

Reversing the Trend? The Possibility that Rule Changes May Lead to Fewer Reverse Payments in Pharma Settlements

Anne Layne-Farrar

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The article begins by laying out a simple framework that makes obvious the incentives at play in generic drug entry, brand challenges, and settlements between the two. Once this common understanding has been established, several rule changes that have taken place are summarized—one in the form of an amendment to Hatch-Waxman and another in a recent decision by the Court of Appeals for the Federal Circuit. These institutional changes may have the consequence of reducing the prevalence of reverse payments. This possibility suggests a different policy tact might be called for, one that shifts emphasis from determining whether or not reverse payments should be *per se* illegal to working with the incentives that firms already face and exploiting those incentives to reduce firms' inclinations to enter into anticompetitive reverse-payment settlements.

*Dr. Anne Layne-Farrar is a Director at LECG. She specializes in antitrust matters where the core issues are at the intersection of intellectual property economics and competition policy.

I. Introduction

The debate over so-called “reverse payments”—where a patent-holding brand name pharmaceutical firm makes a settlement payment to a generic competitor to prevent or delay the generic from entering the branded drug market¹—reached a fevered pitch this year with the introduction of a legislative proposal aimed squarely at settlements involving such reverse payments. Specifically, Senator Herb Kohl (D.-Wisconsin) introduced the “Preserve Access to Affordable Generics Act”² that would make it “unlawful” for parties involved in pharmaceutical patent litigation to sign a settlement agreement in which the generic company:

- (1) receives “anything of value;” and
- (2) “agrees not to research, develop, manufacture, market, or sell the [generic product] for any period of time” but that did not
- (3) “demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh the anticompetitive effects of the agreement.”

That reverse settlements are deemed important enough for their own legislation is indicative of the heat the debate has generated. On one side of the reverse-payment debate is a camp, which includes the Federal Trade Commission Chairman and the Department of Justice’s Chief Economist, that is calling for reverse settlements to be made *per se* illegal. The view maintained by this group is that *all* reverse payments are anticompetitive: The sole reason for a brand firm with patents for a commercially successful drug to make a reverse payment is to delay the generic firm’s entry.³ As Carl Shapiro wrote in 2003, prior to his appointment as the DOJ’s Antitrust Division Deputy Assistant Attorney General for Economic Analysis, “Presumably the patent holder would not pay more than avoided litigation costs unless it believed that it was buying later entry than it expects to face through the litigation alternative.”⁴ Similarly, FTC Chairman Liebowitz points to reverse payments as

“...yet another example of pharmaceutical companies turning competition on its head. Congress enacted the landmark 1984 Hatch-Waxman Act to encourage early generic entry and save consumers money, but these anticompetitive deals threaten to destroy that benefit and make crucial portions of the Hatch-Waxman Act extinct in all but name.”⁵

Indeed, it is the Hatch-Waxman Act that makes reverse payments possible in the first place. Specifically, the 1984 Act enables generic firms to file an “abre-

viated new drug application,” (“ANDA”), with the Food and Drug Administration. To file an ANDA, the generic firm needs only to show that its generic version of the drug works the same as a previously approved pioneer drug. Within the filing, the generic firm must specify whether the pioneer drug’s patent will still be in force at the time of the generic’s entry. The option listed under Paragraph IV of the ANDA states that the pioneer drug’s patent will *not* have expired at the time of generic entry. Paragraph IV ANDA filings trigger a 45 day window for the maker of the pioneer drug to respond by challenging the generic firm’s entry as infringing on its patent.

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This challenge is a form of ex ante infringement case in which the infringement has not actually occurred but is expected to occur when the generic firm actually begins marketing its version of the drug.

Because Hatch-Waxman enables generic drug firms to challenge a brand name drug without actually entering the market and without making any allegations of patent invalidity, the Act lowers the risk of and thus encourages patent challenges. As noted by Chairman Liebowitz above, this was one of the goals of Hatch-Waxman and by all accounts it has been fulfilled.⁶ The complication is that with the increased ex ante generic challenges have come settlements involving reverse payments.

Not all economists and lawyers see reverse payments as inherently anticompetitive, however. On the opposite side of the debate are those who recognize that brand name drug makers can have legitimate, efficiency-based reasons for offering potential generic competitors reverse payments. First, in other contexts it is well recognized that settling a suit rather than litigating to conclusion saves resources and can be pro-competitive.⁷ In recognition of the generally beneficial nature of settlements, Judge Richard Posner has observed,

“Any settlement agreement can be characterized as involving “compensation” to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden “reverse payment,” we shall have no more patent settlements.”⁸

Additionally, some argue that “important economic realities ... can make reverse payments pro-competitive.”⁹ For instance, Dickey et. al. list such factors as: the brand firm’s risk aversion; information asymmetries between the brand and generic regarding the validity of the patents at issue; differing expectations

regarding likely litigation outcomes; and different discount rates as potential legitimate reasons for reverse-payment settlements. The argument here is not that all reverse payments are pro-competitive, but rather that some may be and thus all such settlements should not be banned as *per se* illegal.

Many in the “not-all-bad” camp posit that the issue at the heart of the matter is not an antitrust question, but rather whether the branded drug patent(s) are strong.¹⁰ If so, the brand firm will most likely win the challenge so that settlement, even involving a reverse payment and some delay of generic entry, is welfare-enhancing because it eliminates litigation costs, does not deprive consumers of any reasonably expected period of lower drug costs, and still manages to make the two firms involved better off than if they had continued to litigate.

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Related to the patent validity point is the issue of drug research. As is well documented by now, pharmaceutical research and development (“R&D”) is extremely costly and time consuming. Studies have estimated that the average new drug takes somewhere between 10 to 15 years to go from lab to pharmacy, and that the journey can cost upwards of \$1.3 billion (counting both direct and opportunity costs).¹¹ Moreover, the odds that any one drug tested will eventually be approved are quite small—some estimate on the order of 1 out of every 5,000.¹² With such large and risky upfront outlays necessary for innovation, patent protection plays a key role in ensuring the proper incentives for investments in new drugs. While not all patents will be valid, these industry dynamics suggest some caution in dealing with anything that can cut a patent term short, including pre-expiry generic challenge.

I will admit to falling into this latter more cautious not-all-bad camp. Once we admit the possibility that at least some settlements can be pro-competitive (or at least not harmful), we must move away from *per se* illegality and consider how best to achieve the desired policy objectives. Namely, we want to strike the right balance between upholding valid intellectual property rights and their pivotal (albeit long-term) role in spurring pharmaceutical innovation and the more immediate drug pricing benefits that early generic entry can provide consumers. Thus, if we assume that at least some reverse-payment settlements do not harm consumer welfare, then we need to explore policy options that have the potential to reduce harmful settlements without eliminating settlements altogether.

In the context of that assumption, the analysis presented here considers the various factors that affect a brand firm’s decision to offer a reverse-payment settlement and questions whether and how those factors might be exploited to limit the occurrence of reverse payments in the first instance. If we are able to employ firms’ natural incentives as a means to reduce the prevalence of reverse pay-

ments, we will have a smaller set of cases over which to debate the competition effects and welfare implications.

The article begins by laying out a simple framework that makes obvious the incentives at play in generic drug entry, brand challenges, and settlements between the two. Once this common understanding has been established, several rule changes that have taken place are summarized—one in the form of an amendment to Hatch-Waxman and another in a recent decision by the Court of Appeals for the Federal Circuit. These institutional changes may have the consequence of reducing the prevalence of reverse payments. This possibility suggests a different policy tact might be called for, one that shifts emphasis from determining whether or not reverse payments should be *per se* illegal to working with the incentives that firms already face and exploiting those incentives to reduce firms' inclinations to enter into anticompetitive reverse-payment settlements.

II. The Framework

To make clear the various forces at work in a generic firm's challenge of a patented brand name drug, it is helpful to layout a simple framework. Consider a market with at least two firms, a brand and a generic, referenced B and G respectively. G is considering filing a paragraph IV ANDA in regards to a drug that B is currently supplying. To avoid a complication that does not add insight to our discussion, assume that both firms face the same marginal costs of production, mc : while B clearly incurs research and development costs that G does not, once the drug is approved by the FDA assume that the cost of making and distributing it would be identical for both firms should G enter the market. If G files an ANDA and B responds by challenging G with patent infringement, both firms incur legal costs (L), although those costs may differ across the firms. With these basic assumptions in mind, we can turn to the various scenarios possible under this setup.

A. CASE 1: NO GENERIC ENTRY

G may decide, for whatever reason, not to enter the market in competition with B. In this baseline case, G earns profits from some outside option, π_o , say from pursuing a different generic drug. It is against this outside profit that G will evaluate the alternative of entering the market in competition with B. G will only file an ANDA for B's drug if it expects to earn more in this competition than it can otherwise earn through its alternative options.

B. CASE 2: GENERIC ENTRY WITH NO BRAND CHALLENGE

If G does decide to file a paragraph IV ANDA, several outcomes are possible. First, B may decide, for certain reasons,¹³ not to challenge G's entry into the market. In this case, G would enter the market uncontested and compete with B for sales of the drug. As a result, the price of the drug would fall to the duopoly level.

The duopoly price (P_d) exceeds the competitive price (P_c),¹⁴ which would prevail should several generic firms enter the market in competition with B, but it is lower than the monopoly price (P_m) charged by B prior to G's entry.

Under this scenario, both B and G would earn the duopoly return: $\pi_d = (P_d - mc)(\sigma X_d)$, where X_d is the aggregate quantity of the drug sold in the market given two suppliers only (B and G), a quantity that exceeds the monopoly quantity sold when B faced no competition ($X_d > X_m$), and σ is B's share of the market. If $\sigma = 0.5$, the two firms split the market evenly, but other divisions are certainly possible. Thus, in this case, consumer prices would fall, the aggregate quantity sold would increase, and consumers would be better off (in the short term at least) than if G had not entered. The brand firm, however, is typically worse off. Even though the aggregate quantity sold increases, it is generally the case that the brand firm's price falls by enough that the brand firm earns less than before, when it held a monopoly.¹⁵

C. CASE 3: GENERIC ENTRY WITH BRAND CHALLENGE

Entry with brand firm challenge is slightly more complicated in that there are two potential outcomes. First, B could win the litigation, in which case B would remain a monopolist for the residual term of its patent while G would not be able to enter until after patent expiry. Note that both firms' earnings would be reduced by the litigation expenses they incurred.

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On the other hand, B could lose the infringement challenge, in which case G would be free to enter the market immediately, before the patent expires, and compete with B. But in this case, B's patent would have been invalidated. If any other generic firms (say, firms G_2 through G_n) were interested and capable of entering the market, they would be free to do so without risking an infringement challenge by B. Hence, if B loses its challenge of G's entry, the resulting market could be more competitive; rather than a duopoly, the several firms in the market would earn a competitive return. Making the reasonable assumption that prices fall by more than quantities sold increase, we have $\pi_c < \pi_d < \pi_m$.¹⁶ Again, B and G would also incur litigation expenses along the way.

D. CASE 4: GENERIC ENTRY WITH SETTLEMENT

The final possibility is that B settles with G. In this case, B could offer G a payment not to enter the market for some specified time, perhaps until the patent expires. With settlement, both firms still incur some litigation expense, but less

than they would have if the trial had run its course to a court decision (e.g., litigation expenses L are reduced by some fraction $0 < \lambda < 1$).

Make the realistic assumption that the settlement amount is a multiple of the earnings that G could have made in the duopoly market had B not challenged its entry: $S = \delta(P_d - mc)\sigma_G X_d$, where δ is the multiple and σ_G is G 's share of market. If $\delta \leq 0$ then G pays B a licensing fee to enter the market. In this case, the payment is not "reverse" but rather flows in the typical direction found in patent infringement cases. If $\delta > 0$, however, the settlement involves a reverse payment from B to G . If $\delta > 1$ then the reverse payment amounts to more than the generic could have ever possibly earned by entering the market.

III. Important Decision Parameters

The above discussion points to a number of key factors in generic and brand firms' strategic decisions regarding early entry and competition. First, the difference in the brand firm's expected earnings as a monopolist and as a duopolist (competing with G), less the expected cost of litigation, is pivotal in the brand firm's decision to challenge the generic firm's entry. Assume for the moment that B knows with

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certainty it can win its challenge against G if it spends L_B on the litigation. Then, as long as $\pi_m - \pi_d - L_B > 0$ B 's monopoly earnings are sufficiently above those it could earn in competition with G , even accounting for litigation costs, then it will want to challenge the generic's entry.

Of course, firms are never assured of winning a lawsuit, regardless of the money spent making their case and regardless of their views on patent validity. Thus B 's assessment of the chances of winning the lawsuit will play a role as well, and will affect the expected cost of litigating (L_B). If, on the other hand, $\pi_m - \pi_d - L_B < 0$ then having a "monopoly" on the drug does not translate into supra-competitive earnings that warrant the expense of litigation, even if the brand firm was assured of winning the challenge. This latter scenario could hold, for example, if the brand drug faces competition from a number of close (albeit chemically distinct) substitutes.

The litigation challenge condition above is likely to hold in many instances. For example, when Merck's Zocor drug was alone on the Simvastatin market, it commanded in excess of \$5 billion in annual revenues (profits are unavailable).¹⁷ When the first generic entered, Merck's annual revenue fell to just below \$3 billion (See Figure 1 below). After the second generic entered, Merck's annual revenue fell to below \$1 billion.

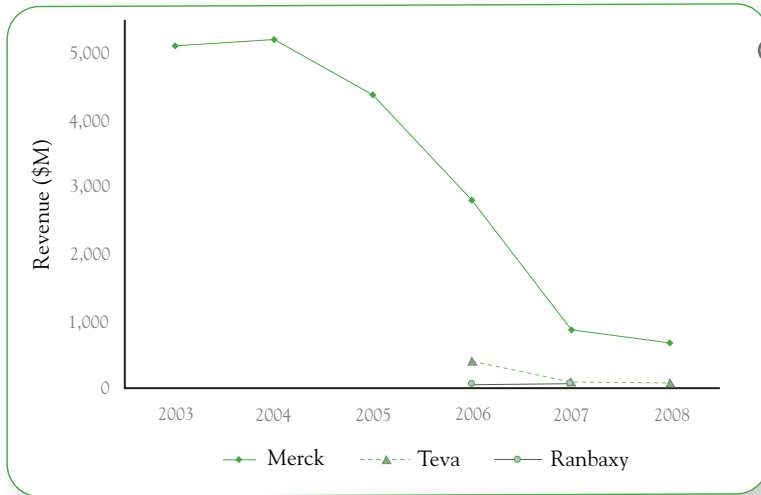


Figure 1

Litigation costs would surely not erode a \$2 billion difference, meaning that Merck had very strong incentives indeed to challenge the first generic’s entry into the production of Simvastatin. Available evidence suggests that such precipitous drops in earnings are not uncommon in the face of generic entry.¹⁸

At the same time that substantial profits are on the line for brand firms, the stakes are considerably smaller for generic firms. The chart below shows the ratio of generic to brand name drug prices as the number of generic firms on the market increases. Note that the first bar, which shows one generic firm earns on average 94 percent of the brand firm’s price, is overstated because it includes so-called “branded generics” offered by the brand firm itself (or by a third party sponsored by the brand firm). In general, industry statistics suggest that if a brand earns \$1 billion as a monopolist, the first generic will earn around \$80 million.¹⁹

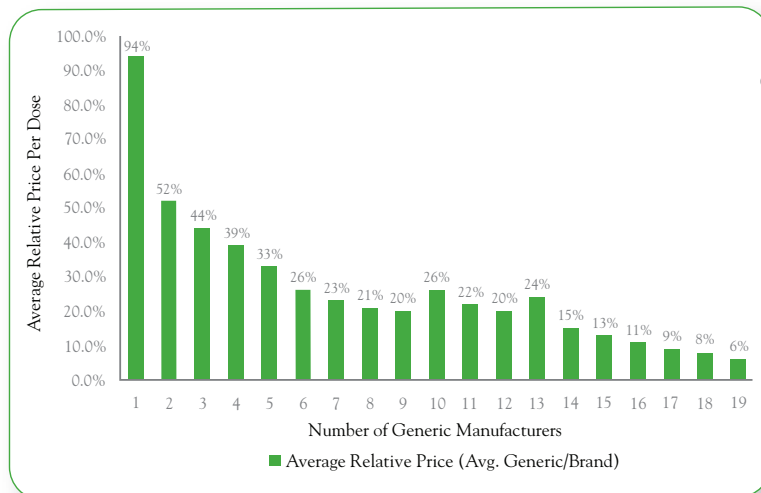


Figure 2

With these various options in mind, the generic will decide on whether to enter the market by evaluating its expected profits under each scenario. To do this, the generic will assign probabilities to possible outcomes.

Given that the condition for a brand firm to challenge a generic firm's paragraph IV ANDA filing ($\pi_m - \pi_d - L_B > 0$) is likely to be met with some frequency, the relevant question is whether litigation will proceed to conclusion or whether the parties will settle. Of course, with such large discrepancies in potential earnings, if the brand finds it worthwhile to challenge the entry the brand is also likely to be able to make a settlement offer that the generic firm cannot refuse. For instance, if the brand was earning \$1 billion a year as a monopolist but its earnings would fall to \$600 million should a generic firm enter the market, the brand would have up to \$400 million (less anticipated litigation fees) with which to pay a generic to stay out of the market and the brand would still be better off than if it abstained from challenging the entry. Given that the generic firms generally expect to earn far less than the brand firm's lost sales, say

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on the order of \$150 million as assumed above, there is clearly quite a bit of latitude for a settlement that can make both parties better off, given the generic filed the ANDA. The question, of course, is whether consumers are worse off, but recall that we have assumed that at least some fraction of these settlements are not harmful.

Observe that with any settlement, the court makes no ruling on whether the brand firm's patent is valid or not. This has important consequences for other generic firms that may be considering whether to enter the market. These firms would still run the risk of patent infringement challenges from the brand firm, as the brand firm has made no concessions regarding the patent's validity. If the settlement involved a licensing fee paid by the first generic, then later generic entrants will likely wait for patent expiry given the generally slim margins they can earn in the marketplace. If the settlement involves a modest reverse payment, later generics will still be likely to wait for patent expiry as they would expect a lower settlement payment than the first entrant obtained because the brand firm has less to lose with a second entrant as compared to the first, and the generic would still have to incur litigation expenses to obtain that settlement. Only if the first settlement involved a lucrative reverse payment would later generics have incentives to attempt early entry, taking the first payment as a signal that the brand firm has ample supra-competitive earnings to allow for multiple reverse payments.

If the brand firm does not offer a settlement to the first generic filer, however, it faces the risk that the court will find its patent is invalid and/or not infringed. In that case, the brand is far more likely to face not one generic (the firm filing),

but potentially many generics since the primary risk associated with generic entry will have been removed. The privately beneficial nature of settlements is in fact one of the bones of contention in the debate over reverse payments; advocates of *per se* illegality point to the two parties' mutual benefit and argue that consumers must be worse off as a result.²⁰

IV. How Settlement Decisions Are Made

Returning to the simple framework above, what condition must be met for the brand firm to attempt a reverse-payment settlement versus litigating to conclusion?²¹ Assuming B challenges G, if the parties settle and the generic delays entry the brand firm would continue to earn its monopoly profit, but would have to pay out of that amount the settlement S and the litigation costs L_B , which is a fraction of the total litigation costs that would have resulted if the trial had run to completion: $\pi_m - S - \lambda L_B$. If the brand firm does not offer a settlement, then with some probability ρ it will win the case and continue to earn its monopoly profit, less the litigation expenses: $\rho(\pi_m - L_B)$. With probability $1 - \rho$ the brand firm will lose the case, multiple generic firms will enter the market once the patent is invalidated,²² and the brand firm will earn a competitive profit: $(1 - \rho)(\pi_c - L_B)$. Combining these last two potential profits for the brand firm, we obtain the expected profit from completing the trial: $\rho\pi_m + (1 - \rho)\pi_c - L_B$. The relevant comparison is then whether the brand firm's expected earnings are higher when it settles or when it takes its chances with a trial.

Working through the algebra, we find that the brand firm will offer a settlement S when the following condition holds:

$$(1) \quad \pi_m - \pi_c > \frac{S - (1 - \lambda)L_B}{1 - \rho}.$$

In words, the condition implies that when the difference between the best and worst possible profit outcomes from the brand firm's perspective (monopoly earnings versus competitive earnings) is larger than the reverse-payment settlement amount required less the additional litigation costs needed to complete the trial, all weighted by the odds of losing the trial, then the brand firm will prefer to pay to settle the case.

Considering a few straightforward comparative statics helps to clarify the intuition behind the reverse-payment settlement condition (1). First, and most obviously, the higher monopoly profits are over the competitive level of profits, the more likely the brand firm will want to settle with the generic firm in order to avoid the risk of an invalidated patent—and with it the entry of multiple generic firms and the lower competitive profits that come with that entry.

Second, and not surprisingly, the smaller the litigation cost savings from settling as opposed to taking the trial to its conclusion, $(1 - \lambda)L_B$, the less likely a

reverse-payment settlement is (again holding everything else constant). This is a traditional component of any settlement decision and is not particular to pharmaceutical reverse-payment deals.

Third, the probability of losing the case also plays a key role in the brand firm's decision to offer a reverse-payment settlement or not. As ρ increases, the fraction on the right hand side of the settlement condition (1), $\frac{S - (1 - \lambda)L_B}{1 - \rho}$, will rise as

well, making it less likely that the profits protected, $\pi_m - \pi_c$, are large enough to justify the settlement. In other words, as the probability of the brand firm's winning the infringement case increases, the chance of a settlement decreases. The converse is, of course, true as well. The mechanism at work here is the risk that an invalidated patent spurs multiple generic firms to enter, and reduces the brand firm's profits below the duopoly level possible with just one generic challenger.

V. The Potential for Multiple Generic Entrants

Thus far the simple framework above has done little more than make some well known incentives explicit. With this common ground understanding in hand, however, let us turn to some less obvious aspects of brand and generic firm competition:

LET US TURN TO SOME LESS OBVIOUS ASPECTS OF BRAND AND GENERIC FIRM COMPETITION: THE POSSIBILITY THAT MULTIPLE GENERIC ENTRANTS MIGHT BE ABLE TO REDUCE THE PREVALENCE OF REVERSE PAYMENTS.

the possibility that multiple generic entrants might be able to reduce the prevalence of reverse payments.

Not too long ago, the rules were such that one and only one generic firm at a time had any incentive to file a paragraph IV ANDA. Under Hatch-Waxman, the first generic filer received 180 days of "exclusivity," during which the FDA provided no other generic company approval to market the same drug. The 180 days started to count down as soon as the first filer began selling its generic product or, in the case of a challenge from the brand firm, when the court ruled that the generic did not infringe the patent and could start selling its product. Of course, with the stakes so often high in these pharmaceutical cases, the parties quickly identified the loopholes in this system: a settlement does not involve a court decision and if the generic does not begin marketing its drug before patent expiry, the 180 day clock would not start ticking until then.

Thus, in 2002, an FTC report expressed concern over so-called generic entry "parking," whereby the first generic filer would "park" its exclusivity period, not competing with the brand firm before patent expiry but preventing other generic firms from entering the market before then.²³ Brand firms would issue unilateral covenants not to sue generic firms over the drug's key patent (but not nec-

essarily for all patents needed to manufacture the drug), but settlement with the first generic filer ensured that it would not enter the market before the brand's patent expired. Such deals essentially amounted to privately beneficial collusion: the brand firm maintained its monopoly while the generic firm obtained a beneficial deal from the brand firm while still maintaining its exclusivity period once it eventually did enter the market.

The courts inadvertently facilitated this practice by holding that later generic filers did not have standing to file for declaratory judgment on the brand firm patent's validity or infringement. Thus, the brand firm's covenant not to sue was seen as removing the threat of infringement suit while the first generic filer's failure to actually market the drug meant its exclusivity was not yet expired.

These obstacles have since been removed, however, with the last piece falling into place in 2008. Importantly, the Hatch-Waxman Act was amended in 2003 so that a first generic filer can now lose its exclusivity period.²⁴ Among the forfeiture events are: 1) failure to market the drug promptly; 2) failure to obtain FDA approval to market the drug in a timely fashion; and 3) the expiry of all the relevant patents. Specifically, the first filer will lose its exclusivity if it has not marketed its drug as of 75 days after receiving FDA approval to do so, 30 months after submitting its application, or immediately upon winning a court challenge from the brand firm. If the first generic filer loses its exclusivity period for one of these reasons, then no generic firm benefits from 180 days of exclusivity. The amendments also added the ability for generic firms to file a counterclaim to delist the brand firm's patent, giving generics an additional weapon in an entry bid.

In regards to the court's role in fostering generic drug parking, the Court of Appeals for the Federal Circuit's ruling in *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.* held in June 2008 that a brand firm's unilateral covenant not to sue does not moot later generic entrants' ability to challenge the brand firm's patent and that filing a paragraph IV ANDA is enough to satisfy standing.²⁵ As a result of these various changes, a second generic filer can now trigger the first filer's 180 day exclusivity period, or the first filer can lose its exclusivity altogether. In combination, the changes thus effectively remove the threat of parking.

The question now becomes whether this new freedom for second and later generic filers affects the incentives for the brand firm and the first generic filer to settle with a reverse payment. To answer this question, return to our discussion of incentives. First, we would expect a lucrative reverse payment to act as a lure to other generic firms capable of entering the market. Seeing a relatively large payment signals to other generic firms that the brand firm does indeed have considerable monopoly profits at stake (e.g., that the left hand side

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of condition (1) is much greater than the right hand side) and is likely capable of making additional payments to other rivals. Whereas before a brand firm could dismiss any such second, third, or later generic filers secure in the knowledge that the settlement terms struck with the first filer in combination with the 180 day blockade would effectively keep these competitors out until patent expiry (or close to it), under the new regime second filers can enter far sooner, either after 180 days or, if the FDA revokes exclusivity from the first filer for a failure to act, as soon as the trial is concluded (assuming a settlement with the second filer has not been reached).

Consider, for example, a patent with 5 years left on its term after the settlement with the first filer is reached. The first generic filer has agreed not to enter before the brand firm's patent term is up, but the second generic firm can file as soon as it learns of the settlement. The second filer will either be successful, in which case it can enter immediately, or the brand will settle with it too. Thus, for the second generic filer's part, as long as its threat of entry is credible, it has an incentive to file: it can either win the challenge and have some period of first mover advantage (de facto exclusivity before other generics can enter),²⁶ or it can reach a settlement and get paid by the brand firm. Weighing against these possible benefits, the second generic firm's downside is limited: with no actual sales on the market yet, it stands to lose its litigation expenses but would have little if anything to pay in damages to the brand firm (this is, indeed, the point of Hatch-Waxman, to lower the risks and hence provide incentives to challenge brand name drug makers). Once again the brand firm is faced with the litigate-settle decision, but this time it has already paid one reverse-payment settlement to the first filer, and has lost the first trial's litigation expenses as well.

Returning to the simple framework above, if the brand firm anticipates the possible chain of events at the time of its negotiations with the first filer, its decision is now based upon the following condition:

$$(2) \quad \pi_m - \pi_c > \frac{S^1 - (1 - \lambda)L_B^1}{1 - \rho^1} + \frac{S^2 - L_B^2}{1 - \rho^2}.$$

This follows because now the first reverse-payment settlement carries with it the knowledge that a second filer will surely come knocking.²⁷ It may be reasonable to assume that the first filer is the strongest generic challenger (that is, it would take the most sales away from the brand firm should it enter the market), but even if the second filer is less capable, two generic competitors instead of one removes the duopoly possibility from the list of market outcomes and typically implies lower earnings for the brand firm.²⁸ Thus, even if the settlement payment required for the second generic filer, S^2 , is smaller than the first settlement, S^1 , the aggregate settlement amount is nevertheless higher. The difference between the brand firm's best case scenario (monopoly profits after winning the first generic challenge) and its worse case scenario (losing patent validity and facing

multiple generic firm entry) must be higher than it was before in order to justify the first reverse-payment settlement amount.

If there are more than two generic firms that could credibly file paragraph IV ANDAs, then the brand firm would have to consider several additional settlements as it contemplated whether to settle with the first filer. Condition (2) could then expand with three or four settlement terms on the right hand side, each one making that first settlement less likely.

VI. The Implications of Multiple Filers

Two important points arise from the above line of reasoning. First, now that the path has been cleared for multiple generic filers, we may indeed see fewer reverse payments. As long as more than one generic firm can offer a credible entry strategy, the brand firm will consider the signal that its reverse-payment settlement with the first generic firm sends to other generic firms. If the first filer is paid amply for delayed entry, the second (third, etc.) generic rivals will see an opportunity to either acquire a lucrative settlement themselves or else to gain a first move advantage from the first filer given its failure to act, hence precipitating their earlier entry. Brand firms with marginal products, that is those with drugs that were just barely making the settlement hurdle before as their “monopoly” profits were not high enough to warrant a settlement payment under condition (1) will likely find that condition (2) is not satisfied at all. Depending on how many products fall into this category, we could see fewer reverse payments than we otherwise would have absent the amendments to Hatch-Waxman and the ruling in *Caraco*.

FIRST, NOW THAT THE PATH HAS BEEN CLEARED FOR MULTIPLE GENERIC FILERS, WE MAY INDEED SEE FEWER REVERSE PAYMENTS.

That is the positive side of the new regime. The second implication is not so positive. Namely, there is likely to be a second order negative effect on the first filer’s incentives to file. If we think of the entry/litigate decisions in a game theory setting, the incentives to file first have weakened with the latest changes to Hatch-Waxman and the court standing requirements. Since it is now possible to lose the 180 day exclusivity period, the first filer has more at risk. If it accepts a lucrative reverse-payment settlement offer from the brand firm and agrees to delay its entry, the FDA can revoke its exclusive status. Thus, when it does eventually enter the market, it may find itself in second or even third place. Moreover, the size of any reverse payment from the brand firm is likely to be smaller now as well. Since the brand firm must consider all potential entrants as soon as the first filer emerges, it is likely to negotiate harder with the first generic filer for a lower settlement amount, thus avoiding a strong signal to other generic firms to enter early.

VII. Adding Product Differentiation

Thus far we have considered drugs in the abstract. However, the above arguments are likely to fit some drug categories better than others. For instance, drugs targeting relatively high risk conditions, such as heart disease or cancer, might offer more price resilience for brand firms.²⁹ If either patients or doctors have a high level of concern over the efficacy and reliability of a generic version, they may be more insistent that a brand name drug be prescribed. In that case, the doctor would indicate “no generic substitutes” on the prescription. Without such explicit physician instructions, however, pharmacies and insurance companies are likely to make generic substitutions as a matter of course in order to keep costs down.³⁰

More broadly, any perception of higher quality or greater reliability on the part of doctors or patients will tend to offer the brand firm some relief from generic competition. It would be surprising if such perceptions enabled the brand firm to fully maintain its monopoly share or price, but any cushion against competition will tend to reduce the difference between the brand firm’s monopoly earnings and its earnings under either duopoly or competition.

Looking back at the litigation condition, this time weighted by the odds of winning the suit, $\rho(\pi_m - \pi_d - L_B) > 0$, it is easy to see that any factor that softens competition (brand recognition, quality perceptions, etc.) will also soften the brand firm’s incentives to challenge generic entrants. As π_d increases, the left hand side of the challenge condition decreases, meaning that it is less likely to be greater than zero. Likewise, the factors that soften price erosion for the brand firm will also reduce the firm’s incentives to offer generic entrants reverse-payment settlements in the case of litigation. We can see this by considering settlement condition (1) $\pi_m - \pi_c > \frac{S - (1 - \lambda)L_B}{1 - \rho}$. Again, the left hand side of the equation

falls as π_c rises, making it harder for the brand firm to clear the inequality and offer the generic the needed reverse-payment settlement of S .

VIII. Policy Considerations

The potential for multiple generic firms to file ANDAs within a relatively short time frame, as discussed above, suggests an important policy question. If there is any possibility that at least some fraction of reverse payments are not harmful to consumers, then making such settlements *per se* illegal is not good policy. Instead, policymakers could consider how to better align incentives to encourage more generic firms to file paragraph IV ANDAs promptly. In other words, unless we are certain that every single reverse payment lowers consumer welfare, the logic presented above offers an alternative route to reducing potentially anticompetitive reverse payments—one that does not require inflexible legislation that

might eliminate some beneficial settlements and might erode important incentives to invest in pioneer drugs.

Little attention appears to have been paid to working with the incentives already in place for brand and generic firms, as compared to debating the rules regarding what settlements should and should not be allowed. I would therefore like to close this article with a suggestion: that scholars and policymakers spend time brainstorming on ways to further amend Hatch-Waxman to encourage multiple generic filers to come forth earlier in the process. They might also consider whether new incentives should be put in place for subsequent filers, after the first generic has paved the way, as a means of restricting first settlements. With additional thought devoted to these paths, we might find that restrictive *per se* legislation is not needed. ▼

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- 1 These settlement payments are referred to as “reverse” because the funds flow from the patent holder (the brand firm) to the would-be licensee (the generic firm), in reverse of the normal course of patent infringement suits where licensees pay patent holders to license valid patents.
 - 2 Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).
 - 3 Note that pharmaceuticals are unique in this regard. Pre-patent expiry challenges are relatively rare in other industries (outside of charging patent invalidity in response to infringement allegations). As explained below, they arise in pharmaceuticals as a result of the Hatch-Waxman Act, which in large part was aimed at increasing patent challenges in pharmaceutical markets. For a discussion of the details of Hatch-Waxman, see Thomas Cotter, *Refining the ‘Presumptive Illegality’ Approach to Settlements of patent Disputes Involving Reverse Payments*, 87 MINN. L. REV. 1789 (2003).
 - 4 Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407-408 (2003); see also C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) for a likeminded argument against reverse payments.
 - 5 See Concurring Statement of Commissioner Jon Leibowitz, *FTC v. Watson Pharmaceuticals et al.* (Feb. 2, 2009), available at <http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf>.
 - 6 FEDERAL TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002)*, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. The study notes that “only 2 percent of generic applications sought [pre-patent expiry entry], but from 1998 to 2000, approximately 20 percent of the generic applications sought entry prior to patent expiration.” at ii.
 - 7 See, e.g., Richard Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEGAL STUD. 399 (1973); Robert Cooter & Daniel Rubinfeld, *Economic Analysis of Legal Disputes and Their Resolution*, 27 J. ECON. LIT. 1067 (1989); Steven Shavell, *The Level of Litigation: Private Versus Social Optimality of Suit and of Settlement*, 19 INT’L REV. L. ECON. 99 (1999).
 - 8 *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (2003). Emphasis in original.
 - 9 Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessments of Patent Settlements in the Pharmaceutical Industry*, (2008) available at <http://www.compasslexecon.com/highlights/Documents/>

Economic_Assessment_of_Patent_Settlements_Dickey_Orszag_and_Tyson.pdf. See also, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L. J. 1033 (2004); and Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002).

- 10 See, e.g., Ken Letzler & Sonia Pfaffenroth, *Patent Settlement Legislation: Good Medicine or Wrong Prescription?*, 23 ANTITRUST 81 (2009).
- 11 See CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, (CBO 2006) available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>; Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL DECISION ECON. 469 (2007); and Joseph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).
- 12 Tufts Center for the Study of Drug Development, *Backgrounder: How New Drugs Move Throughout the Development and Approval Process*, Nov. 1, 2001 available at <http://csdd.tufts.edu/newsevents/recentnews.asp?newsid=4> (last visited September 10, 2009).
- 13 The brand firm may be concerned that its patent will be deemed invalid, which would then invite additional generic entry; or it may view its monopoly earnings on the pioneer drug as insufficient to warrant expensive patent enforcement litigation. We explore the drivers of this decision below.
- 14 I am assuming here only that $P_c < P_d$, thus the "competitive" market may in fact be an oligopoly.
- 15 See, e.g., Robert Cohen, *It's hard to beat generic—As drugs come off patent, major firms feel pinch*, THE STAR LEDGER, Mar. 9, 2008 (noting how major drug makers such as GlaxoSmithKline, Merck, Bristol Myers Squibb, Pfizer, and Sanofi-Aventis faced revenue losses from generic competition for blockbuster drugs); Val Brickates Kennedy, *Pfizer posts 18% drop in first-quarter profit; Pharma giant affirms 2008 financial outlook*, MarketWatch 10, Apr. 17, 2008 (noting an 18 percent drop in Pfizer's profits reflecting increased generic competition for top selling products such as Zyrtec and Lipitor); Peter Loftus, *Battle Over Merck Bone Drug Shows High Stakes Of Generics*, Dow Jones News Wires, Jan. 23, 2009 (noting that Merck stands to lose billions in revenue from generic competition for its drug Fosamax).
- 16 I am abstracting here from any brand name effects. In actuality, the pioneer firm may be able to maintain some price premium over the many generic competitors. Nevertheless, the fact remains that the brand firm's price will be significantly lower than the price it can command when it is the sole supplier of the drug, or even when it is a duopoly supplier with just one generic rival.
- 17 Chriss Schott, Jessica Fye, & Yuriy Prilutskiy, MERCK & CO., INC.: UPDATING MODEL POST GUIDANCE, 4 (J.P. Morgan North America Equity Research, Dec. 5, 2008); Ken Cacclatore et al., TEVA PHARMACEUTICAL: TEVA ABLE TO MANAGE THROUGH – REITERATE OUTPERFORM, 3 (Cowen & Company, Nov. 6, 2008); Ranbaxy, ANNUAL REPORT 2006,10; Ranbaxy, ANNUAL REPORT 2007, 16.
- 18 See *supra* note 15.
- 19 Based on market data for 40 branded drugs that faced generic competition between 1992 and 1998 in Atanu Saha et al., *Generic Competition in the U.S. Pharmaceutical Industry*, 13 INT'L J. ECON. BUS. 15 (2006).
- 20 See Jon Liebowitz, Chairman, Federal Trade Comm'n, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution), Address at the Center for American Progress (June 23, 2009), at 3-4, available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>. As noted above, this view has been challenged by those arguing that brand firms with strong patents are likely to win their infringement case and thus the settlement

saves litigation expenses and court resources without any negative impact on consumers. See *supra* note 10.

- 21 The possibility of a traditional settlement with license fees flowing from the generic firm to the brand firm is ignored here.
- 22 Even if the finding is that the patent is not infringed, the odds of additional generic entry should increase, as they can tailor their entry to not infringe as well.
- 23 See FEDERAL TRADE COMM'N, *supra* note 6.
- 24 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. §§101-1203 (2003).
- 25 Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd, 527 F.3d 1278, (2008).
- 26 Or the second filer may get a (generic) first mover advantage, which can be important in negotiating insurance provider deals. See Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFFAIRS 210 (2004) available at <http://content.healthaffairs.org/cgi/content/full/23/5/210> (noting how Barr Laboratories used its exclusivity period to contract with pharmacy benefits managers and large purchasers for its generic version of Prozac).
- 27 If there is some uncertainty as to whether a second generic will file, the second term on the right hand side can be weighted by a probability parameter. The general point remains, however, that a new term will be added to the settlement condition.
- 28 Observe that the probability that B wins its challenge against G² is written at ρ^2 in condition (2). It is likely, however, that the generic firms will not differ significantly in their planned production and sales of a generic version of the drug. If that is the case, the odds of winning the challenge hinge more on the strength of the patent and less on any particulars of the generic challenger. If the odds of winning are the same in each case, we can combine the two fractions so that:

$$\pi_m - \pi_c > \frac{S^1 - (1 - \lambda)L_B^1 + S^2 - L_B^2}{1 - \rho^1}.$$

Presumably, the litigation costs for the second case would be lower, being able to leverage work done for the first. However, these costs are for the full second trial as that case has not yet begun.

- 29 F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSPECTIVES, 97, 101 (1993); Jeffrey A. Dubin, *Empirical Studies in Applied Economics* 144 (Springer 2001).
- 30 See FEDERAL TRADE COMM'N, CONSUMER PROTECTION – FACTS FOR CONSUMERS, <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea06.shtm>.