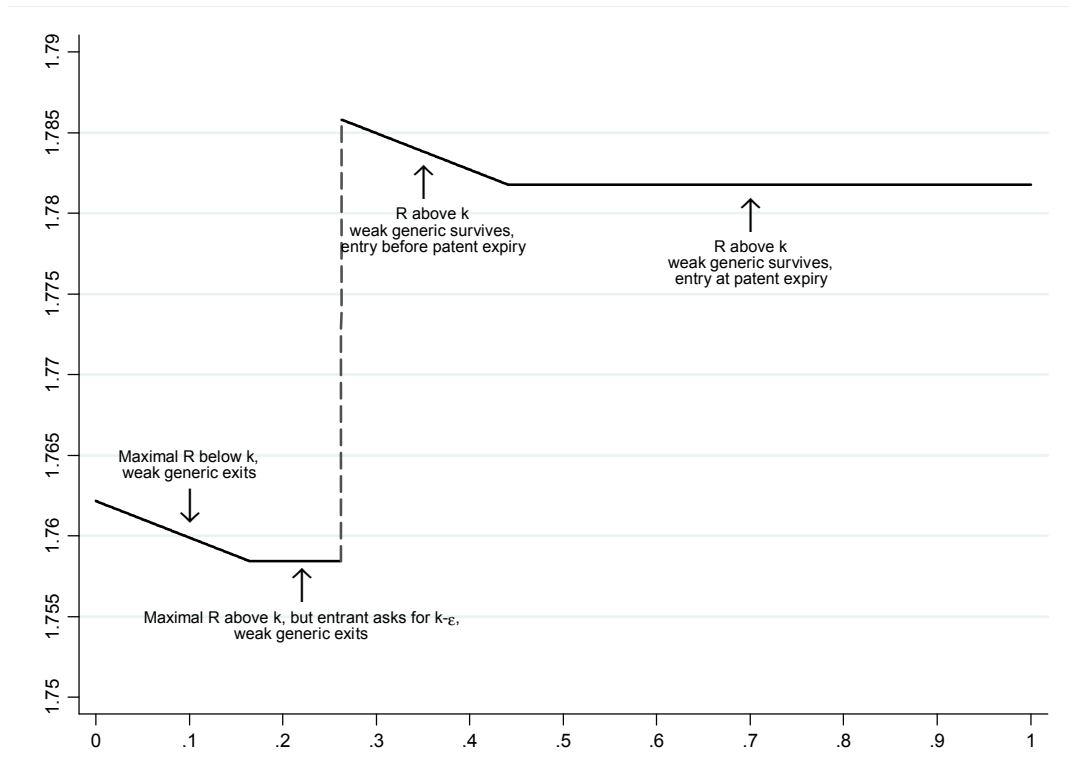
We have also run other simulations. In the second one, we have annulled the cost asymmetry the entrant has with respect to the originator. All the parameters are the same, except the entrant's marginal cost which now becomes 0.



The graph is qualitatively similar to the baseline case, but the perfect symmetry between the entrant and the originator makes it less convenient to allow reverse payments, as they delay the entry of the strong entrant, which is now able to compete more fiercely with the originator. Consumer surplus is still maximum when reverse payments are allowed and \hat{R} allows the weak entrant to remain on the market, but declines more quickly and a "laissez-faire" policy, in this case, yields lower consumer surplus than a ban.²⁸

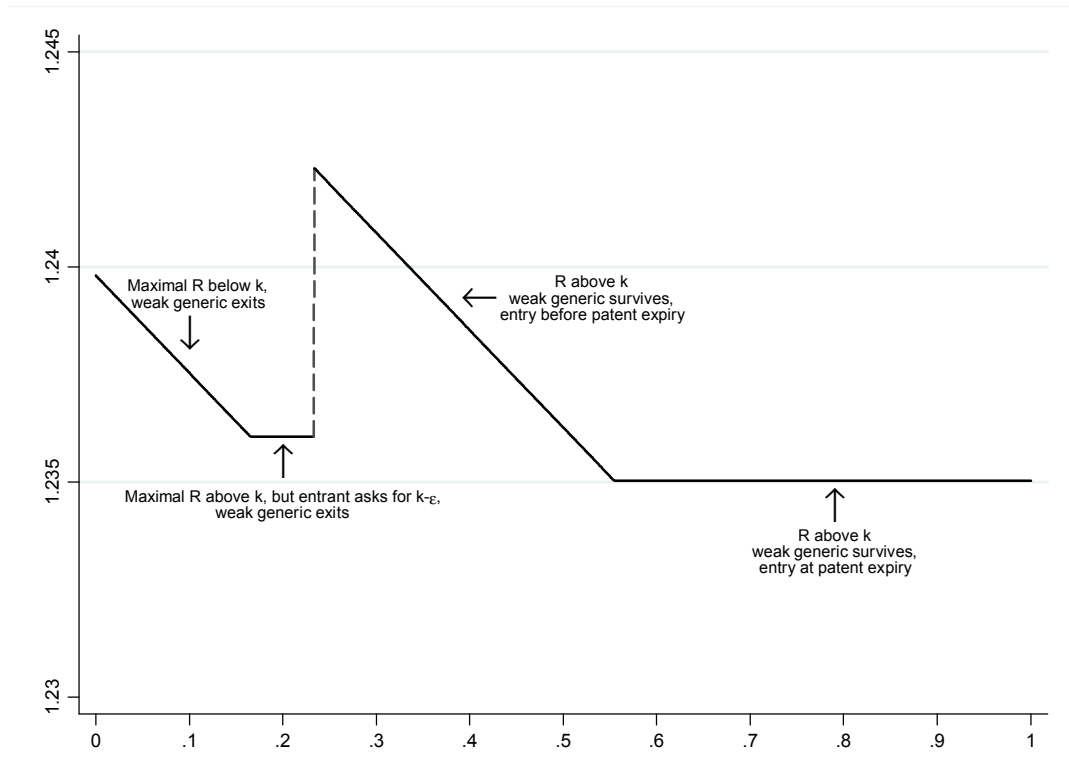
Our third simulation changes the discount factor, which now is equal to 1. Recall that the discount factor can be higher than 1, as the post-expiry period in which the drug is still used may well be longer than the pre-expiry period.

²⁸Note that the cost (a)symmetry can be interpreted in terms of preferences of consumers towards the originator and the generic. The more consumers have a preference towards the originator, the more the situation is alike to the generic having a cost disadvantage.



A higher discount factor (or a higher period in which the drug will be used after patent expiry) makes it more appealing to allow reverse payments, as keeping the generic on the market becomes more important. A higher discount factor also reduces the risk of choosing a too high cap on reverse payment – consumer surplus under a "laissez-faire" policy is closer to the maximal level and much higher than under a ban scenario.

Our fourth simulation increases the number of other generic competitors after patent expiry from two to four (which means that after patent expiry there are six players on the market).



A higher number of competitors after patent expiry reduces the utility of allowing reverse payments, given that competition after patent expiry would in any case be relatively fierce. Consumer surplus is still maximized when reverse payments are used and the cap is the minimum to make the generic producer able to remain on the market, but it decreases more quickly than under the baseline scenario.

In terms of the optimal policy, as these simulation show, we find that the relationship between consumer surplus and the cap on reverse payments is highly non-monotonic. A simple ban on reverse payments seems therefore a too simple rule, as it may reduce consumer surplus under several situations, namely when competition among few players is soft, the economy is in a downturn, the period after patent expiry in which the drug is expected to be used is long or the entrant has a cost disadvantage (or is not seen of the same quality as the originator).

4 Conclusions

When the generic producer may go bankrupt, banning reverse payments can reduce consumer surplus. Banning reverse payments makes the entrant get less than she would with a settlement including a reverse payment, therefore exacerbating her financial problems. A settlement without reverse payments may make it impossible for her to remain on the market, which reduces consumer surplus both before and after patent expiry. The negative effect on consumer surplus, due to the possibility that the generic exits the market, can be greater than

the static consumer surplus loss due to a later entry date, including when this is the patent expiry date. The relationship between consumer surplus and the cap on reverse payments is highly non-monotonic. A positive cap on reverse payments increases consumer surplus under several situations, namely when competition among few players is soft, the economy is in a downturn, the period after patent expiry in which the drug is expected to be used is long or the entrant has a disadvantage with respect to the originator. When few players are able to tacitly collude or compete softly, reverse payments are useful because they allow financially weak players to remain on the market and exert a competitive pressure on the other players. When the economy is in a downturn, the probability that a generic producer has financial problem is higher, which increases the utility of allowing reverse payments and increases competition before and after patent expiry. When the drug is expected to be used during a long period after patent expiry, it becomes more useful to have strong competition after patent expiry and therefore to allow reverse payments, as the potential consumer surplus loss before patent expiry is more easily compensated by the consumer surplus gain after patent expiry. When the entrant has a cost disadvantage or is perceived as of lower quality, the cost of allowing reverse payments is smaller, as the generic producer whose entry is delayed exerts a weaker constraint on the originator's behavior, while the benefit of having more players on the market, thus making competition more fierce, is still present. In some cases even a "laissez-faire" policy of no cap on reverse payments may increase consumer surplus. These features point towards a rule of reason (instead of a ban *per se*) in assessing the competitiveness of reverse payments.

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