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We are apt to fall into the error of thinking that the facts are simple because simplicity is the goal of our quest. The guiding motto in the life of every natural philosopher should be, Seek simplicity and distrust it.

Alfred North Whitehead, *The Concept of Nature*, 1919

I. INTRODUCTION

Cases involving pharmaceuticals settlements to patent litigation with so called “reverse payments” or, as the FTC now prefers to call them, “exclusion payments” have been a source of controversy for some time. The FTC has been fighting these agreements since 2000 on the antitrust grounds that they are agreements between horizontal competitors not to compete. Although the FTC had some early successes, the issue is likely to be an increasing source of frustration to the commission as the trend in appellate decisions has turned against them. The most recent rebuke came in April in the Eleventh Circuit’s decision in the *Androgel* case, where the court articulated (or rearticulated) a rule that protects these settlements from challenge so long as the terms of the settlement are confined to the nominal life of the patent.²

II. HATCH WAXMAN, SETTLEMENTS, AND REVERSE PAYMENTS

So called “reverse payment” settlements arise in context of the process defined by the Hatch Waxman Act that governs competition between brand-name and generic drugs.

Originally passed by Congress in 1984 and amended in 2003, the act includes provisions intended to promote research leading to new drugs and to promote generic drug competition with already approved drugs. If the manufacturer of a generic drug can show that the generic is bioequivalent to an already approved drug, known as the reference listed drug (“RLD”), then the generic manufacturer can rely on the safety and efficacy studies submitted with the RLD’s new drug application (“NDA”). In the NDA the original manufacturer lists any patents that protect the RLD. These are included in the FDA’s “Orange Book” listing of approved drugs. In the abbreviated new drug application (“ANDA”) process created for generics, the generic

¹ Senior Economist, Princeton Economics Group, Princeton NJ. I served as a consultant to Schering Plough Corporation in *In re Schering-Plough Corp.*, FTC Docket No. 9297. I am grateful to Emily Bowers Petkas for assistance.

² *Federal Trade Commission vs. Watson Pharmaceuticals, Inc.*, United States Court of Appeals for the Eleventh Circuit, No 10-12729, April 25, 2012, [http://www.ca11.uscourts.gov/opinions/ops/201012729 .pdf](http://www.ca11.uscourts.gov/opinions/ops/201012729.pdf), last visited 6/20/2012.

manufacturer makes one of four certifications: Paragraph 1 that there is no patent listed with the RLD in the Orange Book, Paragraph 2 that any listed patents have expired, Paragraph 3 that the generic will wait to enter until all listed patents have expired, or Paragraph 4 that any listed patents are invalid or will not be infringed by the generic.

When a paragraph 4 certification is made, the patent holder has 45 days in which to sue the generic applicant for infringement. Doing so triggers a 30-month stay of the generic's approval, unless the infringement litigation is resolved before then. The first generic manufacturer to file an ANDA with a paragraph 4 certification will be allowed 180 days of "generic exclusivity" during which no other generics for the same RLD will be approved once it actually starts marketing the drug.

The settlements that trouble the FTC resolve the infringement litigation that follows a paragraph 4 certification. Specifically, when the settlement specifies some future date at which the generic can begin marketing and calls for a payment or some other valuable consideration to be conveyed from the patent holder to the generic applicant, the FTC views the settlement as suspect. These were originally called "reverse payment" settlements because their critics viewed the payment from the patent holder to the generic as counter-intuitive. In their view the natural way in which payments ought to be made in a settlement is from the generic (the alleged infringer) to the patent holder. Now, presumably to emphasize its view that they are anticompetitive, the commission refers to them as "exclusion settlements," or "pay for delay" settlements.

These are the settlements that the commission, and now the Obama administration, would prefer to be *per se*, or at least presumptively, illegal.

III. THE ECONOMICS OF SETTLEMENTS

At one level the antitrust economics of patent litigation settlements in this context are straightforward. Compared to the alternative of seeing the litigation through to its end, a settlement is pro- or anti-competitive as it hastens or postpones the advent of generic competition. The difficulty is that the outcome of litigation is unknown. If the patent holder prevails, then—absent additional challenges to the patent—entry will not occur until the end of the patent's nominal life. If the generic applicant prevails, then generic entry can take place as soon as the litigation is completed. A settlement that reflects the likelihood of outcomes in the litigation divides the remaining patent life proportionally to the probabilities of the outcomes. If the patent holder stands a 90 percent chance of prevailing and there is a 10 percent chance the generic entrant will prevail, then the entry date that reflects those probabilities comes when 90 percent of the remaining patent life has been exhausted and only 10 percent remains.³

A. The Simplest View of Settlements

In a simple world without the complications of risk aversion, time preference (*i.e.*, the preference for immediate benefits/profit/gratification over postponed gratification) and litigation costs, the parties would only be willing to settle the litigation with an entry date that reflected the probabilities of either side prevailing if they could not make side payments as part of a

³ In the language of economic theory this would be the expected date of generic entry under litigation.

settlement. The patent holder would be unwilling to agree to an earlier entry date, and the generic applicant would be unwilling to agree to a later entry date.

If consumers' risk and time preferences could similarly be assumed away, then consumers would be indifferent between such a settlement and letting the litigation play itself out. Entry at an earlier date would benefit consumers by hastening generic competition, and entry at a later date would harm them by postponing generic competition.

This very simple world is the basis for the FTC's approach to reverse payments. In this setting the only reason the patent holder would have for making a payment to the generic applicant is because it gets something in return. Having assumed all other considerations away, the only possible basis for a quid pro quo is that the patent holder has paid the generic applicant to agree to postpone entry.

B. Litigation Cost and Risk

Reality is not so simple. For one thing, litigation is costly. The opportunity to avoid litigation costs gives both sides in the litigation a reason to be willing to settle on less favorable terms—the patent holder will tolerate earlier entry and the generic applicant will tolerate later entry. Or, the parties could make their concessions in cash, *i.e.*, side payments. Even without an extension of monopoly power, the patent holder would be willing to make a payment to the generic applicant that was less than its litigation costs in order to achieve a settlement.

Some critics of reverse payment settlements have acknowledged this possibility and conceded that reverse payments that do not exceed litigation costs might be acceptable. This allows for larger payments than might be superficially evident. A settlement resolves uncertainty and eliminates the risk brought about by uncertainty. The cost of risk bearing is, therefore, a component of the cost of litigation, and should be included in any litigation-cost cap that might be applied to settlement payments.

C. Information, Expectations, and Entry

Even accounting for litigation cost and risk, the foregoing is still too simple. Bargaining between a patent holder and a generic entrant can be affected by a variety of additional complications. Economic theory shows that these factors affect the possible outcomes of bargaining and the role of side payments, including reverse payments, in achieving settlements.⁴

One such factor is information. Having been in the market for some time, it's likely that the patent holder has better information about the value of the market and future prospects than does the generic applicant. A sophisticated generic bargaining with a better-informed counterparty would take account of the latter's superior information and interpret the other party's willingness to settle as an indicator of market value. This can complicate settlement negotiations in ways that preclude the parties from reaching a settlement if the entry date is the only term over which they can bargain. If, however, the patent holder can offer a cash payment to the entrant,

⁴ For a detailed description of the relationship between reverse payments and settlements described in the paragraphs below see Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, ANTITRUST BULL, 655 – 98 (Fall 2004).

that will be interpreted differently by a sophisticated entrant and can enable a settlement that would otherwise be impossible.

Another area in which the parties are likely to have different information concerns the litigation itself. If the parties have different information that leads them to make different assessments of the probabilities of the outcome of the litigation, then they may be unable to agree on a mutually acceptable entry date in a settlement. Quite apart from the information they possess, if one or both of the parties are overly optimistic about the chances of success in the litigation, the same problem can arise. In both cases the logjam can be broken by the ability to offer a side payment.

Bargaining is also complicated by the prospect of predictable additional entry by other parties, *i.e.*, additional generic manufacturers. Because the patent holder and the generic applicant will evaluate the profitability of market participation after additional entry differently, it may be impossible for them to agree on an entry date for a settlement without a cash payment. In this situation also, the ability to make a cash payment can enable settlements that were otherwise impossible.

There are, in short, a variety of plausible circumstances under which no mutually agreeable settlement is possible if “reverse payments” are prohibited, but in which settlements can be reached if they are not. For purposes of policy towards settlements, the striking thing about these circumstances is that some of the settlements that are made possible by the ability to make reverse payments make all parties—the patent holder, the generic entrant, *and consumers* better off than they would be if the litigation proceeded. And, since, in these circumstances, no settlements are possible without reverse payments, all parties are, therefore, made better off by the ability to include reverse payments in a settlement.

IV. THE LEGAL FIGHT OVER REVERSE PAYMENTS

The FTC has been opposed to reverse payments since it first became involved in these cases in 2000. As described above, the commission’s view of settlements is that the reverse payment is a *quid pro quo*, and that the patent holder must be buying additional monopoly time in return for its payment to the generic entrant. Initially, the commission sought to treat these settlements as *per se* illegal, and it got some support in that regard from a 2003 decision in a Sixth Circuit case involving a drug called Cardizem.⁵

After *Cardizem*, the commission’s view fared less well in the appellate courts. The Eleventh Circuit and Second Circuit have, in effect, ruled that until a patent is *proven* to be invalid or obtained by fraud its holder is entitled to protect the property right it represents using means that include settlements with reverse payments. A settlement—even one with a reverse payment—doesn’t violate antitrust law unless it extends the exclusion of competition beyond the limits of the patent.⁶

⁵ *In Re Cardizem CD Antitrust Litigation*, 332 F.3d 896.

⁶ *Valley Drug Company v. Geneva Pharmaceuticals, Inc.*, 344 F. 3d 1294; *Schering-Plough Corporation v. FTC*, 402 F.3d 1056; *In Re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187; and *Arkansas Carpenters Health and Welfare Fund v. Bayer AG.*, 625 F.3d 779.

The FTC continues to resist the acceptance of reverse payments. While the commission no longer argues that they are *per se* illegal, it continues to advocate a presumption of illegality. The commission would prefer to see courts treat settlements with reverse payments as “inherently suspect,” but allow the parties the opportunity to “establish that their agreement achieves beneficial efficiencies.”⁷ In effect the FTC seeks to shift the burden of proof to the parties to a reverse payment settlement to demonstrate that their agreement is efficient.

There are indications that this modified approach has not found judicial traction. In the *Andrologel* case the FTC made its argument in favor of presumptive illegality. Notwithstanding, the court relied on “the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”⁸ Moreover, in applying this rule the court declined to factor in the FTC’s argument that the patent holder would have been likely to lose the underlying patent litigation.

V. THE WAY FORWARD

The current state of law and economics towards reverse payment settlements appears, then, to be a fairly dismal choice between competing over-simplifications.

On the one hand lies the FTC’s approach of (thinly veiled) blanket condemnation. While it has dropped its advocacy of a *per se* rule, the commission still wants to treat the efficiency benefits of settlements with reverse payments as if they were an ancillary matter. This position is not supported by economic theory. The proposition that settlements should be treated as “inherently suspect” is predicated on an argument drawn from economic theory that the *only* rationale for such a settlement is to delay competition. But, except in the simplest possible—and intrinsically unrealistic—set of circumstances, that conclusion is wrong.

A settlement with reverse payments may be inefficient; it may not. Without a basis in economic theory for inferring that such settlements are inefficient, economics provides no basis for asserting that the settlements are or should be “inherently suspect.” The only other grounds the FTC articulates in favor of their preferred presumption is the assertion that the parties are more likely to have information about the settlement than the government or plaintiffs. But, if that were sufficient basis for a rule of law, then defendants in virtually all antitrust actions would be presumed guilty until they could prove themselves innocent.

On the other hand, the FTC is surely correct to be concerned about a rule that would immunize all settlements with entry within the nominal boundaries of the patent. Some patents are weaker than others. With a weak patent a settlement could extend the expected (likely) duration of generic exclusion and stay within the boundaries of the patent.

One approach would be to have courts hearing antitrust challenges assess the strength of the patent and use that as a basis for assessing the settlement. But that approach is unlikely to

⁷ FTC *amicus curiae* brief in *In Re: K-Dur Antitrust Litigation*, US Court of Appeals for the Third Circuit 10-2077, 79, and 79. This is a private case involving the same parties, products, patent, and agreements as those that were the subject of *Schering-Plough Corporation v. FTC*.

⁸ *FTC v. Watson Pharmaceuticals Inc.*, US Court of Appeals for the Eleventh Circuit No. 10-27729, April 25, 2012.

find judicial favor. The Eleventh Circuit’s description of that process in *Androgel* was colorful and made clear that the judges had no enthusiasm for undertaking it. “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.”⁹

The problem cries out for a better solution, and if one is to be found it will have to emerge from a more sophisticated and nuanced study of the economics of patent settlements. What is needed is a basis for inferring from the nature and terms of the settlement agreement whether or not it is likely to inhibit competition. While we may criticize the FTC for clinging to the over-simplification that all that is necessary to do so is to detect a “reverse” payment, that does not mean that the general approach is without merit—it just means that a more sophisticated version is required. If we are going to draw inferences about the efficiency of a settlement from its terms, then the framework of analysis must include the explicit treatment of circumstances under which settlements can contribute (may be necessary) to the achievement of efficient outcomes and should provide guidance as to how efficiency-enhancing settlements may be distinguished from inefficient settlements.

The stakes are large, and it will be costly to society to get it wrong either way. If we adopt too lenient a standard towards settlements, the cost of drugs and health care in general will be increased by monopoly power. On the other hand, if we adopt too strict a standard, then by limiting the settlement flexibility of patent holders and generic applicants, we will reduce the value of innovation in new drugs and the potential returns to developing generics, with the result that quality of health care is diminished.

The task is formidable, but this is no place for over-simplification.

⁹ *Id.*