

“Reverse Payments” in Settlements of Patent Litigation: Schering-Plough, K-Dur, and the FTC (2005)

John P. Bigelow and
Robert D. Willig*

INTRODUCTION

In 2001, the FTC brought a monopolization case against Schering-Plough, Upsher-Smith Laboratories, and ESI Lederle (a subsidiary of American Home Products), challenging agreements that settled the lawsuits that Schering had filed against Upsher-Smith and ESI for allegedly infringing Schering's patent on its potassium chloride tablet, K-Dur 20. The FTC alleged that these agreements included so-called reverse payments from a patent holder to an accused patent-infringer as part of a deal between them to settle the patent litigation.¹

It was the view of the FTC that such reverse payments are a sure sign that the settlements were anticompetitive restraints of trade because, according to the FTC, they inherently buy protection for the patent holder against competition from the possible entry of the alleged infringer. The defendants argued that the only true reverse payments were directed by the judge in one of the patent cases, that reverse payments may be necessary to achieve socially beneficial settlements of patent litigation, and that there

*The authors served as consultants to Schering-Plough, and Willig gave expert testimony on behalf of Schering-Plough in the case described here.

¹FTC (2001a). Such payments are called “reverse payments” by those who are suspicious of them because they believe that the “natural” direction in which payments should flow in settling patent infringement litigation is from the alleged-infringer/defendant to the patentee/plaintiff, rather than the other way around.

was no showing by the FTC that competition was diminished by the patent settlements.

Over a period of more than five years the case wended its way before an FTC administrative law judge (ALJ), before the full Federal Trade Commission, and into the Eleventh Circuit Court of Appeals, prior finally to being considered for hearing by the Supreme Court. In 2005, when the Supreme Court declined to hear the case, the legal processes were exhausted, and Schering-Plough had prevailed over the FTC; but it was by no means clear that the substantive general issues raised by the case had been resolved.

BACKGROUND

The case arose in the context of competition between generic and brand name pharmaceuticals, a setting with specific institutional and regulatory features that are relevant to this case.² When a pharmaceutical company has developed a new drug, it will generally patent the drug or its formulation or both. Before the drug can be marketed, the Food and Drug Administration (FDA) must be satisfied that it is safe and effective. To demonstrate safety and efficacy, the manufacturer submits a New Drug Application (NDA) to the FDA describing the results of the drug's clinical tests, its ingredients, the results of animal studies, the behavior of the drug in the body, and the drug's manufacturing and packaging. Upon approval of the NDA by the FDA, the manufacturer can begin selling the drug.

Generic drug manufacturers can, in effect, "piggy-back" on the NDA process. The manufacturer of a generic drug can rely on the safety and effectiveness conclusions of the NDA and need submit only an Abbreviated New Drug Application (ANDA), which provides the FDA with sufficient data to determine the generic's bioequivalence (i.e., the ability to deliver the same amount of the drug into a patient's bloodstream in the same amount of time) to an already approved drug. An ANDA generally does not need to include data from new animal and clinical studies.

The ANDA process was created by the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act, which both eased the process whereby generic drugs could win FDA approval and restored some of the patent life lost to manufacturers of new drugs during the drug approval process. This act established how the interaction should operate between manufacturers of brand name drugs, who generally hold patents, and the manufacturers of generic drugs. NDA filers must identify all the patents that they hold that pertain to their product. These are included in the drug's listing in the FDA "Orange Book," which is a list of all FDA-approved drugs.

²For authoritative descriptions of the regulatory context, see FDA (2007a and 2007b).

When a generic drug manufacturer files an ANDA, it must certify “(I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (IV) that the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval.”³ The last type of **certification** (“paragraph IV”) gives rise to the kind of patent litigation involved in this case. The certification must include the ANDA filer’s rationale for believing that the patent is invalid and is supplied not only to the FDA but also to the patent holder. The patent holder has forty-five days in which to file a patent infringement suit against the ANDA filer, and if the patent holder does so, then approval of the ANDA is stayed for thirty months or until either the patent expires or a final determination is made that the patent is invalid or not infringed. The first paragraph IV ANDA filer is allowed a period of 180 days of generic exclusivity, during which additional ANDAs will not be approved. The 180 days run from the first day that the generic is marketed, the patent expires, is found to be invalid, or is found not to be infringed by the ANDA.

The product at the center of the case was Schering-Plough’s sustained-release potassium chloride tablet that is sold under the trade name K-Dur 20.⁴ It is taken to treat potassium deficiency, a common condition for the many patients taking medicine for high blood pressure. K-Dur 20 tablets were the most convenient form of the needed treatment and maximized patient compliance with doctors’ orders. Annual sales of K-Dur 20 tablets were greater than \$200 million at their peak. At the time that the case was brought, Schering held a patent (the “743 patent,” as shorthand for Patent No. 4863743), expiring in September 2006, on the specific coating of K-Dur 20 that slowly releases the potassium chloride over time, making it a sustained-release product.

In 1995, Upsher-Smith Laboratories filed an ANDA for a generic version of K-Dur 20. As the first paragraph IV ANDA filer, Upsher-Smith would be entitled to the 180-day generic exclusivity period. Schering sued Upsher for infringing the 743 patent, and in June of 1997, just before trial was set to begin, the parties reached a settlement. Under the terms of the settlement, Upsher received a royalty-free license to market its generic product beginning in September 2001. Schering licensed five products, including Niacor SR, a sustained-release niacin product, from Upsher for which it paid royalties of \$60 million.

³The details of this certification process and a view of its impacts are well summarized in FTC (2002b), pp. 5–7.

⁴There is substantial agreement among the parties concerning the basic facts in the context of the case that are summarized here. For the details, see FTC (2001b) and Schering-Plough Corporation (2001a and 2001b).

ESI-Lederle, a subsidiary of American Home Products, also filed a paragraph IV ANDA for a generic version of K-Dur 20 in 1995. Schering sued ESI for infringing the 743 patent, and the district court judge placed the parties under the supervision of a magistrate judge to work toward a settlement. Under the magistrate's encouragement a settlement was reached in January 1998 that allowed ESI to begin marketing its product in January 2004. ESI received \$5 million from Schering initially and an additional \$10 million that was contingent on ESI's receiving tentative approval of its product from the FDA by June 30, 1999.⁵ Additionally, Schering paid \$15 million to license two unrelated products from ESI.

The FTC's Complaint Counsel (CC), the lawyers from the FTC who act as plaintiffs arguing the case against the respondents (defendants), formulated the complaint. They charged that both agreements unreasonably restrained trade, that Schering had attempted to monopolize the market for potassium chloride supplements, and that Schering had conspired with Upsher-Smith and ESI to monopolize the market. The payments from Schering-Plough to the other two firms occupied center stage in the complaint's allegations: "By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher-Smith nor ESI would have agreed to delay its entry for so long."⁶

As the case subsequently developed, three complex issues in law and economics were at its center:

1. Is a settlement of a patent infringement case that embodies a reverse payment intrinsically anticompetitive? What might be pro-competitive reasons for reverse payments? Should reverse payments be subject to a *per se* rule or to rule-of-reason treatment?
2. Is it impossible or prohibitively expensive for an antitrust inquiry to evaluate the likelihood of the parties' prevailing in the underlying patent litigation?
3. What is the appropriate standard to use in evaluating whether or not the outcome of a settlement of a patent infringement case is or is not anticompetitive?

The three questions are related, especially from the perspective of a policymaker. If the right way to determine if a settlement is anticompetitive is to compare the outcome of the settlement with the expected outcome of the underlying litigation, then one would need to assess the likelihood of

⁵Tentative approval is given to ANDA filers when the requirements for approval are met, but final approval is stayed because of a patent.

⁶Federal Trade Commission (2001a), para. 64.

alternative outcomes of that litigation to reach a conclusion about the settlement. If that is impossible or impractical, a short-cut rule such as a blanket condemnation of settlements with reverse payments may seem attractive. But such a per se rule might be a significant impediment to settlements of patent litigation, and there is a general view that litigation settlements are socially efficient in that they conserve scarce judicial resources, save on substantial litigation costs, and eliminate otherwise unnecessary risk-bearing by the litigants.

Further, it may be the case that reverse payments can enable pro-competitive settlements of patent litigation with sufficient frequency that per se condemnation of them would cost society more than it would gain by cutting off those settlements with reverse payments that are truly anticompetitive. Thus, it may be the case that a rule-of-reason approach would be best, wherein a weighing of factors, perhaps including the size of the reverse payment, would be permitted to decide the matter on a case-by-case basis.

In what follows, we trace the history of this case, the arguments made, and the conclusions drawn with respect to these fundamental issues.⁷

THE TRIAL

The case was first tried before an administrative law judge (ALJ) within the FTC. That trial commenced on January 23, 2002, and ended on March 28, 2002. It filled 8629 pages of transcript, with forty-one witnesses testifying and thousands of exhibits admitted into evidence. Closing arguments were heard on May 1, 2002.⁸

Reverse Payments

Entry, Litigation, and Expected Entry

While the economists who testified disagreed in their conclusions about the competitiveness of reverse payments, there were aspects of their analyses upon which they agreed. The economists for both sides viewed the patent litigation as an event with a random outcome. With some probability the incumbent/patentee would win, and entry would not take place until the end of the life of the patent; and with some probability the entrant/generic manufacturer would win, and entry would take place sooner.

⁷These issues have engendered a significant outpouring of professional literature. For a more complete and technical articulation of our views, see Willig and Bigelow (2004). For a focus on the social benefits of settlements, see Langenfeld and Li (2003). For a more comprehensive bibliography on the instant issues, see Cotter (2004). For application of some rigorous economic tools to these issues in a delimited setting, see Shapiro (2003).

⁸FTC (2002c), p. 158a.

The economists for both sides compared the date upon which the settlement agreement called for entry with the expected date of entry pursuant to the litigation. The latter is an entry date that would be realized if the life of the patent after the litigation was concluded were divided proportionally to the probabilities of the parties' prevailing in the litigation.⁹ For example, suppose that the remaining life of the patent is twelve years, the course of the litigation will consume two years, and that the probability is 60 percent that the incumbent would win the patent litigation. Eight years from now is the time of entry that would be consistent with two years of exclusivity during litigation and a 60 percent chance of continuing exclusivity for the remaining ten years of the patent's life. The four years of nonexclusivity under the settlement are consistent with the entrant's 40 percent chance of being permitted to compete for ten years following the two years of litigation.

If the demand for the product and the cost of producing it do not change throughout the life of the patent, if the parties were risk neutral, if the parties did not discount the future, and if the litigation were costless, then each of the parties would be indifferent between the litigation and a settlement that provided for entry on the expected date of entry under litigation. To the extent that the parties are risk averse or the litigation is costly, then each of the parties would prefer a settlement with an entry date somewhat less favorable than the expected date of entry under litigation; that is, the incumbent would be willing to accept an earlier date, and the entrant would be willing to accept a later date, to the litigation itself. Likewise, if consumers are risk neutral, any settlement with an entry date before the expected date of entry under litigation is better for consumers than the litigation. If consumers are risk averse, then even some settlement dates after the expected date of entry under litigation are preferred.

Complaint Counsel's Case against Reverse Payments

In order to make its case that Schering had made reverse payments to the two generic manufacturers in exchange for entry delay, CC first had to identify the reverse payments. In the ESI settlement, CC identified the \$5 million initial payment and the \$10 million payment that was contingent on ESI's winning approval from the FDA, drawing special attention to the fact that the later that ESI (AHP) had an approvable product, the less money it would receive. In the Upsher-Smith settlement, CC argued that the \$60 million payment was not a bona fide license fee and was, instead, a payment for delay. In support of this contention, CC argued that the \$60 million payment to Upsher-Smith was "anomalous" in that it was noncontingent (i.e., not tied to performance on Upsher-Smith's part), excessive relative to

⁹More formally, the expected entry date is, in the language of probability, an expected value. Under litigation, the date of generic entry is a random variable. The expected date of entry is the sum of the products of the possible entry dates and their respective probabilities.

payments that Schering made for other licenses, and unsupported by Schering's customary level of due diligence. CC also observed that Schering did not follow up by attempting to obtain regulatory approval for Niacor SR or begin work on manufacturing and marketing the product.

Turning to the economics of reverse payments, CC introduced an economist expert witness who argued as a matter of economic theory that a settlement with a reverse payment must be anticompetitive. The argument rested on two legs. First, he argued (in his expert report) that when confronted with the opportunity to strike an anticompetitive agreement, the firms would necessarily do so. He argued that if it were possible for the incumbent firm to make a payment to the entrant, the firms would never agree to a settlement that provided consumers with the same expected competition as litigation. To do so, he argued would, in effect, be to "leave money on the table."

Second, he analyzed the role of reverse payments in the context of a simple model of the bargain between the incumbent/patentee and the entrant/generic. The assumed structure of that model included only the potential gains to the two firms from the extension of monopoly power and the redistributive (as between the two firms) capacity of payments from firm to firm. In the context of that model he concluded in his report that if the payment received by the entrant is essential to the entrant's being willing to agree to a settlement, then the settlement must reduce competition, and the payment must be compensation for the profits that the entrant forgoes by agreeing to a shorter period of competition. In effect, he argued that the only reason that the incumbent would be willing to pay the entrant would be in exchange for delayed entry, and the only reason that the entrant would be willing to delay entry would be in exchange for a payment.

These summarized arguments can be made clearer in the context of a basic economic model of the parties' incentives to settle a patent case.¹⁰ The two firms are the incumbent (firm I) and the would-be entrant (firm E). The potential economic life of the patent runs from the current time, $t = 0$ through $t = \theta > 0$. The rate of profit of the incumbent as long as it is a monopoly is α per unit of time. The rate of profit of the incumbent as a duopolist after the would-be entrant actually does enter is given by β_I . The rate of profit of the entrant is 0 before it enters and is β_E per unit of time after it enters. Let p , where $0 < p < 1$, be the probability that the incumbent wins the litigation, and let $C_I > 0$ and $C_E > 0$ be the costs of litigation to the incumbent and the entrant, respectively. These represent the expected cash costs of the litigation plus the impacts of the risks of the litigation due to any risk aversion on the part of the litigants, expressed in money terms as risk premiums.

¹⁰For a classic reference on the incentives for litigation settlement, see Priest and Klein (1984). The development in the text is similar to that employed by both parties' economic experts.

Case 9: "Reverse Payments" in Settlements of Patent Litigation

Thus, the expected payoffs (profits) to the incumbent and the entrant from litigation are, respectively,

$$\bar{Y}^I(\theta) = p\alpha\theta + (1-p)\beta_I\theta - C_I \quad \text{and}$$

$$\bar{Y}^E(\theta) = (1-p)\beta_E\theta - C_E.$$

Let t denote the agreed-upon date of entry, at some point between the current time (0) and the end of the potential economic life of the patent (θ), pursuant to a settlement, and suppose that the incumbent firm makes a net transfer ("reverse") payment of B to the entrant. The expected payoffs (profits) to the two firms under such an agreement are

$$Y^I(t, B|\theta) = \alpha t + (\theta - t)\beta_I - B = \theta\beta_I + (\alpha - \beta_I)t - B \quad \text{and}$$

$$Y^E(t, B|\theta) = (\theta - t)\beta_E + B.$$

A settlement involving the agreed-upon date of entry t , together with the reverse payment B , will be acceptable to both parties if, for each of them, the expected payoff under the settlement is greater or equal to the payoff from litigation. Thus, with a rearrangement of the resulting inequalities to focus on t , a settlement is acceptable to both parties if the following holds:

$$p\theta + \frac{B - C_I}{\alpha - \beta_I} \leq t \leq p\theta + \frac{B + C_E}{\beta_E}.$$

It is key to recognize that $\alpha > \beta_I + \beta_E$. This inequality expresses the likely fact that the flow of monopoly profits to the incumbent when it is the only seller of the product at issue is greater than the sum of the flows of the profits to both the incumbent and the entrant when they are competing as duopolists selling the product. This is generally true inasmuch as the monopolist chooses its output level and price to maximize profit, while the duopolists are in part driven in their decisions by their competition against each other, which tends to lower profits even as it likely benefits consumers of the product.

In this typical circumstance, there is a range of values of t that enables settlement on mutually beneficial terms, since with $\alpha - \beta_I > \beta_E$ the left-hand side of the inequality must be less than the right-hand side. Without any reverse payments, $B = 0$, and there will be mutually agreeable entry dates t so long as there are costs of litigation and risk aversion. In fact, with positive litigation costs there will be mutually acceptable settlements that entail entry at an earlier date than $p\theta$, which is the expected date of entry under litigation. There will also be later entry dates that are mutually agreeable.

However, with reverse payments, as B is positive and continues to grow bigger, the dates t that are mutually acceptable grow larger also, signifying

increasingly later entry and more time of monopoly over the product. The intuition is that a later entry date t substitutes more monopoly time for more duopoly time and thereby creates a larger total flow of profits. This result is again due to the key relationship that $\alpha > \beta_I + \beta_E$. The incumbent can share the greater flow of profit with the entrant by means of the reverse payment; and, while the parties are better off, consumers are worse off due to the suppression of competition. In the limit, the entry date can be pushed back to the end of the patent's useful life, θ , and an appropriate reverse payment can make both incumbent and entrant better off than they would have been with litigation. This profit-maximizing arrangement eliminates any possibility of competition and so is both best for the parties and worst for consumers.

In essence, it is this set of analytic arguments that was articulated in the economic testimony of the expert engaged by CC, and it was the logical underpinning of the case brought by CC against Schering-Plough. Moreover, these arguments underlie the FTC's decision to attack reverse payments on a per se or presumptive basis. In the basic model just presented, no good can come from reverse payments because they are not necessary to encourage settlements, they move settlements only in the one direction that suppresses competition; and it is most profitable for the patent litigants to employ reverse payments to eliminate as much competition as they can.

Respondents' Case in Favor of Reverse Payments

Schering's expert witness disagreed with these conclusions as a matter of economic theory. Schering's expert argued that CC's expert had gotten the economics of reverse payments wrong by employing an economic model that was too simple—in effect assuming away the features that give rise to the pro-competitive features of reverse payments. The gist of the critique was that by using a model in which entry delay and monetary payments were the only two aspects of the settlement available to the parties to bargain over, one inevitably emerged as a quid pro quo for the other. By contrast, in a richer and more realistic model, payments from the incumbent to the entrant can be consistent with pro-competitive settlements. For example, litigation is costly, and a settlement (if it doesn't lead to antitrust litigation) is not. An incumbent who is risk averse would be willing to pay to avoid risk. So, a risk-averse incumbent would gain by paying an entrant to agree to a settlement that called for entry on the expected date of entry under litigation.

More importantly, Schering's expert identified circumstances under which reverse payments are essential to achieving pro-competitive settlements. Under such circumstances, by using reverse payments the parties would be able to achieve mutually beneficial settlements that were better for consumers than litigation would have been. If the parties were forbidden to use reverse payments, then no settlement would be possible. These

situations were all excluded by the excessively simple model articulated above but are all quite intuitive and plausible. They are explained in the subsections that follow.

Differences in Discount Rates: Cash-Strapped Entrant

If the entrant firm has a general need for early cash but is unable to secure enough new credit from financial markets, it will discount the future very substantially relative to the present—probably much more so than does the incumbent firm. Litigation yields some positive probability of early cash flow resulting from a win in court, and such a firm would agree only to a settlement with entry at a very early date. However, such an early date would be unacceptable to an incumbent that had a lower discount rate and that believed it had a substantial probability of prevailing in the litigation. Absent the ability to use reverse payments, these two firms will be unable to agree on a settlement, and the (costly) litigation will inescapably proceed. However, the parties could agree on a mutually beneficial settlement with entry before the expected date of entry under litigation if the incumbent were risk averse and was able to make a reverse payment to the entrant to satisfy the latter's need for immediate cash. Both firms and consumers gain from this settlement.

Information Asymmetry

In many cases the incumbent will know more about the value of the market than does the entrant. For example, the incumbent, because it is involved in research and development, may know more about which drugs that could potentially displace the current product are in the pipeline. The rational entrant, knowing that the incumbent has this information that the entrant does not have, must interpret the incumbent's actions with a view toward the inferences that may be drawn from them about the incumbent's information.

Such a process of inference can cause settlement negotiations to break down. The phenomenon at work here is a familiar one. If I offer to sell a late-model used car for an exceptionally low price, the wary buyer's first reaction is likely to be, "What's wrong with it?" The prospective buyer, knowing that I have information about the condition of the car, reasons that I ought not to be willing to sell a high-value car for a very low price, interprets my willingness to sell the car as an indication that it is of low value, and may decline to buy the car.¹¹

To see the consequences of this process in the context of patent litigation settlement, suppose that the value of the patent is either high or low and

¹¹This is the familiar "lemons" or adverse selection problem; see, e.g., Akerlof (1970).

that the incumbent knows which it is, but the entrant does not. Also suppose that when the value of the patent is low, the cost of litigation is too high relative to the value of the patent for litigation to be worthwhile to the incumbent, so if a settlement is not reached the incumbent will concede the result of the lawsuit to the entrant.

Suppose initially that the parties are not permitted to employ a reverse payment in a settlement. A settlement may be impossible. In this setting the incumbent who knows that the value of the patent is low will agree to any settlement that would be acceptable when the value of the patent is high. In other words, there are only two possible types of settlements: those that both types of incumbents will participate in and those that only the low type of incumbent will participate in.

If the entrant expects the former, then it will evaluate possible entry dates on the basis of the probabilities it attaches to confronting a high or low type incumbent. In other words, the entrant must hedge the entry date to which it will agree to take into account the possibility that the value of the patent is low. That assessment may leave the entrant unwilling to agree to an entry date late enough to be acceptable to an incumbent that knows that the value of the patent is high. In that case, there can be no settlement involving both high and low type incumbents. On the other hand, if the entrant expects that the only incumbent that will agree to a settlement is an incumbent that knows that the value of the patent is low, then the entrant has no incentive to agree to a settlement. An incumbent that knows that the value of the patent is low will concede the litigation, allowing the entrant to enter right away. In these circumstances, therefore, no settlement without a reverse payment is possible.

On the other hand, if reverse payments are possible, then an incumbent that knows that the value of the patent is high will be willing to make a cash payment to an entrant in connection with a settlement that saves the incumbent its costs of litigation. The willingness of the incumbent to make a payment to the entrant signals credibly to the entrant that the incumbent knows that the value of the patent is high because an incumbent that knew that the value was low would be unwilling to make such a payment. With this information in hand, the parties can reach an agreement that is mutually beneficial and calls for entry before the expected entry date under litigation, thereby making it beneficial to consumers as well.

A numerical example may help to shed light on this circumstance: The incumbent has private knowledge of the useful life of the patent, and the entrant is aware of that and believes that the life is either six years with probability 0.33, or one year with probability 0.67 (after which entry by producers of similar drugs renders the patent valueless). The flow of monopoly profit is \$3 per year, and the flow of profits to either duopolist is just \$1 (and it is \$0 if the patent is valueless). The patent litigation would go to the incumbent or the entrant with probability 0.5, but the incumbent faces litigation costs of \$3, while the entrant faces no litigation costs at all.

Under these assumptions, if the incumbent knew that the patent were weak with just a one-year life, it would not be willing to litigate in view of its litigation costs, since its return from one year as a duopolist would be \$1, while its expected return from litigation would be $(0.5)(\$3) + (0.5)(\$1) - \$3 < 0$. On the other hand, if the incumbent knew that the patent were strong with a six-year life, it would be willing to settle without any reverse payments only if the agreed entry date were at or later than 1.5 years (since profit from litigation = $(0.5)(\$3)(6) + (0.5)(\$1)(6) - \$3 = \9 = profit from settlement = $(1.5)(\$3) + (4.5)(\$1)$).

However, the entrant will not accept a settlement offer of entry rights at 1.5 years or later. Recall that the entrant thinks that with probability 0.67 the patent is weak and that with probability 0.33 the patent is strong. Consequently, agreeing to a settlement with entry rights at 1.5 years out would yield the entrant in expected profits $(0.33)(6 - 1.5)(\$1) + (0.67)(0) = \1.5 . Here, litigation would yield the entrant $(0.33)((0.5)(6)(\$1) + (0.5)(0)) + (.67)(\$1) = \$1.67$, since the incumbent will not contest the litigation when the patent is weak (and the entrant knows this). Thus, there is no settlement without reverse payments in the situation where the incumbent has private information that the patent is strong because the entrant is worried that the patent is really weak and the settlement would be worthless in that event.

Here a reverse payment can serve as a credible signal to the entrant that the patent is really strong and thus break the impasse that would otherwise make a settlement impossible. Consider the settlement that the incumbent would offer if the patent were strong—with entry allowed after 2.75 years and a reverse payment of \$2.25. On seeing this offer, the entrant would infer that the patent must be strong since if the patent were weak, the incumbent's return from the offer would be one year of monopoly profit of \$3, less the reverse payment of \$2.25, which is less than what the incumbent would make by ceding the patent litigation and earning one year of duopoly profit of \$1.

With the inferred knowledge that the patent is strong, the entrant would accept the offer. This follows because the settlement would earn the entrant $(6 - 2.75)(\$1) + \$2.25 = \$5.5$, while litigating would earn $(0.5)(6)(\$1) + (.5)(0) = \3 . And the incumbent, knowing that the patent is strong, would prefer the settlement to litigation, since the settlement would earn it $(2.75)(\$3) + (6 - 2.75)(\$1) - \$2.25 = \9.25 , while litigation would return $(0.5)(6)(\$3) + (0.5)(6)(\$1) - \$3 = \9 .

In this example of a simple instance of asymmetric information, the employment of reverse payments makes a settlement possible where it would otherwise be impossible. Here, as in a rich set of other such examples, among the settlements made possible are Pareto improvements over anything that can be attained without reverse payments since the agreed entry date is earlier than the expected date under litigation. (In this example the expected date of entry under litigation is three years, while the date

of entry under the settlement is 2.75 years, all given that the patent is strong. If the patent is weak, then there will be no settlement and a duopoly for one year.)

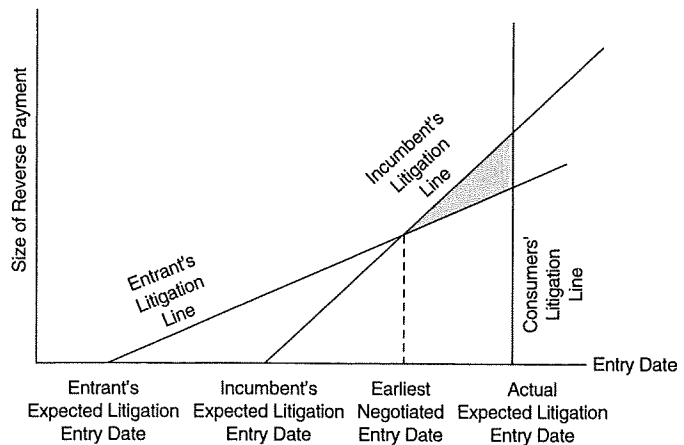
Varied Assessments of Success: Overoptimism

A third set of circumstances under which reverse payments may be essential to pro-competitive settlements arises when the parties to the litigation hold different assessments of their chances of success. When the probability that the incumbent believes it will prevail and the probability that the entrant believes it will prevail sum to more than 100 percent, the incumbent's estimate of when the expected date of entry under litigation will occur will be later than the entrant's estimate. Under these circumstances it may be impossible for the parties to agree on a settlement entry date that is compatible with their respective expectations.

However, if reverse payments are permitted, negotiations become easier. This conclusion may be seen in a simple diagram. Consider Figure 9-1, in which the entry date in the settlement is measured on the horizontal axis, and the size of the reverse payment is measured along the vertical axis. The points on the diagram represent different possible settlements. If no reverse payments are allowed, then the only possible settlements are on the horizontal axis.

On the assumption that the firms are risk neutral and there are no litigation costs, continuing the litigation is equivalent to a settlement with no reverse payment and entry at the expected date of entry under litigation. If the parties vary in their assessment of success in the manner described above, then the incumbent's expected litigation entry date is later than the entrant's. These points are plotted on the horizontal axis.

FIGURE 9-1 Settlement with Varied Assessment of Success



We draw an indifference curve through the expected entry litigation entry date showing all the combinations of entry dates and reverse payments that are indifferent to the litigation for each firm. Both lines slope upward. The line for the incumbent slopes upward because a later entry date is needed to compensate the incumbent for making a larger reverse payment, and the line for the entrant slopes upward because the entrant is willing to accept a later entry date if it receives a larger reverse payment. The incumbent's line slopes up faster because each month of delay is worth more to the incumbent than it is to the entrant. Each additional month's delay brings the incumbent an increase in profit equal to the difference between monopoly profit and one firm's duopoly profit. Each additional month's delay costs the entrant one firm's duopoly profit. Since monopoly profit exceeds the sum of both firm's duopoly profits, the former is larger than the latter.

The incumbent would be willing to agree to any settlement on or below the incumbent's indifference curve (labeled "Incumbent's Litigation Line" in the diagram). The entrant would be willing to agree to any settlement on or above the entrant's indifference curve (labeled "Entrant's Litigation Line" in the diagram). Any settlement below the incumbent's line and above the entrant's line is agreeable to both firms. The fact that there are no mutually agreeable settlements on the horizontal axis reflects the impossibility of a settlement without a reverse payment.

The diagram also shows the actual expected litigation entry date. That expected entry date is based on the actual probabilities of the firms' prevailing, which may be different from the perceptions of either firm. On the assumption that consumers are also risk neutral, their indifference curve is a vertical line. The vertical line starting at the actual expected litigation entry date shows all the settlements that are indifferent to litigation for consumers. Consumers prefer settlements to the left of that line. When, as illustrated in Figure 9-1, the actual expected entry date occurs after the expected litigation dates of the two firms, there can be settlements, like those shown in the shaded region of the diagram, that are mutually agreeable to the two firms and are preferred to litigation by consumers. None of these settlements is possible without reverse payments.

Other Circumstances

The foregoing are three examples of circumstances under which reverse payments can enable the parties to achieve mutually agreeable settlements that are beneficial to consumers and are not possible without reverse payments. In addition to these, Schering's economist also described additional examples in circumstances of follow-on entry by additional generic manufacturers and the generic exclusivity provisions of the Hatch-Waxman Act.¹²

¹²These and similar circumstances are also described in Willig and Bigelow (2004).

In summing up this section, it should be recognized that the circumstances described are all examples where reverse payments may be necessary to effectuate socially desirable settlements. At the same time, in all of these circumstances, reverse payments could also be used as an element of settlements that support the extension of monopoly beyond what the patent litigation would otherwise yield in expected value. Thus, reverse payments are powerful tools that can be used to support anticompetitive as well as pro-competitive agreements in the sets of circumstances described here.

Per se, the Rule of Reason, and Shifting the Burden of Proof

In its trial brief, CC urged the ALJ to treat the reverse payments as per se unreasonable restraints of trade. "Because the nature of the agreements gives rise to an obvious inference of anticompetitive effects, they are unlawful per se unless they have a plausible justification. Respondents offer two purported justifications, but neither is plausible."¹³ The basis for the inference referred to here is the presence of the reverse payment. CC leaves the door open in principle for the settlements to be defended upon the showing of "plausible justification" but in so doing would shift the burden of proof to the companies.

If the ALJ would not treat the settlements under the per se rule, CC was prepared to argue that they were summarily illegal under the rule of reason: "In the absence of plausible justifications, the agreements can be condemned as per se illegal. And even if per se treatment is not indicated, the Supreme Court made clear in *NCAA* that inherently anticompetitive restraints can be condemned under the rule of reason, if upon examination, the offered justifications are found to be inadequate. Under these standards the agreements can be summarily condemned."¹⁴ Once again the CC's approach would effectively shift the burden of proof to the firms to demonstrate that the agreements could be "justified."

CC defended this shift by arguing that it had made a prima facie case against the settlements, "Once plaintiffs make a prima facie showing that an agreement is anticompetitive, it is defendants' burden to come forward with a plausible procompetitive justification."¹⁵ What is the basis of this showing? CC conceded that it was relying on an inference that the settlements were anticompetitive. CC's expert witness testified that as a matter of economic theory, settlements with reverse payments were necessarily anticompetitive. That would support the inference, but Schering's expert had testified that CC's expert had the theoretical conclusion wrong—that it was not true as a

¹³FTC (2002a), p. 6.

¹⁴FTC (2002a), p. 44.

¹⁵FTC (2002a), p. 41, citing *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 770 (1999).

matter of economic theory that a settlement with a reverse payment was necessarily anticompetitive. CC preferred to relegate this evidence to a second stage of the analysis, that of attempting to justify an already presumptively anticompetitive agreement. At that stage CC dismissed the arguments on the grounds that Schering's witness did not offer evidence that the circumstances he described pertained to the specific agreements in question.¹⁶ However, if CC's prima facie case rested on the proposition that settlements with reverse payments are necessarily anticompetitive, and if that conclusion is wrong, then the second stage of the analysis should never have been reached because the argument failed at the first stage.

Evaluating the Underlying Patent Litigation

Schering's expert witness concluded from his analysis of the economic theory of reverse payments that evaluating the underlying patent so as to compare the settlement entry date with the expected date of entry under litigation was necessary to determine if a settlement was anticompetitive. Since settlements with reverse payments can be either pro-competitive or anticompetitive, examining settlements for the presence of a reverse payment will not distinguish pro-competitive from anticompetitive agreements.

CC disagreed, arguing that determining the probabilities of the outcomes of the underlying litigation is not only unnecessary but also impossible: "We will never know who would have won the patent cases. . . . Still less can we quantify each party's chance of success. There simply is no known methodology for handicapping trials or for testing the reliability of predictions."¹⁷ Additionally, CC expressed concern that, "by advocating tests that are impossible to apply they (Respondents) adopt a rule that would effectively immunize such settlements. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach patent settlements that involve payments for delay, consumers are far better served by an analysis that places the burden on defendants to show that a reverse payment was not for delay, than one that would permit reverse payments for such settlements as a matter of course."¹⁸ This argument also serves to explain why CC sought to shift the burden of proof to the respondents.

THE INITIAL DECISION

Five months after the trial began, on June 27, 2002, the ALJ handed down his decision ("The Initial Decision"). Except for some procedural questions

¹⁶FTC (2002a), p. 58.

¹⁷FTC (2002a), p. 55.

¹⁸FTC (2002a), p. 60.

(such as finding that the case lay within the jurisdiction of the FTC, that the challenged practices impinged on interstate commerce, and that Schering-Plough and Upsher-Smith are corporations within the meaning of the FTC Act), the ALJ ruled against CC in virtually every substantive respect. He found that CC had failed to prove or define a relevant product market; that the agreements between Schering and Upsher-Smith and between Schering and ESI did not unreasonably restrain competition and were not unfair methods of trade; that Schering did not have monopoly power in the relevant product market, which the ALJ found to be "all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement"; that Schering did not unlawfully engage in conduct to preserve monopoly power in the relevant product market; that Schering did not conspire unlawfully with Upsher-Smith or ESI to preserve monopoly power in the relevant product market; and that CC failed to meet its burden of proof.¹⁹

The Economics of Reverse Payments

The ALJ did not find it necessary to decide whether reverse payments are or are not intrinsically anticompetitive. First, he rejected the application of a per se rule on the grounds that patent splitting and reverse payments were issues that were too novel for application of the per se standard.²⁰ In rejecting the per se rule, he also touched on the question of the appropriate standard of comparison for anticompetitiveness. He concluded that because it is not clear that in the absence of the agreements the generics would have entered earlier than the entry dates in the settlements, the agreements cannot be condemned per se.²¹ He also found that Schering's conduct did not extend beyond the rights conferred by the patent. Similarly, the ALJ rejected a so-called quick-look analysis because he found pro-competitive effects sufficiently "plausible" that the quick-look approach was not appropriate.

Turning to a full-fledged rule-of-reason analysis, the ALJ concluded that the CC had not proved anticompetitive effects because it had not proved that a better settlement or litigation would have resulted in entry before the agreed-upon dates.²² This does not necessarily mean that the ALJ rejected the logic of CC's (and its witness') argument that reverse payments are anticompetitive. Instead he rejected, in effect, the contention that CC had proved that a reverse payment took place. The ALJ concluded that CC had failed to demonstrate that the value of the Niacor license that Schering obtained from Upsher-Smith was not commensurate with the \$60 million

¹⁹FTC (2002c), pp. 339a-340a.

²⁰FTC (2002c), pp. 299a-301a.

²¹FTC (2002c), pp. 303a-308a.

²²FTC (2002c), p. 310a.

that Schering paid for it.²³ The ALJ cited CC's own expert witness for the proposition that the payment to Upsher-Smith was not for delay if it represented fair value for the license.²⁴ With respect to the payment to ESI, the ALJ criticized CC's expert witness for relying on "what he [the witness] characterized as an 'assumption' that if ESI had won its patent suit, it might have been able to enter before March 2002."²⁵ Based on these findings, the ALJ concluded that the challenged settlements were of a kind that both CC and its witness had conceded were permissible.²⁶

Evaluating the Patent

In contrast to his views on reverse payments, on the subject of evaluating the patent the ALJ agreed with CC. He concluded that, "There is no way to determine the date or the outcome of the judicial determination of the patent litigation."²⁷ However, notwithstanding this finding, the ALJ was not willing to shift the burden of proof to the respondents. Responding to the CC's argument that the respondents' proposed rules would "immunize" anticompetitive settlements, the ALJ decided, "simply because, based upon the theories it advanced in this case, Complaint Counsel cannot prove whether Upsher-Smith and ESI would have come on the market earlier than September 2001 and January 2004, but for the \$50 million and \$15 million payments, does not relieve Complaint Counsel of its burden of proof."²⁸

The Standard for Anticompetitiveness

The ALJ held that in order to prove that the settlements were anticompetitive, CC had to define a relevant market and show that Schering had market power in that market. The ALJ rejected CC's arguments that both steps were unnecessary and concluded that without this foundation, CC could not prove an anticompetitive effect.²⁹ The ALJ rejected as "circular" the argument that Schering must have had market power or it would not have paid Upsher-Smith and ESI not to compete.³⁰ The ALJ concluded that CC had not proved that Upsher-Smith and ESI had been paid to stay off the market because, as CC acknowledged, CC could not even show that the two generics could have been on the market before the expiration of the patent.³¹

²³FTC (2002c), pp. 237a-249a, Findings of Fact 290-326.

²⁴FTC (2002c), p. 200a, Findings of Fact 172.

²⁵FTC (2002c), p. 261a, Findings of Fact 379.

²⁶FTC (2002c), p. 317a.

²⁷FTC (2002c), p. 264a, Findings of Fact 393.

²⁸FTC (2002c), p. 313a.

²⁹FTC (2002c), pp. 281a-282a.

³⁰FTC (2002c), p. 330a.

³¹FTC (2002c), p. 312a.

THE COMMISSION'S DECISION

CC appealed the ALJ's decision to the full Commission, which, unlike appeals courts accepting cases from lower courts, hears appeals from decisions of ALJ's "de novo," which means that the Commission can—and in this case did—review the record and make new findings of fact to replace those of the ALJ. (By contrast, generally, an appeals court is limited to reviewing the lower courts' interpretation and application of the law to the facts that the lower court has found.) The Commission noted that while it had pursued a number of cases involving generics, this was the first one to come before the full Commission after a full trial and with a complete record.

In December of 2003 the Commission made public its opinion, which reversed the ALJ, finding that the agreements were unreasonable restraints of trade and imposing an order prohibiting the parties from being party to an agreement to settle a patent infringement claim in which an ANDA filer both receives something of value (beyond up to \$2 million in legal fees) and agrees not to market or develop the ANDA product for some period of time. The order also forbade the parties from being party to an agreement in which an ANDA filer agrees to forgo selling or developing a product that is not subject to a patent claim.³²

Reverse Payments

The Commission disagreed with the ALJ that the licenses that Schering received were adequate consideration for the payments it made to the two generics. Consequently, the Commission rejected the ALJ's conclusion that the adequacy of compensation meant that the payments were not for delay. In fact, the Commission concluded that the payments were anticompetitive. The Commission denied that it was shifting the burden of proving that the settlements were not anticompetitive to the respondents and attributed the burden of proving that they are anticompetitive to the prosecutor.³³ However, the Commission apparently found that the following logic satisfied that burden: The payments must have had some offsetting consideration. In the absence of proof that the offsetting consideration was something else, it is "logical to conclude that the quid pro quo" was entry delay.³⁴ Employing this logic, the Commission was willing to conclude that the settlements had an anticompetitive effect, so it was not surprising that it also ruled that CC need not have defined a relevant market.

³²FTC (2003a and 2003b).

³³FTC (2003b), p. 59a.

³⁴FTC (2003b), pp. 76a–77a.

Applying the Rule of Reason and Fixing the Burden of Proof

Notwithstanding its description of the burden of proof, the Commission followed the line of CC and interpreted Schering's expert's critique of the argument that settlements with reverse payments are necessarily anticompetitive as an "affirmative justification" for the settlements rather than an attack on the CC's *prima facie* case. The Commission evaluated the testimony of Schering's expert as an "ancillarity claim"—in other words, as a claim that the agreement to delay entry (the ancillary agreement) was necessary to achieve the pro-competitive benefits of the agreement to settle the patent litigation (the main agreement).

Within this framework, the Commission could and did accept the testimony of Schering's witness as correct without concluding that it undermined CC's case against the settlements:

We also recognize, as he (Schering's expert) testified, that there may be hypothetical situations where a procompetitive settlement could require payment of some money to the generic challenger. This means that we are unwilling to say reverse payments included in a settlement agreement are always illegal. On the other hand, the mere articulation of hypothetical circumstances where reverse payments could ultimately facilitate an efficiency-enhancing settlement does not mean that a particular settlement is legal. If Complaint Counsel have made out a *prima facie* case that the agreement was anticompetitive, the burden is on these Respondents to demonstrate that these hypothetical circumstances describe the realities of the present case. They have not done so.³⁵

This line of reasoning, however, involved a paradoxical interpretation of the testimony of Schering's expert, since it assumed that CC had made out its *prima facie* case, whereas that case relied fundamentally on the very proposition that Schering's expert challenged.

Evaluating the Patent Litigation

The Commission concluded that it was possible to determine whether the settlements were likely to have had anticompetitive effects without assessing the merits of the patent litigation. In reaching this conclusion, the Commission rejected the relevance of the presumption that Schering's patent was valid until proved invalid, pointing out that the issue in the patent litigation with Upsher-Smith was whether or not Upsher's product infringed Schering's patent—a question upon which Schering bore the burden of proof in the patent litigation. The Commission also drew a

³⁵FTC (2003b), p. 89a.

distinction between calculating the amount of damages and fixing liability, concluding that for purposes of the latter the parties' perceptions of the probabilities of prevailing in the litigation were more important than the actual probabilities.

The merits of the patent litigation may be crucial in an action for damages but we are here concerned only with legal liability, and we focus on the state of the world *as it was perceived by the parties* at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out.³⁶

Additionally, the Commission held that inquiries into the merits of the patent case would not be conclusive and that the uncertainties that firms would hold about patent litigation would chill settlements if their legality under antitrust law depended on an ex-post assessment of the settled patent litigation.

THE ELEVENTH CIRCUIT DECISION

Schering-Plough and Upsher-Smith appealed the Commission's decision to the Eleventh Circuit Court of Appeals, and on March 8, 2005, that court handed down an opinion setting aside the Commission's decision and vacating the Commission's order.³⁷

Reverse Payments

The appeals court rejected both the Commission's factual findings concerning the particular settlements in this case and its reasoning on the subject of reverse payments in general.³⁸

With respect to the Upsher-Smith settlement, the court agreed with the ALJ that the evidence supported the conclusion that the \$60 million was a bona fide payment for the licenses.³⁹ With respect to the ESI settlement, the court found that the factual record was "far less developed" than

³⁶FTC (2003b), pp. 83a-84a.

³⁷*Schering-Plough Corporation, Upsher-Smith Laboratories, Inc., v. Federal Trade Commission*, 402 F.3d 1056.

³⁸The court reviewed the FTC's findings of fact and economic conclusions under the "substantial evidence" standard. According to the court's description of that standard, "The FTC's findings of fact, 'if supported by evidence, shall be conclusive'" (*Schering-Plough v. FTC*, p. 1062, citing 15 U.S.C. § 45(c)). The court went on to explain that, "We may, however, examine the FTC' [s] findings more closely where they differ from those of the ALJ. 'Substantial evidence is more than a mere scintilla,' and we require 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion'" (*Schering-Plough v. FTC*, p. 1062 with internal citations omitted).

³⁹*Schering-Plough v. FTC*, p. 1070.

that pertaining to the Upsher settlement, that the patent litigation was certain to be "a bitter and prolonged process," and that the settlement was "within the patent's exclusionary power."⁴⁰

The appeals court did not attempt to weigh the relative merits of the economic analyses of incentives put forward by the expert witnesses for the two sides. Instead, the court flatly rejected the view that any economic analysis of incentives was an adequate basis to conclude that settlement agreements were unreasonable restraints of trade.

The Commission did not expressly adopt [CC's expert witness]'s theories, but his rationale and the Commission's conclusions became one and the same. The Commission is quite comfortable with assenting to [the witnesses]'s rather amorphous "incentive" theory despite its lack of empirical foundation. Unfortunately, [the witnesses]'s so-called incentives do not rise to the level of legal conclusions. We understand that certain incentives may rank high in these transactions, but it also true that the possibility of an outside impetus often lays dormant. The simple presence of economic motive weighs little on the scale of probative value.⁴¹

Likewise, the appeals court rejected the Commission's own reasoning on the subject.

Although it claimed to apply a rule of reason analysis, . . . the Commission pointedly states that it logically concluded that "*quid pro quo* for the payment was an agreement by the generic to defer entry date beyond the date that represents an otherwise reasonable litigation compromise." We are not sure where this "logic" derives from, particularly given our holding in *Valley Drug*.⁴²

In fact, the appeals court viewed reverse payments as natural consequences of the Hatch-Waxman apparatus. The court pointed out that prior to Hatch-Waxman a generic manufacturer would need to enter the market and begin producing its product in order to challenge an incumbent's patent. Doing so would be a risky proposition for the generic because the damages to which it would be subject are the lost monopoly profits of the patentee, which are likely to be greater than any profits that the generic entrant earns.

Under Hatch-Waxman, by contrast, a challenge to a patent may be initiated simply by filing an ANDA with a Paragraph IV certification. The court took the view that this change altered the balance of bargaining power in favor of patent challengers, so that it was more likely that settlements would involve payments to the generic challenger.⁴³ The court did not make clear what implications this argument has for the question of whether or not

⁴⁰*Schering-Plough v. FTC*, pp. 1071-1072.

⁴¹*Schering-Plough v. FTC*, p. 1069.

⁴²*Schering-Plough v. FTC*, p. 1073.

settlements with reverse payments are anticompetitive except to observe that in this setting treating all settlements with reverse payments as antitrust violations would discourage settlements.⁴⁴

Per se and the Rule of Reason

In view of its analysis of reverse payments, it is hardly surprising that the court declined to find reverse payments per se illegal. The court also declined to apply the rule-of-reason analysis, concluding, "We think that neither the rule of reason nor the per se analysis is appropriate in this context."⁴⁵ The court concluded that neither analysis was appropriate because the objective of both is to determine if the challenged conduct has an anticompetitive effect on the market. The court concluded that an anticompetitive effect is necessarily present because patents are, by their nature, exclusionary and preferred to focus on whether or not the effect of the challenged conduct went beyond the reach of the patent. Specifically, the court concluded that an analysis of antitrust liability should include "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."⁴⁶

Applying this standard, the court took notice of the facts that there had been no allegations that either the 743 patent was invalid or that Schering's patent suits had been shams. On the presumption that the patent is valid the court concluded that the proper analysis was "whether there is substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the 743 patent."⁴⁷ For the reasons described above, the court concluded that there was not.⁴⁸

Evaluating the Underlying Patent

Echoing the logic of Schering's expert witness, the appeals court concluded that, because reverse payments are not intrinsically anticompetitive, it was necessary to evaluate the underlying patent litigation.

Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money can not be the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent.⁴⁹

⁴³*Schering-Plough v. FTC*, p. 1074.

⁴⁴*Schering-Plough v. FTC*, p. 1075.

⁴⁵*Schering-Plough v. FTC*, p. 1065.

⁴⁶*Schering-Plough v. FTC*, p. 1066, citing *Valley Drug*, 344 F.3d at 1312.

⁴⁷*Schering-Plough v. FTC*, p. 1068.

⁴⁸*Schering-Plough v. FTC*, p. 1075-1076.

⁴⁹*Schering-Plough v. FTC*, p. 1076.

CERTIORARI

In August 2005 the FTC asked the Supreme Court to consider hearing the case (i.e., to grant certiorari).⁵⁰ Revealing a disagreement between the two agencies, the Department of Justice (DOJ) filed a brief in May 2006 asking the Supreme Court not to take the case.⁵¹

It appears from its petition that the most urgent issue to the Commission in pressing its Supreme Court appeal was its concern over how the appeals court language concerning the "scope of the exclusionary potential of the patent" is to be understood. There are at least three different ways in which that phrase could be understood. First, the exclusionary scope of the patent could be determined by the actual probabilities of the parties prevailing in the patent litigation. From this perspective, a settlement with a negotiated entry date exceeds the exclusionary scope of the patent if the agreed-upon entry date is later than the expected date of entry under litigation. By the second interpretation of the exclusionary scope of the patent, a settlement exceeds the exclusionary potential of the patent if the parties believe they are moving back the expected entry date. A third interpretation of the exclusionary scope of the patent would simply be its life under the assumption that the patent would be upheld in the patent litigation. By this standard, any settlement that included negotiated entry during the life of the patent would not exceed the exclusionary scope of the patent.

The Commission's certiorari petition articulates a concern that the appeals court decision would be interpreted as applying the third interpretation of the scope of the patent.

[The Appeals Court] failed to appreciate that parties settling litigation deal in uncertainties . . . The standard the court set down gives patentees free rein to "buy off" potential competitors. The sweeping nature of the court of appeals' rule derives from its approach to assessing the "exclusionary potential of the patent." The court based its reasoning upon the statutory presumption of patent validity, and upon a demonstrably *incorrect* extension of that presumption to the patent infringement issues most relevant here, and ruled that the "exclusionary power" of the patent at issue here encompassed a right to exclude both Upsher and ESI from the market "until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent."⁵²

⁵⁰FTC (2005b).

⁵¹United States of America, *On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit, Brief for the United States as Amicus Curiae, Federal Trade Commission v. Schering-Plough Corporation, et al.* (May 2006).

⁵²FTC (2005b), pp. 14–15.

The Commission makes it clear that its preferred interpretation of “the exclusionary scope of the patent” is the second one above, to assess the exclusionary scope of the patent by the parties’ perceptions and to discern the perceptions as inferences from the parties’ actions.

The Department of Justice appeared to read the appeals court decision less drastically. For example, in its amicus curiae the DOJ observed that the appeals court found the ESI settlement within the patent’s exclusionary power only after observing that the FTC had not rebutted testimony from a Schering expert witness that Schering would have won the underlying patent case.⁵³ Thus, this decision is consistent with either the first or the third interpretation of the scope of the patent. More generally, the DOJ summarized its reading of the appeals court decision by asserting that it did not foreclose reliance on an ex ante view of the strength of the infringement claim in determining whether the settlement, including any reverse payment, delayed entry beyond the exclusionary potential of the patent.⁵⁴

In its request for a Supreme Court hearing, the Commission identified reverse payments as the central issue and sought to pose the question in a way that assumed that they are anticompetitive. In dramatic contrast, the DOJ described the principal issue for Supreme Court review in a fashion that left open the characterization of the impact of reverse payments. Here is their language for the sake of the comparison:

FTC Question Presented

Whether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger’s entry into the market, is an unreasonable restraint of trade.⁵⁵

DOJ Question Presented

Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.⁵⁶

In June of 2006 the Supreme Court declined to hear the case. The Court did not explain the reasons for its decision to deny certiorari, and the case ended.

⁵³United States (2006), pp. 6–7.

⁵⁴United States (2006), p. 18.

⁵⁵FTC (2005b), p. I.

⁵⁶United States (2006), p. I.

REFLECTIONS

From the beginning, the FTC—either through its Complaint Counsel or, later through the Commission itself—maintained two positions. First, reverse payments in patent litigation settlements are intrinsically anticompetitive; and second, it is neither necessary nor possible to inquire into the strength of the underlying patent in order to determine whether or not a settlement is anticompetitive. The two positions are related. The first can provide a justification for the second. The Commission's position, which relied on a conclusion from a particular economic theory embraced by its expert witness, was attacked on the economic grounds that the theory was wrong and on the legal grounds that the economic theory is insufficient for the rule of law that the Commission advocated.

By the end of the case, the Commission was arguably in a worse position than it had been in when the case began. The Commission found itself attempting to preclude the imposition of a rule from the circuit court that, at least as the Commission saw it, would permit any settlement to patent litigation that allowed entry within the nominal life of the patent. If the Commission believed that this state of affairs had been reached because it had persisted in pursuing its two positions together, it might have reason to regret ever having taken up the case in the first place.

At this juncture, it is of greatest importance to set aside for the moment the question of whether or not one believes that the Commission's or the Respondent's arguments were the stronger in this case and to address the long-run issue of the best policy toward agreements that settle patent litigation. While it is not our ambition to resolve this issue here, the history of the FTC's litigation against Schering-Plough seems to have illuminated a few lessons that bear on any such resolution:

(1) The parties to a patent dispute will generally have incentives to settle in order to avoid costly and risky litigation, and these incentives are more aligned than not with social benefits. (2) It does follow from economic logic that the parties to a patent dispute both could benefit from a settlement that significantly protected the incumbent patent holder from the chance of competition from the accused infringer and provided a net payment in return from the patent holder to the accused infringer. As such, the benefits to the parties would come at the expense of competition and consumer welfare. (3) It also follows from economic logic that the opportunity to employ reverse payments may be necessary for socially beneficial and pro-competitive settlements to be reached, due to such common situations as asymmetric information, excess optimism, and differential cash needs between the parties to the patent dispute. (4) It may very well be the case that it is not feasible for an antitrust inquiry to reach reliable judgments about the likelihoods of the litigation outcomes of a patent dispute.

These four lessons have implications for policy. They seem to imply that a per se rule against reverse payments would, at this point in our inexperience,

be unduly restrictive of settlements and hence unwise. They imply that a safe harbor for agreements that settle patent disputes would foster anticompetitive outcomes that benefit the parties to the patent disputes but that harm consumers. They imply that we cannot rely on a quantitative comparison between the agreed date of competitive entry and an assessment of the odds of the possible outcomes of the patent litigation.

The remaining implication is that more experience by antitrust agencies and courts, along with more economic research, is needed to formulate indirect tests for whether a settlement is likely to benefit or harm competition. While we may not be able to measure the probabilistically expected date of entry under litigation, we may nevertheless be able to assess whether the date of entry under the settlement is likely to come before or after that expected date on the basis of the character of the settlement negotiations and their context, as well as on the basis of the size and compensations for any reverse payments. The resulting challenge clearly needs carefully crafted, articulated, and tested "second best" solutions. If the legacy of the *FTC v. Schering-Plough* cases is the motivation for aware and talented economists and lawyers to tackle this problem, then that could be the best outcome from the whole matter.

REFERENCES

- Akerlof, George. "The Market for Lemons: Qualitative Uncertainty and the Market Mechanism." *Quarterly Journal of Economics* 84 (1970): 488-500.
- Cotter, Thomas. "Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship." *Antitrust Law Journal* 71 (2004): 1069-1097.
- Federal Trade Commission. *Complaint*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation, Complaint, March 30, 2001a. <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>.
- Federal Trade Commission. *Complaint Counsel's Statement of the Case*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, Inc. and American Home Products Corporation, September 18, 2001b. <http://www.ftc.gov/os/adjpro/d9297/010918ccsotc.pdf>.
- Federal Trade Commission. *Complaint Counsel's Trial Brief*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation, Complaint, January 23, 2002a. <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>.
- Federal Trade Commission. *Final Order*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation, December, 2003a; reproduced in Federal Trade Commission, *Appendix to Petition for a Writ of Certiorari, Federal Trade Commission v. Schering-Plough Corporation, et al.*, August, 2005a. <http://www.ftc.gov/os/2005/08/050829scheringploughappendix.pdf>.
- Federal Trade Commission. *Generic Drug Prior to Patent Expiration: An FTC Study*, July, 2002b.

Case 9: "Reverse Payments" in Settlements of Patent Litigation

- Federal Trade Commission. *Initial Decision by D. Michael Chappell, Administrative Law Judge*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, Inc. and American Home Products Corporation, June 27, 2002c; reproduced in Federal Trade Commission, *Appendix to Petition for a Writ of Certiorari, Federal Trade Commission v. Schering-Plough Corporation, et al.*, August, 2005a. <http://www.ftc.gov/os/2005/08/050829scheringploughappendix.pdf>.
- Federal Trade Commission. *Opinion of the Commission*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation, December, 2003b; reproduced in Federal Trade Commission, *Appendix to Petition for a Writ of Certiorari, Federal Trade Commission v. Schering-Plough Corporation, et al.*, August, 2005a. <http://www.ftc.gov/os/2005/08/050829scheringploughappendix.pdf>.
- Federal Trade Commission. *Petition for a Writ of Certiorari, Federal Trade Commission v. Schering-Plough Corporation et al.*, August 2005b. <http://www.ftc.gov/os/2005/08/050829scheringploughpet.pdf>.
- Langenfeld, James, and Wenqing Li. "Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers." *Antitrust Law Journal* 70 (2003): 777-818.
- Priest, George L., and Benjamin Klein. "The Selection of Disputes for Litigation." *The Journal of Legal Studies* 13(1) (January 1984): 1-55.
- Schering-Plough Corporation. *Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and ESI-Lederle*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, Inc. and American Home Products Corporation, September 18, 2001a.
- Schering-Plough Corporation. *Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and Upsher-Smith*, In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, Inc. and American Home Products Corporation, September 18, 2001b.
- Schering-Plough Corporation, Upsher-Smith Laboratories, Inc., v. Federal Trade Commission*, 402 F.3d 1056.
- Shapiro, Carl. "Antitrust Limits to Patent Settlements." *RAND Journal of Economics* 34 (2003): 391-411.
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research. "Abbreviated New Drug Application (ANDA) Process for Generic Drugs." www.fda.gov/cder/regulatory/applications/anda.htm.
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research. "New Drug Application (NDA) Process." <http://www.fda.gov/cder/regulatory/applications/NDA.htm>.
- United States of America. *On Petition for a Writ of Certiorari to the United States Court of Appeals for The Eleventh Circuit, Brief for the United States as Amicus Curiae, Federal Trade Commission v. Schering-Plough Corporation, et al.*, May 2006.
- Willig, Robert D., and John P. Bigelow. "Antitrust Policy towards Agreements That Settle Patent Litigation." *The Antitrust Bulletin* 49 (Fall 2004): 655-698.