Information Economics and Policy 64 (2023) 101044

Contents lists available at ScienceDirect

Information Economics and Policy

journal homepage: www.elsevier.com/locate/iep

Pay-for-delay settlements and patent expansion practices☆

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ARTICLE INFO

JEL classification:
K21
L12
L41

Keywords:
Reverse payments
Pay-for-delay
Patent's strength
Pharmaceutical industry
Litigation
Settlement
Asymmetric information

ABSTRACT

Pay-for-delay (reverse payments) settlements and patent expansion practices (PEP), such as preemptive patenting, product hopping and evergreening, have been criticized for their potential anticompetitive effects. This paper shows that reverse payments and PEP are strategic substitutes and, when the information over the patents' strength is asymmetric and patents' strength is endogenous, a ban on reverse payments may reduce consumer surplus. This effect is stronger the more generic competition reduces industry profits. When the cost of using PEP is sufficiently high, a ban on reverse payments is optimal, otherwise it is optimal to allow reverse payments at the minimal level consistent with the originator not engaging in PEP. Results are qualitatively robust to allowing PEP to increase patent quality and consumer surplus.

1. Introduction

Patent litigations between originators (patent-holders) and potential generic entrants are common in the pharmaceutical industry. They involve uncertainty and costs, which firms can avoid through a settlement. Such settlements state when the generic manufacturer is allowed to enter the market and may involve a payment between the parties. When the paying party is the originator, these payments are called "reverse" or "pay-for-delay", as they are generally thought to delay generic entry.[1] They can cover collusive agreements and have been prosecuted in many jurisdictions. In the US, in 2003, the FTC found the agreements under which the originator paid a generic producer to avoid litigation and stay out of the market until patent expiry anticompetitive.[2] In 2013, the Supreme Court in the Actavis decision stated that reverse payment agreements should be assessed under a strict rule of reason and the variables to be considered include their size and relative scale with respect to the avoided litigation costs.[3] In the same year, the European Commission (EC) fined Lundbeck and other companies for delaying the entry of generic citalopram through the use of reverse payments.[4] In 2014, the EC fined Servier and some generics companies for delaying the generic entry of perindopril — a decision partially overturned by the EU General Court in 2018.[5,6] In 2020, the decision of fining GSK by the CMA was backed up by the ECJ for delaying generic entry of paroxetine.[7]

This paper is the first one in the literature analyzing the relationship between reverse payments and endogenous patents' strength. Several patent practices may be described as the originator endogenously choosing the patent strength. Examples of this are blocking patents –

☆ I thank the editor Marc Bourreau, Giacomo Calzolari, Joe Harrington, Ángel L. López and two anonymous referees for their valuable comments.
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[1] Reverse payments address the trade-off between rewarding originators and fostering generic entry. In the US, the Hatch-Waxman Act (1984) addresses the same trade-off. It gives a six months exclusivity period to the first generic entrant and further generic entry may occur only after this period.

[2] These are the Bristol-Myers, Cardizem, and the Valley Drug-Geneva Pharmaceuticals cases, where the branded manufacturer paid the potential generic entrants to avoid litigation and to enter the market only at patent expiry. The FTC found these agreements anticompetitive, although in the appeal of the Valley Drug-Geneva Pharmaceuticals case the agreements were not deemed illegal, as they did not extend beyond the patent terms.

[3] http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

[4] European Commission Press Release 19 June 2013, Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines. The Commission's decision was eventually upheld by the General Court.

[5] http://europa.eu/rapid/press-release_IP-14-799_en.htm.

[6] https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-12/cp180194en.pdf.

[7] http://curia.europa.eu/juris/document/document.jsf?text=&docid=222887&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1.

https://doi.org/10.1016/j.infoecopol.2023.101044
Received 1 February 2022; Received in revised form 19 June 2023; Accepted 11 July 2023
Available online 17 July 2023

patent filings hampering the grant of other patents –, preemptive patenting or patent thickets – patents on similar variations of the original patent to expand the breadth of patent protection –, and product hopping or evergreening – practices expanding the lifetime of patent protection, for example by changing the formulation of the drug before generic competition. The I-Mak report (2018) shows that the top 12 brand drugs on the US market are protected by 848 patents (71 per drug), which provide an average of 38 years without generic competition. While it is possible that a stronger patent – or a higher number of patents for the same invention – may require more innovative effort and yield a larger marginal contribution to social welfare, these practices certainly involve a social cost, as they reduce static competition and are costly from the originator's point of view. Schankerman and Schuett (2021), in a framework involving patent office examination, fees, and endogenous validity challenges in the courts, show that almost half of all patents are issued on inventions that do not require the patent incentive. Richards et al. (2020) discusses the legal background and the patenting practices originators use to unduly extend the period of exclusivity. Gurgula (2020), from the legal perspective, outlines the pharmaceutical strategic patenting and provides arguments for the intervention of competition law.

Including patent expansion practices in the analysis of reverse payments is likely to yield new valuable insights. Does the lack of PEP, which is a substitute for reverse payments from the originator's point of view, leave some potential for a wrong conclusion to be drawn about the optimal treatment of reverse payments? Does the non-inclusion of PEP mean that banning reverse payments is less useful than it would seem? Or, on the contrary, does allowing for PEP to increase social welfare mean that reverse payments should be prosecuted even more strictly, in order to push originators to engage in PEP and, therefore, to have higher quality patents?

Excluding or prohibiting *per se* such patent expansion practices is not easy. Patterson (2007) reports that, in the US, the Court of Appeals for the Federal Circuit and several district courts have upheld field-of-use licenses – agreements under which the originator grants the use of his invention – that prohibited activities otherwise permitted by patent law, such as the repair and resale of patented products. By upholding license provisions that prohibited previously permitted activities, the courts have allowed patentees to expand the scope of patent infringement liability.[8]

The relationship between endogenous patent strength practices and reverse payments has not been analyzed formally. The aim of this paper is to consider how incentives to strike potentially anticompetitive settlements, such as those involving reverse payments, are affected when firms can also engage in the aforementioned practices providing an alternative means of protecting monopoly rents and how prohibiting reverse payments, which has been on the table in many jurisdictions in the last decade, affects the originators' incentives to engage in similar apparently anticompetitive practices such as PEP. This paper considers both the case of PEP neutral towards the social value (quality) of the patent and the case of PEP increasing the social value of the patent.

This paper considers, on one hand, the originator's incentives to invest in patent strength and, on the other hand, asymmetric information about a probabilistic patent strength. This paper follows Shapiro (2003) and Lemley and Shapiro (2005) in considering patents as probabilistic property rights. Moreover, asymmetric information on the patent strength means that one party has an informative advantage, while the other party draws its expected success from a commonly known distribution function. Thus, the parties may not agree on the probability of the patent being held as valid and infringed. This assumption is crucial to observe litigations in equilibrium.[9] This framework can describe both (i) patent infringement and (ii) patent invalidity. In case (i), the entrant knows the products and processes used to get the drug and their closeness to the patent, while the originator has an imprecise estimate of them. In (ii), the originator went through the process of obtaining the patent and knows how solid it is, while the entrant has a less accurate estimate of it, mainly deriving from the available public information. Other papers treating the information on patent strength as asymmetric are Duchene and Serfes (2012), Shapiro (2003), Willig and Bigelow (2004), Maier-Rigaud et al. (2019). Duchene and Serfes (2012) show that even non-reverse settlements entailing a fixed fee can be anticompetitive. Shapiro (2003) and Lemley and Shapiro (2005) conclude that reverse payments are typically anticompetitive. Willig and Bigelow (2004), instead, show that reverse payments can increase consumer surplus in some circumstances. Maier-Rigaud et al. (2019) demonstrate that diverging beliefs over the patent's strength may lead to settlements with an earlier generic entry date. Dickey et al. (2009) discuss the impact of risk aversion on settlement decisions. Lemus and Temnyalov (2020) show that follow-on products can cause litigation in the absence of asymmetric information and have an ambiguous effect on delays. Dickey and Rubinfeld (2012) and Mungan (2013) show that reverse payments may increase generic competition and reduce the originator's incentive to invest. Manganelli (2020) shows that when the parties' entry decisions are considered and the information on the patents' strength is asymmetric, reverse payments may increase consumer surplus by allowing settlements with generic entry before the counterfactual entry date and through litigation, a fraction of which ends up with generic entry. This paper builds on Manganelli (2020) and extends its framework to analyze the impact of reverse payments, the originator's decision to engage in patent expansion practices, and asymmetric information on the patent strength, on generic entry, and consumer surplus.

Considering the expected strength of the patent as reflecting the value of the innovation to society, any strategy aimed at extending the monopoly period beyond that is welfare decreasing; thus, from this perspective, both pay-for-delay settlements as well as PEP should be prohibited. However, if regulators cannot prohibit PEP but can ban pay-for-delay, the paper shows when they should ban them and when they should allow them up to a maximal cap.

Moreover, this paper considers the possibility that PEP efforts may be welfare enhancing, so that restricting reverse payments – which then increases PEP – has a benefit that is not captured by the previous literature. In other words, the addition of welfare-enhancing PEPs could change the conclusions of Manganelli (2020), because some of these innovations could be valuable and banning reverse payments could encourage them. This would yield an additional reason to ban reverse payments.

Throughout the paper, any lemma, proposition or corollary coming from Manganelli (2020), either directly or through adaptations, will be called "Result", to distinguish it from the original lemmas, proposition and corollaries of the present paper.

The paper is structured as follows: Section 2 introduces the basic framework; Section 3 presents the complete information case; Section 4 shows the asymmetric information case; Section 5 considers an uniform distribution for the patent strength; Section 6 analyzes the case of quality-increasing PEP; Section 7 discusses the model and Section 8 concludes.

[8] The literature on the practices extending patent protection include Gilbert and Newbery (1982), Fudenberg et al. (1983), Salant (1984), Vickers (1985), Meurer (1989), Riordan and Salant (1994), O'Donoghue (1998), Hopenhayn and Squintani (2011), Hemphill and Sampat (2012), Moir (2017), and Salzenbacher and Wettstein (2020). Dwivedi et al. (2010) discusses several cases of PEP in the pharmaceutical industry.

[9] Without it, the parties could agree on the probability that the patent is held valid and infringed and split the surplus accordingly. An alternative to asymmetric information on the patent strength is to assume asymmetric priors (divergent expectations) about the likelihood that the plaintiff will win on final judgement. This yields qualitatively identical results.

2. Model

There is an antitrust authority (AA), an originator (O) and a generic entrant (E). The entrant is ready to enter at date 0 and the patent's period ends at date 1. In the first stage, the AA sets a cap $\overline{R}$ on reverse payments. This cap may depend on the parameters of the model, as per the Actavis decision. In the second stage, the originator may engage or not in PEP, i.e. he invests a sum $I \in \{\underline{I}, \bar{I}\}$, with $\underline{I} < \bar{I}$, which affects the subsequent patent's strength. This investment is public. If the originator has invested $\underline{I}$, the patents' strength θ is distributed according to the twice differentiable cumulative density function $F(\theta)$. Assume $f(\theta) > 0$ for any θ. If the originator has invested $\bar{I}$, i.e. he has engaged in PEP, the patents are ironclad: $\theta = 1$.[10] Normalize $\underline{I}$ to 0. In the third stage, if the originator has invested $\underline{I}$, he privately learns the patent's strength $\theta \in [0, 1]$. In the fourth stage, the entrant makes a take-it-or-leave-it settlement offer. The offer consists of a generic entry date $D \in [0, 1]$ – the fraction of the remaining patents' period in which the entrant commits not to enter – and a payment $R \in [0, \overline{R}]$ from the originator to the entrant.[11] In the fifth stage, if the originator accepts it, D and R are enforced, otherwise the parties litigate.[12]

The timing is:

1. **Policy choice.** The AA chooses a cap $\overline{R} \geq 0$.
2. **Originator's investment.** The originator publicly incurs a cost $I \in \{\underline{I} = 0, \bar{I}\}$.
3. **Originator's signal.** If the originator invested $\underline{I}$, he receives the private signal θ.
4. **Entrant's decision.** The entrant makes a settlement offer.
5. **Originator's decision.** The originator accepts or rejects the offer.

Denote $\overline{\pi}$ the originator's monopoly profits, $\underline{\pi}$ the originator's duopoly profits and $\underline{\pi}_E$ the entrant's duopoly profits. Assume that $\overline{\pi} > \underline{\pi} + \underline{\pi}_E$, i.e. monopoly profits are larger than industry duopoly profits.[13] This framework encompasses all standard models of competition such as Bertrand with homogeneous or differentiated products, as long as the differentiation is small enough, Cournot and Hotelling.[14]

The next section discusses the benchmark with complete information.

3. Benchmark

In stage 5, if the parties litigate they expect to obtain:

Originator: $\theta\overline{\pi} + (1 - \theta)\underline{\pi}$
Entrant: $(1 - \theta)\underline{\pi}_E$.
If the parties settle, they obtain:
Originator: $D\overline{\pi} + (1 - D)\underline{\pi} - R$
Entrant: $(1 - D)\underline{\pi}_E + R$.

The originator accepts the settlement if and only if it is at least as profitable as litigating, which yields:

$$D \geq D(\theta) = \theta + \frac{R}{\overline{\pi} - \underline{\pi}}. \tag{1}$$

or, equivalently,

$$\theta \leq \theta(D) = D - \frac{R}{\overline{\pi} - \underline{\pi}}. \tag{1 bis}$$

The minimal entry date (1) the originator can accept increases in R and θ and decreases in $(\overline{\pi} - \underline{\pi})$. A higher patent's strength θ makes the originator more confident of winning the litigation and less willing to accept an early entry. A higher R makes the settlement more costly, which makes the originator less keen on settling and accepting an early entry. The net cost of the settlement R is weighted over the loss $(\overline{\pi} - \underline{\pi})$ of allowing an earlier entry.

In stage 4, the entrant proposes a settlement offer. Define a solution *interior* when the entrant makes an offer such that D is strictly below 1. From Manganelli (2020) we have the following results:

Result 1. In an interior solution, the entrant proposes the maximal possible payment $\overline{R}$.[15]

Proof. When the entrant offers a settlement fulfilling (1), the originator accepts it. Therefore the entrant's profits when she offers (1) with equality are $\pi_E = \left(1 - \theta - \frac{R}{\overline{\pi} - \underline{\pi}}\right)\underline{\pi}_E + R$. Its derivative with respect to R is positive because $\overline{\pi} - \underline{\pi} > \underline{\pi}_E$.□

The intuition is that the entrant selects the maximum R because by doing so it is able to prolong the duration of the monopoly, a fact that maximizes industrial profits. A marginally higher R makes the earliest entry date acceptable by the originator (1) higher by $1/(\overline{\pi} - \underline{\pi})$. This makes the entrant lose $\underline{\pi}_E/(\overline{\pi} - \underline{\pi})$ in market profits but gives her $1 > \underline{\pi}_E/(\overline{\pi} - \underline{\pi})$ in reverse payment.

Result 2. Capping reverse payments $\overline{R}$, for the AA, is a perfect substitute to capping the latest entry date $\overline{D}$. Setting a cap on both is equivalent to setting a cap on one variable.[16] Thus, the model can be reinterpreted in terms of the AA imposing a latest entry date instead of a maximal reverse payment.

Result 3. Under complete information, a higher cap on reverse payments delays the proposed entry date because of Result 1 and (1).

Proof. From Result 1, the originator proposes the cap on reverse payments in interior solutions. The derivative of (1) with respect to R is $1/(\overline{\pi} - \underline{\pi})$, which is positive.□

The intuition is that reverse payments prolong the monopoly duration, so both parties find it convenient to allow the originator to remain the monopolist for a longer period and share these additional profits with the entrant through the reverse payment.

These results lead to the following lemma.

Lemma 1. *With complete information, a higher cap on reverse payments does not change the originator's incentive to engage in PEP.*

[10] PEP consists of many patent filings or, in general, many patent strategies aiming at strengthening the originator's monopoly. As the I-Mak report (2018) shows, the top 12 brand drugs on the US market are protected by 848 patents (71 per drug), providing 38 years of protection from generic competition on average. It is reasonable to assume, in similar scenarios, that the patent's strength is almost ironclad due to such a number of patent filings. This is consistent to assume that PEP (taken as a binary variable, like in the model) will make the patent's strength equal to 1. Appendix D analyzes the case of PEP marginally increasing patent strength.

[11] We can consider the more general stage "the entrant *litigates or* makes a settlement offer" with identical results. The idea is that, if the entrant wants to litigate, she can make a settlement offer that would be rejected for sure, i.e. $D = 0$ and $R \to +\infty$.

[12] One could wonder whether, in the first stage, the AA should set a cap on both R and D. If the cap included D, the entrant would have an incentive to misrepresent the date when she is ready to enter. This could create litigations over this date and additional legal uncertainty.

[13] This is consistent with Branstetter et al. (2016) and Castanheira et al. (2019), who show that generic entry involves an industry profit destruction.

[14] For example, consider the reverse demand function $P = 1 - Q$ and $c = 0$. In Cournot competition, monopoly profits are equal to $\overline{\pi} = 1/4$ and duopoly profits are $\underline{\pi} = \underline{\pi}_E = 1/9$. In Bertrand competition with homogeneous goods, monopoly profits are $\overline{\pi} = 1/4$ and duopoly profits are $\underline{\pi} = \underline{\pi}_E = 0$.

[15] In corner solutions, i.e. when the proposed entry date is 1, the entrant proposes the reverse payment such that the originator is indifferent between accepting and litigating when $D = 1$, that is $R = (1 - \theta)(\overline{\pi} - \underline{\pi})$

[16] R and D^* have a biunivocal correspondence in (1), so capping reverse payments is a perfect substitute to capping the latest entry date. For more details, see the Discussion.

Proof. The entrant prefers a settlement fulfilling (1) rather than litigating. The originator's settlement profits are $\pi_O = D\overline{\pi} + (1 - D)\underline{\pi} - R$ and, by substituting (1) into π_O, we obtain $\pi_O = \theta\overline{\pi} + (1 - \theta)\underline{\pi}$. R is not present in this expression, so a higher cap on reverse payments does not increase the originator's profits and, therefore, his incentives to engage in PEP.[17]□

Consider now consumer surplus (CS). When the parties settle, consumer surplus is $CS_S = D\underline{S} + (1 - D)\overline{S}$, where $\underline{S}$ is consumer surplus under monopoly and $\overline{S}$ is consumer surplus under duopoly, with $\overline{S} > \underline{S}$. When the parties litigate, following Shapiro (2003), we have $CS_L = \theta\underline{S} + (1 - \theta)\overline{S}$.

Proposition 1. *With complete information, a ban on reverse payments is optimal.*

Proof. A higher cap on reverse payments does not change the originator's incentives to use PEP. When the originator engages in PEP, the policy on reverse payments is irrelevant. When the originator does not engage in PEP, given the entrant's proposal (1), consumer surplus is:

$$CS = \left(\theta + \frac{R}{\overline{\pi} - \underline{\pi}}\right)\underline{S} + \left(1 - \theta - \frac{R}{\overline{\pi} - \underline{\pi}}\right)\overline{S}.$$

The derivative of CS with respect to R is $-(\overline{S} - \underline{S})/(\overline{\pi} - \underline{\pi})$, which is negative.□

Given that, with complete information, a higher cap on R does not change the use of PEP, then there is no trade-off from the AA's point of view: it is optimal to ban reverse payments, to make generic entry occur as soon as possible.

The next section considers the model with asymmetric information.

4. Asymmetric information case

4.1. Entrant's settlement offer

When the patent strength is not common knowledge, stage 5 remains identical to the complete information benchmark. In stage 4, if the originator has invested $\underline{I} = 0$, the entrant chooses the originator's type (the realized patents' strength θ) to make indifferent between settling and litigating. Denote this realization the one "targeted" by the entrant: $\widehat{\theta}$. The entrant's problem is:

$$\begin{aligned} \max_{\{\widehat{\theta},R\}} \pi_E^{\overline{R}}(\widehat{\theta}) &= \int_{\widehat{\theta}}^{1} [(1-\theta)\underline{\pi}_E] dF(\theta) + F(\widehat{\theta})[(1 - D(\widehat{\theta}))\underline{\pi}_E + R] \\ s.t.\quad 0 &\le \widehat{\theta} \le 1 \\ s.t.\quad 0 &\le D(\widehat{\theta}) \le 1 \\ s.t.\quad 0 &\le R \le \overline{R} \end{aligned} \tag{2}$$

The originator litigates if the actual patent's strength θ is above $\widehat{\theta}$, in which case the entrant's expected litigation profits are $\int_{\widehat{\theta}}^{1}[(1 - \theta)\underline{\pi}_E]dF(\theta)$. The originator settles when the actual patent's strength is at most $\widehat{\theta}$. This occurs with probability $F(\widehat{\theta})$ and the entrant's expected settlement profits are equal to $(1 - D(\widehat{\theta}))\underline{\pi}_E + R$.

The first order condition of (1 bis) with respect to $\widehat{\theta}$ is:

$$F(\widehat{\theta})\underline{\pi}_E = f(\widehat{\theta})[(\widehat{\theta} - \widehat{D})\underline{\pi}_E + \overline{R}]$$

The LHS is the marginal benefit of an earlier generic entry – the profit gain from a marginal anticipation of entry multiplied by the probability of settlement. The RHS is the marginal cost of an earlier generic entry – the profit loss of litigation versus settlement multiplied by the increase in the probability of litigation.

Define a solution *interior* when the first two constraints in (1 bis) do not bind. We use the following results adapted from Manganelli (2020).

Result 4. In an interior solution, when the originator invests $\underline{I} = 0$, the entrant proposes the maximal possible payment $\overline{R}$.

Proof. The first order condition of (1 bis) with respect to R is:

$$\frac{d\pi_E^{\overline{R}}(\widehat{\theta})}{dR} = F(\widehat{\theta})\left(\frac{\overline{\pi} - \underline{\pi} - \underline{\pi}_E}{\underline{\pi}_E}\right).$$

We have $F(\widehat{\theta}) > 0$ and $\overline{\pi} - \underline{\pi} - \underline{\pi}_E > 0$ by assumption. Therefore, this FOC is strictly positive. This means that, also with asymmetric information, the parties prolong the monopoly period as much as possible.□

Result 5. In an interior solution, when the originator invests $\underline{I} = 0$, the optimal $\widehat{\theta}$ is implicitly defined by:

$$g(\widehat{\theta}) = \frac{(\overline{\pi} - \underline{\pi})\underline{\pi}_E}{\overline{R}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)}, \tag{3}$$

where $g(\widehat{\theta})$ is defined as $g(\widehat{\theta}) = f(\widehat{\theta})/F(\widehat{\theta})$.

Proof. By taking the first order condition of (1 bis) with respect to $\widehat{\theta}$, setting it equal to 0, using (1), dividing both sides by $F(\widehat{\theta})\overline{R}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)$ and recalling that $g(\widehat{\theta}) = f(\widehat{\theta})/F(\widehat{\theta})$ we get the result.□

Assume that $f(\theta)$ is such that the hazard rate $h(\widehat{\theta}) = f(\widehat{\theta})/(1 - F(\widehat{\theta}))$ is monotonically increasing in $\widehat{\theta}$. This means that $g(\theta)$ is decreasing in $\widehat{\theta}$. The optimal $\widehat{\theta}$ can be expressed as:

$$\widehat{\theta} = g^{-1}\left(\frac{(\overline{\pi} - \underline{\pi})\underline{\pi}_E}{\overline{R}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)}\right)\rangle 0. \tag{4}$$

Being $g(\widehat{\theta})$ decreasing in $\widehat{\theta}$, also g^{-1} is decreasing in $(\cdot)$. As a consequence, we have:

Result 6. A higher cap on reverse payments increases the targeted realization $\widehat{\theta}$.

A higher cap on reverse payments increases industry profits and makes the entrant less willing to risk litigation. Therefore the entrant targets a higher $\widehat{\theta}$, which makes the originator more willing to settle.

When instead the originator invests $\overline{I}$, there is the following lemma.

Lemma 2. *When the originator invests $\overline{I}$, the originator remains the monopolist and gets $\pi_O = \overline{\pi} - \overline{I}$.*

Proof. When the originator invests $\overline{I}$, the patent's strength is $\theta = 1$. Therefore, the entrant offers $D(1) = 1$ and $R = 0$, which the originator accepts.□

In this case, the originator remains the unchallenged monopolist for the patent's duration.

4.2. Originator's patent's strength decision

Consider now the originator's investment $I \in \{0, \overline{I}\}$. The originator's profits are:

$$\pi_O^{\overline{R}}(I) = \int_{\widehat{\theta}}^{1} [\theta\overline{\pi} + (1 - \theta)\underline{\pi}]dF(\theta) + F(\widehat{\theta})[D(\widehat{\theta})\overline{\pi} + (1 - D(\widehat{\theta}))\underline{\pi} - R] - I. \tag{5}$$

[17] The originator's settlement profits, with complete information, are identical to his litigation profits because he has no informative advantage and the entrant makes the take-it-or-leave-it offer, extracting all the surplus. Other bargaining rules, such as Nash bargaining, would allow the originator to get a share of the surplus. In this case, allowing reverse payments would reduce his incentives to engage in PEP even with complete information, reinforcing the results of Section 4. The same would happen if we had the originator making the take-it-or-leave-it offer – see Appendix A.

The originator's expected litigation profits are equal to $\int_{\hat{\theta}}^{1}[\theta\overline{\pi}+(1-\theta)\underline{\pi}]dF(\theta)$. With probability $F(\hat{\theta})$ the parties settle and the originator's settlement profits are equal to $D(\hat{\theta})\overline{\pi}+(1-D(\hat{\theta}))\underline{\pi}-R$. The next proposition discusses the impact of reverse payments on the originator's incentives to invest on the patent's strength.

Proposition 2. *A higher cap on reverse payments reduces the originator's incentives to engage in PEP.*

Proof. When the originator invests $\overline{I}$, using the previous lemma we have $\pi_O(\overline{I})=\overline{\pi}-\overline{I}$. When the originator invests $\underline{I}$, a higher cap on reverse payments increases the targeted realization (Result 6), so the relative weight of litigation profits decreases. Settlement profits are higher or equal than litigation profits, because the originator accepts the settlement if and only if it is at least as profitable than litigating. Therefore, a higher cap on reverse payments, by reducing the relative weight on litigation profits, increases $\pi_O(\underline{I})$. Denoting the relative incentive to invest in patents' strength as $\pi_O(\overline{I})-\pi_O(\underline{I})$, we have $d(\pi_O(\overline{I})-\pi_O(\underline{I}))/dR < 0$.□

This means that in some parameter sets the originator would not use PEP ($I=\underline{I}$) if reverse payments are allowed and instead uses it ($I=\overline{I}$) if reverse payments are banned. Reverse payments offer the originator a second way out of generic competition and are strategic substitutes of PEP. The next subsection considers the impact of the originator's decision on consumer surplus.

4.3. Consumer surplus

When $\pi_O(\overline{I})\leq\pi_O^{\overline{R}}(\underline{I})$, the originator invests $\underline{I}=0$ and expected consumer surplus is:

$$CS^{\overline{R}}(\hat{\theta})=\int_{\hat{\theta}}^{1}[\theta\underline{S}+(1-\theta)\overline{S}]dF(\theta)+F(\hat{\theta})[D(\hat{\theta})\underline{S}+(1-D(\hat{\theta}))\overline{S}], \tag{6}$$

When the realized patent strength is above $\hat{\theta}$, parties litigate and CS is $\int_{\hat{\theta}}^{1}[\theta\underline{S}+(1-\theta)\overline{S}]dF(\theta)$. On the other hand, with probability $F(\hat{\theta})$, the parties settle. A higher R increases $\hat{\theta}$, which reduces the weight on litigation CS and delays entry in the case of settlement.

When $\pi_O(\overline{I})>\pi_O^{\overline{R}}(\underline{I})$, the originator invests $\overline{I}$, patent strength is $\theta=1$ and consumer surplus is $CS^{\overline{R}}(1)=\underline{S}$. Note that R affects $\hat{\theta}$, which in turn affects the originator's profits and therefore his decision of engaging in PEP. This leads to the following proposition.

Proposition 3. *In order to maximize consumer surplus, when $\pi_O(\overline{I})\leq\pi_O^{\overline{R}=0}(\underline{I})$ the optimal policy is a ban on reverse payments. When $\pi_O^{\overline{R}=0}(\underline{I})<\pi_O(\overline{I})$, the optimal policy is a cap $\hat{R}$ such that $\pi_O^{\hat{R}}(\underline{I})=\pi_O(\overline{I})$.*

Proof. Consumer surplus when the originator invests $\overline{I}$ is at its minimal value $\underline{S}$ because monopoly CS $\underline{S}$ is lower than the weighted average of monopoly CS $\underline{S}$ and duopoly CS $\overline{S}$ represented by (6). When the originator's profits while engaging in PEP $\pi_O(\overline{I})$ are lower than those not engaging in it when reverse payments are zero $\pi_O^{\overline{R}=0}(\underline{I})$, the optimal policy is a ban on reverse payments, because there is no point in delaying entry and reducing the probability of litigation if the originator would not use PEP anyway. Instead, if the originator would engage in PEP when reverse payments are banned, $\pi_O(\overline{I})>\pi_O^{\overline{R}=0}(\underline{I})$, the optimal policy is to allow reverse payments such that $\pi_O^{\hat{R}}(\underline{I})=\pi_O(\overline{I})$, which makes the originator not use PEP and makes it possible that actual consumer surplus is higher due to the possibility of generic entry.□

This proposition can be seen in the other way round: a prohibition on reverse payments increases the originator's incentives to engage in PEP. Such a prohibition, which at first may seem procompetitive, may make consumers worse off because the originator, not having the tool of reverse payments to defend his monopoly profits, may decide to use PEP to prevent generic entry. In Manganelli (2020) reverse payments have a different role, as the focus of that paper was on the parties' investments; when the parties would invest regardless of the existence of reverse payments, the optimal policy was to ban them. Instead, when the originator would invest but the entrant would not, when reverse payments are banned, the cap on reverse payments should be such that the entrant recovers her investment cost. A similar reasoning is applied when the originator would not invest in the absence of reverse payments. Here, instead, the objective of allowing reverse payments is to increase the threat point of the originator with respect to engaging in PEP. Reverse payments allow the parties (and, in particular, the originator) to obtain higher profits in case of settlement, which reduces his incentives to engage in PEP.

In order to have a closed-form solution for the optimal policy, we need to posit a distribution function for the patent strength. The next section analyzes the uniform case.

5. Model - uniform patent's strength

Assume the patent's strength is uniformly distributed between 0 and 1. The targeted patent strength (4) becomes:

$$\hat{\theta}=\frac{\overline{R}(\overline{\pi}-\underline{\pi}-\underline{\pi}_E)}{(\overline{\pi}-\underline{\pi})\underline{\pi}_E}. \tag{7}$$

We use lemma 4 of the online appendix of Manganelli (2020):

Result 7. The more generic competition reduces industry profits, where this reduction can be expressed by $(\overline{\pi}-\underline{\pi}-\underline{\pi}_E)$, the faster the change is in the targeted patent's strength due to reverse payments.

How quickly R reduces (7) depends on the profit reduction due to generic entry $(\overline{\pi}-\underline{\pi}-\underline{\pi}_E)$ and inversely depends on the originator's profit loss $(\overline{\pi}-\underline{\pi})$ and the entrant's profits $\underline{\pi}_E$.[18] This means that the more generic competition reduces industry profits, the more there is scope for the parties to avoid litigation by offering a better settlement to the originator.

The originator's profits when he invests $\underline{I}=0$ are:

$$\pi_O(\underline{I})=\int_{\hat{\theta}}^{1}[\theta\overline{\pi}+(1-\theta)\underline{\pi}]d\theta+\hat{\theta}\left[\left(\hat{\theta}+\frac{R}{\overline{\pi}-\underline{\pi}}\right)\overline{\pi}+\left(1-\hat{\theta}-\frac{R}{\overline{\pi}-\underline{\pi}}\right)\underline{\pi}-R\right].$$

This can be rewritten as:

$$\pi_O(\underline{I})=\frac{(1+\hat{\theta}^2)(\overline{\pi}-\underline{\pi})}{2}+\underline{\pi}, \tag{8}$$

where $\hat{\theta}$ is defined in (7). By substituting (7) in (8), one obtains:

$$\pi_O(\underline{I})=\frac{(\overline{\pi}+\underline{\pi})}{2}+\frac{R^2(\overline{\pi}-\underline{\pi}-\underline{\pi}_E)^2}{2(\overline{\pi}-\underline{\pi})\underline{\pi}_E^2}. \tag{9}$$

Taking the derivative with respect to R, we obtain:

$$\frac{d\pi_O(\underline{I})}{dR}=\frac{(\overline{\pi}-\underline{\pi}-\underline{\pi}_E)^2}{(\overline{\pi}-\underline{\pi})\underline{\pi}_E^2}R>0, \tag{10}$$

which is positive because all the factors are positive. This leads to the following proposition.

Proposition 4. *Reverse payments increase the originator's profits without PEP. The more generic competition reduces industry profits, the more reverse payments reduce the originator's incentives to engage in PEP.*

From Result 7, the more generic competition reduces industry profits, the faster the change is in the targeted patent's strength and the reduction of the probability of litigation. The more generic competition

[18] For example, if competition tended to homogeneous Bertrand ($\underline{\pi}=\underline{\pi}_E\to 0$) the denominator would tend to 0 and $d\hat{\theta}/dR$ would tend to infinity.

reduces industry profits, the more reverse payments become attractive to share monopoly profits and the less the originator has incentive to engage in PEP.

In terms of the optimal cap, Proposition 3 becomes:

Proposition 5. *When the patent is uniformly distributed, when* $\bar{I} \geq \bar{I}^* = \frac{\bar{\pi}-\underline{\pi}}{2}$*, the optimal policy is a ban on reverse payments; when* $\bar{I} < \bar{I}^*$*, the optimal cap on reverse payments is*

$$\widehat{R} = \frac{\underline{\pi}_E \sqrt{(\bar{\pi}-\underline{\pi})(\bar{\pi}-\underline{\pi}-2\bar{I})}}{\bar{\pi}-\underline{\pi}-\underline{\pi}_E}. \tag{11}$$

Proof. The first part of the proposition directly comes from $\pi_O(\bar{I}) \leq \pi_O^{\bar{R}=0}(\underline{I})$ with $R = 0$. By using the originator's profits when he engages in PEP $\pi_O(\bar{I}) = \bar{\pi} - \bar{I}$ and when he does not $\pi_O(\underline{I})$ in (9), with $R = 0$, and solving for $\bar{I}$, the result is obtained. The second part of the proposition comes from setting the originator's profits with PEP $\pi_O(\bar{I}) = \bar{\pi} - \bar{I}$ equal to those without it (9) and solving for R.□

Corollary 1. *The optimal reverse payment decreases with the cost of engaging in PEP and decreases with the industry profits reduction due to generic entry.*

The first part comes from the fact that, when the cost of PEP is higher, engaging in it is less attractive and therefore there is less need for a lenient policy on reverse payments – the cap is lower and may reach 0 when the cost of PEP is high enough. The second part means that, the stronger the market competition, the less the market is interesting for the entrant and therefore the reverse payment the originator will pay will be lower.

6. Quality-increasing PEP

This section discusses the case where PEP increases the quality of the patent. This represents the cases where PEP requires a stronger innovative effort, entailing a marginal contribution to social welfare. An example may be the discovery of a variant of the original patent which yields better health outcomes. In general, this case means that monopoly consumer surplus, when the originator engages in PEP, increases with respect to the baseline scenario $\underline{S}$. Define σ the additional consumer surplus due to PEP – so that monopoly CS under PEP is $\underline{S} + \sigma$ – and consider the optimal policy. When the originator does not engage in PEP, consumer surplus is (6). When patent quality increases due to PEP, a new trade-off emerges: PEP creates a monopoly during the entire period, but yields a higher consumer surplus than under monopoly without PEP, while when the originator does not engage in PEP the parties can litigate and settle with a generic entry date potentially before patent expiry, yielding the duopoly consumer surplus with some probability and/or during some period. Intuitively, when PEP increases the patent quality, the parameter sets where reverse payments increase consumer surplus shrink. In particular, prohibiting reverse payments when the equilibrium probability of litigation $1 - F(\theta)$ is low and/or generic entry would occur late ($D(\theta)$ close to 1) may become optimal.

In order to have a closed-form solution, consider the case of uniform distribution of the patent strength. When $\theta \sim U[0,1]$, consumer surplus without PEP (6) becomes

$$CS^{\bar{R}}(\widehat{\theta}) = \bar{S} - \frac{1+\widehat{\theta}^2}{2}(\bar{S}-\underline{S}) - \widehat{\theta}(\bar{S}-\underline{S})\left(\frac{R}{\bar{\pi}-\underline{\pi}}\right), \tag{12}$$

where $\widehat{\theta}$ is defined in (7). Consumer surplus with PEP is $CS^{PEP} = \underline{S} + \sigma$. Therefore, PEP increases consumer surplus when

$$\sigma \geq (\bar{S}-\underline{S})\left[\frac{1-\widehat{\theta}^2}{2} - \widehat{\theta}\left(\frac{R}{\bar{\pi}-\underline{\pi}}\right)\right]. \tag{13}$$

This leads to the following proposition.

Proposition 6. *When the patent is uniformly distributed and PEP increases patent quality by* σ*,*

(i) *when* $\bar{I} \geq \bar{I}^* = \frac{\bar{\pi}-\underline{\pi}}{2}$*, the optimal policy is to ban reverse payments;*
(ii) *when* $\bar{I} < \bar{I}^* = \frac{\bar{\pi}-\underline{\pi}}{2}$*, the optimal policy is to allow reverse payments equal to (11) if and only if* $\sigma < \sigma^* = (\bar{S}-\underline{S})\left[\frac{\bar{I}(\bar{\pi}-\underline{\pi}+\underline{\pi}_E)}{(\bar{\pi}-\underline{\pi})(\bar{\pi}-\underline{\pi}-\underline{\pi}_E)} - \frac{\underline{\pi}_E}{(\bar{\pi}-\underline{\pi}-\underline{\pi}_E)}\right]$
(iii) *otherwise, the optimal policy is to ban reverse payments.*

Proof. See Appendix B.□

Condition (ii) states that it is preferable to have the originator using R rather than PEP when the cost of engaging in PEP is high, the profits the originator would lose due to generic entry would be low, the generic's profits would be low, and the profit reduction due to generic entry would be high. The intuition is that when the cost of PEP $\bar{I}$ and the profit reduction $(\bar{\pi} - \underline{\pi} - \underline{\pi}_E)$ are small, or the profit loss for the originator $(\bar{\pi} - \underline{\pi})$ and the entrant's profits $\underline{\pi}_E$ are high, the optimal reverse payment to induce the originator not to use PEP (11) increases. This makes it more costly, from the consumer surplus point of view, to allow reverse payments and, therefore, it makes it relatively more appealing to make the originator engage in PEP.

7. Discussion

The results are mainly driven by the following assumptions and limitations.

(1) **Single entrant.** Consistently with the Hatch-Waxman Act, which guarantees a 180-days exclusivity to the first entrant, this model considers a single entrant and generally does not extend to a setting with multiple entrants.
(2) **Bargaining rule.** A necessary condition for the results is that the originator obtains some additional surplus when settling the dispute with respect to litigation. This makes reverse payments reduce his incentive to engage in PEP and potentially increase consumer surplus.[19] The model does not generalize to other timing assumptions.
(3) **Settlement offer and private information.** The model describes the case of patent validity (the informed party is the originator) and switching the identity of the informed party and the one making the offer describes the case of patent infringement. Switching the party making the offer, when we switch the party receiving the private information, is a technical requirement to avoid the multiplicity of equilibria of signalling games. This is the approach followed by Bebchuk (1984). The present paper does not give a complete characterization of the signalling game where the originator both receives the private signal and makes the offer either. However, Appendix A shows that, in this case, no pooling or semi-separating equilibrium exists.

[19] If the originator did not get *any* additional surplus when settling, he would not be interested in reverse payments and generally in any strategy increasing settlement profits. This is quite extreme and not realistic, given the amount of cases where reverse payments were used. The Nash bargaining solution gives additional surplus to both parties when they settle, compared to when they litigate – see Appendix A.1. In a setting with asymmetric information, however, Nash bargaining cannot be used, because due to the asymmetric information the threat point of the two parties is not common knowledge.

(4) **Cap on D**. Setting a cap only on R is easier than a cap including D. The reason is that capping D would create an informational problem about the date when the generic is ready to enter the market – she would have an incentive to pretend it is earlier than it is, so that she could ask for higher settlement profits. This could create litigations over the date when the entrant is actually ready to enter, while a cap only on R avoids this and is consistent with the Actavis decision.

(5) **Evergreening**. In the specific case of evergreening as PEP – making the patent protection last longer than initially due – the relative convenience of allowing reverse payments would further increase, as evergreening would make the monopoly outcome longer than $D = 1$.

(6) **Public PEP**. We assume that the originator's investment in PEP is public. This simplifies the model and is realistic, as the number of patents filed for a product or process, their characteristics and their length is public. Moreover, it is in the interest of the originator to make the investment in PEP public, as this deters generics from litigating.[20]

(7) **Dual PEP**. We assumed that the investment in PEP is dual. Appendix 4 shows that results are robust to considering PEP a continuous investment that makes patents marginally stronger.

(8) $\theta = 0$ **when no PEP**. We assumed that the patent has a probabilistic strength θ between 0 and 1 in case of no PEP and $\theta = 1$ in case of PEP. If we flipped this assumption – strength $\theta = 0$ in case of no PEP, meaning that the patent is completely useless in case of litigation, and probabilistic strength θ between 0 and 1 in case of PEP – results would not hold. Online Appendix 2 shows this and discusses why this case is less relevant.

(9) **Litigation costs and period**. Following Shapiro (2003) and Lemley and Shapiro (2005), the model does not include the litigation costs and litigation period. This means that the model is suited to describe cases where litigation costs are sufficiently small compared to market profits and the litigation period is sufficiently short compared to the patent length.

(10) **Asymmetric information**. Finally, the model hinges on asymmetric information over the patent strength, a common assumption in the literature, but results would hold also under asymmetric priors – i.e. the parties having exogenously divergent expectations about the patent strength.[21]

8. Conclusions

Reverse payments and patent expansion practices (PEP) such as blocking patents, preemptive patenting, product hopping, patent thickets and evergreening, have been criticized for their potential anticompetitive effects. Prohibiting reverse payments has seemed easier to implement, both in the US and the EU, than proihibiting PEP and, in some cases, courts have allowed patenting practices that expand protection beyond the patent terms. This paper analyzes the impact of policies on reverse payments on the originator's decision to engage in PEP and consumer surplus when the patent's strength is endogenous and the information over it is asymmetric.

The patent's strength is considered probabilistic (Shapiro, 2003) and strategies aimed at extending the monopoly period beyond that are welfare decreasing. Thus, from this perspective, both pay-for-delay settlements as well as PEP should be prohibited. However, PEP has been harder to prohibit than pay-for-delay settlements. The paper shows when reverse payments should be banned and when they should be allowed with a cap on them.

The results show that reverse payments are strategic substitutes of PEP, as they offer the originator a second way to avoid generic competition, and a ban on reverse payments increases the originator's incentive to engage in PEP. This effect is stronger the more generic competition reduces industry profits. In terms of the optimal policy, it is found that when the cost of using PEP is sufficiently high, a ban on reverse payments is optimal; otherwise, it is optimal to allow reverse payments at the minimal level consistent with the originator not engaging in PEP. This means that the maximal allowed reverse payment depends on the market characteristics, such as the originator's monopoly profits and the entrant's potential profits. Such reverse payments increase consumer surplus through two channels: first, generic entry may occur before patent expiry and, second, with some probability the parties litigate, which can end up with the generic entering the market. A policy aiming at incentivizing generic entry should therefore consider the cross-effects between reverse payments and PEP. Results show that the non-inclusion of PEP in the analysis would end up in prohibiting reverse payments too frequently and that a strict policy uniquely on reverse payments may increase the originator's use of PEP, undermining its objective of increasing generic entry and competition. Results are qualitatively robust to allowing PEP to increase patent quality and consumer surplus.

Data availability

No data was used for the research described in the article.

Appendix A. Originator receiving the signal and making the take-it-or-leave-it offer

Consider the case where the Originator (O) decides whether to engage in PEP or not, receives the signal about the patent strength, and decides whether to pursue pay-for-delay settlement or not.

The timing is (in *italics* are the changes with respect to the model in the paper):

1. **Policy choice.** The AA chooses a cap $\overline{R} \geq 0$.
2. **Originator's investment.** The originator publicly incurs a cost $I \in \{\underline{I} = 0, \overline{I}\}$.
3. **Originator's signal.** If the originator invested $\underline{I}$, the originator receives the private signal θ.
4. ***Originator*'s decision.** The *originator* makes a settlement offer.
5. ***Entrant*'s decision.** The *entrant* accepts or rejects it.

In such a setting, the originator's offer acts as a signal of the patent strength, which is a substantial change and leads to the well-known problems of

[20] A similar conclusion is in Duchene and Serfes (2012), who show that, when the originator and the entrant agree on a high fixed license fee from the generic to the originator, this sends a credible signal to the other generics that the patent is strong and, therefore, entry will not be profitable.

[21] Divergent expectations would push the parties to litigate, when the divergence is high enough, when the originator does not engage in PEP. So reverse payments would retain their ability to incentivize the originator not to engage in PEP, which is the key to these results.

multiplicity of equilibria of signalling games. However, it can be shown that there exists no (non-degenerate) pooling equilibrium or semi-separating equilibrium.

First, we look for an equilibrium where any originator's type makes the same (pooling) settlement offer. Denote α the probability that the entrant accepts the offer. A necessary condition for its existence is that the strongest type ($\theta = 1$) prefers to make the pooling offer rather than deviating. A possible deviation is an offer that will be rejected for sure, e.g. $D = 1$ and $R = 0$, so that litigation will ensue. This deviation yields $\pi_O = \overline{\pi}$ to the originator of type $\theta = 1$, while the pooling offer yields $\pi_O^P = \alpha[D\overline{\pi} + (1-D)\underline{\pi} - R] + (1-\alpha)\overline{\pi}$. We have that π_O^P is strictly lower than $\overline{\pi}$ for any $D < 1$ and $R > 0$. Therefore, the only candidate pooling offer such that the strongest originator's type $\theta = 1$ does not deviate is $D = 1$ and $R = 0$, which is a degenerate offer where entry never occurs and originators never pay any reverse payment. No other pooling equilibrium can exist, as the strongest type would prefer to deviate to an offer causing litigation for sure. The same reasoning applies to any semi-separating equilibrium, i.e. the highest type $\theta = 1$ deviates from whatever (non-degenerate) candidate settlement offer, as no settlement can give him more profits than under litigation with full certainty of winning.

A1. Nash bargaining

Consider the case with common knowledge about the patent strength where the originator decides whether to engage in PEP or not and then the settlement surplus is shared with a Nash bargaining solution.

The settlement surplus is $(\pi_O^S - \pi_O^L) + (\pi_E^S - \pi_E^L)$, which yields $\left[\theta\overline{\pi} + (1-\theta)\underline{\pi} + \frac{R}{\underline{\pi}_E}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)\right] - [\theta\overline{\pi} + (1-\theta)\underline{\pi}] + [(1-\theta)\underline{\pi}_E] - [(1-\theta)\underline{\pi}_E] = \frac{R(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)}{\underline{\pi}_E}$.

Denote β the bargaining power of the originator (and therefore $1 - \beta$ the bargaining power of the entrant).

So, when the originator does not use PEP, he obtains

$$\pi_O(\underline{I}) = \theta\overline{\pi} + (1-\theta)\underline{\pi} + \beta\frac{R}{\underline{\pi}_E}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E).$$

When instead he uses PEP, he obtains $\pi_O(\overline{I}) = \overline{\pi} - \overline{I}$.

The derivative of $\pi_O\pi_O(\underline{I})$ with respect to R is $\beta(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)/\underline{\pi}_E$, which is positive because $\overline{\pi} > \underline{\pi} - \underline{\pi}_E$. So the main result holds: reverse payments reduce his incentives to engage in PEP.

Appendix B. Proof of Proposition 6

When $\pi_O(\overline{I}) \le \pi_O^{\overline{R}=0}(\underline{I})$, i.e. when $\overline{I} \ge \overline{I}^* = \frac{\overline{\pi}-\underline{\pi}}{2}$, the originator does not use PEP even when reverse payments are prohibited. In that case, it is optimal to prohibit them, as generic entry may occur both through litigation and agreed entry potentially before patent expiry, when PEP is not used. Therefore, any positive reverse payment would reduce the probability of litigation and delay generic entry.

When $\pi_O(\overline{I}) > \pi_O^{\overline{R}=0}(\underline{I})$, i.e. when $\overline{I} < \overline{I}^* = \frac{\overline{\pi}-\underline{\pi}}{2}$, the originator would use PEP when reverse payments are prohibited. In that case, consumer surplus under PEP is higher than the one without PEP with a ban on reverse payments ($R = 0$) if

$$\sigma \ge \frac{(\overline{S} - \underline{S})}{2}. \tag{B.1}$$

If (B.1) is fulfilled, i.e. the increase in patent quality due to PEP is large enough, the AA prefers to prohibit reverse payments and push the originator to engage in PEP. Note that this is a sufficient condition for PEP to increase CS. If this is not fulfilled, it may be optimal for the AA to allow reverse payments to avoid that the originator engages in PEP.

If (B.1) is not fulfilled, then the AA may prefer the originator to use a positive reverse payment instead of PEP. For this to occur, reverse payments must make the originator's profits at least equal to his profits with PEP: $\pi_O(\overline{I}) = \pi_O^{\overline{R}}(\underline{I})$. The resulting reverse payment is (11). With this result, the AA compares whether CS is higher under PEP or under R (12). By using (11) in (7) and (12), CS is higher when the originator uses R than when he uses PEP if and only if:

$$\boldsymbol{\sigma} < \boldsymbol{\sigma}^* = (\overline{S} - \underline{S})\left[\frac{\overline{I}(\overline{\pi} - \underline{\pi} + \underline{\pi}_E)}{(\overline{\pi} - \underline{\pi})(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)} - \frac{\underline{\pi}_E}{(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)}\right]. \blacksquare$$

Appendix C. Numerical Simulations

Assume consumers have the following utility function:

$$U(q_O, q_E) = \alpha_O q_O + \alpha_E q_E - \left(\beta_O q_O^2 + 2\gamma q_O q_E + \beta_E q_E^2\right)/2, \tag{C.1}$$

where α_i and β_i are positive ($i = O, E$), $\beta_O\beta_E - \gamma^2 > 0$, and $\alpha_i\beta_j - \alpha_j\gamma > 0$ for $i \ne j$.

Direct demand functions are:

$$q_O = a_O - b_O p_O + c q_E,$$

$$q_E = a_E - b_E p_E + c q_O,$$

where $a_i = (\alpha_i\beta_j - \alpha_j\gamma)/(\beta_O\beta_E - \gamma^2)$ and $b_i = \beta_i/(\beta_O\beta_E - \gamma^2)$ and $c = \gamma/(\beta_O\beta_E - \gamma^2)$.

Consider the case $\gamma > 0$, i.e. differentiated Bertrand competition with substitute goods. This allows for patients and prescribers to prefer the original drug over its generic variants, though they have the same active principle. Profits are given by $\pi_i = p_i q_i$, total surplus is $U(q_O, q_E)$ and consumer surplus is $U(q_O, q_E) - p_O q_O - p_E q_E$.[22] The equilibrium price and quantity are $p_i^* = (2a_i b_j + a_j c)/(4b_O b_E - c^2)$ and $q_i^* = b_i(2a_i b_j + a_j c)/(4b_O b_E - c^2)$. When the originator engages in PEP, the inverse demand is $p_O = \alpha_O - \beta_O q_O$, which yields an equilibrium price of $p_O^M = \alpha_O/2$ and a quantity of $q_O^M = \alpha_O/2\beta_O$.

The patent strength is distributed according to a uniform distribution between 0 and 1. The simulations allow the asymmetry between the parties (which can be interpreted as the difference in their demand or marginal costs) and the patent quality due to PEP to vary. The expected consumer surplus is computed in each case. The baseline scenario is:

$$\alpha_O = 100, \quad \alpha_E = 80, \quad \beta_O = 1, \quad \beta_E = 1, \quad \gamma = 0.75, \quad \overline{I} = 500, \quad \sigma = 0.$$

These parameters yield $\overline{\pi} = 2.500$, $\underline{\pi} = 1.357$, $\underline{\pi}_E = 309$, $\underline{S} = 1.250$, and $\overline{S} = 3.015$.

Consumer surplus (y-axis) is evaluated as a function of the allowed reverse payment (x-axis), considered as a fraction of the entrant's profits E. This yields the following graph (Fig. C.1).

When reverse payments are banned, or sufficiently low, the originator engages in PEP and remains the monopolist. When the allowed reverse payment is sufficiently high, the originator avoids PEP and tries to defend his monopoly through a settlement involving a reverse payment. In this area, consumer surplus is maximal through the possibility of litigation and, in case of settlement, entry before patent expiry. As the allowed reverse payment increases, the parties agree on a higher reverse payment, targeting a higher patent strength $\widehat{\theta}$, which reduces the probability of litigation and implies a later entry date (Fig. C.2).

The second simulation reduces the asymmetry between the parties. All the parameters are the same as above, except $\alpha_O = 80$.

In this case, the optimal reverse payment, as a fraction of E, becomes smaller, because the smaller asymmetry allows the entrant to enjoy higher profits and the interval where reverse payments increase CS widens. Making the originator not engage in PEP is more compelling, because the smaller asymmetry between the parties makes it more important to have competition on the market. This makes reverse payments more attractive and reduces the cost of choosing an excessively high one. The possibility of litigation and entry before patent expiry keep CS higher than the monopoly level for a larger interval of reverse payments.

The third simulation allows PEP to increase patent quality. The parameters are the same as in the benchmark case, except $\sigma = 400$.

An increase in patent quality due to PEP, with $\sigma < \sigma^*$, increases CS compared to the baseline scenario, but not as much as the optimal reverse payment (11).[23] Reverse payments still increase CS, but now choosing an excessively large one is more costly, as the area where reverse payments increase CS shrinks (Fig. C.3).

Appendix D. Continuous PEP

This Appendix checks the robustness of the results when we allow PEP to be continuous, rather than dual. Denote θ the final patent strength including the PEP investment and θ_0 the randomly drawn patent strength. Consider the following PEP technology:

$$\theta = \theta_0 + (1 - \theta_0)\frac{I}{\overline{I}}, \tag{D.1}$$

or, equivalently,

$$\theta = \theta_0\left(\frac{\overline{I} - I}{\overline{I}}\right) + \frac{I}{\overline{I}}.$$

Notice that this equation encompasses the dual case: when $I = 0$, then $\theta = \theta_0$, so that the final patent strength is the one randomly drawn; and when $I = \overline{I}$, then $\theta = 1$.

The entrant's problem is (1 bis), i.e.

$$\begin{aligned}
\max_{\{\widehat{\theta},R\}} \pi_E^{\overline{R}}(\widehat{\theta}) &= \int_{\widehat{\theta}}^1 [(1-\theta)\underline{\pi}_E]dF(\theta) + F(\widehat{\theta})[(1 - D(\widehat{\theta}))\underline{\pi}_E + R] \\
s.t. \quad 0 &\le \widehat{\theta} \le 1 \\
s.t. \quad 0 &\le D(\widehat{\theta}) \le 1 \\
s.t. \quad 0 &\le R \le \overline{R}
\end{aligned}$$

By following the same steps of Section 4.1, the first order condition of (1 bis) with respect to $\widehat{\theta}$ is:

$$F(\widehat{\theta})\underline{\pi}_E = f(\widehat{\theta})[(\widehat{\theta} - \widehat{D})\underline{\pi}_E + \overline{R}]$$

Result 4 holds and Result 8 becomes:

Result 8. In an interior solution, when the originator invests $\underline{I} = 0$, the optimal $\widehat{\theta}$ is implicitly defined by:

$$\left(\frac{I}{\overline{I} - I}\right)g(\widehat{\theta}) - \frac{I}{\overline{I}} = \frac{(\overline{\pi} - \underline{\pi})\underline{\pi}_E}{\overline{R}(\overline{\pi} - \underline{\pi} - \underline{\pi}_E)}, \tag{D.2}$$

where $g(\widehat{\theta})$ is defined as $g(\widehat{\theta}) = f(\widehat{\theta})/F(\widehat{\theta})$. Assume that the hazard rate $h(\widehat{\theta}) = f(\widehat{\theta})/(1 - F(\widehat{\theta}))$ is monotonically increasing in $\widehat{\theta}$, so that $g(\theta)$ is

[22] Considering prices net of marginal costs is without loss of generality as, if marginal costs m_O and m_E are positive, we can replace α_i with $\alpha_i - m_i$ and a_i with $a_i - b_i m + c m_j$.

[23] With this parameter set, we have $\sigma^* = 690$, so the condition $\sigma < \sigma^*$ is fulfilled.

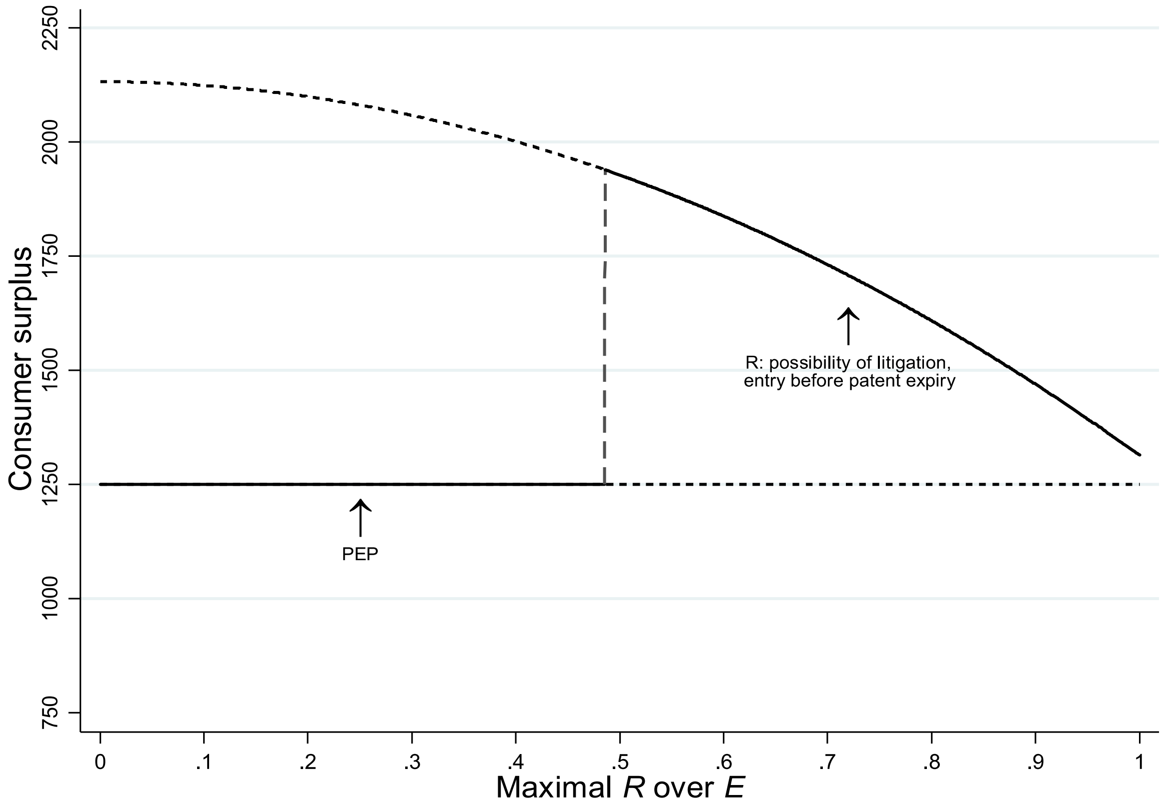

Fig. C.1. Benchmark: $\alpha_O = 100$, $\alpha_E = 80$, $\beta_O = 1$, $\beta_E = 1$, $\gamma = 0.75$, $\bar{I} = 500$, $\sigma = 0$.

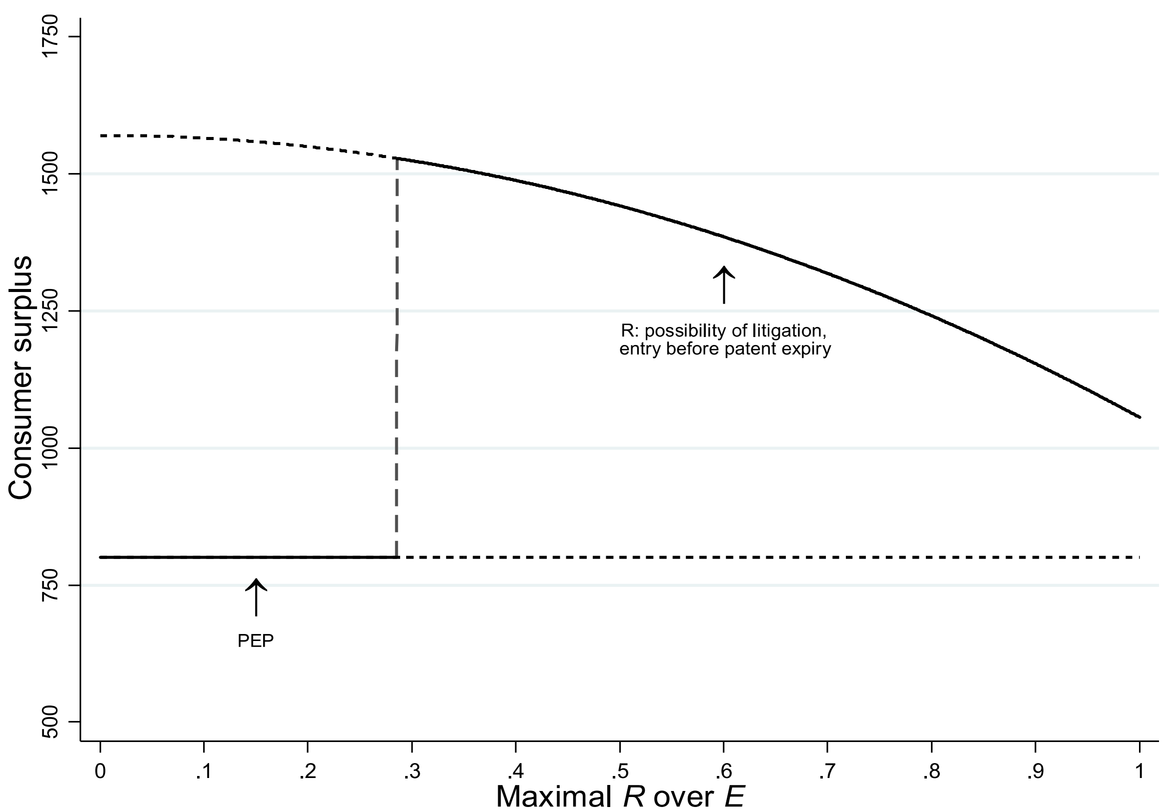

Fig. C.2. Lower asymmetry: $\boldsymbol{\alpha_O = 80}$, $\alpha_E = 80$, $\beta_O = 1$, $\beta_E = 1$, $\gamma = 0.75$, $\bar{I} = 500$, $\sigma = 0$.

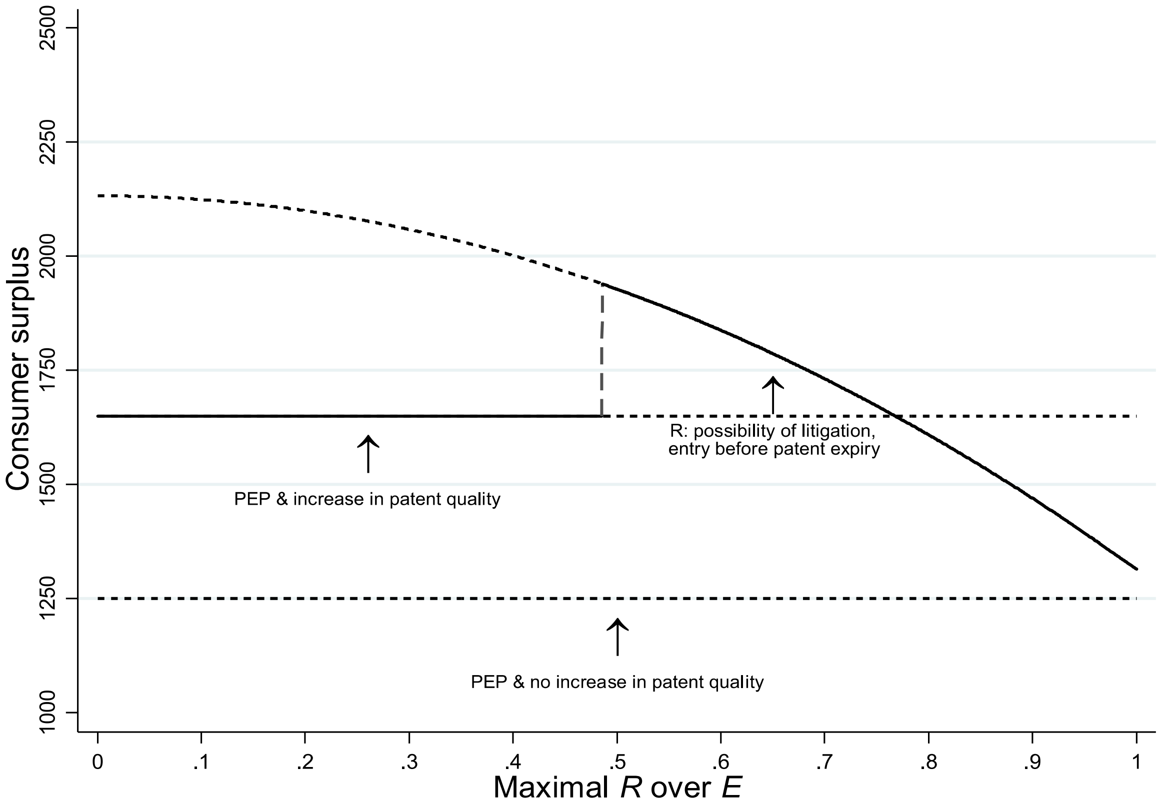

Fig. C.3. CS-incr. PEP: $\alpha_O = 100$, $\alpha_E = 80$, $\beta_O = 1$, $\beta_E = 1$, $\gamma = 0.75$, $\bar{I} = 500$, $\boldsymbol{\sigma} = \mathbf{400}$.

decreasing in $\widehat{\theta}$. The targeted patent strength becomes:

$$\check{\theta} = \frac{I}{\bar{I}} + g^{-1}\left(\frac{(\overline{\pi} - \underline{\pi})\pi_E}{\overline{R}(\overline{\pi} - \underline{\pi} - \pi_E)}\right)\left(1 - \frac{I}{\bar{I}}\right). \tag{D.3}$$

What we need to show is that reverse payments increase the targeted patent strength $\check{\theta}$ less when I is higher.

The FOC of $\check{\theta}$ with respect to R is:

$$\frac{d\check{\theta}}{dR} = \frac{dg^{-1}\left(\frac{(\overline{\pi}-\underline{\pi})\pi_E}{\overline{R}(\overline{\pi}-\underline{\pi}-\pi_E)}\right)}{dR}\left(1 - \frac{I}{\bar{I}}\right), \tag{D.4}$$

which is positive because both elements are positive. In particular, $\frac{dg^{-1}(\cdot)}{dR}$ is positive because of Result 6 (a higher R increases the targeted realization $\widehat{\theta}$).

The FOC of $\frac{d\check{\theta}}{dR}$ with respect to I (which is equivalent to the FOC of $\frac{d\check{\theta}}{dI}$ with respect to R) is:

$$\frac{d\frac{d\check{\theta}}{dR}}{dI} = \frac{d\frac{d\check{\theta}}{dI}}{dR} = -\frac{1}{\bar{I}}\frac{dg^{-1}\left(\frac{(\overline{\pi}-\underline{\pi})\pi_E}{\overline{R}(\overline{\pi}-\underline{\pi}-\pi_E)}\right)}{dR} < 0. \tag{D.5}$$

$\frac{d\frac{d\check{\theta}}{dR}}{dI}$ is negative, which means that (i) a higher investment in PEP I reduces the effect that R has on the targeted patent strength $\check{\theta}$ and (ii) a higher reverse payment R reduces the originator's incentives to engage in PEP. Proposition 2 therefore holds also when the investment in PEP is continuous.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at 10.1016/j.infoecopol.2023.101044.

References

Bebchuk, L.A., 1984. Litigation and settlement under imperfect information. RAND J. Econ. Autumn 15 (3), 404–415.

Dickey, B.M., Rubinfeld, D.L., 2012. Would the per se illegal treatment of reverse payment settlements inhibit generic drug investment? J. Compet. Law Econ. 8 (3), 615–625.

Dickey, B., Orszag, J., Tyson, L., 2009. An economic assessment of patent settlements in the pharmaceutical industry. Ann. Health L 19, 367.

Duchene, A., Serfes, K., 2012. Patent settlements a a barrier to entry. J. Econ. Manage. Strategy 21 (2), 399–429.

Dwivedi, G., Rangan, L., Patil, S., 2010. Evergreening: a deceptive device in patent rights. Technol. Soc. 32 (4), 324–330.

Fudenberg, D., Gilbert, R., Stiglitz, J., Tirole, J., 1983. Preemption, leapfrogging and competition in patent races. Eur. Econ. Rev. 22 (1), 3–31.

Gilbert, R.J., Newbery, D.M.G., 1982. Preemptive patenting and the persistence of monopoly. Am. Econ. Rev. 72 (3), 514–526.
Gurgula, O., 2020. Strategic patenting by pharmaceutical companies - should competition law intervene? Int. Rev. Intell. Property Competition Law 51, 1062–1085.
Hemphill, C.S., Sampat, B.N., 2012. Evergreening, patent challenges, and effective market life in pharmaceuticals. J. Health Econ. 31 (2), 327–339. https://doi.org/10.1016/j.jhealeco.2012.01.004. Epub 2012 Feb 9. PMID: 22425766.
Hopenhayn, H.A., Squintani, F., 2011. Preemption games with private information. Rev. Econ. Stud. 78 (2), 667–692.
I-MAK, 2018. Overpatented, Overpriced. Report.
Lemley, M.A., Shapiro, C., 2005. Probabilistic patents. J. Econ. Perspect. 19 (2), 75–98. Spring 2005
Lemus, J., Temnyalov, E., 2020. Pay-for-delay with Follow-on Products. Review of Industrial Organization 1–18.
Maier-Rigaud, F., Blalok, N., Gannon, O., 2019. Reverse payments: an EU and US perspective. In: Figueroa, P., Guerrero, A., Elgar, E. (Eds.), EU Law of Competition and Trade in the Pharmaceutical Sector, pp. 35–108.
Manganelli, A.G., 2020. Reverse payments, patent strength, and asymmetric information. Health Econ. 30 (1), 20–35.
Meurer, M., 1989. The settlement of patent litigation. RAND J. Econ. 20 (1).
Moir, H.V.J., 2017. Exploring Evergreening: Estimating the Cost of Low Patent Standards. working paper.
Mungan, M.C., 2013. Reverse Payments, Perverse Incentives, Scholarship Repository. Florida State University College of Law.
O'Donoghue, T., 1998. A patentability requirement for sequential innovation. RAND J. Econ. 29 (4), 654–679.
Patterson, M., 2007. Contractual expansion of the scope of patent infringement through field-of-use licensing. Fordham Law Arch. Sch. Hist.
Richards, K.T., Hikey, K.J., Ward, E.H., 2020. Drug Pricing and Pharmaceutical Patenting Practices. Congressional Research Service.
Riordan, M.H., Salant, D.J., 1994. Preemptive adoptions of an emerging technology. J. Ind. Econ. 27 (3).
Salant, S.W., 1984. Preemptive patenting and the persistence of monopoly: comment. Am. Econ. Rev. 74 (1), 247–250.
Salzenbacher, G.T., Wettstein, G., 2020. Drug insurance and the strategic behavior of drug manufacturers: evergreening and generic entry after medicare Part D. J. Health Econ. 72.
Schankerman, M., Schuett, F., 2021. Patent screening, innovation, and welfare. Rev. Econ. Stud. 1–48.
Shapiro, C., 2003. Antitrust limits to patent settlements. RAND J. Econ. RAND Corporation 34 (2), 391–411.Summer
Vickers, J., 1985. Pre-emptive patenting, joint ventures, and the persistence of oligopoly. Int. J. Ind Organiz 2 (3), 261–273.
Willig, R., Bigelow, J.P., 2004. Antitrust policy towards agreements that settle patent litigation. Antitrust Bull. Fall.