

Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal

BY RONALD W. DAVIS

HOW SHOULD ANTITRUST analyze a patent settlement where (a) consideration flows from the patentee to the alleged infringer (a “reverse payment”) and (b) the alleged infringer promises to respect the rights claimed by the patentee?¹ Writing in the Spring 2006 issue of this magazine, James Burling² summarized the then unhappy state of the law. Since then we have gone from bad to worse. The Federal Trade Commission, which thinks reverse payment settlements should be presumptively unlawful, but was shot down by the Eleventh Circuit,³ saw the Justice Department sabotage its appeal to the Supreme Court⁴—a confrontation between the two agencies without precedent in antitrust history.

Whatever the merits of the Commission’s position, it is not in a position to take effective enforcement action, at least through administrative litigation. (Suing in district court—outside the Eleventh Circuit—may, however, be an alternative for the FTC.⁵) Meanwhile, although the Antitrust Division thinks the FTC is wrong, the Division has not articulated a clear rule to resolve antitrust challenges to reverse payment settlements.

There is a conflict among the lower federal courts, with an arguable trend in favor of permissiveness—if not outright *per se* legality—of reverse payment settlements.⁶ But a bill pending in Congress would make such settlements *per se illegal*.⁷ And the commentators are all over the lot.

This article summarizes and comments on the differences between the two agencies, provides a Baedeker to the views of courts and commentators, and suggests a way to dig ourselves out of this hole. Let us begin with a hypothetical.

The Hypothetical. Phrmco has a patent on a chemical compound or on a formulation, for example, a time release mechanism. Happily for Phrmco, its patented product or formulation is so successful that the patent affords actual market power. Challenger Co. wants to make and sell a generic version of Phrmco’s product or formulation. To that end, Challenger seeks approval from the Food and Drug Administration. Under the procedures of the Hatch-Waxman Act,⁸ Challenger files a so-called paragraph IV certification,⁹ asserting either that Phrmco’s patent is not valid or that Challenger’s formulation does not infringe the patent, or possibly both. Under the Hatch-Waxman Act, the filing of the certification is a constructive act of infringement.¹⁰ Phrmco sues for infringement. Neither Phrmco’s claim of patent infringement nor Challenger’s assertion of invalidity and/or non-infringement is “objectively baseless”; in other words, neither position is a sham.¹¹

At some point prior to final resolution in court the parties settle. As a part of the settlement, Challenger agrees to respect Phrmco’s claimed patent rights (in whole or in part) and thereby contractually limits its own commercial freedom. There is thus an agreement in restraint of trade.¹²

In our hypothetical, the settlement also includes significant economic consideration flowing from Phrmco to Challenger. (The consideration might be cash, it might be a side deal on terms favorable to Challenger, or it might be a license of the patent in question, again on favorable terms.¹³ Whatever the form, this is the “reverse payment.”)

The FTC issues an administrative complaint charging that the settlement violates FTC Act Section 5,¹⁴ which embodies the jurisprudence of Sherman Act Section 1. Direct purchasers also sue in federal district court, seeking recovery for claimed anticompetitive overcharges on the theory that the settlement agreement is an unreasonable restraint of trade which permitted the settling parties to share profits derived from artificially high prices. Indirect purchasers sue under applicable state antitrust laws. What is the result?

Old Precedent. Older cases suggest, in general terms, that, while there is a strong public policy in favor of settlement of litigation, an IP settlement involving restraints of trade is not exempt from scrutiny under Section 1 and may be unlawful if the settling parties go beyond the scope of the IP rights in question.¹⁵ These older precedents address situations that are arguably distinguishable from the hypothetical, and provide no definitive answer to the legality of reverse payment patent settlements.

Recent Cases. More recently, settlements involving five different drugs, in circumstances roughly similar to the hypothetical, have given rise to litigation. In *Cardizem*¹⁶ the district court and the Sixth Circuit held that an interim settlement of the patentee’s infringement claim whereby the challenger agreed *inter alia* not to enter the market before a final and unappealable judgment of non-infringement—and received cash payments—was a *per se* illegal market allocation agreement. The Sixth Circuit’s succinct discussion of the

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merits could be read to say that paying a competitor to stay off the market in a patent settlement is always per se illegal, but is better construed to hold only that the settlement was per se illegal given several egregious circumstances, going beyond the simpler hypothetical presented above. (The settlement (1) covered generic products whether or not they infringed a patent held by the branded firm, (2) used Hatch-Waxman provisions to game the system so that third parties were precluded from competing, and (3) did not settle the patent litigation, but granted a sort of private preliminary injunction on terms different from those a real court would have ordered.)

In *Terazosin*,¹⁷ where the issue to be litigated was patent validity, not infringement, the district court thought the settlement was a per se illegal market allocation. The Eleventh Circuit, however, reversed and remanded, instructing the district court to consider whether the settlement involved agreements outside the scope of the patent. On remand in 2005, the district court embraced the controversial probabilistic theory of patent rights (of which more shortly), and again held the settlement per se illegal because the agreement provided for a negotiated stay pending appeal even though the district court in the patent case had found the patent invalid.

In *Schering-Plough*¹⁸ the FTC ruled that, at least in the absence of an alternative persuasive explanation, a reverse payment in a patent settlement may be presumed to compensate the challenger for settling in a more anticompetitive way than would otherwise have occurred. (The Commission maintained, however, that it is all right to settle infringement litigation by an agreement under which the challenger agrees to respect the patent and stay off the market for a period ending before the expiration of the patent.)

On appeal, the Eleventh Circuit cited its holding in *Terazosin (Valley Drugs)* and reversed, holding that the settlement was lawful because it was within the scope of the patentee's rights. The Eleventh Circuit's reasoning is hard to follow, inasmuch as the issue in *Schering-Plough* was infringement, not patent validity, and there had been no judicial determination as to whether the challengers' products did or did not infringe.¹⁹

In *Tamoxifen*²⁰ a majority of the Second Circuit panel agreed with the district court that it was lawful for parties litigating a patent validity challenge to settle—while the case was on appeal from a judgment of *invalidity*—and to agree that the challenger would respect the patentee's rights and receive a substantial sum of money in exchange. The court emphasized that unlike such cases as *Cardizem*, the settlement did not adversely affect the rights of third parties. *Ciprofloxacin*,²¹ in the Eastern District of New York, had facts similar to *Tamoxifen* and reached the same result.

Several reverse payment settlements have been the subject of FTC consent decrees,²² and, since 2003, legislation has required such settlements to be notified to the antitrust agencies.²³ But with the FTC's setback in the Eleventh Circuit,

and the Second Circuit's decision in *Tamoxifen*, it has been, according to the FTC, open season for anticompetitive reverse payment settlements.²⁴

Seven Solutions

Amidst wide disagreement, almost everyone agrees on one important point. If a legal claim is objectively baseless, and if there is subjective intent to interfere with a competitor rather than to seek judicial relief, the legal claim is a sham and pursuing it may violate the Sherman Act.²⁵ If there is no right to ask a court to grant judgment upholding a sham claim, a fortiori there is no right to purport to “settle” a sham claim by entering into an otherwise illegal market allocation.²⁶

But with the FTC's setback in the Eleventh Circuit, and the Second Circuit's decision in *Tamoxifen*, it has been, according to the FTC, open season for anticompetitive reverse payment settlements.

That leaves the question of what rule should apply to settlements of non-sham claims of patent infringement, bearing in mind that a non-sham claim may still be a weak claim. With that thought in mind, we turn to the first of several proposed solutions.

1. In the hypothetical, the settlement is an agreement, but there is no restraint of trade—and hence nothing to analyze under the per se rule or the rule of reason.

An agreement between competitors that does not restraint trade is outside the scope of Section 1 of the Sherman Act. In the hypothetical, however, Challenger gives a contractual commitment limiting its competition with Phrmco—a restraint of trade in almost anyone's lexicon. Even so, the 2–1 majority in *Tamoxifen* appeared to think not that the agreement was per se legal, but rather that it was not a restraint of trade at all.

In *Tamoxifen* the issue was patent validity, not infringement, and the patentee paid money to keep the challenger out of the market *after* a district court finding in the challenger's favor. The Second Circuit admitted that these two circumstances, taken together, smelled fishy,²⁷ but decided on second thought that (1) it really had no way of knowing what the Federal Circuit (which loves patents) would have done with the appeal, so that the challenger's victory in the district court really did not count for much, and (2) the fact of a large reverse payment did not imply very much, one way or the other, about the actual strength of a patent claim.²⁸

The court's point that reverse payments are not necessarily an indication of weak patent claims seems counterintuitive, but may nevertheless be sound. But the Second Circuit's musings on the metaphysical unknowability of the actual strength of the patent²⁹ merit skeptical consideration. The

court's analysis would have been much more persuasive if the antitrust plaintiffs intended to rely solely on the fact of a reverse payment and the fact of a finding for the challenger in the district court. But the complaint alleged that the Federal Circuit *would have* upheld the finding of invalidity³⁰: one supposes that the plaintiffs intended to prove at trial that the patent was in fact invalid, not merely to rely on indirect evidence that it might be invalid.

Assessing likelihood of success on the merits is something courts do every day in ruling on preliminary injunctions and stays pending appeal, and the strength of a class action plaintiff's case is a consideration in settlement approval decisions. The Second Circuit's discovery of an absolute bar against the introduction of evidence bearing on likelihood of success on the patent appeal is contrived and unpersuasive. Accordingly, its conclusion that "the behavior of the defendants alleged in the complaint would not violate antitrust law,"³¹ rests on shaky ground.

In short, the first of the seven solutions will not fly: we cannot legitimately deny that we are dealing with a real restraint of trade, which is unlawful unless it is legally reasonable.

2. The settlement restrains trade, but it is per se reasonable.

With a few exceptions,³² the per se legality approach finds scant support with the commentators, who, by and large, propose novel rules that try to balance IP considerations, antitrust considerations, and the policy in favor of settlement. By contrast, Judge Richard Posner almost endorsed (and may have meant to endorse) a per se legal approach in *Asahi Glass*.³³ There he observed, in triple dictum,

"Reverse payment" patent settlements, that is, settlements *unlike* the one between [the parties in the case at bar], in which the patentee explicitly pays the alleged infringer to stay out of the market, are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive. At any rate, the theory, good or bad, is inapplicable here.³⁴

The Eleventh Circuit's opinion in *Schering-Plough* may also be read to hold that settlements of non-sham litigation are per se legal if the restraint of trade does not exceed the scope of the claims the patentee asserted in the litigation. The FTC reads the Eleventh Circuit that way,³⁵ while, by contrast, the Justice Department thinks that the Eleventh Circuit would have considered evidence of the underlying strength or weakness of the infringement claim if there had been any such evidence to consider in the record before it.³⁶

Is one of the agencies playing games here? No, the Eleventh Circuit decision in *Schering* is so profoundly ambiguous that either interpretation is legitimate, though the FTC seems to have the better of the argument.



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Citing its earlier decision in *Valley Drug*, the Eleventh Circuit said it was reiterating that "the proper analysis of antitrust liability requires an examination of: (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."³⁷ "Here," it said, "we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal."³⁸

But what was the basis for this "finding"? The dispute in the case was about infringement, not the validity of the patent. If the challengers' time-release formulations did not in fact infringe, then their promise not to compete must have been a promise not to do something they would have been permitted to do under the patent. Yet infringement or not was never adjudicated. Therefore, some argue, if the Eleventh Circuit affirmatively "found" that the agreement in restraint of trade was within the scope of the patent—which is what the court said—the court must have meant that any settlement of a non-sham patent claim is per se lawful. On the other hand, based on the court's references to the absence of an FTC finding on the strength of the infringement claim,³⁹ it may be (just barely) possible to read the Eleventh Circuit as saying that the FTC bore the burden of proving a restraint outside the scope of the patent's protection, and that it simply failed to meet that burden. But if *that* is what the court meant, it used peculiar language to convey its meaning.

In short, Judge Posner's triple dictum in *Asahi*, the Eleventh Circuit's ambiguous decision in *Schering*, and limited support among the commentators provide little solid ground for the per se legality solution.

3. The settlement is per se illegal.

Don't like the rule of per se legality for reverse payment settlements? Well, then, how about a rule of per se *illegality*?

Legislation introduced in the wake of the Supreme Court's denial of certiorari in *Schering-Plough* would make such settlements per se illegal under Section 5 of the FTC Act.⁴⁰ As currently drafted, the legislation does not refer to the Sherman Act, and it would not, read literally, overrule cases like *Tamoxifen*. If the statute were enacted, reverse payment

patent settlements would be legal per se in the Second Circuit and per se illegal in FTC proceedings! (The FTC, choosing its words carefully, has said that it supports the intent of the legislation.⁴¹ In *Schering-Plough*,⁴² however, the FTC said that reverse payment settlements are not per se illegal or even “inherently suspect.”)

Proposed legislation aside, there is some support among the commentariat for per se illegality,⁴³ but not very much. *Cardizem* is sometimes cited as standing for a per se rule against reverse payment settlements. But the district court emphasized not only the reverse payment but also that the settlement

- covered generic products whether or not they infringed a patent held by the branded firm,
- used the Hatch-Waxman Act provisions to game the system so that third parties were precluded from competing, and
- did not settle the patent litigation, but granted a sort of private preliminary injunction on terms different from those a real court would have ordered; accordingly, the settlement was less defensible on efficiency grounds than a settlement that puts patent litigation entirely to rest.⁴⁴

The Sixth Circuit’s discussion was much looser, but is fairly read to base its finding of per se illegality not only on market allocation through reverse payment, but also on the three plus factors, listed above, that the district court identified.⁴⁵

In sum, Rep. Waxman and his colleagues are out on a limb in proposing legislation that would make reverse payment settlements per se illegal, at least for purposes of the FTC Act. They need some help in framing a more balanced approach. Will they find the help they need in solutions 4, 5, 6, or 7, or perhaps in my own modest proposal?

Solutions 4 through 7: The Fork in the Road

If there is a restraint of trade, and it is neither per se legal nor per se illegal, then, one might suppose, it must be subject to the rule of reason because that is all that is left. The rule of reason normally requires the weighing of the anticompetitive effects of a practice against its procompetitive effects.⁴⁶ But, as Professor Hovenkamp and others have noted:

[T]he traditional “rule of reason” analysis is not a good fit for practices that would be unlawful per se but for the presence of an IP claim. The rule of reason is designed to assess whether a practice tends to diminish market-wide output. By contrast, the disputed issue in these . . . cases concerns the likely validity and scope of the claimed IP rights, and the reasonableness of the settlement as one among many outcomes of the IP dispute. That is, these cases should be decided on IP grounds because the agreements in this middle category are pro-competitive if, but only if, the patent in question is valid and infringed. Antitrust’s rule of reason cannot help with that IP inquiry.⁴⁷

No one argues that after-the-fact determinations of patent validity and infringement would be easy to make.⁴⁸ Nor does

anyone—or almost anyone—deny that the saving of time and resources that a settlement brings about is an important efficiency relevant to the antitrust analysis.⁴⁹ Moreover, large reverse payments may sometimes be associated with weak patent claims, but economic analysis of reverse payment settlements does not support broad generalizations about whether they are pro- or anticompetitive.⁵⁰

What to do? Here we come to a fork in the road. Those who take the right fork say that the answer depends (or at least mainly depends) on the strength of the patentee’s claim: if the patentee was bound to win the lawsuit anyway, there is no harm, and hence no foul, from a reverse payment. If, on the other hand, the patentee was going to lose on validity or infringement—and employs a reverse payment to snatch victory from the jaws of defeat—there is harm, and there is a foul.

Commentators who choose the right fork still have all manner of disagreements among themselves about, among other things,

- whether a large reverse payment permits the inference that the parties thought the IP claim was weak;
- how one might go about making a post-settlement determination about the strength of the patent or the case for infringement;
- whether a patentee enjoys an absolute right, or only a qualified right, to settle a claim it was probably going to win anyway; and
- whether the settlement of a weak patent claim by means of a reverse payment is always to be deemed anticompetitive, or only sometimes.

Some who take the right fork would put the actual strength of the IP claim at the head of a laundry list of “factors” to be considered in determining reasonableness (solution 4, discussed below). Some, but not many, would bite the bullet and have the antitrust court rule on the merits of the IP claim that the parties thought they had settled (solution 5). Some would make the question turn, not on the “actual” strength of the IP claim, but instead on what the settling parties reasonably thought about the strength of the IP claim, and the likely outcome of the litigation, at the time when they settled (solution 6).

Of course, litigation to the bitter end is not the only alternative to a reverse payment settlement. Hence, continued litigation is not the only “but-for world.” For example, instead of litigating to a conclusion the parties might have settled on terms *not* involving a reverse payment, and those terms *might* have been more favorable to consumers. For that reason, some avoid the right fork—emphasis on the actual strength of the IP claim—and instead take the left fork, focusing on whether the reverse payment made the settlement more anti-consumer, one might say, than it otherwise would have been. That is solution 7.

4. The settlement is subject to the rule of reason—and reasonableness is to be determined by pouring lots of factors into the pot and stirring them around.

Dissenting from the Second Circuit's holding in *Tamoxifen*, Judge Pooler said he would apply a rule of reason to reverse payment settlements, in which the tribunal would "consider all the circumstances affecting a restrictive agreement."⁵¹ He would "rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement"⁵² Applying those thoughts to the facts of the case before him, he opined: "[B]ecause plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate [to survive a Rule 12(b)(6) challenge]."⁵³

Though plausible, Judge Pooler's test is loose enough so that different judges would have plenty of room to apply the "test" in inconsistent ways—and that, in turn, would cast great doubt on the finality of any reverse payment settlement.

Other commentators identify a variety of suggested ways to apply the rule of reason. For example, Hovenkamp, Janis, and Lemley suggest

the following rule. In an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful, shifting the burden of proof to the infringement plaintiff. The infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.⁵⁴

Thomas Cotter agrees that reverse payment settlements should rebuttably be presumed illegal—because, until more definitive studies demonstrate the contrary, it may be assumed that reverse payment reflects a patentee's lack of confidence in the strength of its claim—but would find the agreement legal if, notwithstanding the adverse inference, the parties show that they actually thought the patent claim had a "high probability of success."⁵⁵

Richard Gilbert and Willard Tom argue that five factors should be considered, suggesting that concerns should be greater insofar as

- the size of the payment from the patentee to the challenger is a large fraction of the monopoly profits from the patented drug (suggesting that the patentee has a high expectation that the patent is invalid);
- the transactions costs that are saved by a settlement are small;
- the settlement has not been subjected to judicial review (and ideally, inspection and comment by third parties);

- the patentee would not have been likely to obtain a preliminary injunction against the generic challenger; and/or
- the terms of the settlement clearly delay the date at which a judicial finding of invalidity is likely to occur.⁵⁶

Others have discussed the issue in general terms, without suggesting a structured inquiry.⁵⁷ All of these loose, factor-based solutions leave huge discretion in the hands of the court and, therefore, huge uncertainty about the finality and, indeed, the legality, of a settlement.

5. The settlement is subject to the rule of reason, and is to be found unreasonable if, but only if (as shown by a preponderance of the evidence at the antitrust trial), the patent was in fact invalid or the challenger's product in fact did not infringe the patent.

Solution 5 is clean and straightforward. A patent is either valid or it is not; if it is valid, the challenger's product either infringes or it does not. If the patent is valid and infringed by the challenger's product, so the argument goes, the challenger's contractual obligation to recognize the patent cannot injure competition, whether or not that contractual commitment is accompanied by a reverse payment. Conversely, if a patent is either invalid or not infringed, a challenger's promise not to compete is anticompetitive and hence legally unreasonable.

This simple approach is objectionable, however, because

- it conflicts with the rule that the legality of a settlement should be judged at the time when it was made;⁵⁸
- it is contrary to the principle that settlements should be encouraged, and that they should be final;
- it imposes a severe penalty if, for example, the parties to the IP litigation settle in the mutually mistaken belief that the patentee's claims are strong, when in fact (as determined later) the claims are weak; and
- it would impose a large burden on the antitrust plaintiff, which would be forced to put on a full patent trial in circumstances where the former contestants—the challenger and the patentee, the parties with the most knowledge of the relevant technicalities—have now become friends and are defending the reasonableness of their settlement against an antitrust challenge.

Solution 5 is included for the sake of completeness. I am not aware of anyone who espouses it, although Kevin McDonald advocates a variant:

[I]n a proper antitrust analysis of Hatch-Waxman settlements, we should not attempt to measure the possible outcomes of a single lawsuit (which cannot rationally exclude false positives). We should conduct instead an orderly rule of reason analysis, which begins by measuring the patent. If the patent is valid and the exclusion of competition no broader than that inherent in the patent, then in the words of the Federal Circuit "that ends the inquiry." If there is reason to believe that the patent is invalid, then the antitrust analysis may begin, considering all relevant circumstances.⁵⁹

This sounds like per se legality where the patent is in fact

valid and infringed, but something other than per se illegality where the patent is in fact invalid or not infringed. I think McDonald is on to something. For now, hold that thought.

6. The settlement is subject to the rule of reason, and is to be found reasonable if, and only if, at the time it was entered into, it was more likely than not that the patentee would have prevailed in litigation on the merits.

Solution 6 differs from solution 5 in that it asks what the parties reasonably thought or should have thought at the time of the settlement (ex ante, as some like to say) about the strength of the claims, rather than calling for an ex post determination of the “real” strength of the patent claim.

The Antitrust Division does not adopt solution 6 but seems to move in that direction: “competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed *ex ante*.”⁶⁰ The Division’s language is guarded: it speaks of “taking into account” likelihood of success viewed ex ante, but there are many ways in which one may take something into account. Somewhat more helpfully, the Division offers a procedural suggestion and a good analogy:

A court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner’s litigation success. Rather, a court could conduct a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties’ negotiations.⁶¹

7. The settlement is subject to the rule of reason, and is to be found reasonable if, and only if, the reverse payment is determined not to be consideration for a more anticompetitive outcome than would have resulted from some other settlement or other resolution of the patent dispute.

That appears to be the FTC position, with the additional provisos that

- a large reverse payment should be presumed anticompetitive, unless the parties defending the payment show some other business rationale,⁶² and that,
- unless the position of either side in the IP litigation is a sham, the parties are free to settle—they enjoy a safe harbor, one might say—if they settle on terms that permit the challenger to enter the market at some point prior to the expiration of the patent.⁶³

For example, if the patentee’s claim is weak but non-sham, entry might take place very quickly, whereas if the patentee’s claim is strong, entry might take place not long before expiration—to reflect the high degree of confidence that the patentee has in the strength of its patent.

The FTC position takes what I call the left fork in the road: except in the extreme case where an IP claim is a sham, the FTC would not consider evidence about the

actual strength of the patent or about what the parties reasonably *thought* was the actual strength of the patent at the time they settled the IP case.⁶⁴ The Commission’s approach would condemn settlements of strong patent claims, if a reverse payment were involved.⁶⁵ Conversely, so long as reverse payments are avoided, the FTC’s solution would bless anticompetitive settlements of weak claims. For example, a weak but non-sham claim of IP rights might justify an agreement under which the challenger postpones entry by two or three years out of the ten-year life of the patent. Two or three years, of course, is plenty of time to earn monopoly profits.

Why this resolute refusal to examine the merits? The Commission offered several reasons. Let us look at its rationale, the Justice Department’s rejoinder, and the views of the commentators.

First, said the Commission, the issue in *Schering* was infringement, not patent validity, and there was no reason for the Commission to assume that the challengers’ formulations infringed, or that they did not infringe.⁶⁶ Right so far. “In fact,” the Commission continued, “we make neither assumption but rather focus on the effect that Schering’s payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.”⁶⁷

The Commission’s analysis is hard to follow. Clearly, the Commission’s ignorance as to whether the challenger’s product actually infringed the patent does not establish that knowledge of that fact would be irrelevant to the antitrust determination. But perhaps that was not what the Commission meant. Maybe it meant to say that the relevant but-for world is not the hypothetical world in which the patentee and the challenger would have litigated to the bitter end, but instead the but-for world in which the parties would have settled, but without a reverse payment. The Justice Department says the FTC opinion could be read this way, and asserts that that is how the Eleventh Circuit did read it.⁶⁸ But in a confusing statement in its petition for certiorari, the Commission denies that it was picking between but-for worlds.⁶⁹ So it is hard to know what to make of the Commission’s first stated reason for eschewing the merits.

Second, according to the Commission, precedent does not clearly require a finding as to the merits.⁷⁰ Third, said the Commission, the legality of a restraint should be judged at the time it was entered into, not second-guessed based on later developments.⁷¹ That sounds reasonable, but does not, of course, prove that antitrust should disregard what the parties reasonably thought about the strength of the IP claims at the time they settled.

Fourth, an after-the-fact inquiry about the merits is likely to be unreliable because the issues are technical and hard to understand. The challenger will have switched sides and will now pooh-pooh the strength of its claim in order to support the settlement. In addition, it would be awkward for counsel supporting the complaint to step into the challenger’s

shoes and argue non-infringement or invalidity in an administrative proceeding.⁷²

In rebuttal, one might observe that proving what the world would have been like but for a restraint is always tough. Here, however, the challenger and the patentee will have probably thought long and hard, and sought expert advice, about the strength of the IP case prior to settlement, so there should normally be relevant information and documents to guide the tribunal. To the argument that the FTC lacks expertise on patent validity and infringement, one might respond that it is in a better position to acquire such expertise than the average district judge or federal jury.

Fifth, said the FTC, its safe harbor providing that “if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack,” permits settling parties to have greater certainty that their settlement will put litigation to rest than would a rule permitting an antitrust tribunal to make an *ex post* determination of the merits of the IP case. That is surely so, but it merely states a conclusion, without offering a reason, about how best to balance the benefits of settlement against the public interest in anticompetitive settlements of weak patent claims.

In its petition for certiorari the FTC advanced yet another argument: the highly controversial probabilistic view of patent property, associated with Carl Shapiro and others:⁷³

Although all property rights are subject to legal uncertainties, the “probabilistic” nature of the property interest created by the patent laws makes it especially important to take such uncertainty into account. Unlike forms of property that are defined in terms of title to tangible items with clearly defined boundaries, the exercise of rights conferred even by a valid patent requires that the boundaries of the patent’s coverage be delimited in relation to an accused infringing product. . . . As both economists and legal scholars have remarked, “a patent is not a right to exclude, but rather a right to *try* to exclude.”⁷⁴

On this view, if a patentee has only a 50-50 shot in litigation, then any settlement in which the patentee achieves more than 50 percent of the nominal blocking power of the patent is a violation of the rights of consumers.⁷⁵ The same reasoning would apply to make it unlawful for a patentee with a 75 percent chance of prevailing in litigation to achieve by settlement more than 75 percent of the nominal blocking value of the patent. Such a settlement exceeds the scope of the patent rights—viewed “probabilistically”—even though the patentee probably would have won the litigation, had it proceeded.

The Commission, apparently, wants to apply the probabilistic theory only to reverse payment settlements, but its logic would extend to other situations. It is common, for example, to settle infringement actions by granting a license to the challenger. If the patentee has a 75 percent chance in litigation, but the license guarantees 90 or 100 percent of the profit it would have earned, then the settlement is vulnera-

ble under the FTC’s reasoning, even if the Commission might not choose to prosecute in that circumstance. For that reason and others, the probabilistic theory is highly controversial.⁷⁶

In its opposition to the FTC’s petition for certiorari, the Justice Department argued, among other things, that

- the FTC was wrong to think that a reverse payment settlement in a Hatch-Waxman context is presumptively illegal, because even patentees with strong claims may find it rational to make such payments⁷⁷; and
- the FTC likewise erred in failing to take into account the likelihood of success on the patent claims, viewed *ex ante*.⁷⁸

The Justice Department asserted that the FTC placed “undue weight on the parties’ subjective views of the strength of the claims as reflected in the settlement agreement, as opposed to a more objective assessment of the claims based on evidence extrinsic to the settlement.”⁷⁹ It noted, without approval, the FTC’s embrace of the probabilistic theory of patent property.⁸⁰

A Conclusion—and a Proposal

To conclude, our excursion through the multitude of proposed solutions and policy considerations indicates that the solution to the reverse payment conundrum turns on the answer to four key questions:

1. *Does the policy in favor of protecting the rights of patentees, taken together with the policy that settlement of litigation is efficient and is to be favored, trump the general antitrust rule that one may not pay a potential entrant not to enter the market even if the recipient of the payment probably would not have entered anyway?* Put another way, should patentees enjoy a right to settle claims on which they would likely prevail in litigation, so long as the settlement does not go beyond the terms of the patent, even if they make reverse payments? The better answer is yes.

2. *Is the policy in favor of protecting the rights of patentees, taken together with the policy that settlement of litigation is efficient and is to be favored, so strong that it extends an unqualified right for patentees to settle non-sham claims they would probably lose if they litigated to a final conclusion?* The better answer is no, at least where there is a reverse payment and the settling parties cannot demonstrate that the weakness of the patent claim, not the big bucks, was the real reason why the challenger stayed out of the market.

This is not only the best answer on policy grounds, it is also the best answer on political grounds. Reverse payment pharmaceutical settlements do not pass the public’s smell test. The extreme pro-settlement views of the *Tamoxifen* court and others cannot stand. The only question is whether the ultimate resolution will be sensible or not.

3. *Is the presence of a substantial reverse payment, without more, a good indication of the strength or weakness of the patentee’s claim?* The better answer is no, patentees with strong patent claims may well pay to reduce uncertainty.

4. *Is the strength of a patent claim metaphysically unknowable by an antitrust court, or unduly speculative as a matter of law, or just too difficult to prove?* The better answer is no. Proof, by a preponderance of the evidence in an antitrust proceeding, of what would happen in a but-for world of continued patent litigation is no more problematic than proof of the but-for world in other antitrust litigation.

These considerations lead to a modest proposal:

If, at the time of settlement, a reasonable person in the shoes of the patentee and the challenger would reasonably believe that the patentee was more likely than not to prevail in litigation to the bitter end, then the patentee and the challenger should enjoy an unqualified right to agree to restrain trade by an agreement in which the challenger does no more than respect the patentee's claimed rights. However, in an

antitrust challenge to a settlement of patent litigation occurring in a Hatch-Waxman context, if the agency or antitrust plaintiff shows, by a preponderance of the evidence, that (i) the settlement restrains trade (in that the challenger agrees to respect the patentee's claimed rights and thus refrain from competition), (ii) at the time of the settlement, reasonable persons in the position of the challenger and the patentee would have believed that the patentee was more likely than not to lose on its claim of validity and/or infringement, (iii) there is a substantial reverse payment, (iv) the parties to the settlement cannot offer some persuasive, competitively benign explanation for the reverse payment, and (v) the settlement helps to create or sustain market power, to the detriment of consumers, the restraint of trade in the settlement agreement is legally "unreasonable." ■

¹ And thus, arguably, "restrains trade" within the meaning of Sherman Act Section 115 U.S.C. § 1. A reverse payment settlement may also be challenged under Section 2, 15 U.S.C. § 2, to the extent it allegedly aids in the acquisition, maintenance, or expansion of monopoly power. But since monopoly power is not required to prove a violation of Section 1, the Section 1 case will normally be easier to prove.

² James C. Burling, *Hatch-Waxman Settlements: The Battle for a Benchmark*, ANTITRUST, Spring 2006, at 41. See also Robert A. Milne & Michael J. Gallagher, *Recent Activity on the Brand-Generic Drug Patent Settlement Front*, ANTITRUST, Spring 2004, at 18.

³ Schering-Plough Corp., FTC Docket No. 9297, 2003 WL 22989651 (Dec. 8, 2003) (FTC Opinion), *rev'd*, Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

⁴ Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006) (DOJ Amicus Brief); see also Supplemental Brief for the Petitioner, FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006).

⁵ In *FTC v. Warner Chilcott*, Civ. Action No. 1:05-CV-2179-CKK (D.D.C. Nov. 7, 2005), the Commission sought injunctive relief against a deal between a branded company and a potential generic challenger, whereby the challenger agreed not to enter and received a substantial payment; the deal was not made in the context of a pending patent litigation. By asking for an injunction from a district court—rather than bringing administrative litigation—the Commission apparently aimed (a) to avoid an appeal to the Eleventh or the Second Circuit and (b) to create favorable law in the D.C. Circuit, which it could then present as creating a clear conflict among the circuits. An October 23, 2006 FTC press release reported that the case has been settled. See <http://www.ftc.gov/opa/2006/10/chilcott.htm>.

⁶ See *infra* text accompanying notes 16–21.

⁷ The Preserve Access to Affordable Generics Act, S. 3582, introduced by Senators Kohl, Leahy, Grassley, and Schumer, *text available at* <http://icreport.loc.gov/cgi-bin/query/z?c109:S.3582.IS>.

⁸ Formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁹ See 21 U.S.C. 355(j)(2)(A)(vii)(IV).

¹⁰ Because the infringement is constructive, not actual, and because Challenger is not actually making and selling the allegedly infringing product, Challenger may defend patent litigation without the enormous financial risk of damages it would run if actual sale of the allegedly infringing product were a precondition of litigation. Thus, the parties to patent litigation in a Hatch-Waxman context may have an unusually high incentive to settle the litigation with a reverse payment. But does the fact that Hatch-Waxman increases the challenger's and the patentee's incentives to enter into reverse payment settlements—if it is a fact—tell us anything about whether such settlements violate the Sherman Act? I don't see why it should, and neither does Rep.

Waxman. See Motion and Brief of Representative Henry A. Waxman as Amicus Curiae in Support of Petitioner, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

¹¹ See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993).

¹² The settlement may be final, with an admission of validity and infringement, and a contractual commitment to respect Phrmco's claimed patent rights. Or the settlement may be in the nature of a negotiated preliminary injunction or stay pending appeal; for example, Challenger may agree not to enter following a district court judgment in its favor, unless and until that judgment is affirmed on appeal. The settlement may or may not allow Challenger into the market at some point prior to the expiration of the patent—either as Phrmco's licensee, or otherwise.

¹³ Marc Schildkraut makes a good argument that almost all patent settlements involve "reverse" economic consideration in some form, and the logic of condemning straightforward reverse payments would sweep much more broadly than proponents of that logic may intend. Marc C. Schildkraut, *Patent Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

¹⁴ 15 U.S.C. § 45.

¹⁵ See *Standard Oil Co. v. United States*, 283 U.S. 163 (1931) (settlement of legitimate patent conflict is not necessarily a violation of the Sherman Act); *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (patent settlement in furtherance of a conspiracy to monopolize was illegal).

¹⁶ *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms. v. Kroger Co.*, 543 U.S. 939 (2004).

¹⁷ *In re Terazosin Chloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000), *rev'd sub nom. Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied.*, 543 U.S. 939 (2004), *on remand*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

¹⁸ *Schering* FTC Opinion, *supra* note 3.

¹⁹ In *Schering* there was a big side show about whether a side deal between the patentee and one of the settling parties was or was not one-sidedly in favor of the challenger—and thus a disguised way of paying cash to the challenger to stay out of the market. The Eleventh Circuit's skepticism about the FTC's factual findings was legally adventuresome, and the Justice Department's defense of the Eleventh Circuit was strained. But that dispute has no bearing on the issues discussed here.

²⁰ *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *aff'd*, 429 F.3d 370 (2d Cir. 2005), *amended*, 2006 WL 2401244 (Aug. 10, 2006).

²¹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), 363 F. Supp. 2d 513 (E.D.N.Y. 2005).

- ²² Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp., FTC Docket No. 9297 (Apr. 5, 2002) (consent order as to American Home Products); Bristol-Myers Squibb Co., FTC Docket No. C-4076 (Apr. 13, 2003) (consent order); ; Abbott Labs., FTC Docket No. C-3945 (May 26, 2002) (consent order); Geneva Pharms., Inc., FTC Docket No. C-3946 (May 22, 2000); Hoechst Marion Roussel, Inc., FTC Docket No. 9293 (Apr. 4, 2001) (consent order).
- ²³ Medicare Modernization Act of 2003, §§ 1112–1115 (amending the Hatch-Waxman Act).
- ²⁴ Prepared Statement of the Federal Trade Commission on Barriers to Generic Entry, Special Committee on Aging, U. S. Senate, Delivered by FTC Commissioner Jon Leibowitz, (July 20, 2006) (Leibowitz Testimony), available at <http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf>.
- ²⁵ See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60–65 (1993).
- ²⁶ E.g., Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1307, n.19. (11th Cir. 2003); Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003).
- ²⁷ 2006 WL 2401244 at *17.
- ²⁸ *Id.* at *13–*16.
- ²⁹ *Id.* at *13.
- ³⁰ See *id.* at *7.
- ³¹ *Id.* at *1.
- ³² See, e.g., Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, 2 MERGERS & ACQUISITIONS TAX J. 30, 37–38 (2001); see also Mark L. Kovner, Colin R. Kass & Avery W. Gardiner, *Applying the Noerr Doctrine to Pharmaceutical Patent Litigation Settlements*, 71 ANTITRUST L.J. 609 (2003).
Kent Bernard and Willard Tom would legalize all reverse payment settlements of non-sham patent claims, a standard they characterize as “imperfect” but “likely to do less harm than any alternative.” Kent S. Barnard & Willard Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: the Need for Context and Fidelity to First Principles*, 15 FED. CIRCUIT B.J. 617, 632 (2006).
- ³³ Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986 (N.D. Ill. 2003) (Posner, J., sitting by designation as district judge) (citations omitted).
- ³⁴ *Id.* at 994. The remarks were triple dictum because (1) there was no reverse payment in the case before him, (2) there was no reason to think the patent settlement was questionable on antitrust grounds, and (3) the plaintiff lacked standing. Supporters of per se legality have also drawn comfort from something Judge Posner said a little earlier in the same opinion: “If . . . there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.” *Id.* at 992. But this quote supports per se legality only if one believes that reverse settlements are never “suspicious”—and many see them as highly suspicious, especially where the payment is large and the patent claim seems weak.
- ³⁵ Petition for a Writ of Certiorari at 12, FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006).
- ³⁶ DOJ Amicus Brief, *supra* note 4, at 17–18.
- ³⁷ Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).
- ³⁸ *Id.* at 1076.
- ³⁹ *Id.* at 1072.
- ⁴⁰ See *supra* note 5.
- ⁴¹ Leibowitz Testimony, *supra* note 24, at 20.
- ⁴² Schering FTC Opinion, *supra* note 3, at 29.
- ⁴³ See Lisa M. Natter, *Infringement Lawsuits: The Continuing Battle Between Patent Law and Antitrust Law in the Pharmaceutical Industry*, 18 LOY. CON.S. L. REV. 363 (2006); Keith Leffler & Christopher Leffler, *The Probabilistic Nature of Patent Rights*, ANTITRUST, Summer 2003, at 77; W. Lindsey Wilson, *Comment, Antitrust Solutions to Pharmaceutical Abuses: An Examination of Agreements Between Brand-Name and Generic Pharmaceutical Manufacturers*, 2001 L. REV. M.S.U.-D.C.L. 1227 (2001); Marcy L. Lobanoff, *Comment, Anti-competitive Agreements Cloaked as “Settlements” Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331 (2000).
- ⁴⁴ *Cardizem*, *supra* note 16, 105 F. Supp. 2d at 704–05.
- ⁴⁵ Because of the presence of some of these same factors, the district court’s 2000 decision in *Terazosin* (which was reversed), 164 F. Supp. 2d 1340, and its 2005 decision on remand, 325 F. Supp. 2d 1279, likewise provide only weak support for the view that a pure reverse payment settlement is per se illegal.
- ⁴⁶ Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1728 (citing 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 1507–08 (2d ed. 2003)).
- ⁴⁷ Hovenkamp et al., *supra* note 46, at 1724–25 (footnotes omitted).
- ⁴⁸ “A legal regime that could instantaneously and costlessly distinguish invalid patents from valid patents and infringing uses from non-infringing uses would have little reason to tolerate patent infringement settlements that included an agreement by the alleged infringer to exit the market” Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 754 (2002) (footnote omitted).
- ⁴⁹ *Id.* at 749. An exception is David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 336–37 (2000).
- ⁵⁰ See James Langenfeld & Wenqing Li, *Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights*, 39 U.S.F. L. REV. 57 (2004); but see Hovenkamp et al., *supra* note 47.
- ⁵¹ *Tamoxifen*, *supra* note 20, 2006 WL 2401244 at *35.
- ⁵² *Id.*
- ⁵³ *Id.*
- ⁵⁴ Hovenkamp et al., *supra* note 38, at 1758 (footnote omitted). O’Rourke and Brodley rightly note that the rule is ambiguous, because a “significant” likelihood of success means different things to different people. Maureen A. O’Rourke & Joseph A. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1767, 1783 (2003).
- ⁵⁵ Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1091 (2004).
- ⁵⁶ Richard J. Gilbert & Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 78–79 (2001).
- ⁵⁷ See, e.g., Kristopher L. Reed, *A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements Under the Hatch-Waxman Act*, 40 GONZ. L. REV. 457 (2005); Melissa R. Leuenberger-Fisher, *In re Terazosin Hydrochloride Antitrust Litigation: An Argument for the Rule of Reason*, 24 BIOTECHNOLOGY L. REP. 417 (2005); John E. Lopatka, *A Comment on the Antitrust Analysis of Reverse Payment Patent Settlements: Through the Lens of the Hand Formula*, 79 TUL. L. REV. 235 (2004).
- ⁵⁸ See, e.g., *Valley Drug*, 344 F.3d at 1306.
- ⁵⁹ Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68, 75.
- ⁶⁰ DOJ Amicus Brief, *supra* note 4, at 11.
- ⁶¹ *Id.* note 1 (citations omitted). See also Crane, *supra* note 49, at 750, 790.
- ⁶² Schering FTC Opinion, *supra* note 3, at 26.
- ⁶³ *Id.* at 25–26.
- ⁶⁴ *Id.* at 33–34. See also Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1 (2005).
- ⁶⁵ Curiously, however, the Commission observed that as far as private claims for damages are concerned, the settlement of a strong patent claim with a

reverse settlement would be *damnum absque injuria* because the strength of the patent claim would mean that a private plaintiff could not show, by a preponderance of the evidence, that the settlement caused it injury. *Schering* FTC Opinion, *supra* note 3, at 32.

⁶⁶ *Id.* at 30.

⁶⁷ *Id.* at 31.

⁶⁸ See DOJ Amicus Brief, *supra* note 4, at 15–16.

⁶⁹ The Commission's analysis never assumed that different settlements between the parties would necessarily have replaced those under investigation. Rather, the Commission used a *hypothetical* no-payment compromise as a benchmark to assess "the difference between the amount of competition [resulting from the actual settlements] * * * versus the amount of competition that was likely to occur had it not been for the payment to delay * * *." Pet. App. 76a (quoting expert witness). Where a patent holder makes a payment to a challenger in order to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.

FTC Petition for Certiorari in *Schering* at 18–19. But if the patentee's claim is strong and the settlement lets the challenger in early, continuation of the litigation would probably have left consumers worse off than they were under the settlement.

⁷⁰ *Schering* FTC Opinion, *supra* note 3, at 31.

⁷¹ *Id.* at 32–33.

⁷² *Id.* at 34–35. Conspicuous by its absence from the FTC position is the argument that the validity of patent rights is metaphysically unknowable in post-settlement antitrust litigation, or that the outcome that would have been

reached in settled litigation is unduly speculative as a matter of law. Compare *Schering* FTC Opinion, *supra* note 3, at 35, with *Tamoxifen*, 2006 WL 2401244 at *13 (outcome in another case is unknowable); Motion to File Amicus Curiae Brief and Brief of Bayer Corporation as Amicus Curiae in Opposition to Certiorari at 16, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273).

⁷³ See Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *RAND. J. ECON.* 391 (2003); Hovenkamp et al., *supra* note 46.

⁷⁴ FTC Petition for Certiorari in *Schering* at 16 (citations and footnotes omitted). As probabilistic theory proponents like to emphasize, a surprisingly large percentage of patent challenges succeed. *Id.* at 17.

⁷⁵ *Id.* at 76.

⁷⁶ See Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *ANTITRUST*, Summer 2003, at 70; Keith Leffler & Christopher Leffler, *In Response to Kevin McDonald: The Probabilistic Nature of Patent Rights*, *ANTITRUST*, Summer 2003, at 77; Merrill Hirsh, *Are False Positives Really So Negative? A Response to Kevin McDonald*, *ANTITRUST*, Summer 2003, at 83; Kevin McDonald, *With Malice Toward None: A Brief Rejoinder to Leffler and Shapiro*, *ANTITRUST*, Summer 2003, at 85. See also Schildkraut, *supra* note 13.

⁷⁷ DOJ Amicus Brief, *supra* note 4, at 10–11.

⁷⁸ *Id.* at 11.

⁷⁹ *Id.* at 12.

⁸⁰ *Id.* at 12.

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