Reverse Payments in Pharmaceutical Patent Disputes

Andrew Glidden

Reverse payment, uncharitably known as "pay for delay," is a practice resulting from the 1984 Hatch-Waxman Act. The Act attempted to encourage competition in the pharmaceutical market, primarily by reducing the barriers to entry then faced by generic drug manufacturers - principally patents and the New Drug Application (NDA) requirement. Hatch-Waxman created a new FDA approval process for generics and private incentives to challenge weak/invalid patents, thereby reducing unjustifiable rents accruing to brand-name manufacturers. This law, together with other reforms such as “generic substitution” laws, is widely credited with expanding the generic share of the pharmaceutical market from 19% to over 80% since its passage.

Under Hatch-Waxman, a generic manufacturer may file an "abbreviated new drug application" (ANDA), which would reference the brand-name manufacturer's research on the safety and efficacy of the drug rather than requiring the full FDA approval process used for new drugs. Hatch-Waxman requires that the ANDA filer certify that the relevant patents are soon to expire (or already have), that relevant patents have not been filed, or that controlling patents are either irrelevant or invalid; this last is known as Paragraph IV certification. Because Paragraph IV certification frequently involves expensive litigation, prospective competitors would face substantial first-mover *disadvantages*, as they pave the way for other competitors who are able to free-ride on the litigant’s efforts.

To overcome this limitation and encourage patent challenges and market entry, Hatch-Waxman grants the first Paragraph IV ANDA filer exclusive generic status for 180 days *after marketing* and prohibits the FDA from approving Paragraph IV ANDAs submitted by other firms during this period.

Subsequent litigation is generally resolved through settlement. It is in the interest of the brand-name firm to extend its patent monopoly and its attendant rents as long as possible. On the other hand, the generic firm benefits by entering the market as quickly as possible. Regardless of the entry date, both would prefer the patent be in force because this preserves the barriers faced by other firms. This partially shields both from full competition and allows the challenging generic firm to split rents with the brand-name firm beyond its 180 day exclusivity period.

The terms of the settlement usually entail authorization to enter the market (with or without royalty payments to the patent-holder), cross-licensing or other business arrangements, agreement by the brand-name manufacturer not to launch a competing generic, and payments by the brand-name to the generic.

The FTC is particularly concerned about this last settlement condition: if the patent is weak (and thus likely to be overturned), a payment from the brand-name to the challenger represents a possible payoff in exchange for pushing back the entry date. This would delay the partially-competitive duopoly scenario, thereby increasing the aggregate profits of the two firms and reducing the welfare of consumers, who must pay higher prices for brand-name drugs in the absence of a generic competitor. Thus, the FTC has been strongly advocating that settlements involving payments from patent-holders to their challengers be banned by statute, or be declared presumptively illegal by courts as anti-competitive arrangements in restraint of trade. The following assessment will examine the merits of the FTC’s claims and evaluate whether a ban on reverse payments is justified.

Assessment of FTC Estimate on the Welfare Cost of Reverse Payments

The FTC estimated the cost to consumers resulting from "pay for delay" at $3.5 billion annually. To arrive at this estimate, the FTC multiplied the expected consumer savings from generic competition, the market penetration of generics relative to brand-name drugs, the average difference in market entry delay between "reverse-payment" settlements and "standard" settlements, and a guess as to the percentage of litigation that would be settled with reverse payments in the future.

The FTC's estimate has many methodological flaws. Its cardinal sins are in implicitly assuming that the distribution of each of the factors involved is independent and taking the product-of-averages as the average-of-products. The averages of the four factors cannot simply be multiplied together. If the factors used in the FTC estimate are correlated, or any of the factors exhibits large variance, a radically different picture emerges. Unfortunately, the FTC has concealed the disaggregated information from the public, making it impossible to determine how each variable is distributed, and making their conclusions unverifiable at best.

The estimate arbitrarily assumes that the savings resulting from using generics instead of brand-name drugs are more or less uniform, and that market penetration of generics will also remain about constant. This is by no means the case. One would expect that drugs produced in relatively high quantities would experience the greatest decline in price after generic competition, because these would have a relatively low ratio of fixed to marginal costs and sufficient volume to split the market among multiple firms. In this case, the brand-name firm faces lower average fixed costs, and can tolerate some decline in price. Low-volume drugs, in contrast, face much higher average fixed costs. A brand-name firm may not be able to reduce its price substantially owing to these fixed costs. Also, because the absolute profitability of low-volume drugs will be lower than "blockbuster" drugs, generics will have little incentive to enter the market, especially considering the higher average fixed costs and the availability of alternatives for labor and capital. Low-volume drugs can thus be expected to have relatively small price declines in the face of generic competition, and less likelihood of generic penetration. By averaging across all drugs, the FTC inflates both the percentage savings and penetration resulting from generic competition for low-volume drugs. If reverse payments primarily involve low-volume drugs, the estimate will be inflated - and yet in *none* of the scenarios mentioned in the FTC report are the penetration/price differences varied to accommodate this issue, nor has the FTC provided sufficient information to judge the proportion of reverse payment cases involving low-volume drugs.

Even if the consumer savings resulting from market entry were uniform, they are likely to be overstated. This is because they are comparisons of the *list* price, and not the actual price, which is affected by factors such as rebates, free samples to medical doctors, and negotiations with insurance companies.

The FTC then estimates the difference in time to entry between standard and reverse-payment settlements. As they observe, over a 10 year period, 66 of 218 settlements included a cash transfer from the brand-name to the generic. The entry dates set in these settlements were, on average (and weighted for sales), 17 months longer. The FTC found that this result was statistically significant at the 1% level, writing, "...there is less than a 1% chance that this large a difference in average time to entry would be observed if the amount of delay from the two types of agreements were drawn from the same statistical distribution."

Of course the two types of agreements are not "drawn from the same statistical distribution". *Different drugs are different*. Could it be that reverse payments are used for some settlements because the drugs

involved vary on some critical dimension? The FTC is committing one of the greatest errors in statistics, conflating correlation and causation. Perhaps it is not the reverse payment responsible for the relative delay, but some other factor unique to the drug that justifies both delays and reverse payments. Perhaps the duration remaining on the challenged patent is significantly longer to begin with. This would justify both the apparent delay and a payment to the generic, which faces a high discount rate. Or perhaps the firm believes strongly that it would prevail in litigation, but recognizes the inherent danger involved by admitting even a small chance of failure where a critical patent is concerned. Patent litigation is notoriously unpredictable, and comes with high rates of reversal on appeal (the FTC estimate does not account for these reversals, thereby overstating the success rate of challenges and thus the "social" cost of settling). As if this risk were not enough, a brand-name firm can lose substantial market share and price control if it loses in district court and cedes ground to generic challengers, even if it ultimately prevails on appeal. A risk-averse firm may offer a reverse payment simply as a form of insurance (or less charitably, as a kind of "protection" fee). Alternatively, perhaps there is a causal link, but something about the drug justifies it, such as the brand-name's heavy investment in fixed R&D and plant costs, which demand the delay and the attendant rents to recoup - especially if low product volumes are involved. Reverse payments may well be correlated with delayed entry, but this fact by itself does not indicate that the purpose or effect of a reverse payment is to secure a delay.

The FTC report goes on to estimate the dollar value of the pharmaceutical market affected by reverse-payment settlements by multiplying the total market by both the percentage of drugs settled and the proportion of reverse payments settlements in recent years. Once again, the FTC has not accounted for the fact that different drugs have different sales volumes. The fact that 15% of *drugs* are settled does not imply that 15% of the *dollars* are as well.

Furthermore, it does not necessarily follow that this method can quantify the savings resulting from banning reverse payments. As the FTC notes, some settlements would simply not happen. Some cases would be litigated, which is a cost unto itself. This carries the possibility that the patent is in force for its full duration through an unsuccessful challenge that might have been settled. Other patents would never be challenged in the first place. And some patents wouldn't exist in the face of the risk of IP expropriation of this sort. Measuring the costs of reverse payments is not particularly meaningful unless it is done in relation to feasible alternatives, and the FTC has not presented such an alternative scenario.

There remain two other obvious flaws in the FTC analysis. First, it assumes that "purchasers discount future savings at the same rate as they expect drug prices and quantities to increase, [so] all future savings can be expressed in terms of today's dollars without complicated net present value calculations." Yet health care inflation has generally outpaced both inflation and the market as a whole. If market returns reflect consumer discount rates for savings, there is an obvious disparity that demands reconciliation before this assumption can be used. Moreover, "savings" is not a homogeneous quantity – it is composed of a variety of assets with varying levels of risk and return. The assumption that discount rates are equal to drug inflation costs is convenient, but ultimately unreasonable.

Finally, the FTC estimate takes the settlement history in the post-*Schering* era as a guideline for settlement rates in the industry. *Schering* is the case that asserted that reverse payments were *not* anticompetitive *per se*. Given that the majority of the increase in settlements occurred following *Schering*, it is wholly irrational to assume that this settlement rate would persist if new legislation declaring reverse payments illegal passes. It would be expected that the settlement rate would drop significantly by introducing the threat of anti-trust prosecution in the wake of a settlement.

Arguments in Opposition to a Ban on Reverse Payments

The burden of proof rests on those who would intervene in the market - that is, those who wish to see reverse payments declared illegal *per se*. This is because economic interactions are generally extremely complex, and outsiders often lack critical information that justifies non-standard arrangements. Well-intentioned interventions based on deficient information generally harm market participants. The burden of proof has not been met.

First and most generally, to ban reverse payment on the grounds of consumer welfare is to assume implicitly that the patent is invalid. How can the patent settlement be "anticompetitive" unless the patent was invalid? After all, the outcome of the suit would be that there are at least two competitors, compared to just one in the case where the patent holder prevails in court. There is a circularity of reasoning here: the courts are being told that they should strike down (presumptively valid) patents on the grounds that a challenger to the patent has dropped its suit!

Second, the FTC has not offered a reason explaining why the problem of reverse payments isn't worse than we observe. Why should the settlement set the generic entry date *before* the patent expiration date? If "pay for delay" indeed increases aggregate profits, extending the entry date as far out as possible can be part of a strategy that grants the generic greater returns than any other alternative: the patent holder need only pass on a share of the excess rents greater than the revenues the generic could have earned in the market. After all, Hatch-Waxman provides that:

> (I) Effectiveness of application.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

A consequence of the quoted statutory language above is that the exclusivity period can actually extend through the life of the patent, so long as the ANDA is filed under Paragraph IV certification (that is, as long as the ANDA is filed while the patent is in effect). So why has this never been observed? Is the FTC really saying that brand-name firms are clever enough to devise "pay for delay," but not clever enough to extend their monopoly privileges indefinitely through strategic interactions with generics? (It turns out that this would only have been an issue until 2003, when the Medicare Modernization Act added provisions for forfeiture of exclusivity, including the expiration of the patent and failure to market. Nevertheless, the absence of this type of strategic interaction prior to 2003 is relevant. Additionally, the more recent addition of forfeiture rules casts doubt on the magnitude of the delays in contemporary reverse payment settlements compared to standard cases.)

Third, if reverse payment is such a winning strategy, why isn't it *more* prevalent? The FTC has not offered an explanation as to why some settlements *do not* involve reverse payments. If the existence of reverse payments reflects some purpose - as it surely does, though not necessarily a nefarious one - then it stands to reason that the absence of reverse payments does as well. As noted above, advocates of a reverse payment ban presume that any delay increases aggregate profits, at the expense of consumers - so delays should *always* be in the interests of both firms. The fact that they are not pursued uniformly suggests that this is not the case. By extension, there must be some rational, legitimate purpose behind reverse payments.

Advocates of *per se* illegality have overstated their case. The argument that reverse payments should be presumptively illegal relies on the premise that these arrangements systematically extend brand-name exclusivity, yet the duration of brand-name exclusivity has been constant or declining. Generic market penetration is at an all-time high. Indeed, patents are being challenged earlier and more often than ever before. This is because challengers have substantial incentives to challenge, but face no risk of damage exposure and benefit from imperfections in the legal system that produce uneven outcomes in court. (Successful patent challenges are frequently overturned on appeal, and vice-versa.) This incentive structure has raised concerns that generic firms as a whole might be "prospecting," since it can be profitable to challenge a patent even with single-digit odds of prevailing in court. Far from casting doubt on reverse payments, this evidence suggests that there is an excess of patent challenges in the pharmaceutical industry, which would tend to weaken the effectiveness of IP protections. Overall, this would be expected to result in broader patent claims and reduce R&D investment both upstream (the brand-name's original research) and downstream (derivative research by others). Broader patents would also reduce the likelihood of successful litigation, thereby casting doubt on the FTC's estimate of the proportion of patents likely to be successfully challenged in future years.

As amici petitioners in *FTC v. Actavis* observe, the definition of "reverse payments" used by the FTC is expansive and indefensible ("a "reverse payment" settlement [is] any settlement that involves a component other than a negotiated entry date" that benefits the generic). Under this definition, the brand-name firm could not even offer to compensate the generic for its litigation costs! This definition extends even to cases where there are no net payments from the brand to the generic, and to patent challenges in other industries. For example, an agreement not to launch an Authorized Generic in competition with the challenging generic firm would qualify as a reverse payment, as perhaps it should: the brand's sacrifice of revenue to the generic is effectively the same as a cash transfer. But this agreement is essentially a reduced form of exclusive licensing arrangements, which are common in license agreements in many industries. What makes pharmaceutical companies uniquely unable to settle on these terms? Would this standard spill over into other industries? Nor has the FTC indicated whether generic firms paid royalties in exchange for this consideration. A true reverse payment must confer net value on the generic, and the FTC has not demonstrated that this is the case. It may not even be possible to demonstrate, because every settlement contains unique business arrangements of uncertain value to either firm, such as IP purchases, risk sharing, supply agreements, settlement of other litigation, etc. The amicus brief goes on:

> In total, between fiscal years 2004 and 2009, 88 percent of the settlements Petitioner characterized as "reverse payment" settlements were categorized as such because of contemporaneous business transactions (44 percent), agreements not to launch brand-authorized generics (38 percent), or both (three percent), or a payment that was less than tangible saved litigation expenses (three percent)...If these settlements had not been categorized as reverse payment settlements, only four percent of all settlements over this six year period, eight settlements in total, would have been categorized as reverse payment settlements.

The FTC's 2010 assessment of the consumer welfare costs of "pay for delay" *explicitly* approved of some of the practices it claims are illegitimate reverse payments. It appears the FTC is trying to have it both ways. This approach makes sense from a Public Choice perspective: the FTC is acting in a way that will maximize its discretionary authority. While this is to the advantage of FTC officials, it does not clearly benefit either firms or consumers because it adds an addition cost in the form of policy uncertainty.

The FTC estimate of consumer welfare losses stemming from reverse payments is shaky. There are substantial oversights and gaps in the assessment for every factor considered in the FTC report. The estimate assumes that each factor can simply be multiplied together, without considering that these factors might not be independent. Consequently, each factor is inflated, and this inflation is compounded in the final estimate by the action of arithmetic. The FTC also wrongly assumes that the settlement rate will remain constant despite the reintroduction of anti-trust threats by statutorily overturning *Schering*.

The FTC also overestimates the delays. Not all firms are immediately capable of taking advantage of patent challenge victories. Furthermore, under the Medicare Modernization Act, the exclusivity period is forfeited if the generic does not begin marketing within 75 days of the effective application approval date or 30 months after the application submission date. Even if reverse payments do result in longer delays to marketing, these delays cannot be arbitrarily long. Indeed, 30 months after filing is fairly minimal considering the time necessary to litigate, build or retool plants, form supply agreements, etc.

In addressing issues in industrial organization, it is imperative to adopt a *comparative institutional* view. Decisions about reverse payments do not come in a vacuum - they are bound to influence other aspects of business decisions. Even under the presumption that these agreements are costly by themselves, their existence may be a necessary cost to enable other, obviously beneficial arrangements. The FTC's central argument is that the delay of duopoly competition reduces the welfare of consumers by establishing a higher price for innovative drugs in the absence of a generic competitor. But it is not appropriate to use "competitive" pricing as the standard. Doing so assumes that generic competition is the norm - the nirvana fallacy. Monopoly rents will exist so long as a patent is in force. With this in mind, the option of reverse payment may be necessary to have the litigation (and subsequent settlement). If reverse payments are presumptively illegal, there would be no "pay for delay" scheme, but neither would there be a patent challenger, meaning that the realized patent duration – and its associated rents - extend longer than even a "pay for delay" case. The litigation and settlement can only reduce the price paid by consumers. Taking the generic price point as a reference point is inappropriate so long as patents are in play.

Reverse payments meet a need. As noted above, firms face asymmetric hazards in litigation; the brand is risk averse because it has substantially more to lose. Even with an extremely strong patent, it may opt to use a settlement involving reverse payment as a form of insurance against low-probability catastrophic loss. Generic companies also face high discount rates. The two firms' differing opinions as to the strength of the patent make settlement, aided by a reverse payment, possible. There are even some cases where the "exploitation" of consumers - charging above marginal cost - is *necessary* to recoup substantial fixed costs. Seen in this light, the proportion of reverse payments that could be argued as anti-competitive also enable critical R&D. This would almost certainly be the case for low-volume drugs that would otherwise be abandoned.

Presumptive illegality is bound to have significant negative consequences, whether implemented by courts or by statute. If implemented by courts, it would violate at least one significant rule of jurisprudence, namely that courts cannot take cases without a plaintiff with standing (a specific, judicially remediable harm). A prohibition on "pay for delay" would violate liberty of contract and put courts in a position of overturning voluntary agreements with no demonstrable victims – unless consumers are taken to be victims by being charged a higher price than they might like. But consumers will always prefer lower prices to higher ones, making this standard unworkable as a policy rule. The object of good policy is not necessarily to lower prices, but rather to establish conditions under which prices adequately account for

opportunity costs. In assessing whether it is appropriate to bring anti-trust law to bear, policymakers need to have *accurate* pricing, rather than *lower* pricing, as their standard.

The presumptive illegality of reverse payments is liable to chill R&D efforts, as innovative firms face increased risk of IP expropriation by generics. This is especially the case for pharmaceutical firms that have less diversification, such as start-ups. Consumers are far better off with expensive drugs than no drugs at all.

Expropriation risk is particularly present for low-volume drugs, which require prices substantially in excess of marginal cost to recoup high per-unit R&D and plant costs. Such firms may not be able to do so in the face of competition. The supposedly "excess" prices create strong incentives for generic entry. A ban on reverse payments could eviscerate the low-volume drug market. If low-volume drugs are especially susceptible to IP expropriation, firms will likely abandon research efforts on relatively rare diseases and disorders.

Presumptive illegality would also increase the risk of anti-trust persecution, chilling settlements and patent challenges more generally as businesses rearrange their affairs to avoid official attention. Assuming that these settlements are always and everywhere anti-competitive means foregoing cases in which they serve a useful, rational purpose.

In sum, the FTC has not adequately presented a case for intervention, and there is reason to believe that doing so will introduce more market inefficiencies and other problems than it solves.

Alternatives to a Ban

Despite all the above, one might still insist that these settlements reduce consumer welfare. If that is the case, it would be better to attack the root cause of the settlements rather than the content of the settlements directly. What the FTC is really concerned about, implicitly, is monopoly rents accruing to holders of invalid patents. Therefore, policy should aim not to restrict reverse payments, per se, but to minimize the impact of invalid patents. There are many avenues toward this end worth exploration.

Rather than ban the contents of some set of settlement agreements, the government could devote greater resources to the Patent Office to reduce the issuance of duplicative or otherwise invalid patents, or institute patent audits wherein outstanding patents are randomly (or deliberately) reviewed, and revoked if necessary. Or it could restrict or eliminate patents altogether. Many economists and legal scholars have concluded in recent years that the patent system actually discourages innovation, on balance. Others have argued that the value of patents is modest in relation to R&D costs, and that other mechanisms are more useful for IP protection. One might imagine that in the absence of patents, firms would expand these sorts of informal protections. They might create trade associations that would create and enforce private IP protections to make research investments feasible, or protect their discoveries as trade secrets, or otherwise find new ways of delivering their products in ways that are resistant to information leakage.

Alternatively, the government could rely on private enforcement of patent law based on the Hatch-Waxman Act. Nothing stops other generic firms from their own patent suits, except Hatch-Waxman. A modest reform could involve applying the stay on competing ANDA filings and patent litigation only to successful challenges, and not settlements. Under this system, a "pay for delay" scheme (or any settlement) would not deter other generics from their own suits, thereby substantially reducing the potential abuse of the "cork in the bottleneck" effect created by the 180-day exclusivity period. Weak

patents would collapse under the threat of constant litigation by multiple potential competitors. Hatch-Waxman could also be amended along the lines of the Medicare Modernization Act, expanding the set of conditions triggering exclusivity forfeiture.

In much more general terms, the government could also establish a new rule banning settlements of any kind once patent litigation begins. If the stakes of litigation are raised to all-or-nothing, both sides are encouraged to come to an agreement *prior* to the engagement of the courts. This would reduce caseloads, encourage cooperation, and *de facto* weaken wrongfully issued patents. Encouraging out-of-court remedies to the greatest extent possible will tend to reduce litigation costs and produce outcomes that are mutually satisfactory. Such a reform would also tend to reduce the use of courts as part of an overt threat display. (Of course, the threat of litigation is omnipresent, but this would relieve the courts from wasting time and effort on partially-evaluated cases whose only purpose is to signal the generics' insistence on market entry.) Because patent cases in particular have far-reaching consequences in terms of the number of firms and terms of competition in the market, both sides should be fully committed to their positions once a case reaches the courts, so that the best arguments and information come out (and thus conclusively validate or invalidate the patents in question). This could be enforced by requiring courts to render a decision, regardless of negotiations that may occur during litigation. However, this solution faces the hazard that the generic intentionally offer weak arguments to drive courts to rule in favor of the brand-name firm; this might be mitigated by courts adopting a loser-pays principle to increase the stakes for both sides and discourage generics from challenging patents to exploit “pay for delay” mechanisms.

Whatever remedy might be most appropriate to the problem of unwarranted rents accruing to patent holders, reverse payments have not been shown to be sufficiently problematic to warrant government intervention banning them, and doing so is likely to have significant deleterious consequences. The government should refrain from such a ban.