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Plus ça change, plus c'est la même chose

I. INTRODUCTION

Thirteen years ago—in 2000—the Federal Trade Commission ("FTC") and private plaintiffs began fighting certain kinds of settlements that sometimes arise in litigation over patents for pharmaceutical products. Initially dubbed "Reverse Payment" settlements and later "Pay for Delay" settlements by their critics, the challenged settlements come about when the manufacturer of a branded and patented drug settles patent infringement litigation with a would-be manufacturer of a generic version of the same drug on terms that include a payment from the brand-manufacturer *cum* patent-holder to the generic-manufacturer *cum* alleged-infringer and a specified date upon which the generic is permitted to start selling.

The settlements' foes called them reverse payment settlements because they viewed these settlement payments as moving in the wrong direction. To them the "natural" sort of payment in a patent litigation settlement would be a payment made *by* the alleged infringer *to* the patent holder. A payment *by* the patent holder *to* the alleged infringer seemed unnatural. Hence, the term "Reverse Payment."

The term "Pay for Delay" is even more pointed, reflecting the contention that settlements of this kind constitute agreements in which an incumbent producer of a branded pharmaceutical pays a potential generic competitor to stay out of the market, thereby extending the duration of the incumbent's profitable monopoly power. This is the theory under which the FTC and private plaintiffs challenged these agreements as violations of antitrust law.

From the beginning, even the defenders of specific settlements conceded that Reverse Payment settlements could be used to inhibit competition. Thus, at the time these cases were first being brought they raised (at least) two important questions for courts, enforcement officials, litigants, and policy makers:

1. How strong is the case that the challenged settlements are intrinsically anticompetitive?
2. If Reverse Payments cannot be universally condemned, how are courts to distinguish between those that are anticompetitive and those that are not?

Since the time the first cases were brought, there have been multiple cases litigated. The Second, Third, Sixth, and Eleventh Circuit Courts of Appeals have all weighed in on how these cases ought to be handled and, last June, the Supreme Court was heard from in *FTC v. Actavis*.

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After all the effort and talent that has been devoted to grappling with these cases, two important questions facing courts, enforcement officials, litigants, and policy makers are:

1. How strong is the case that the challenged settlements are intrinsically anticompetitive?
2. If Reverse Payments cannot be universally condemned, how are courts to distinguish between those that are anticompetitive and those that are not?

II. BACKGROUND

A. NDAs and ANDAs

The litigation from which these settlements arise is—in part—a creation of the regulatory process laid out by the Hatch Waxman Act, which governs Food and Drug Administration ("FDA") approval of brand and generic pharmaceuticals. Before a drug may be marketed, the FDA must be satisfied that it is safe and effective. When a new drug is developed its manufacturer submits a New Drug Application ("NDA") to the FDA in which the developer describes the scientific evidence supporting its request that the FDA find the drug safe and effective. Once such a drug is approved, the Hatch Waxman Act allows a manufacturer of a generic version of that same drug to avoid repeating all the tests and trials that the original manufacturer undertook. All the generic manufacturer has to show is that its version of the drug makes the same amount of the same active ingredient(s) available to patients in the same time frame, a standard that is known as "bioequivalence."

Since the showing that a generic manufacturer has to make is more modest than that required from a new drug manufacturer, a generic manufacturer is able to submit an Abbreviated New Drug Application ("ANDA") that describes the evidence supporting bioequivalence and otherwise references the original NDA. This process makes it possible for generics to be approved more quickly, which was one purpose of the legislation.

B. ANDAs and Patents

Another purpose of the legislation was to establish the process whereby disputes between brand manufacturers and would-be generic manufacturers over patents would be resolved. The FDA maintains a list—the "Orange Book"—of the patents that NDA holders claim as protection for their approved drugs. When a generic manufacturer files an ANDA, it makes one of four certifications, depending on its position vis à vis the brand manufacturer's patent(s).

For our purposes, the relevant certification is the so called "Paragraph IV" certification that the patent claimed by the brand manufacturer is either invalid or will not be infringed by the proposed generic. The Hatch Waxman Act makes the act of filing a paragraph IV certification grounds for filing a patent infringement suit and gives the NDA filer 45 days in which to do so. Once such a suit is timely filed, the ANDA is automatically stayed for 30 months or until the patent litigation is resolved. As an added incentive to file paragraph IV certifications, once the first filer's ANDA is approved and the generic is marketed, the FDA will not approve any additional generic versions of the same drug for 180 days.

C. Settlements

The infringement suits triggered by paragraph IV certifications are the lawsuits in which the challenged settlements are reached. In a typical settlement of the kind, the brand-

manufacturer/patent-holder agrees to drop the infringement claim; the generic-manufacturer agrees to drop the challenge to the patent; both sides agree on a date (and, perhaps, some conditions) after which the generic is free to enter the market; and the patent-holder and the generic entrant agree on some consideration that the brand-manufacturer will provide to the generic entrant.

The combination of a negotiated entry date and a brand-to-generic payment raises the ire of settlement critics. They interpret the settlements as market-division agreements in which a monopolist (the brand manufacturer) pays off a potential competitor (the generic manufacturer) to stay out of the market for a while. This, they say, prolongs the period in which the incumbent enjoys monopoly power.

III. THE ECONOMICS OF REVERSE PAYMENT SETTLEMENTS

A. What Does it Mean to Delay Entry?

If the principal objection to Reverse Payment settlements is that they delay entry, then it is fair to ask, "relative to what?" In other words, what is the alternative to the challenged settlement, and did the settlement create an outcome with greater monopoly power and less social surplus?

In the context of disputes involving patents, it's important to phrase the question that way rather than to make the point of comparison an idealized competitive marketplace. The point of patents, after all, is to confer monopoly power on an innovator as an incentive for bringing innovative products to market. If the application of antitrust law to settlements isn't to vitiate the purpose of patent protection, then the patent holder ought not to be subject to antitrust liability merely for protecting the rights conferred by the patent.

So the question becomes: What would the world have looked like if the parties had not reached the Reverse Payment settlement, and would that world have been more competitive than the world created by the settlement?

One way of answering that question is to presume that the patent is valid, and that absent the settlement it could and would be enforced until the end of its life. That presumption came to be embodied in the "Scope of the Patent Test." It was the Eleventh Circuit's embrace of the Scope of the Patent Test that was the apparent motivation for FTC's appeal of the *Actavis* case to the Supreme Court. The Scope of the Patent Test had the virtue of simplicity. Absent sham litigation or fraud on the patent office, one need only compare the negotiated date of entry under a settlement with the nominal expiration date of the patent. If the former came on or before the latter, then as long as the range of products covered by the settlement didn't extend beyond those covered by the patent, the settlement would be held not to extend the patentee's monopoly power and so was protected from antitrust attack.

As its critics emphasize, the Scope of the Patent Test does not acknowledge that the protection afforded by an untested patent is uncertain. A patent may be invalid and/or it may not apply to a particular generic manufacturer's production or product. That means that the scope of protection provided by a challenged patent is probabilistic. When the patent is challenged all the parties with an interest in the affected product—the patentee, the generic challenger, and consumers—are, effectively, rolling the dice. Perhaps there is a 70 percent chance that the

patentee would prevail in the infringement suit, and a 30 percent chance that the putative infringer would prevail. If the nominal life of the patent has ten years remaining, then the expected life of the patent once it's subject to challenge is not ten years, but seven (70 percent probability times 10 years).

The expected life of an uncertain patent provides a point of comparison that takes account of the uncertainties of patent litigation. As such, it provides a way of evaluating a settlement that takes account of the strength or weakness of the underlying patent. Under certain circumstances comparing a settlement date with the expected life of a patent provides a rigorous basis for evaluating the effect of a settlement on competition relative to continuing the underlying litigation to its ultimate conclusion.[2] A settlement that calls for entry on or before the expected entry date does no harm to competition and should be permitted. A settlement that calls for entry after the expected entry date delays entry, harms competition, and should be subject to antitrust attack.

In order to apply this standard, one must be able to calculate—or at least estimate—the expected date of entry. Doing so requires an estimate of the probabilities of the possible outcomes of the litigation. Since patent litigation is complex, that's a tall order. It is often described as requiring the antitrust court to encompass within its consideration of the settlement all the issues of the patent litigation.[3]

B. Paying for Delay

Critics of Reverse Payment settlements, like the FTC, maintain that the presence of the Reverse Payment in the settlement eliminates the need for an inquiry into the merits of the patent case. In its brief to the Supreme Court the FTC articulated this argument, saying,

> The **most natural inference is** that the payment has purchased an additional increment of market exclusivity.[4]

This was consistent with the position the Commission had taken in its decision—later reversed—in its case against Schering Plough, which the Commission also quoted it its brief to the Supreme Court.[5]

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, **it is logical to conclude that** the *quid pro quo* for the payment was

[2] The requirement is that consumers be "risk neutral," which—roughly speaking—means that they do not require compensation for risk bearing. If consumers are not risk neutral, then the extent of their risk aversion must be taken into account also, used to calculate an appropriate "risk premium" for risk bearing. Recognition of consumer risk aversion tends to make litigation look less attractive to consumers and settlement more attractive because the former embodies risk while the latter does not.

[3] In the *Actavis* case the Circuit Court's description of that task was: "If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task." *FTC v. Watson Pharmaceuticals Inc.*, US Court of Appeals for the Eleventh Circuit No. 10-27729, April 25, 2012.

[4] *FTC v. Watson Pharmaceuticals,* Supreme Court of the United States, No. 12-146, Brief for the Petitioner, January 2013, p. 36, **emphasis** added. (Hereafter, "FTC Brief")

[5] FTC Brief, *id.*, at 34 – 35.

> an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.[6]

Note the emphasized language in these two passages, "the most natural inference is," and "it is logical to conclude that." In effect, the FTC is arguing that since the parties would have an incentive to collude anticompetitively to delay entry and to effect such an agreement with the help of a reverse payment, we should conclude that the presence of a reverse payment signals anticompetitive intent and effect. This begs the question, "What reasons could a patentee have for paying an alleged infringer in a settlement other than anticompetitive delay?" The FTC would have us believe that—with a few modest and insignificant exceptions—there are no other reasons.

C. Why Pay if Not for Delay?

To which, Economics says, "Not so fast." There are pro-competitive reasons why a patentee would be willing to make a settlement payment to the putative infringer.

1. Litigation Costs

The least controversial of these has to do with the costs of litigation. Even the FTC acknowledges that a settlement payment to the putative infringer that is "commensurate with the litigation costs that the brand name manufacturer avoided…is most naturally understood to reflect the Parties' agreed division of their savings from avoiding Litigation, it does not suggest that the compromise date of generic entry specified in the settlement reflects anything but the parties' true assessment of the merits of the litigation."[7]

The litigation cost component may, however, prove to be more significant than some anticipate. That's because the costs of litigation to the patentee include the cost of risk bearing inherent in litigation. Where a highly lucrative drug is concerned the uncertainty born by the patentee in litigation is substantial. To the extent that the patentee is risk averse, the effective cost of that risk bearing — the "risk premium" — is also large. Therefore, the patentee's avoided cost of litigation may well prove to be significantly higher than one might imagine if one just looked at costs like attorneys' fees and the costs of experts.

2. Bargaining Over Settlements

In addition to litigation costs, there are a number of complexities to bargaining between litigants in a patent infringement case that can give rise to settlements with payments from patentee to putative infringer that do not injure competition.[8]

a. Differing Information About the Market

For example, when the two parties do not have the same information and expectations about the future value of the market that can affect their bargaining. In particular when the

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[6] Federal Trade Commission, *In the Matter of Schering-Plough Corporation, et al.*, Docket No. 9297, Opinion of the Commission, December, 2003. p. 26, *italics* in original; **emphasis** added.

[7] FTC Brief, *supra* note 4 at 38.

[8] The following paragraphs summarize conclusions that are described in more detail—and with greater rigor—in Robert D. Willing & John P. Bigelow, *Antitrust Policy Towards Agreements that Settle Patent Litigation*, THE ANTITRUST BULL. 655 – 698 (2004), (hereafter, "Willig & Bigelow").

patentee knows more about future market prospects than does the putative infringer, bargaining becomes more complicated. The infringer now needs to interpret the patentee's offer in order to decipher what it signals about the information that patentee knows that the would-be generic does not.

In a setting like that, a willingness on the part of patentee to settle with early entry may rationally be construed as a sign that future prospects for the market are poor—thereby inhibiting settlement. A patentee can, however, credibly signal confidence in the market by its willingness to accompany a settlement with later entry by a payment to the generic entrant.

b. Differing Expectations of Success in Litigation

Bargaining is also affected if the parties have differing expectations about the likelihood of success in the litigation. If both sides hold high probabilities of success, their confidence can prevent their reaching a settlement. That would happen if the earliest date upon which the patentee would be willing to accept generic entry in a settlement came after the latest date the would-be generic entrant would accept for entry.

The ability to make a Reverse Payment, however, can break the logjam. That's because each week of additional delay is more valuable to the patentee than it is to the entrant. Therefore, as the Reverse Payment becomes larger, the earliest date the patentee would accept moves back as does the latest date the entrant would accept. But, the latest date the entrant would accept moves back faster. So, eventually the latest date the entrant is willing to accept catches up with the earliest date the patentee would accept and a settlement becomes possible.

c. Additional Generic Entry

Another potentially complicating factor for bargaining between the patentee and the entrant is the prospect of additional entry by other generic producers. That prospect can cause the patentee and the generic to view the end-stage of the product life differently, creating the same kind of obstacles to settlement created by excessive optimism. When that happens, for the same reasons described above, the ability to make a Reverse Payment can restore the parties' ability to reach a settlement.

d. Pro-Competitive Settlements With Reverse Payments

Each of these situations makes a clear case that Reverse Payments can be pro-competitive. That's because the analysis shows that for each of these phenomena (differing information about the market, differing expectations of success, prospective additional entry), there can be circumstances where no settlements are possible without Reverse Payments, but where there are possible settlements with Reverse Payments which both parties would prefer—and are also preferred by consumers—to continuing the litigation.[9]

IV. COMPETING SIMPLE RULES

To be sure, the foregoing does not describe circumstances under which Reverse Payment settlements are guaranteed to be pro-competitive, but they do show that under quite realistic circumstances they may be. Moreover, when they are pro-competitive, it is the intrinsic character

[9] *See* Willig & Bigelow, *id.*

of the settlement that is pro-competitive. In other words, these are not cases in which an inherently anticompetitive settlement is redeemed because it also gives rise to some incidental or ancillary efficiencies that offset the anticompetitive harm. These Reverse Payment settlements are pro-competitive because they lead to the advent of generic competition sooner than could be expected.

That is why an approach that presumes Reverse Payment settlements are anticompetitive but allows that presumption to be rebutted if there are sufficient offsetting efficiencies is inadequate. The real problem policy makers and courts have wrestle with is to distinguish Reverse Payment settlements that harm competition from Reverse Payment settlements that promote competition. That's a complex problem that ultimately turns on whether the settlement allows entry earlier or later entry than the expected non-settlement alternative.

Throughout much of the time that Reverse Payments have been debated, both sides have sought to avoid addressing this question. On the one hand, critics of Reverse Payments, such as the FTC, advocated simply presuming that Reverse Payment settlements must be anticompetitive. The burden of grappling with complexities was to be laid on the settling parties by "allowing" them to rebut the presumption by showing offsetting efficiencies. On the other hand, under the scope of the patent test, settlements are compared, not to the expected outcome in their absence, but to the nominal letter of the patent grant.

V. THE RULE OF REASON AFTER ACTAVIS

In *Actavis* the Supreme Court declined to endorse either simplification. Reverse Payment settlements are to be subject to a full-fledged rule of reason analysis, without the presumption advocated by the FTC that they are guilty of being anticompetitive until proven innocent.

The decision expresses confidence that lower courts will be able to grapple with this problem:

> As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences…. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.[10]

This expression of confidence is not accompanied by much guidance. The Court appears to believe that assessing the likely merits of the underlying patent case will prove unnecessary:

> To say [that the FTC should prove its case in a rule of reason analysis] is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory.[11]

[10] Supreme Court Of The United States, *Federal Trade Commission v. Actavis, Inc. Et Al.,* Slip Opinion, p. 21, (hereafter, "Actavis").

[11] Actavis, *id*. at 21.

It is not clear if this passage is meant to instruct lower courts not to consider the patent's validity. It would be unfortunate if it were, since a comparison between the negotiated entry date and the expected entry date arising from litigation is the economic determinant of whether the settlement is pro- or anti-competitive. Therefore, such a comparison may hardly be said to shed "minimal light…on the basic question—that of the presence of significant unjustified anticompetitive consequences."[12]

The closest the Court comes to offering guidance lies in the suggestion that the size of the Reverse Payment might be used as a basis for inferring anticompetitive effect:

> [I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham). An *unexplained* large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness….In a word, 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.[13,14]

The difficulty with implementing this advice will surely be determining what constitutes an "unexplained large reverse payment." As explained above, reverse payments can certainly be consistent with pro-competitive settlements. And, there is no basis in the theory describing those pro-competitive settlements to believe that the associated payments are "small." So, the question is likely to be whether or not a large Reverse Payment is "unexplained."

Since efficient Reverse Payment settlements arise from complex bargaining situations, analyses of possible explanations are likely to be complex and difficult. That, of course, is exactly the objection to attempting to analyze the strength of the underlying patent. In other words, the dilemma facing lower courts and litigants attempting to carry out the mandate of the *Actavis* decision is likely to be the choice between adjudicating the merits of the underlying patent and adjudicating the motives and strategic position of parties to a complex bargaining problem.

It will hardly be surprising if this leads to a renewed search for simple rules of thumb. The challenge will be to ensure that any rules that do emerge are well grounded in economics.

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[12] Actavis, *id*. at 21.

[13] Actavis, *id*. at 18 -19, *italics* added.

[14] The Court also included in this passage an observation about risk and the size of the payment. "The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm." The observation that the risk premium required by a patentee is related to the likelihood of their prevailing in the litigation is correct. However, that does not alter the fact that the larger that risk premium is, the larger the Payment a patentee would be willing to make in a settlement that did *not delay entry*. [Actavis, *id*. at 19.]