Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III

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I. INTRODUCTION

Once again, I will address the issue of litigation settlements between companies that hold patents on pharmaceutical products (sometimes “pioneers”) and would-be generic entrants (“generics”) who challenge the validity of the patent and/or a claim of infringement.1 In my two earlier papers, I discussed various aspects of those settlements and acknowledged some evolution in views with progressively deeper immersion in the subject. This paper will focus on one subject which has been the focus of a particularly lively debate, namely, the legality of those settlements in which the generic agrees to defer entry for a period of time in return for the pioneer’s monetary payment. A payment of this kind is sometimes called a “reverse payment” to distinguish it from more familiar settlements that involve the payment of a royalty to the patentee.

In my second paper, published in 2001, I concluded that reverse payments raised serious legal issues. Two years later, in In re Schering-Plough Corp.,2 the Commission unanimously held that respondent Schering-Plough Corporation’s two reverse payment settlements violated § 5 of the Federal Trade Commission Act. The debate continues, however, because judicial reaction to the opinion has been somewhat less than


† Member of the D.C. Bar. The views expressed here are my own and not necessarily those of my former colleagues in the Federal Trade Commission (the Commission) or of my colleagues in, or clients of, my present law firm. It would not surprise me if some of the above strongly disagree; this is a tough subject.

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enthusiastic. The Court of Appeals for the Eleventh Circuit reversed the Commission summarily, and the Supreme Court declined to hear the case. In 2006, the Court of Appeals for the Second Circuit granted summary judgment against private plaintiffs in In re Tamoxifen Citrate Antitrust Litigation, a case predicated on the theory that a similar settlement violated the antitrust laws. As detailed below, both the majority and dissent in Tamoxifen analyzed the legality of reverse payments in ways fundamentally different from the Commission’s approach in Schering.

In light of these opinions (and others), it is appropriate to go back to square one and once more highlight the basic policy issues that these cases present. This discussion will focus on the Tamoxifen opinion, with passing reference to other decisions. Obviously, reasonable people can disagree on these issues, but I still believe the Commission’s approach in Schering was correct.

II. THE FUNDAMENTAL DILEMMA

The old adage that “hard cases make bad law” may or may not be true, but “hard cases” are surely hard to decide. The fundamental problem in this particular set of cases is that there are two apparently compelling lines of argument that point in opposing directions.

The first line of argument flows from the exclusionary rights conferred by a patent; the presumptive validity of patents; the strong judicial policy in favor of settlements; and the consequent conclusion that any settlement which permits generic entry on or before patent expiration cannot be anticompetitive, even if it provides for a reverse payment.

The second line of argument flows from the fact that Congress has passed a statute specifically designed to facilitate earlier entry by generic competition, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. This statute provides specific incentives for both patentees and challengers designed to encourage litigation to a conclusion, and because of the special economic dynamics of the pharmaceutical market, reverse payment settlements will defeat the objectives of the statute.

3. Schering-Plough Corp., 402 F.3d at 1058.
5. In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006).
A. Application of the First Line of Argument in Tamoxifen

A patentee has an absolute right to bar competition from any products that infringe its patent, and a patent is presumptively valid absent clear and convincing proof to the contrary. If it ultimately turns out that a patent is indeed valid and infringed, it is hard to see how consumers can be harmed by any settlement that provides for generic entry before the patent expiration date, regardless of whether the settlement contains a reverse payment. Consumers cannot complain simply because the patentee has chosen to share some of the “monopoly” profits with a potential challenger in the settlement. In these circumstances, it is not appropriate to speculate on whether consumers might have been even better off if the settlement had been structured in a different way. The straightforward simplicity of the argument, coupled with judicial preference for settlements, has obvious appeal.

For these reasons, the ultimate conclusion of the Tamoxifen majority may well be correct; it was appropriate to dismiss the complaint. It appears from the face of the opinion that patent validity, not infringement, was the determinative issue in the patent case that had been settled. In the period between the settlement and the Second Circuit opinion, the validity of the patent had apparently been upheld in three separate lawsuits.

However, one apparent problem is that, generally, the antitrust validity of a settlement agreement should be determined as of the date on which the agreement was signed, rather than the date the antitrust case is decided (or even the date the record in the antitrust case is closed). In Tamoxifen, the only available judicial precedent was a lower court opinion that held the patent at issue invalid. This apparent problem is not all that serious in the context of a private suit for damages. Even if it were assumed that the original settlement had been illegal, subsequent events could undercut a damage claim. Subsequent events do not transform an illegal agreement into a legal one; they just break the chain of causation between the illegal act and the market consequences. There are similar examples in other areas of antitrust. One example is a price fixing agreement, which is illegal per se. Such an agreement does not give rise to a damage claim if the parties thereafter have ignored it. Perhaps a somewhat closer analogy is a per se illegal agreement not to compete

7. The term “monopoly” is used here simply to refer to the patentee’s monopoly over its patented product. The shorthand expression does not signify that the patentee has monopoly power in a relevant market. Ill. Tool Works v. Indep. Ink, Inc., 126 S. Ct. 1281, 1284 (2006).
8. Tamoxifen, 466 F.3d at 194–95.
9. Id. at 204.
10. Id.
after some future date. Such an agreement would not cause damage if the party that gives the promise is barred from entry for other reasons—perhaps an import barrier—before the restriction becomes effective.

Assume, however, that an antitrust prosecutor, not a damage claimant, must assess the antitrust legality of a settlement before the merits of the underlying patent case have been resolved, and infringement is also an issue. The Commission confronted this situation in *Schering* and in a number of other cases that have been resolved by consent decrees. For reasons explained below, it is also a situation that continues to confront the Commission. What then?

**B. Application of the Second Line of Argument in the Commission’s Schering Opinion**

The line of argument that induced the Commission to take an adverse view of reverse payments in the *Schering* opinion may be restated as follows. In the Hatch-Waxman Act, Congress created a number of special incentives and rewards, in aid of an overarching objective of speeding generic entry without chilling innovation. To analyze these special features and their effects on the dynamics of settlement, it is necessary first to summarize some salient features of the Act.

The complex Hatch-Waxman provisions are outlined in many opinions, including the Commission’s opinion in *Schering*. For purposes of this discussion, the most significant elements begin with a process that enables a would-be generic competitor to get prompt FDA approval of its drug so long as it certifies that—for various alternative reasons—its sales will not infringe on a pioneer manufacturer’s patent rights. The most common certification (a “paragraph IV” certification) declares either that the pioneer’s patent is invalid or that the generic would not infringe. A generic that selects this form of certification must notify each affected patentee.

If no patentee brings an infringement action within forty-five days, the generic may get immediate FDA approval and start to sell its product. If, however, a patentee brings an infringement action within this

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15. *Id.* § 355(j)(2)(B).

period, the patentee is entitled to an automatic stay for a period that is likely to last up to thirty months.¹⁷ It will terminate earlier if there is a judicial decision on the merits of the action.¹⁸ As a result, pioneers effectively receive an automatic preliminary injunction, and generics receive the opportunity to litigate patent issues before they have actually entered the market and incurred crushing damage exposure. As an added incentive, the FDA rules give the first generic challenger the right to market a generic product exclusively for 180 days.¹⁹ This incentive can also benefit the pioneer because other generic challengers are not allowed to enter the market until 180 days after the first challenger enters.

Because of the particular dynamics of competition between pioneers and generics in the pharmaceutical industry, these special incentives have consequences that may not be immediately obvious. It is now generally recognized that the total profits available to the pioneer in the absence of generic entry exceed the total profits of both the pioneer and the generic after generic entry.²⁰ Thus, a pioneer can afford to “buy off” a generic challenger by a settlement under which the generic delays entry. In return for the generic’s delayed entry, the pioneer pays the generic an amount equal to, or in excess of, the profit the generic could expect to earn if it entered earlier. Therefore, the generic has a powerful incentive to use the Hatch-Waxman process to speed approval of its drug and embark on the first patent challenge, but it has no incentive whatsoever to pursue litigation to the end. In fact, when reverse payments are allowed, the generic may obtain more by settlement than it could have obtained by outright victory in the patent case. This fact alone distinguishes Hatch-Waxman settlements from settlements outside the ambit of the statute.

The pioneer patentee also has a strong incentive to settle, but for different reasons. The pioneer will make considerably more money over the life of the patent if it can win on the merits without buying off a challenger. However, the pioneer faces much more significant downside risks than does the generic. The patent could be declared invalid, a decision that could have a collateral estoppel effect in challenges by later generics. A settlement with the first challenger will avoid this risk, and under the applicable rules, it will block entry by later generics until 180 days after the first generic actually enters. Therefore, the pioneer has a

¹⁷ Id.
¹⁸ If the patentee does not sue within the time period, it does not waive its claims; instead, it does not get the automatic stay. Id.
¹⁹ Id. § 355(j)(5)(B)(iv).
powerful incentive to pay off the first generic challenger in return for its delayed entry, just as the generic has a powerful incentive to accept.

All of this may be of limited public concern except for the fact that the overarching objective of Hatch-Waxman was to speed the entry of generic drugs, a policy that was reaffirmed in 2003.21 It is simply impossible to read the story of the multiple blockades erected as a result of the settlement in Tamoxifen22 and conclude that this is the litigation model Congress contemplated. Broad judicial tolerance of reverse payments will simply convert Hatch-Waxman into a facilitating vehicle for generics to collect a species of “greenmail.”23 In fact, because Hatch-Waxman settlements can block later generic challenges, there is some potential for collusive litigation between the pioneer and a generic that is complaisant from the start.

III. CRITIQUE OF THE TAMOXIFEN OPINION

It may be that the bottom-line decision in Tamoxifen is correct because it appears ex post that the patent is valid, and in the absence of an infringement dispute, the patentee was entitled to its patent monopoly for the full term. If, however, the question is antitrust legality before the patent issues have been conclusively decided, the settlement appears in a very different light. Even the Tamoxifen majority views the settlement as “suspicious,”24 but the majority also seems to believe that it had no realistic alternatives. Perhaps the best way to test that conclusion is to track some of the decision points in the opinion to see whether there were alternatives that would be more consistent with the objectives of the underlying statute.

A. The Structure of the Opinion

The Tamoxifen opinion first emphasizes the legality of the settlement agreement at the time it was signed and concludes with a brief discussion of subsequent events that also undercuts a claim for damages. As suggested earlier, it would have been relatively economical and uncontroversial for the majority to say that intervening decisions about patent validity were fatal to the damage claim; therefore, it did not need to

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22. See infra text accompanying notes 56–60.

23. It is not at all surprising that the Generic Pharmaceutical Association supported the legality of these payments in Schering. See In re Schering, 402 F.3d 1056, 1057 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

24. Tamoxifen, 466 F.3d at 208.
consider the legality of the settlement agreement. The opinion obviously took the long route to send a message to be applied in future cases. That the opinion recognizes the existence of difficult choices also makes Tamoxifen a more interesting subject for analysis than the cursory conclusions of the Eleventh Circuit in Schering.

B. Apparently Obvious Statements with Underlying Complexities

The Tamoxifen opinion begins with a series of propositions that are non-controversial on the surface but which may gloss over some underlying complexities.

First, the court states: “We begin our analysis against the backdrop of our longstanding adherence to the principle that ‘courts are bound to encourage’ the settlement of litigation.” It is hard to quarrel with this general proposition, and this policy perhaps has special force in the context of patent litigation. When it comes to litigation under the Hatch-Waxman Act, however, Congress has chosen to put its thumb on the scale. To facilitate the introduction of generic substitutes, Hatch-Waxman seeks to encourage patent challenges, and reverse payments make it very easy for the litigating parties to thwart that underlying objective.

While the plain language of the Hatch-Waxman Act does not outline the permissible parameters of pioneer-generic settlements, it does establish certain procedures for the conduct of pioneer-generic litigation in aid of clear objectives. Because agreements to defer generic entry plainly would be per se illegal, absent this litigation context, the Commission in Schering attempted to give appropriate deference to congressional policy expressed in the original Hatch-Waxman Act. The

25. See discussion supra Part II.A.

26. This is not uncommon. The Commission’s own opinion in Schering expressed views on the legality of reverse payments, In re Schering-Plough Corp., No. 9297, 2003 FTC LEXIS 187, at *60–67 (F.T.C. Dec. 8, 2003), followed by a detailed factual inquiry into whether there was a reverse payment in the first place, id. at *89–169. The idea was to separate general principles from some case-specific facts.

27. It is hard for me to view Schering dispassionately, but I cannot escape the conclusion that the opinion is driven by the court’s erroneous belief that a challenger bears the burden on the issue of infringement as well as the issue of validity. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

28. Tamoxifen, 466 F.3d at 202 (quoting Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004)).

29. As the court stated in dicta in In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F. Supp. 2d 188, 204 (E.D.N.Y. 2003), “the challenged agreements allowed [the generic] to accept cash in exchange for an agreement to halt the process . . . encouraged by the Hatch-Waxman Amendments and beneficial to consumers.”

Medicare Prescription Drug, Improvement, and Modernization Act of 2003\textsuperscript{31} is even more explicit about settlements. In that statute, Congress gave the Commission special responsibilities for review of pioneer-generic settlements,\textsuperscript{32} after the Commission’s jaundiced views on reverse payments were well known. Given this history, it is hard to argue that Congress wanted the Commission merely to apply the standard hornbook principle that settlements are prohibited if and only if they restrict entry beyond the time or the coverage of a patent.\textsuperscript{33} Therefore, although a general policy in favor of settlements remains viable, and perhaps imperative in many contexts, Hatch-Waxman settlements are different.

Second, another facially uncontroversial statement with trouble brewing underneath is the observation that, when determining legality, it is necessary to look at the world as it existed at the time of settlement.\textsuperscript{34} This position makes sense because parties who contemplate settlement are entitled to some certainty. However, the Tamoxifen court does not address the more controversial question of whether and how a court should examine the subjective expectations of the settling parties themselves, as part of that determination.

For example, is it necessary to find out how optimistic or pessimistic the settling parties were about their litigation chances? This would be a problematic exercise. For good reason, other areas of antitrust law tend to downplay the importance of subjective indicia of “intent.” The evidence may be of even more limited relevance in the present context. There are the standard objections that intent evidence may be manipulated and that because a corporation has a large number of actors, each with his own “intent,” it is artificial to attribute subjective intent to the entity as a whole. Moreover, when it comes to litigation settlements, the best evidence on subjective views about litigation prospects is likely to be contained in privileged communications.\textsuperscript{35}

Finally, absent evidence that one party or another viewed its own claim as a sham, it would be unclear how to use such evidence, even if it were available. Take the simplest possible case, where each party evaluates its chances of success at 50/50. If the Tamoxifen court is right and


\textsuperscript{32} Medicare Prescription Drug, Improvement, and Modernization Act of 2003 §§ 1112–1118.

\textsuperscript{33} Contra Tamoxifen, 466 F.3d at 212–13.

\textsuperscript{34} See id. at 203–04.

\textsuperscript{35} In Schering, there was some record evidence that indicated both Schering and Upsher-Smith, the generic challenger, expected generic entry promptly upon expiration of the thirty month automatic stay. See In re Schering-Plough Corp., No. 9297, 2003 FTC LEXIS 187, at *47–55 (F.T.C. Dec. 8, 2003).
reverse payments are essentially per se legal when entry restrictions are limited to the scope of the patent, then such evidence adds nothing. If the Tamoxifen court is wrong and reverse payments are suspect, it is also unhelpful. For example, we cannot conclude that the only reasonable settlement would be one that provides for generic entry halfway along the remaining patent life because the individual parties may have very different risk tolerances.

Another possibility would be for the antitrust court itself to undertake a mini-trial on the merits of the underlying patent claim to decide whether particular settlement terms would likely result in competitive harm. The question of whether such a mini-trial is necessary is linked to the issue of how to take appropriate account of the preclusive power of a patent.

IV. THE PRECLUSIVE EFFECT OF A PATENT

The Tamoxifen and Schering courts relied on the presumptive validity of a patent to support the conclusion that any settlement that does not exceed the exclusionary scope of a patent must also be valid. Within these parameters, both decisions find that a patentee can pay whatever it takes to buy off a potential challenger. Apparently, an antitrust court cannot declare such a settlement illegal—at least without its own inquiry into the merits of the patent case. No shortcuts are possible. We now consider, first, whether this principle should be applied to settlements where patent infringement is an issue and, second, whether the principle should be modified in validity disputes under Hatch-Waxman procedures.

A. The Infringement Issue

The Eleventh Circuit premised its Schering opinion on the fundamentally mistaken notion that the generic challenger has the burden of proof on both the issue of infringement and the issue of validity. If this were the law, one could argue for the default assumption that a patentee has a right to exclude, bounded only by the term and scope of its patent. But, this is not the law. Because infringement was an issue between the parties to the settlement in Schering, the Commission found that it was

36. See Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006) (“Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the ... [relevant] patent was invalid or that their products... did not infringe Schering’s patent.”).

37. It is clear that a patentee has the burden of proof on the issue of infringement. See, e.g., Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1578 (Fed. Cir. 1993).
impossible to make any initial assumptions about the preclusive power of a patent.\footnote{Schering, 2003 FTC LEXIS 187, at *68–70 (F.T.C. Dec. 8, 2003).}

The Commission did, however, rely on the special characteristics of patent litigation when it declined to apply the Sixth Circuit's per se condemnation of reverse payments.\footnote{Id. at *69–70.} Ordinarily, it would be as per se illegal for an incumbent to pay a potential competitor for delayed entry as it would be to compensate the competitor for a permanent commitment to stay out of the market. However, when the incumbent is a patentee that might ultimately have been able to establish its right to exclude a generic competitor, the Commission was, and is, willing to entertain some justifications for a payment not to compete. This is still a long way from saying that the payments are essentially per se legal if the non-compete agreement does not delay entry beyond expiration of the patent.

The Commission emphasized that infringement was an important issue in the Schering case.\footnote{Id. at *74–76.} A case without the infringement issue may be different because of the presumption of patent validity. Some controversy exists about the appropriate strength of that presumption today given the problems that some perceive in the patent approval process.\footnote{See, e.g., FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (Oct. 2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf.} However, in Schering, the Commission was not driven by any view on the appropriate global balance between the domains of patent law and antitrust law. Rather, the Commission was affected by an appreciation of what Congress was trying to accomplish in Hatch-Waxman.

\subsection*{B. The Validity Issue}

Given the default assumption that a patent is valid, how should a court approach a settlement when validity is the only issue? It may be necessary for an antitrust tribunal to examine the merits of the patent case to determine whether a private party has been injured. However, it is not necessarily efficient to require it when the Commission reviews settlements pursuant to its congressional mandate\footnote{See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, §§ 1112–1118, Pub. L. No. 108-173, 117 Stat. 2066, 2461–64 (codified at 21 U.S.C.A. § 355 (West Supp. 2006)).} or when a court reviews a prosecutor's action. Some problems with this approach are outlined in the Commission's Schering opinion.\footnote{Schering, 2003 FTC LEXIS 187, at *68–79.} Perhaps the most significant problem is that the parties to a reverse payment settlement, with greatest
access to the facts, are no longer in an adverse relationship when the settlement is challenged. Instead, they have a mutual interest in asserting that the generic challenge was problematic from the start. Another difficulty is that an ex post mini-trial on the merits would make it hard for parties to assess the legality of their settlements ex ante.

If a mini-trial on the merits is impractical, how should the Commission or an antitrust court look at the settlement in a case that involves only a challenge to patent validity and where the merits of the patent claim are unclear? The Second Circuit in Tamoxifen said simply that the exclusion rights granted under a presumptively valid patent, coupled with a strong public policy in favor of settlements, will immunize any settlement that does not preclude competition outside the scope of the patent. This is overly simplistic. Consider the analogy of the antitrust principles applied to patent licenses. An argument could be made that every restriction in a patent license should be presumptively lawful. Because the patentee has a legal right to exclude all competition, even a restricted license allows more competition than could otherwise have taken place. But this facially compelling argument will not immunize a patent license that contains a price-fixing restriction.

How can this be? The answer is that a judge-made rule has declared certain conduct to be "so plainly anticompetitive" that it is deemed illegal per se across the board, even though in a particular case it may be less restrictive than an alternative legal arrangement. This rule can apply when the legal alternative is a refusal to license a patent altogether, just as it can apply in other contexts. For example, a per se illegal resale price agreement may be less restrictive than a legal grant of an exclusive territory.

For reasons explained in the next subsection, broad tolerance of reverse payments not only will defeat Hatch-Waxman's fundamental objective to motivate first challengers, but, even more perversely, it will enable the settling parties to preempt subsequent generic challengers. If the preclusive effect of a patent does not overcome a presumption against

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44. Id. at *77–78.
45. Id. at *78–79.
per se illegal license restrictions, the preclusive effect should not necessarily overcome a much weaker presumption against settlements that threatens to turn the impact of Hatch-Waxman upside down.

C. Special Hatch-Waxman Arguments

The Tamoxifen court, like a number of others, seemed to accept the proposition that reverse payments are a natural and inevitable by-product of the Hatch-Waxman Act. Additionally, the court suggested that prohibiting reverse payments would make it impossible to settle pioneer-generic patent litigation. The argument is that the statute has dramatically shifted the traditional balance of power because the pioneers now risk so much more than the generics do. The Tamoxifen court stated that “reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them.” In fact, the court went even further by suggesting that without reverse payments, pioneers “would be required to litigate each threatened patent to final, unappealable judgment.”

The first, and perhaps most important, response to this speculation is that it has no factual basis. The Commission has closely monitored pioneer-generic settlements, as Congress mandated it to do in 2003, and it recently published a report on this activity. Of fourteen pioneer-generic settlements filed with the Commission in fiscal year 2004, none included a reverse payment. In fact, even before the Commission’s first enforcement action, a study found that eleven of twenty settlements with first generic challenges did not include reverse payments. Parties to these settlements could obviously reach agreement without them. If, however, reverse payments are routinely allowed, generics will have a natural and inevitable incentive to sell out their claims, delay entry more than they would otherwise, and blockade others behind them. This already may have started to happen.

50. Tamoxifen Litigation, 466 F.3d at 212–13.
51. Id. at 206.
52. Id. at 212.
54. Id. at 3.
The blockade of other generics has significant effects, and deserves some elaboration. As the *Tamoxifen* court pointed out, a change in FDA rules has given the first generic challenger a 180-day exclusivity period from the date of its own entry, regardless of whether it has successfully defended the pioneer’s infringement action.\(^{57}\) Thus, to the extent that the reverse payment results in later entry by the first challenger than would have occurred, subsequent generic challengers are held up as well. The *Tamoxifen* court is correct that it is not an antitrust offense, standing alone, for the first generic to take advantage of the exclusivity granted by the FDA rule. However, in a case where a court must look at the likely competitive harm ex ante, rather than damages ex post, it would be appropriate to consider that the settlement delays entry not only by the first generic but also by subsequent challengers.

Consider, for example, the rough analogy of an import restriction, referred to earlier in another context.\(^{58}\) It does not violate the antitrust laws if a company takes advantage of import restrictions imposed by trade laws. Nevertheless, if a company is contemplating a merger in an industry with import restrictions, the existence of the restrictions will affect the analysis of market shares and likely competitive effects.\(^{59}\)

Obviously, the FDA rule change that made it easier for the first generic to earn 180-day exclusivity was designed to provide another incentive for the first generic to step up to the challenge. But the rule change has also conferred a benefit on the pioneer. Later challengers are blockaded, in all likelihood for at least thirty months and potentially a great deal longer, if settlements like that in *Tamoxifen* are tolerated. After the pioneer settles with the first challenger for an extended entry delay, it can safely ignore the threat of additional generic entry.\(^{60}\)

Notwithstanding these offsetting advantages, it may well be true that Hatch-Waxman benefits generics much more than pioneers because generics’ litigation risks are so much less. However, Congress has the right to modify the parties’ traditional bargaining power as it chooses and for ends that it deems appropriate. The decision to change the traditional balance of bargaining power is a political one within the purview of elected officials. The change may mean that pioneers will need to settle for earlier generic entry than they would otherwise, but it is really not

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57. *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 192 (2d Cir. 2006).
58. See discussion supra Part II.A.
60. Declaratory judgments are unavailable to these additional generic challengers if the pioneer simply does not threaten to sue. *See* Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1338 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 473 (2005).
relevant whether people in agencies or on the bench think this is a good idea.

Courts also tend to forget that parties who do not want to play by Hatch-Waxman rules can still choose to play by the old rules. A pioneer that wants to force generic challengers to accept the traditional litigation risks does not need to challenge the generic’s certification within the statute’s forty-five day period. Rather, it can simply wait for a generic to enter before it files suit. While the pioneer gives up an automatic thirty month stay, it does have the potential to collect crushing damages, measured by its own lost profits rather than the undoubtedly smaller profits of the generic. Thus, it is reasonable to conclude that a pioneer that chooses to accept the benefits of the law cannot thereafter undercut the objectives of the law by buying off the generic challenger. Similarly, it is reasonable to conclude that a generic that has chosen to avail itself of the advantages conferred by Hatch-Waxman does not have an unbounded right to sell out for a share of the pioneer’s profits at consumers’ expense.

V. PRACTICAL ADVANTAGES OF THE COMMISSION’S APPROACH IN SCHERING

The Tamoxifen court was “not unaware of a troubling dynamic” associated with the conduct that it chose to uphold as a matter of law but seemed strangely convinced (despite contrary facts) that any alternative rule would “outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions.” Even the dissent was unable to come up with an approach other than an open-ended rule of reason inquiry, “weighing various factors including the strength of the patent as it appeared at the time of the settlement.” It is strange that neither the majority nor the dissent was even willing to consider a more practical alternative. It is demonstrably false that reverse payments are essential for settlement, so per se legality is not the only available option. Nevertheless, no one outside the academic world seems to agree with the practical alternatives that the Commission set out in Schering. However, that does not mean the Commission’s approach in Schering was wrong. The advantages of that approach may be summarized briefly as follows.

Reverse payments are not per se illegal, but they do raise serious issues in the Hatch-Waxman context. It is difficult to come up with an appropriate shorthand expression to describe reverse payments. The term inherently suspect that is used in other contexts does not quite fit because

61. Tamoxifen, 466 F.3d at 211.
62. Id. at 212.
63. Id. at 225 n.3 (Pooler, J., dissenting).
64. See supra text accompanying notes 53–55.
that term suggests a focus on the nature of the conduct rather than the nature of the market.\textsuperscript{65} The suspicion of reverse payments arises out of a special market characteristic, namely the economic fact that generics can earn more by an agreement to defer their entry into the market than they could earn by winning their patent challenge and competing in the market. Moreover, the pioneers have a powerful incentive to pay generics something more than they would earn by entry because the sum is still less than the amount the pioneer would lose if the generic did enter. If this is allowed as a matter of course, then settlement can defer entry for the entire remaining patent life, and Hatch-Waxman is a dead letter.

On the other hand, the Commission did recognize that most cases will settle and that parties need some practical guidance on ways to do it. Therefore, the Commission stated that it would not attack a settlement that merely provided for some entry between the settlement date and the date of patent expiration.\textsuperscript{66} The idea is that an agreed-on split is likely to reflect a compromise of each party’s individual litigation expectations. If these litigation expectations have been affected by the special Hatch-Waxman procedures, so be it.

It is true that reverse payments may resemble other deals that accommodate a generic challenger. The \textit{Tamoxifen} court, for example, questioned whether there was any distinction between a reverse payment and a more traditional settlement,\textsuperscript{67} which might include a reduced royalty or a compromise on damages. But unlike a reverse payment, neither of these alternatives has the potential to offer greater rewards in settlement than can be obtained by outright victory. In any event, the Commission’s \textit{Schering} opinion did not need to address either alternative.

It is also possible that a reverse payment could enable a generic to compete more effectively after the additional delay. The Commission acknowledged that there might be a so-called “cash-starved” generic justification.\textsuperscript{68} Moreover, the Commission recognized that litigation is expensive and that a pioneer may be willing to avoid the nuisance of a lawsuit. The proposed order was intended to recognize this reality.\textsuperscript{69}

\textsuperscript{65} \textit{See In re Schering-Plough Corp.}, 2003 FTC LEXIS 187, at *37–38 (F.T.C. Dec. 8, 2003) (“[T]he facts of this case require us to look beyond the nature of the challenged restraint and consider the nature of the market.”).

\textsuperscript{66} \textit{Id.} at *78 (“Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack.”).

\textsuperscript{67} \textit{In re Tamoxifen Citrate Antitrust Litigation}, 466 F.3d 187, 207 n.20 (2d Cir. 2006).

\textsuperscript{68} \textit{See Schering}, 2003 FTC LEXIS 187, at *83, in which the Commission acknowledged that up-front support to a “cash starved” generic could have “competitive benefits” but also pointed out that the issue of financial need had been waived.

\textsuperscript{69} As explained in \textit{Schering}, 2003 FTC LEXIS 187, at *184–85, the order prohibited reverse payments generally, but provided an exception for litigation costs up to $2 million. An order which
These, and perhaps other justifications, explain why the Commission was not willing to say that reverse payments are per se illegal. Nevertheless, it is obvious that the per se legality rule, which the Second Circuit adopted, is not the only alternative. Here, as in so many other areas, always is not the only alternative to never.

VI. CONCLUSION

The Commission essentially got things right in Schering, notwithstanding the Eleventh Circuit’s abrupt reversal and the Second Circuit’s more considered, but still flawed, treatment of the issues in Tamoxifen. The question becomes, what happens now?

Public statements of individual commissioners and public testimony authorized by the Commission as a body suggest that the agency has not reversed its position. There is a sharp split in the circuits: two circuits clearly oppose the Commission’s view, one would likely tolerate it, and the rest are uncertain. Thus, the Commission can forum shop if it is willing to give up the advantage of administrative litigation and proceed directly in a federal court. And, of course, so can private plaintiffs.

Other options are also available. The Commission might decide to proceed administratively against a reverse payment settlement where there are objective indications that the patent claims are weak. If a violation were found, it would likely be appealed to a previously unsympathetic circuit, but the case could test the outer limits of that circuit’s toleration for reverse payment settlements. Another alternative for the Commission might be efforts to seek legislative clarification.

The Commission has not yet signaled what it intends to do, and this uncertainty complicates the job of those who advise pharmaceutical companies in Hatch-Waxman litigation today. It may not be easy for an antitrust advisor to advocate caution when the recent trend of judicial decisions seems favorable to reverse payment settlements and when they appear to be increasingly common.

“fences in” the future conduct of a wrongdoer does not necessarily establish a rule of law for everyone, so the $2 million should not be interpreted as an upside limit.


71. See In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S. Ct. 2929 (2006).

72. See In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).

73. From the Commission’s standpoint, the comparative advantages of the administrative process are less apparent in follow-on cases than in a case of first impression like Schering.
But, litigation risks continue. Pharmaceutical companies might have been better served if the Supreme Court had decided to hear the Schering appeal, although it is understandable if some of the companies disagree. In any event, antitrust consequences of reverse payments will remain in doubt until the Supreme Court decides to resolve the matter, a stronger consensus emerges in the courts of appeal, or Congress intervenes.