

An Empirical Approach To Reverse Payment Settlements

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For well over a decade, litigants and courts have hotly debated whether patent settlement agreements that involve a payment from the branded drug company to the generic accused infringer (so-called “reverse payment settlements”) violate the antitrust laws. From the standpoint of economics, a key issue is whether or not the branded drug company’s patent is valid, and has been infringed. If the generic manufacturer is infringing a valid patent, then under the patent laws, the branded drug company has the right to enforce its patent and exclude the potential generic entrant. However, if the branded drug company’s patent is invalid — or the generic manufacturer does not infringe the patent — then the branded drug company does not have this exclusionary right and a settlement containing a large reverse payment that both avoids an adverse decision on patent validity (and/or infringement) and induces the generic manufacturer to delay entry may be viewed as anti-competitive.[1]



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Thus, a key question that arises in a reverse payment settlement antitrust case is how best to assess whether the underlying patent was valid and infringed. Of course, these patent issues could be relitigated as part of the antitrust case. In *Federal Trade Commission v. Actavis*, however, Justice Stephen Breyer suggested an abbreviated approach to this question. In particular, he stated that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”[2] Subsequent decisions — including the California Supreme Court’s recent finding in *In re Cipro* — have expressed support for this abbreviated approach. Indeed, the California court put this view very succinctly when it wrote, “stronger patent, smaller settlement; weaker patent, bigger settlement.”[3]

We describe below a model that recognizes that the size of the settlement payment can provide useful information about patent validity, but amends this insight in an important way. We show that it is crucial to view reverse payment settlements not in absolute terms but in proportion to the branded drug company’s lost profits in the event of generic entry. While other studies have touched on this issue, we also provide simple numeric examples to show why reverse payment settlements can be large, even if the branded drug company believes that it is unlikely to lose its patent suit.[4] More generally, we show how our model can be used to calculate the branded drug company’s range of beliefs about the likelihood that it will lose its patent suit. We also explain how this calculated likelihood can be used to compute the expected duration of the patent, an analysis suggested in the *Cipro* decision.

Our model involves two firms: (1) firm B, which supplies a branded and patented pharmaceutical product, and (2) firm G, which proposes to offer a generic equivalent to the branded product that can potentially compete with the branded product. There is an open question as to whether G's product infringes B's patent.

Consequently, B sues G for patent infringement, preventing G from entering the market. B and G subsequently settle the issue, agreeing that G's product infringes and that G must refrain from marketing its generic version of B's drug.[5] In return, B provides G with some form of consideration. For the sake of simplicity, we will assume that the consideration paid is cash and refer to the settlement amount as S.

We refer to the present value of B's future profits in the absence of entry by G as $B^{\text{no entry}}$. Likewise, we refer to the present value of B's future profits with entry from G as B^{entry} . Because B will typically earn much greater profit without competition from G, we know that $B^{\text{no entry}}$ exceeds B^{entry} .

Next, we consider how much B can earn if G agrees to settle. In that case, B will earn the present value of its future profits with no entry, less the settlement amount.[6] Given our framework, B's payoff from settlement can be expressed as $B^{\text{no entry}} - S$.

Finally, we consider how much B can earn if it decides to litigate. If it litigates, B's earnings will depend critically on the probability that it will lose its patent suit, which we designate $\text{Pr}(\text{Loss})$. With this definition of $\text{Pr}(\text{Loss})$, the probability that B will win its patent suit is $1 - \text{Pr}(\text{Loss})$.[7] Given this framework, we know that:

If B loses in court, B will earn $\text{Pr}(\text{Loss}) * B^{\text{entry}}$.

If B wins in court, B will earn $(1 - \text{Pr}(\text{Loss})) * B^{\text{no entry}}$.

Since one of these two outcomes must take place, on average, B will earn the sum of these two values less its cost of litigation, C_B .[8] Thus, B's payoff from litigation is:

$$\text{Pr}(\text{Loss}) * B^{\text{entry}} + (1 - \text{Pr}(\text{Loss})) * B^{\text{no entry}} - C_B$$

Economic analysis tells us that B will prefer to settle rather than litigate as long as the payoff from settlement exceeds the expected payoff from litigation. The conditions under which B would prefer to settle are as follows:

$$B^{\text{no entry}} - S \geq \text{Pr}(\text{Loss}) * B^{\text{entry}} + (1 - \text{Pr}(\text{Loss})) * B^{\text{no entry}} - C_B$$

We rearrange this equation to identify a range for B's perceived $\text{Pr}(\text{Loss})$ that is consistent with the size of the settlement payment, S:

$$\text{Pr}(\text{Loss}) \geq (S - C_B) / (B^{\text{no entry}} - B^{\text{entry}})$$

This equation shows that if the difference between B's profits with and without entry is very large — as could be the case for a very successful branded drug — then a large settlement can be consistent with B's belief that it is unlikely to lose its patent suit. Thus, reverse payment settlements should not be viewed in absolute terms but in proportion to the extra profit that B protects through settlement. The greater this protected profit, the more likely it is that a settlement that appears large in absolute terms

will nonetheless be consistent with B's belief that its patent case is strong.

We can now use the equation above to calculate — on a case-by-case basis — B's range of beliefs regarding $\text{Pr}(\text{Loss})$. We can determine this range empirically, because each reverse payment settlement case will provide the data that is needed to compute $B^{\text{no entry}}$, B^{entry} and S , while C_B is easily estimated.[9] In addition, the model allows us to calculate $\text{Pr}(\text{Loss})^*$, which is the lower bound on this range of beliefs.

In Table 1 below, we perform these calculations, computing B's range of beliefs about $\text{Pr}(\text{Loss})$ under two different scenarios. In Scenario (1), the settlement payment is \$400 million, while in Scenario (2) the settlement payment is \$300 million. While both settlement payments are large in absolute terms, one might expect the \$400 million settlement to be more indicative of an agreement likely to have anti-competitive effects than the \$300 million settlement. However, our numerical example shows that the opposite is true.

In Scenario (1), we assume that B earns profits of approximately \$1.3 billion per year on its drug. With generic entry, we assume that B will earn about 16 percent of those profits for the next ten years.[10] Using a discount rate of 12 percent, we find that $B^{\text{no entry}}$ is about \$8.5 billion and B^{entry} is about \$1.4 billion. Assuming a litigation cost of \$10 million, our model shows that the \$400 million settlement payment is consistent with a minimum probability of loss ($\text{Pr}(\text{Loss})^*$) of 5 percent. Put differently, the \$400 million settlement offered by B is consistent with the expectation that B is 95 percent likely to prevail in its patent infringement suit. [11]

In Scenario (2), the settlement payment is lower (\$300 million) but the patent is also much less valuable than in Scenario (1). In Scenario (1), exclusivity provides B with 1.3 billion dollars in profits annually; in Scenario (2) exclusivity provides B with only \$58 million in annual profits. As in Scenario (1), we assume that under Scenario (2), B will earn 16 percent of its pre-entry profits if G enters. Using this information — along with the prior discount rate of 12 percent and litigation cost of \$10 million — we find that B's minimum probability of loss in Scenario (2) is greater than or equal to 95 percent.

The dramatic difference between B's beliefs about $\text{Pr}(\text{Loss})^*$ in Scenario (1) versus Scenario (2) is driven by the difference between B's profits with and without entry. In Scenario (1), this difference is over \$7 billion. While B may believe that it has a low probability of losing its patent suit, it has an incentive to pay G a \$400 million settlement — which appears large in absolute terms — because that amount is small in proportion to the amount that B stands to lose if G enters. In contrast, in Scenario (2), B's willingness to pay G a \$300 million settlement — almost all of the \$306 million profits that B stands to lose if G enters — indicates that it believes that it has a high probability of losing its patent suit.

Thus far, we have shown that we can infer B's beliefs about the likelihood that it will lose its patent suit from readily available data. Therefore a defendant could potentially use this model to demonstrate that its reverse payment settlement was consistent with the belief that its patent was strong. Further, these calculations could be used to aid courts in a Cipro-style analysis.

In its recent decision in the Cipro case, the California Supreme Court stated that in the case of a reverse payment settlement, the patent holder is only entitled to profits from exclusivity over the average expected duration of the patent, regardless of its beliefs about the strength of its patent (see e.g., In re Cipro at 149–50). Under such a rule, our computed probabilities could be used to determine that average expected duration. Suppose that the remaining patent term were ten years and that $\text{Pr}(\text{Loss})^*$ were 5 percent. In that case, there is a 5 percent likelihood that B's patent will be found invalid (or noninfringed) and a 95 percent likelihood that the reverse will apply. With these computed probabilities,

the average expected duration of the patent would be equal to 5 percent *0 + 95 percent *10 = 9.5 years.[12]

In conclusion, our model demonstrates that it is important to evaluate the settlement not in absolute terms but in proportion to the losses that the patent holder stands to incur from generic entry. We believe that use of this model will provide courts — and litigants — with an improved method for quantifying branded firms’ beliefs about patent strength and/or expected patent life in antitrust actions.

**Table 1: A Numeric Example Illustrating B’s Beliefs about the Probability of Loss
(Units: \$ in Million)**

Remaining Patent Life: 10 years			
Scenario		[1]	[2]
[a] Settlement Amount	S	\$400	\$300
[b] Branded Profits (no Entry)	$B^{\text{no entry}}$	\$8,543	\$364
[c] Branded Profits (w Entry)	B^{entry}	\$1,367	\$58
[d] Difference between [b] & [c]	$B^{\text{no entry}} - B^{\text{entry}}$	\$7,176	\$306
[e] Litigation Cost	C_B	\$10	\$10
[f] Branded belief about minimum likelihood of loss	$\text{Pr(Loss)}^* = \frac{S - C_B}{B^{\text{no entry}} - B^{\text{entry}}}$	5%	95%

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[1] This logic is discussed in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (U.S. 2013), both in Justice Breyer’s majority opinion, *id.* at 2230-31, and Chief Justice Roberts’ dissenting opinion, *id.* at 2240 and 2244 (Roberts, C.J., dissenting).

[2] *Id.* at 2236-37 (opinion of the court).

[3] *In re Cipro Cases I & II*, 61 Cal. 4th 116, 135 (2015).

[4] See, e.g., Edlin, Aaron et al. (2013) “Activating Actavis,” 28 *Antitrust* 16.

[5] Our model abstracts from many of the institutional details associated with Hatch Waxman patent challenges. However, these details are not pertinent to our primary conclusions.

[6] Note that B typically allows G to enter the market prior to the expiration of B’s patent. We abstract from this case in our simple model, but it is easily addressed by deducting B’s lost profits due to this

early entry from B's pay-off from settlement.

[7] For example, if the probability that the patent is invalid is .25, then the probability that the patent is valid is $1 - .25$ or .75.

[8] The expected value of a party's uncertain pay-off can be computed as the probability-weighted average of the various payment amounts it might receive. For example, if the probability that B's patent is invalid is .25, B's profit in the absence of entry () is \$100 million, and B's profit with entry is \$10 million, then on average B will earn $(.25 * 10) + (.75 * 100) = 2.5 + 75 = \77.5 million.

[9] As Roberts notes in his dissenting opinion, studies have found that in these kinds of disputes, average litigation costs are around \$10 million per suit. See Actavis at 2243-44 (Roberts, C.J., dissenting) and studies cited therein.

[10] The approximately 84% reduction in branded company profits due to entry corresponds with patterns observed in industry studies and academic research. See, e.g., Huckfeldt, Peter J. and Knittel, Christopher R. (2012) "Pharmaceutical Use Following Generic Entry: Paying Less and Buying Less," http://web.mit.edu/knittel/www/papers/hk_latest.pdf. Note that our present value calculations can be easily adjusted to allow the first generic entrant to enjoy a 6 month exclusivity period, during which both B and G enjoy higher profits.

[11] By focusing on $\text{Pr}(\text{Loss})^*$ —the smallest probability of loss that is consistent with the size of the settlement payment—we avoid the error of overstating this probability and identifying anti-competitive behavior where none exists.

[12] As noted previously, our test is focused on avoiding the error of overstating B's probability of loss. However, our model assumes that B is risk neutral. $\text{Pr}(\text{Loss})^*$ would be less than the 5% in this example if B were not risk neutral but risk averse—i.e., if B preferred a payment X that it received with certainty to an uncertain outcome with an expected value equal to X.

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