Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be *Per Se* Illegal.

by Joshua P. Davis[*]

One of the most pressing issues in antitrust law is how to assess settlements of patent disputes that involve payments from brand name to generic drug manufacturers. At stake are billions of dollars, both in inflated prices to consumers attempting to meet their medical needs and in exposure to liability for drug manufacturers. This Article applies the economics of dispute resolution to clarify the costs and benefits of various approaches to assessing patent settlements in the context of the Hatch-Waxman Act. It concludes that reverse payments should be banned under a *per se* rule, unless and until courts are presented with evidence that brand name drug manufacturers are at some sort of systematic disadvantage in their settlement negotiations with generic drug manufacturers, an unlikely possibility.

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I. Introduction.

This Article addresses one of the most pressing, prominent, and contentious issues in antitrust law today: How to assess settlements of patent disputes that involve payments from brand name to generic drug manufacturers in the context of the Hatch-Waxman Act.[1] The underlying disputes arise when a drug manufacturer develops a generic equivalent to a brand drug. In a typical situation, the generic manufacturer files an application with the Food and Drug Administration (the FDA) for approval to market the generic drug. The brand name drug manufacturer then claims that the generic drug would infringe one or more of its patents. In response, the generic manufacturer asserts that its product does not infringe or claims that the applicable patent is not valid. In short, the firms disagree about whether the brand manufacturer has the legal right to prevent the generic manufacturer from bringing its drug to market. If the brand has that right, it can continue to demand the high prices associated with its right to exclusivity without losing sales to the generic. If not, entry of the generic drug will take most of the brand drug's sales and drive down prices to many drug purchasers in the process.[2]

The Hatch-Waxman Act puts in place the legal regime for resolving these disputes. As other scholars have shown, including Michael Carrier and C. Scott Hemphill, the Hatch-Waxman Act ("Hatch-Waxman" or the "Act") was intended to encourage challenges to drug patents.[3] Various attributes of the Act confirm this purpose, including the provision allowing generic drug manufacturers to challenge a brand patent without actually bringing a drug to market and risking exposure to damages for patent infringement.[4]

As a result, under Hatch-Waxman the prospect of generic competition is likely to give rise to disputes. Generally speaking there are two ways to resolve these disputes: litigation or settlement. Litigation can resolve the respective rights of the parties in an authoritative manner. But it is costly and risky. Settlement can be far less expensive and more expeditious. But it does not allow for a judicial pronouncement of the parties' rights.

The lack of an authoritative determination matters because drug manufacturers are not the only ones affected by these patent disputes. Purchasers of drugs may pay artificially inflated prices if the manufacturers resolve the litigation in a way that leaves

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[1] *See, e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 631 (2009) (characterizing the issue as "the most important unresolved issue in U.S. antitrust policy, measured by economic importance and high-level judicial attention.").

[2] Some purchasers may remain loyal to the brand, so loyal that the brand manufacturer may raise its prices after generic entry, maximizing its profits from the select few buyers who are committed to the brand.

[3] *See* Michael Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Instability*, 108 MICH. L. REV. 37, 41 (2009); Hemphill, *supra* note 1, at 638; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006).

[4] The generic drug manufacturer can do so by filing an Abbreviated New Drug Application and certifying under Paragraph IV that any relevant patent either is invalid or would not be infringed by the generic drug. *See infra* Part II.

intact patent rights that would not have survived a legal challenge.[5] If a brand name manufacturer would have failed to prevent the generic manufacturer from coming to market in a court of law, any settlement that delays generic competition raises antitrust concerns. Settlement of the patent dispute may provide a means for the brand name manufacturer to maintain more sales at higher prices than a free market would allow. In other words, settlement of the patent dispute may constitute an antitrust violation.

This risk is particularly high when the settlement includes a payment from the brand manufacturer to the generic manufacturer. These payments are characterized as "reverse" because the brand manufacturer has accused the generic manufacturer of patent infringement but rather than demanding damages in settlement the brand manufacturer pays a sum of money—often a very large sum of money—to the generic manufacturer.[6] Cash flows in a direction that is the opposite of what one might (initially) expect. In other words, in reverse payment cases, the brand manufacturer pays money to the generic manufacturer in exchange for the generic manufacturer's agreement not to compete.

When reverse payments facilitate antitrust violations, they are violations of the most deleterious kind. Agreements not to compete—and thereby to inflate prices to purchasers—are a principal concern of the antitrust laws.[7] True, patent rights create an exception to the general antitrust rule favoring competition. But to the extent that reverse payments are used to protect invalid patents or to stop non-infringing conduct, they are an illegal means by which a "market price [can be] jacked above the competitive level,"[8] causing just the type of harm the antitrust laws are designed to prevent.

Various options are available for determining whether drug manufacturers' settlements violate the antitrust laws. In evaluating these options, the standard law and economics framework for assessing dispute resolution mechanisms proves useful. That framework seeks to minimize two costs: the costs of errors in adjudication and the transaction costs of the dispute resolution process.[9] Attention to these costs can produce the most efficient rule for assessing patent settlements.

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[5] This formulation assumes that the actual result in litigation would have been the right result. An alternative framing of the point would be that prices are improperly inflated when a patent *should* not survive a legal challenge, even though it is possible that it *would*. The subtle but important distinction between whether a patentee *should* or *would* prevail in litigation depends on acknowledging the possibility of adjudicative error and abandoning a strongly positivist view of the nature of right outcomes in litigation (which is probably wise). For a discussion of this issue see Joshua P. Davis, *Taking Uncertainty Seriously: Revising Injunction Doctrine*, 34 RUTG. L. J. 363, 405-10 (2003). I do not explore this distinction here because it does not matter for present purposes. The rule I propose will minimize error costs whether or not we distinguish the actual outcome from litigation from the correct result. *See infra* nn.133-35 and accompanying text.

[6] David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000); *see also* Hebert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 19 (2004) (explaining how generics are increasingly not serving their designated functions).

[7] *See, e.g.*, RICHARD A. POSNER, ANTITRUST LAW 2 (2d ed. 2001).

[8] *Id*.

[9] *See* ROBERT G. BONE, CIVIL PROCEDURE: THE ECONOMICS OF CIVIL PROCEDURE 125-49 (2003) (explaining the framework); *see also* Robert G. Bone, *Modeling Frivolous Suits*, 145 U. PA. L. REV. 519, 537-76 (1997) (same).

In assessing reverse payments, some courts have endorsed the finality and certainty of settlement rather than conduct any meaningful inquiry into efficiency.[10] That approach is inappropriate for at least two reasons. First, as other scholars have noted,[11] it is at odds with the underlying purposes of the Hatch-Waxman Act. Concerned about the escalating costs of medication in the U.S., Congress sought to encourage challenges to brand patents.[12] The provision allowing a patent challenge without the generic having to bring a drug to market reflects this intention.[13] As a result, courts should not rely on a general policy in favor of settlement to treat virtually all resolutions of disputes between drug manufacturers as desirable.

A second reason to apply an economic analysis—rather than simply deferring to patent settlements—is that it is the predominant paradigm for dealing with antitrust issues in general. Chicago School law and economics—with its emphasis on efficiency, as economists understand that term—has come to dominate antitrust law.[14] Courts routinely rely on the notion of efficiency in formulating and applying antitrust doctrines.[15] If attention to efficiency cannot justify allowing reverse payments, then courts should not countenance them.[16]

The law and economics framework—with its attention to error costs and transaction costs—allows an assessment of the different ways courts might address settlements of patent disputes. Assume a drug purchaser challenges a settlement between brand and generic drug manufacturers involving a reverse payment. The drug purchaser argues that the settlement is in effect a means of collusion. The drug manufacturers have agreed to delay generic entry and share the spoils of supra-competitive prices, even though the brand drug manufacturer had no legal right to keep the generic drug off the market. The drug purchaser claims this collusion violates the antitrust laws.

A first option for a court assessing this claim would be to take the default approach in our system for evaluating an antitrust claim, reliance on the so-called Rule of

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[10] *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) (holding reverse payments are legal unless the underlying patent dispute involves sham litigation or fraud on the patent office); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (same).

[11] *See* Carrier, *supra* note 3, at 41-49; Hemphill, *supra* note 3, at 1556.

[12] *See* H.R. Rep. No. 98-857 pt.1 at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2650; H.R. Rep. No. 98-857 pt.2 at 4 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2688.

[13] Some courts that have suggested that the effect of this provision on encouraging patent challenges may have been inadvertent. *See, e.g.*, *Hydrochloride Antitrust Litig.*, 261 F.Supp. 2d 188, 252 (E.D. N.Y 2003) (suggesting Hatch-Waxman Act "has the unintended consequence of altering the litigation risks of patent lawsuits"). That view is at odds with the overall purpose of the legislation, which was, in part, to enhance competition in the pharmaceutical industry. *See* 130 Cong Rec. 24427 (Sept. 6, 1984); *see also* Carrier, *supra* note 3, at 47 (noting intention of Hatch-Waxman Act to encourage generic challenges); Hemphill, *supra* note 3, at 1605-06 (same).

[14] *See, e.g.*, POSNER, *supra* note 7, at viii-ix.

[15] *Id*.

[16] Given Richard Posner's instrumental role in integrating microeconomic analysis into antitrust doctrine, it is surprising—and disappointing—that he has suggested reverse payments should generally be legal without any careful assessment of the economic inefficiency they cause. *See Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp. 2d 986, 992-93 (N. D. Ill. 2003) (Posner, J.).

Reason.[17] The purchaser in the antitrust action would have to show that the anticompetitive effects of the settlement outweigh its procompetitive effects.[18]

One straightforward application of the Rule of Reason would be to require the drug purchaser to show that the brand manufacturer did not have a right to prevent generic competition. Along these lines, a court might require the purchaser to make the same showing a generic manufacturer would have had to make to defeat a claim of patent infringement. Upon this showing, antitrust law should not allow the brand and generic manufacturers to agree not to compete. Doing so would be in effect to extend the scope of the patent beyond the brand manufacturer's legal rights. That is an antitrust violation.[19]

This approach does well in terms of error costs, particularly in cases in which the preponderance of evidence standard would apply.[20] That standard tends to minimize errors in resolving disputed legal rights, at least if the harms from false positives and false negatives are of equal magnitude.[21] But this approach to the Rule of Reason would entail substantial transaction costs. Litigation between drug purchasers and manufacturers would likely consume a great deal of the time and money of the parties, the courts, and others, even if the antitrust litigation settles at some point.

A second option is to treat settlements between drug manufacturers as resolving the patent dispute for all purposes, perhaps subject to some limited review to ensure the patent claim was not frivolous or the product of fraud on the patent office.[22] In other words, if there is any legitimate controversy, a settlement of that dispute would automatically be legal. This option would essentially involve a rule of *per se* legality.

The *per se* legality rule would limit transaction costs. Determining whether any valid controversy exists—whether the claim of patent infringement is a mere sham—should be relatively quick and inexpensive.[23] And drug purchasers would rarely bring

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[17] *See, e.g., Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (noting Rule of Reason is presumptive approach to agreements that may be in restraint of trade).

[18] *Id.*

[19] Posner, for example, in *Asahi Glass* recognizes that an agreement not to compete—if it is not adequately supported by a patent right—should constitute an antitrust violation. *See Asahi Glass*, 289 F. Supp. 2d at 991-92.

[20] As discussed below, the preponderance of error standard ordinarily minimizes error costs. *See infra* notes 102-04 and accompanying text. Courts require a patent holder to prove infringement under the ordinary preponderance of evidence standard to claims of infringement, but they require the patent challenger to show patent *in*validity by clear and convincing evidence. *Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. 956, 993 & n. 60 (F.T.C. Dec. 8, 2003); *see also* Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 47 (2007) (noting clear and convincing evidence standard applies to claim of patent invalidity).

[21] *See infra* notes 111-16 and accompanying text.

[22] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) (taking this approach); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (same).

[23] It is worth noting that the "sham" exception to the rule that reverse payments are generally legal is not much of an exception at all. It is already an antitrust violation for a brand manufacturer to bring sham litigation to deter generic competition, whether or not it results in a settlement involving a reverse payment. *See Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993); *Eastern*

antitrust claims because they would have such poor prospects. But this option would produce substantial error costs.[24] It is akin to deciding automatically against a generic drug manufacturer if a brand name manufacturer merely makes a colorable claim of patent infringement. We would never so casually reject a generic manufacturer's assertion of the invalidity of a patent or non-infringement. We would not take such an approach because it would lead to wild inaccuracy. For the same reason, we should not analyze antitrust claims of drug purchasers in this way.

These first two options, then, appear to force courts to choose between high transaction costs and high error costs. But there is a third option.[25] It would allow courts to avoid the costs and difficulty of evaluating disputed patent rights and to allow settlements between drug manufacturers to do their work for them in minimizing error costs. The key is to align the interests of generic drug manufacturers and drug purchasers. That can be done by banning reverse payments as *per se* illegal. Brand and generic manufacturers would then be forced to settle solely by compromising on the date of generic entry. Generic drug manufacturers would have incentive to promote the interests of drug purchasers—the earlier generic entry occurs, the more money the generic drug manufacturer will make and the sooner the purchasers will benefit from competition over price.[26]

Condemning settlements between drug manufacturers if they involve reverse payments fares well in terms of error and transaction costs. Generally speaking, if drug manufacturers are forced to settle only by compromising on the date of generic entry, one would anticipate the agreed date of generic entry to be at least a late as the expected value entry date based on the outcome of litigation.[27] Settlement for an expected value entry date would have various salutary qualities: it has the same expected error costs as litigation (lower error costs if one takes into account risk aversion); and, unless the drug manufacturers have very disparate views of the likely outcome of litigation, engage in aggressive strategic behavior, or the like, settlement should be possible based on

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R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). So the exception provides no claim that existing law would not allow anyway.

[24] *See* Carrier, *supra* note 3 at 67 & n. 210.

[25] Carrier suggests a fourth option—a presumption of illegality. Carrier, *supra* note 3, at 38, 76. As discussed below, however, such an approach would lead to high error and transaction costs. *See infra* part III.E.4. Determining whether a reverse payment corrects a settlement that would otherwise inappropriately favor a generic manufacturer would entail great inaccuracy and expense. *Id*.

[26] Determining whether compromise over the date of generic entry is the sole basis for compromise might not always be easy. Various arrangements might disguise compensation to the generic in exchange for inflated brand profits. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 633 (2009). But litigating this issue would be less time-consuming and expensive than both identifying reverse payments and assessing whether they meet some standard of legality.

[27] As discussed below, even with a ban on reverse payments, the date of generic entry is likely to be later than the expected value entry date, including because the brand manufacturer can use the automatic thirty month stay as a lever in negotiations and because the generic will be willing to trade delay for a guarantee that it will receive its 180 day exclusivity period. *See infra* part III.E.4.a. Allowing reverse payments would thus tend to increase error costs.

adjusting the date of generic entry.[28] Settlement translates into low transaction costs. So this option is quite attractive.

Reverse payments, in contrast, threaten to drive a wedge between the interests of generic manufacturers and purchasers. The payments allow the brand manufacturer to share profits from its drug monopoly with the generic manufacturer in exchange for a delay in generic entry. The generic manufacturer then benefits at the expense of drug purchasers rather than by offering those purchasers low-priced drugs. [29] For this reason, such payments generally should not be allowed.[30]

To be sure, in some circumstances there might be a legitimate justification for allowing reverse payments. In theory, a brand manufacturer for various reasons might be willing to allow generic entry on a date earlier than the one that represents the expected outcome of litigation.[31] If so, a reverse payment may shift the compromise date of generic entry toward the expected value of litigation, decreasing error costs.

But addressing this possibility in an overly simplified way has led many commentators astray.[32] To determine whether a brand manufacturer should be permitted to make a reverse payment, an analysis would be necessary of various factors in settlement. We cannot look at just one factor in isolation and permit a reverse payment on that basis. Doing so would lead to arbitrary results. Any variation from expected value should be considered carefully.

Indeed, for various reasons one would expect the agreed date of generic entry to be later than the expected value entry date, including because brand manufacturers are entitled to an automatic stay on generic entry of 30 months simply by filing a lawsuit alleging infringement and because a generic manufacturer is likely to be more concerned with ensuring that it obtains an agreement from the brand manufacturer entitling it to the

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[28] For this reason, the vast majority of cases settle. *See, e.g.*, Joshua P. Davis, *Toward a Jurisprudence of Trial of Trial and Settlement: Allocating Attorney's Fees by Amending Federal Rule of Civil Procedure 68*, 48 ALA. L. REV. 65, 67 & n. 10 (1994) (citing Marc Galanter & Mia Cahill, *"Most Cases Settle": Judicial Promotion and Regulation of Settlements*, 46 STAN. L. REV. 1339, 1339-40 (1994)).

[29] *See* Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III*, 30 SEATTLE U. L. REV. 377, 391 (2007) (explaining how generic manufacturers have powerful incentives to file the first patent challenge but little incentive to pursue litigation).

[30] *See also* Herbert Hovenkamp, *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1722 (2003) and Carrier, *supra* note 3, at 78 (citing Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 RES. L. & ECON. 475, 484 tbl.4 (2004) (noting that consumer welfare was reduced in 92 percent of cases based on one model used to analyze reverse payment-based settlements). For the same reason, the ban should apply to licensing arrangements or royalty payments that achieve the same result by other means, that is, restrain generic competition in exchange for compensation from the brand manufacturer. *See* Hemphill, *supra* note 1, at 633 (discussing various ways drug manufacturers can disguise reverse payments). But a discussion of that issue is beyond the scope of this Article.

[31] *See, e.g.*, Marc G. Schildkraut, 71 ANTITRUST L.J. 1033, 1035 (2004) (suggesting brand manufacturer's aversion to risk, or generic manufacturer's excessive optimism, may cause settlement entry date later than expected value of litigation).

[32] *See, e.g.*, Michael Carrier, *supra* note 3, at 76-77; (suggesting reverse payment approximating brand manufacturer's litigation costs should be legal); Hovenkamp, *et al.*, *supra* note 30, at 1758 (same).

exclusive right to sell the generic drug than with obtaining the earliest possible date of generic entry.[33] Reverse payments are therefore highly likely to increase—not to decrease—error costs.

Moreover, judicial efforts to determine whether a reverse payment adjusts the date of generic entry toward—rather than away from—the expected value in a given case would be fraught with difficulties. First, such a determination might well be inaccurate, particularly given the united front the drug manufacturers would present. A court would have a hard time gauging the merits of the brand dispute, and would have even more difficulty assessing the dynamics in settlement that might lead the parties to stray from that expected value in one direction or another. Second, judges would be unlikely to have much appetite for the effort. There is a high risk that they would defer to whatever putative procompetitive justification the drug manufacturers offer for the reverse payments, however improbable. Third, the transaction costs would be high. Indeed, efforts at judicial oversight could end up depriving courts and parties of the benefits in reduced transaction costs of allowing some settlements between drug manufacturers in the first place. We might as well simply assess whether the patent infringement claim would have won.

For these reasons, there should be a general ban on reverse payments (as well as on other mechanisms that drug manufacturers might use to skew settlements from an expected value date[34]). Indeed, Congress is currently contemplating such a ban, a legislative measure recently approved by the relevant Subcommittee in the House of Representatives[35] and soon to be marked up in the Senate Judiciary Committee.[36]

The ban on reverse payments, however, should remain open to revision. If brand drug companies can show they systematically make deals less favorable to themselves than the expected value of litigation—an unlikely possibility—then courts should consider doing some case by case analysis, perhaps allowing brand manufacturers to pay an amount approximating the cost of litigation, as some scholars and the FTC have recommended.[37] Until that evidence is forthcoming, however, the most efficient rule is likely to be a *per se* ban on reverse payments.

In making arguments along these lines, some scholars have taken to characterizing patent rights as "probabilistic rights."[38] They are essentially correct in

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[33] See infra part III.E.4.a.

[34] *See* Hemphill, *supra* note 1, at 633 (discussing various ways drug manufacturers can disguise reverse payments).

[35] The Subcommittee on Commerce, Trade, and Consumer Protection of the House Energy and Commerce Committee approved H.R. 1706, The Protecting Consumer Access to Generic Drugs Act of 2009, in June, 2009. I am grateful to Michael Carrier for pointing out this legislation.

[36] This statement was accurate in August, 2009. The Senate version of the House bill is S. 369, the Preserve Access to Affordable Generic Act. Again, my appreciation goes to Michael Carrier for apprising me of these events.

[37] *See, e.g.*, Carrier, *supra* note 3, at 76-77 (suggesting reverse payment approximating brand manufacturer's litigation costs should be legal); Hovenkamp, *et al.*, *supra* note 30, at 1758 (same).

[38] Mark A. Lemley & Carl Shapiro, Probabilistic Patents, 19 J. ECON. PERSP. 75, 75-76, 95 (2005); Cristofer Leffler & Keith Leffler, Settling the Controversy Over Patent Settlements: Payments by the Patent

doing so. But that term risks making patent rights sound more exceptional than they are. All rights are probabilistic in the practical sense that a court has a certain likelihood of enforcing them.

What is special—although by no means unique—about patent rights is that they determine the legal entitlements not only of drug manufacturers but also of drug purchasers. It is true that a generic manufacturer has a right to bring a drug to market only if it does not infringe a brand manufacturer's valid patent. But it is also true that drug purchasers have a right to prevent brand and generic drug manufacturers from agreeing not to compete unless that competition would infringe a valid patent. From this perspective, what is unusual is not that courts might upset a settlement between drug manufacturers, but that they might treat that settlement as binding on drug purchasers.

Consider a similar problem in a more mundane setting. A, B, and C each claim an individual ownership right in fee simple absolute to Blackacre. A and B then agree to settle their claims against one another by splitting the property between them. If C filed a lawsuit seeking to establish her ownership, it would be extraordinary to suggest that the settlement between A and B would extinguish her rights.[39] Indeed, under ordinary circumstances, she would not even be bound by a judgment after trial between A and B.[40]

So, too, is it extraordinary to treat a settlement between drug manufacturers as eliminating the right of drug purchasers under the antitrust laws to a market free from collusion. Black letter law bars drug manufacturers from agreeing not to compete, unless patent rights empower them to do so.[41] In the ordinary course, drug purchasers should have the opportunity to prove that the generic drug would not infringe the valid patent rights of the brand manufacturer. A choice to deviate from this ordinary course requires a compelling justification.

This Article acknowledges that such a compelling justification may exist, but only if the drug manufacturers compromise on the date of generic entry as the sole basis for settlement. That rule does not abrogate the general policy in favor of settlement. Such a policy should apply—as it does in the case of Blackacre—only to the parties to a settlement.

Holder Should Be Per Se Illegal, 21 RES. L & ECON. 475, 484 (2004); Carl Shapiro, Antitrust Limits to Patent Settlements, 34 RAND J. ECON. 391, 395 (2003); see generally Steven W. Day, Leaving Room for Innovation: Rejecting the FTC's Stance Against Reverse Payments in Schering-Plough v. FTC, 57 CASE W. RES. L. REV. 223, 233–36 (2006).

[39] The analogy to property rights is not as far-fetched as it initially may seem. Others have compared the right to a competitive market to property rights. *See, e.g.*, Carrier, *supra* note 3, at 23 (highlighting arguments that scholars have offered that "[c]onsumers. . . have a 'property right' to the competition that would have prevailed in litigation.").

[40] Generally, only parties or privies to litigation are bound by the outcome. *See Taylor v. Sturgell*, 128 S.Ct. 2161, 2172-73 (2008).

[41] *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 991-92 (Posner, J.) (recognizing agreement not to compete—if it is not adequately supported by a patent right—should constitute an antitrust violation); *Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. at 971-72 (same).

Part II provides some background on reverse payment settlements and reviews the scholarly research showing that the Hatch-Waxman Act created a legal regime encouraging challenges to brand patents. Part III explains the economics of dispute resolution and applies them to various options for assessing settlements of patent disputes under antitrust law. Part IV concludes.

II. Background and Premises.

A. The Importance of Reverse Payment Cases.

Reverse payments under the Hatch-Waxman Act regime do not give rise to just another antitrust problem. Given the importance of the drugs at issue, the amount of money at stake, and the attention spent by courts and commentators, determining the right standard for evaluating reverse payments is one of the most pressing antitrust issues of our time. C. Scott Hemphill, a leading scholar on the topic, goes so far as to characterize it as "the most important unresolved issue in U.S. antitrust policy, measured by economic importance and high-level judicial attention."[42]

The medication subject to reverse payments could not be much more significant. They include: Cardizem, which treats angina and hypertension and prevents heart attacks and strokes;[43] K-Dur 20, used to treat low potassium levels caused by hypertension medication;[44] tamoxifen, a medicine for breast cancer and the most prescribed cancer drug in the world;[45] and ciprofloxacin hydrochloride, a common antibiotic.[46]

Nor is the financial impact minor. One of the most sophisticated and complete analyses to date, by Hemphill, suggests as a conservative estimate that buyers have overpaid by $16 billion as a result of reverse payments.[47] Another study by the FTC concludes that "even with conservative assumptions and limitations, eliminating. . . pay-for-delay settlements would. . . save consumers $35 billion over ten years."[48] With stories appearing regularly in the newspaper about ordinary Americans going without medications that they cannot afford,[49] artificially inflated prices for drugs cost lives.[50]

B. The Hatch-Waxman Act and Its Policy in Favor of Efficient Challenges to Brand Patents.

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[42] Hemphill, *supra* note 1, at 631.
[43] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 899-903 (6th Cir. 2003).
[44] *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058-62 (11th Cir. 2005).
[45] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193-99 (2d Cir. 2006).
[46] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327-30 (Fed. Cir. 2008).
[47] Hemphill, *supra* note 1, at 650-51, 662.
[48] John Leibowitz, *"Pay-for-Delay" Settlements in the Phamaceutical Industry, www.ftc.gov/speeches/leibowitz/090623**payfordelay**speech.pdf.*
[49] *See, e.g.*, Walecia Konrad, *Health Care You Can't Afford Not to Afford*, N.Y. TIMES, January 16, 2009 (citing Kaiser Permanente studies on patients who avoid medical care); New York Times, "Health-care costs hitting even those with insurance," May 4, 2008.
[50] *See, e.g.*, Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES & REV. 415, 420, 427-28 (2004).

Concern about the high cost of medicine figured in crafting the legal regime that governs patent disputes between prescription drug manufacturers. That regime is codified in the Hatch-Waxman Act ("Hatch-Waxman" or the "Act") of 1984 and its subsequent amendments.[51] In enacting the Hatch-Waxman Act, Congress sought to increase generic competition.[52] It did so in part by encouraging generic manufacturers to challenge brand patents.[53] Some background is necessary to understand this point.

Ordinarily, a drug manufacturer must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") to receive approval to market a drug.[54] That process is expensive, lengthy and involved.[55] To facilitate generic entry, Hatch-Waxman allows a generic firm to piggyback on the NDA, filing an Abbreviated New Drug Application ("ANDA") that relies on the brand manufacturer's safety and effectiveness studies.[56] To qualify for an ANDA, a generic manufacturer must show that the generic drug is functionally equivalent to the brand drug (that they have the same active ingredient, route of administration, bioequivalence, and the like).[57]

To invoke the ANDA process, a generic firm must make a certification under one of four paragraphs: Paragraph I, no brand drug manufacturer has indicated a relevant patent exists that could be infringed; Paragraph II, any such patent has expired; Paragraph III, the generic manufacturer will await the expiration of any brand patent before seeking FDA approval; or Paragraph IV, any relevant brand patent is invalid or will not be infringed by the generic drug.[58]

The reverse payments under discussion arise when a generic manufacturer certifies under Paragraph IV. This certification constitutes a constructive infringement of the patent, although it does not give rise to damages.[59] The brand manufacturer then has 45 days to file a legal action and, if it does so, is entitled to a stay, generally of 30 months.[60] The stay acts in effect like a preliminary injunction, preventing the generic manufacturer from marketing its product.[61]

Various provisions of the original Act—and amendments to it—make clear the intent to encourage generic competition to brand patents. First, the initial firm to file a patent challenge obtains a 180-day period of exclusivity.[62] Other generic drugs cannot come to market during that period, providing an incentive to compete with the brand

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[51] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified as amended at 21 U.S.C. § 355 (1994).
[52] *See* Carrier, *supra* note 3, at 42, 45.
[53] *Id*. at 47.
[54] *Id*. at 45.
[55] *Id*.
[56] *Id*. at 46.
[57] *Id*.
[58] *Id*.
[59] *Id*. at 47.
[60] *Id*. at 46-47; Hemphill, *supra* note 3, at 1566 n. 50.
[61] *See* Carrier, *supra* note 3, at 46-47.
[62] 21 U.S.C. § 355(j)(5)(B) (iv)

drug.[63] Second, an amendment to the Act causes forfeiture of this exclusivity period under certain circumstances, including if the generic manufacturer fails to market its drug, fails to pursue FDA approval promptly, or enters into an agreement that a court finds to violate the antitrust laws, such as an agreement involving an illegal reverse payment.[64] This limitation is designed to prevent a generic firm from conspiring with a brand firm to delay all generic competition. Third, the Act restricts the 30-month stay to the brand manufacturer in various ways, including ending the stay upon a determination that the relevant brand patent is invalid or not infringed,[65] and limiting the stay to patents submitted to the FDA before a generic's filing of an ANDA.[66] Fourth, an amendment to the Act requires drug manufacturers to report settlements of patent disputes to the Federal Trade Commission and the Department of Justice so that the government can monitor any potentially anticompetitive conduct.[67] Together these provisions encourage generic competition to brand patents, including through challenging the validity of a patent or a claim of infringement.[68]

But these provisions are imperfect. They leave open the possibility of anticompetitive agreements between brand and generic drug manufacturers. A brand manufacturer, for example, can delay generic competition through a reverse payment to a first generic competitor[69] or by entering into successive agreements with generic manufacturers when they threaten to enter the market.[70]

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[63] The MMA of 2003 allows multiple generic firms to qualify for exclusivity if they file on the same day. A letter from the CBO to Sen. Hatch explains, "If multiple applicants each submit the first ANDA containing a patent challenge for a particular drug product on the same day, then each qualifies as a first applicant and eligibility for the exclusivity period is shared." http://www.cbo.gov/doc.cfm?index=4513&type=0

[64] Carrier, *supra* note 3, at 48. *See generally* 21 U.S.C. § 355 (j)(5)(D)(i) (2009) (listing the six events that may trigger forfeiture, which are failure to market, withdrawal of application, amendment of certification, failure to obtain tentative approval, entering into an agreement with another applicant, the listed drug application holder or patent owner, or patent expiration). The finding of an antitrust violation has to be in a judicial "decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken," 21 U.S.C. § 355 (j)(5)(D)(i)(I), so it appears that forfeiture does not occur until the time to appeal from a federal trial court has expired or a federal appellate court rules against the brand manufacturer.

[65] Carrier, *supra* note 3, at 48.

[66] *Id*. at 47.

[67] *Id*. at 47-48.

[68] *See generally* Hemphill, *supra* note 3, at 1614-16 (arguing that reverse payments are inconsistent with framework of the Hatch-Waxman Act as encouraging generic challenges to brand patents).

[69] A single settlement might suffice to delay generic entry if, for example, other generic manufacturers are not yet ready to come to market.

[70] *See, e.g., F.T.C. v. Cephalon, Inc.*, 551 F.Supp.2d 21, 23-24 (D.D.C. 2008) (noting brand manufacturer allegedly entered settlements paying off four different generic drug manufacturers to delay generic entry); *see also* C. Scott Hemphill, Drug Patent Settlements Between Rivals: A Survey, at 15 (2007), http://ssrn.com/abstract=969492. Moreover, a brand manufacturer can create a bottleneck by settling with the first generic to file an ANDA. The Act originally allowed this bottleneck by permitting the first generic to file an ANDA to retain its 180-day exclusivity period, even after it settled its patent dispute with the brand manufacturer. Hemphill, *supra* note 1, at 130-31. An amendment to the Act sought to fix this problem. It provides for forfeiture of the 180-day exclusivity period of the first generic filer if there is a settlement such that "a court signs a settlement order or a consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed." 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(BB). But there is little reason to think a settlement involving a reverse payment would give rise to a court action of

The policy embodied in the Hatch-Waxman Act of encouraging patent challenges can be understood as consistent with the broader aims of antitrust law. The dominant approach in antitrust has come to be the promotion of efficiency.[71] To the extent that the law can be interpreted so that generic challenges to brand patents are encouraged when they would promote efficiency, the Hatch-Waxman Act and background antitrust principles can serve a common purpose.

The same is true in regard to patent law, although this possibility is less obvious. Patent law is designed to promote innovation by conferring a legal monopoly. But that monopoly is of limited duration. And it is available only for inventions that meet certain criteria. In other words, patent law has built into it limitations on the monopoly profits of a putative patent holder. As long as an approach to reverse payments provides the same benefits to a patent holder as would be available in a court of law—and the approach I propose would have just that effect—then patent law can be reconciled with the policies in the Hatch-Waxman Act and antitrust doctrine. Moreover, as others have argued, if there is any tension between the Hatch-Waxman Act and patent law, the more specific aims of the Hatch-Waxman Act should prevail.

C. Assumptions.

With this background in mind, this Article proceeds under a few simplifying assumptions. First, it assumes that the goal of the various legal regimes at issue—the Hatch-Waxman Act, patent law, and antitrust law—are designed to promote efficiency.

Second, the Article accepts in general that patent law and antitrust law are efficient. So, for example, it assumes that a patent holder's monopoly is efficient if and only if the patent holder would be entitled to that monopoly under proper application of patent law. Along similar lines, this Article further assumes that the ideal resolution of a patent dispute would be its instantaneous and cost-free resolution at trial under the ordinary evidentiary and fact-finding rules. This assumption is important. The Article will use as a benchmark for minimizing error costs the expected value of this imaginary, instantaneous adjudication of the underlying patent dispute.

Third, the Article treats the legality of reverse payments under antitrust law as an open issue. It assumes that whether reverse payments are legal, and the circumstances under which they may be legal, have not been resolved in any authoritative manner. In reality, legal authorities have reached mixed results on this issue. Some courts have held that reverse payments are *per se* illegal.[72] Others have held that they are in effect *per se*

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this sort. On the other hand, there is an argument that once the first generic filer settles the patent dispute, its ANDA filing is not "lawfully maintained," and therefore the generic manufacturer may no longer have a right to the exclusivity period. *See* Hemphill, *supra* note 1, at 661 n. 128.

[71] *See* POSNER, *supra* note 7, at ix.

[72] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (condemning agreement to delay generic entry as per se illegal); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809-12 (D.C. Dir. 2001) (suggesting similar approach in dicta).

legal.[73] The federal government has adopted various positions over time with the FTC largely critical of reverse payments,[74] the Solictor General somewhat more sympathetic to them in the past,[75] and the Department of Justice recently expressing an ambiguous view, one that appears to be skeptical of their legality.[76]

D. What Constitutes a Reverse Payment?

A final preliminary issue is worth addressing. This Article assumes that drug manufacturers, drug purchasers, lawyers, and courts are able to identify reverse payments. In other words, it proceeds from the premise that the relevant decision-makers will know reverse payments when they see them.

This premise is realistic in some cases. Some reverse payments are obvious. At times, brand manufacturers have been upfront that they are paying generic manufacturers to delay competition.[77] This was particularly likely to be true in the early cases, when drug manufacturers were relatively naïve about the risk of antitrust liability.

As criticism of reverse payments has grown, and the risk of public and private legal action has increased with it, brand drug manufacturers have adjusted their behavior. They are more likely to disguise reverse payments in various ways, perhaps as secret side deals or as inflated payments to generic manufacturers for rights that they would not otherwise purchase. After an extensive study, Hemphill concludes, for example, that brand manufacturers often pay generic manufacturers as part of legal arrangements that rarely, if ever, occur, except when the drug manufacturers also happen to be resolving a patent dispute that includes an agreement to delay generic entry.[78] Hemphill is likely correct that these arrangements should be treated as reverse payments. But analysis of that issue is beyond the scope of this Article.

III. The Economics of Assessing Settlements of Patent Disputes Under Antitrust Law.

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[73] *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323, 1341 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187, 190 (2d Cir. 2006); *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005).

[74] *See, e.g., Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Courts and Competition Policy Committee of the H. Comm. On the Judiciary* (2009) (prepared statement of the Federal Trade Commission).

[75] *See, e.g., Brief for the United States as Amicus Curiae, Schering-Plough Corp.*, 126 S.Ct. 2929, at 11 (2006) (No. 05-273) (suggesting judicial evaluation of likelihood of success on claim of patent infringement).

[76] *See* Brief for the United States in Response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund v. Bayer, AG*, 05-2852-cv, 29-32 (2d Cir.filed July 6, 2009).

[77] *See, e.g.,In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902-03 (describing undisguised reverse payment).

[78] *See* Hemphill, *supra* note 1, at 666-69.

From an economic perspective, two concerns in dispute resolution are primary: error costs and transaction costs.[79] The ideal method of resolving conflicts minimizes the sum of the two.

Error costs reflect disparities between the correct outcome and the actual outcome in a case.[80] Three factors contribute to the error costs of a particular dispute resolution mechanism. First, there is the accuracy of the method for deciding particular cases. The more accurate the method, the lower the error costs.[81]

The second factor is the relative harm from false positives and false negatives, that is, an erroneous decision in favor of plaintiffs or defendants. If errors in one direction are more harmful than the other—if plaintiffs winning erroneously causes greater damage than defendants winning erroneously or *vice-versa*—then that provides a reason to give one party the benefit of the doubt. Courts should hedge in favor of an error in the direction likely to cause the least harm.[82]

The third factor is the base rate at which plaintiffs or defendants should prevail. If plaintiffs tend to bring claims that are meritorious then a decision method that tends to err in their favor is less likely to produce incorrect results. The converse proposition is true as well.[83]

Transactions costs include the time, money, and energy consumed in resolving a dispute. Both litigation and settlement involve transaction costs, although in settlement they are usually lower. But the two are not mutually exclusive. And failed efforts to settle may increase rather than decrease total transaction costs.[84]

A. Antitrust Standards.

Put most simply, in antitrust cases courts will generally adopt one of two standards: the Rule of Reason or a *per se* rule.[85] The Rule of Reason involves a case by

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[79] *See* Bone, *supra* note 9, at 531-76 (explaining the framework as well as expected value litigation).

[80] The notion of a correct outcome that is different from the actual outcome gives rise to difficult philosophical problems. *See* Joshua P. Davis, *Expected Value Arbitration*, 57 OKL. L. REV. 47, 90-91 (2004); Davis, *supra* note 5, at 424-26. Sometimes economists treat the actual outcome at trial (or on appeal) as automatically correct. *See id*. at 409 & n. 142 (citing John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 HARV. L. REV. 525, 542 (1978); RICHARD A. POSNER, ECONOMIC ANALYSIS OF THE LAW, § 2.13, 554 (4th ed. 1992)). The more sound argument is likely that the right outcome and the actual outcome are meaningfully different. *See, e.g*., *id*. at 405-10 (arguing in favor of that distinction). In either case, as noted below, *infra* notes 133-35 and accompanying text, the argument of this Article turns out to be the same whether or not one recognizes the possibility of errors in litigation, so I do not dwell on this issue.

[81] Bone, *supra* note 9, at 534.

[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] Of course, the law is much more complicated than this. There are also intermediate standards—sometimes called "quick look"—that are more flexible than a *per se* rule but less involved than the Rule of Reason. *See* POSNER, *supra* note 7, at 39-40. Some commentators have suggested that the pure Rule of Reason analysis and *per se* rule actually mark the ends of a continuum. Edward Brunet, *Antitrust Summary*

case weighing of the procompetitive and anticompetitive effects of behavior. In contrast, if conduct is *per se* illegal, courts have determined that its anticompetitive effects so clearly outweigh its procompetitive effects that proof that the conduct occurred is sufficient to establish a violation of the law.[86] Similarly, although courts do not always use this phrasing, some behavior is so obviously procompetitive that it is treated as *per se* legal.[87]

The Rule of Reason gives rise to relatively high transaction costs but relatively low error costs, at least in most cases. The thorough analysis of procompetitive and anticompetitive effects is expensive, consuming a great deal of time and money. It often requires extensive discovery to determine the nature of the market at issue, as well as a battle of economists to predict the likely effects of restraints on competition. On the other hand, the Rule of Reason allows a court to adjust application of antitrust law to the circumstances of each case.[88]

A *per se* rule, in contrast, entails relatively low transaction costs, but runs the risk of relatively high error costs. Once a litigant establishes that behavior falls within this rule, no further inquiry is necessary to determine whether an antitrust violation has occurred. Price fixing between horizontal competitors is an example. Proof of price fixing suffices. No analysis is necessary of whether it might serve some procompetitive purpose, or whether the conduct actually led to materially higher prices or reduced output.[89] This categorical rule streamlines litigation. But it can result in errors. For this reason, courts generally say they will condemn conduct as *per se* illegal only if experience has shown it is so consistently anticompetitive that they need not assess any procompetitive effects it may have.[90] (They might also treat conduct as *per se* illegal or legal if there were a strong asymmetry in harms from false positives and false negatives, but courts do not generally couch their analysis that way.)

Judgment and the Quick Look Approach, 62 S.M.U. L. Rev. 493 (2009). And various categorical rules constrain even the Rule of Reason analysis. But the simpler model is useful for purposes of exposition, even if it is somewhat stylized.

[86] Note that to establish liability plaintiffs still must demonstrate fact of damage or impact. *In re Hydrogen Peroxide Antitrust Litig*., 552 F.3d 305, 311 (3d Cir. 2008).

[87] A simple contract to exchange goods or services for money, for example, is an agreement in restraint of trade, but courts generally treat it as *per se* legal for purposes of Section 1 of the Sherman Act.

[88] The transaction costs associated with the Rule of Reason in general is a matter of some dispute. For example, Michael Carrier has done an empirical analysis showing that in the last decade courts have rejected 97% of Rule of Reason cases because plaintiffs failed to prove a significant anticompetitive effect, generally on a motion to dismiss or at summary judgment. Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827, 829 (2009). What is unclear is the reason for this high percentage. Possibilities include judicial hostility to Rule of Reason claims and the difficulty and expense of proving even meritorious claims under the Rule of Reason. We also must take care in drawing inferences from Carrier's analysis. He including only those opinions reaching a final result, which would exclude denials of motions to dismiss and for summary judgment and jury verdicts. The risk is that, in effect, he considered (virtually) only those cases in which defendants prevailed.

[89] Note that a showing of impact is nevertheless necessary to prove civil liability in a private lawsuit—impact or fact of damage is an element of such an antitrust claim—but not to establish an antitrust violation.

[90] *See* RICHARD A POSNER, ANTITRUST LAW 39-40 (2d ed. 2001) (discussing relative costs and benefits of Rule of Reason and *per se* rule).

B. Options for Assessing Patent Settlements.

Economics provides a valuable framework for analyzing the most plausible approaches to assessing challenges to patent settlements. Several options are available. First, a court could undertake a Rule of Reason analysis, showing no deference to the fact that the manufacturers settled their patent dispute.

One way purchasers should be able to prevail under that standard is by establishing that the generic manufacturer should have won the patent dispute. After all, in general no conduct is perhaps more anticompetitive than when competitors agree not to compete.[91] For that reason, such conduct constitutes an antitrust violation unless it is protected by a patent right or some similar exception to antitrust law.[92] The Rule of Reason understood in this way fares well in terms of error costs, but it is unattractive because it entails relatively high transaction costs. The resulting litigation would likely prove prolonged and expensive in many cases.[93]

A second approach would be to adopt a rule of *per se* legality. Any settlement between brand and generic manufacturers would be legal under the antitrust laws. No court or commentator has gone quite this far, but the Second and Federal Circuits have come close. They have held that settlements—even if they include reverse payments—do not violate the antitrust laws unless purchasers can establish that the claim of infringement was a sham or the brand manufacturer committed fraud on the patent office.[94] The high error costs of this option make it unwise, even though it has low transaction costs.

Fortunately, a third approach is available that is elegant in its simplicity. It condemns settlements of patent disputes as *per se* illegal if they entail a reverse payment. This approach has low error costs because it aligns the interests of the generic manufacturer with purchasers: the generic manufacturer has incentive to drive a hard bargain over the date of generic entry to increase its own profits, which will at the same time drive prices down. The approach also has low transaction costs because it automatically condemns settlements under specified conditions and it should be relatively

[91] For a discussion of the deleterious effects when competitors are able, through agreement, to simulate the pricing of a monopolist see, *e.g.*, *id*. at 9-18.
[92] *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 991-92 (Posner, J.) (recognizing agreement not to compete—if it is not adequately supported by a patent right—should constitute an antitrust violation); *Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. at 971-72 (same). There are, of course, other exceptions to the general ban on competitors agreeing not to compete, *see, e.g.*, *Texaco, Inc. v. Dagher*, 547 U.S. 1 (2006) (discussing possibility of procompetitive agreements among competitors as part of joint venture), but I assume none of them is relevant to the cases we are discussing. If any were, the drug manufacturers could, of course, raise it in the antitrust litigation.
[93] *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1043 (2004) (explaining the relationship between agreements and odds of successful litigation).
[94] *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323, 1341 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187, 190 (2d Cir. 2006).

easy to detect if those conditions are met.[95] And it should permit settlements to occur. After all, the vast majority of cases settle, even without the prospect of sharing monopoly profits through a reverse payment.[96]

C. The Rule of Reason: No Deference to Manufacturers' Settlements.

The first approach to assessing the legality of a settlement of a patent dispute would be to apply the default standard in antitrust cases: the Rule of Reason. Under the Rule of Reason, purchasers of the drugs at issue would be required to show that a settlement between brand name and generic drug manufacturers had greater anticompetitive than procompetitive effects.

The Rule of Reason analysis might naturally turn on whether the brand manufacturer should have won its patent dispute with the generic manufacturer. If so, the settlement is merely an alternative means for the brand manufacturer to protect its patent rights. If not, any delay in generic entry would extend the effects of a patent beyond its legal term, causing the sort of anticompetitive harm that antitrust law does not allow.

This interpretation of the Rule of Reason is consistent with the legal framework that applies when a brand manufacturer claims its patent should prevent a generic drug manufacturer from bringing a competitive drug to market. The economics are functionally the same. It is not clear why it should matter whether a challenge to the brand patent comes from a generic manufacturer or from purchasers of the drug at issue.

For this reason, it is odd that the Federal Circuit purported to invoke the Rule of Reason in holding that a settlement between drug manufacturers violates the antitrust laws only if the patent claim is a sham or the brand manufacturer committed fraud on the patent office.[97] That is a rule of *per se* legality with a narrow exception, not an application of the Rule of Reason.

It is also worth noting that an alternative version of the Rule of Reason is possible. Rather than evaluate the underlying claim of patent infringement, a court might attempt to apply the Rule of Reason by assessing whether a settlement between drug manufacturers is reasonable. I will discuss this approach below.[98] Some commentators have made a proposal along these lines,[99] as has the Department of Justice in a recent

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[95] *See* Hovenkamp, *et al*., *supra* note 30, at 1762 (2003). However, as noted in II.D *supra*, reverse payments may be disguised, giving rise to disputes in litigation and attendant transaction costs.
[96] *See supra* note 28.
[97] *In Re Cipro* at 1336 ("We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent….In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.").
[98] *See infra* notes 171-77 and accompanying text.
[99] *See, e.g.*, Carrier, *supra* note 3, at 34.

filing.[100] It turns out that this application of the Rule of Reason would produce high error costs and high transaction costs and, for that reason, has little to recommend it.

1. Error Costs.

a. The Rule of Reason Fares Well at Minimizing Error Costs.

Application of the Rule of Reason does a reasonably good job of minimizing expected error costs, if the harms from false positives and false negatives are symmetric. The ordinary way to pursue this effort would be to allow drug purchasers to prevail under the Rule of Reason if they prove that the generic drug manufacturer should have won in its litigation against the brand manufacturer. The purchasers might show, for example, that the generic drug does not infringe the brand patent. The purchasers could make this showing under the ordinary preponderance of evidence standard. That should minimize error costs. (A variation may be appropriate for litigation about patent validity to reflect current practice: as noted below, there is a presumption of patent validity that gives rise to a clear and convincing evidence standard.[101])

Our legal system generally minimizes error costs under conditions of uncertainty by applying the preponderance of evidence standard.[102] A plaintiff prevails if she establishes that she is more likely than not correct on any given factual issue. Generally speaking, this approach makes sense.[103] Resolving factual issues using the preponderance of evidence standard minimizes error costs, if the harm from errors in each direction tends to be of the same magnitude.[104]

So, for example, assume a brand manufacturer claims that a generic drug infringes its patent rights. The generic manufacturer disagrees, acknowledging the validity of the patent but claiming that there is no infringement. The preponderance of evidence standard ordinarily will minimize the error costs in resolving this dispute, assuming an error in favor of or against infringement would cause equal social harm.[105]

To see this, assume that an error would cause $1 million in harm. If a court wrongly finds infringement occurred, the harm to drug purchasers and others would be $1 million. If the error is an incorrect conclusion of non-infringement, the brand

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[100] *Arkansas Carpenters Health and Welfare Fund*, et al. *v. Bayer, AG*, et al., 05-2851-cv(L) (2d Cir. filed July 6, 2009) at 30-31.
[101] *See infra* notes 108-110 and accompanying text. *See also Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. 956, 993 & n. 60 (F.T.C. Dec. 8, 2003) (discussing presumption of validity).
[102] Davis, *supra* note 5, at 377 & nn. 33-37.
[103] Some potential anomalies are worth noting in this regard. First, this standard applies to each factual issue independently rather than to the case as a whole. It is difficult to make sense of this approach as a way to minimize error costs. *See id*. at 458-60. Second, we do not generally think of contested issues of law in these terms. However, one could argue that a judge's decision about her best view of the law in effect implicitly applies the equivalent of a preponderance of evidence standard. For an analysis along these lines see *id*. at 424-26.
[104] *Id*. at 393-97.
[105] *See, e.g., id*.; Saul Levmore, *Probablistic Recoveries, Restitution, and Recurring Wrongs*, 19 J. LEGAL STUD. 691, 693-94 (1990).

manufacturer will suffer a loss of $1 million. The outcome that will minimize error costs depends on the odds regarding which is the right result. If the chance is greater than even that infringement occurred, the best bet is to decide in favor of the brand manufacturer. If there is, say, a 55% chance of infringement, than the expected error cost from deciding in favor of the brand manufacturer is $450,000 (45% of $1 million) and the expected error cost of deciding in favor of the generic manufacturer is $550,000 (55% of $1 million). Reverse the odds and the error costs are reversed, too. Finally, if the odds of infringement are even, so are the error costs.

Applying this general principle, plaintiffs should prevail in challenging patent settlements as antitrust violations if they can meet the preponderance of evidence standard. In other words, if, for example, a drug purchaser can prove that it is more likely than not that the generic drug did not infringe the brand patent, she should win her antitrust claims. The odds are that the settlement between the drug manufacturers undermines competition without a basis in patent rights.

A few qualifications are appropriate in regard to this point. First, the accuracy of court decisions may be compromised because drug purchasers may not be as well situated to challenge a claim of patent infringement as a generic drug manufacturer. The purchasers are unlikely to have the same access to crucial information or to be as sophisticated about the technical and perhaps legal aspects of a patent dispute. The most likely consequence of this difficulty is that purchasers would lose antitrust claims when they should not.[106]

A second qualification is that brand name drug manufacturers have a significant strategic advantage in litigation. They benefit from delay. Under the Hatch-Waxman Act, brand name drug manufacturers are able to keep a generic drug off the market for thirty months merely by filing a prompt lawsuit against the generic manufacturer.[107] And, in any case, generic manufacturers may be unwilling to bring their drugs to market without a favorable judicial ruling to protect them from damages for patent infringement. During this period, the brand manufacturer enjoys its patent monopoly, even if a court later rules that the brand manufacturer never had the right to prevent generic competition. Use of this delay will skew the results of trial in a brand manufacturer's favor—at least as compared to an idealized, instantaneous decision on the merits by a court. It therefore will cause error costs.

A third qualification pertains to the presumption in favor of patent validity.[108] Applying a preponderance of evidence standard to antitrust claims by drug purchasers

[106] Of course, competitors might bring claims.

[107] *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2009). Note that this period will be abbreviated if the patents expire, or a judge determines them not to be valid or infringed. *Id*. *See also* Brief for the United States in Response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund v. Bayer, AG*, 05-2852-cv, 3 (2d Cir.filed July 6, 2009).

[108] It is worth noting that this presumption does not apply to infringement; courts do not presume that a generic drug infringes a brand patent, only that the brand patent is valid. *Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. 956, 993 & n. 60 (F.T.C. Dec. 8, 2003).

would not honor this presumption.[109] But the presumption could be incorporated in the burden that drug purchasers have to carry in prevailing on their antitrust claims. A purchaser making a claim that a reverse settlement is illegal because the brand patent was invalid would then have to satisfy the same clear and convincing evidence standard that the generic drug manufacturer would have faced in the initial litigation. (Alternatively, the presumption could be eliminated, perhaps to counterbalance the disadvantages purchasers face in patent litigation, as discussed in the previous two paragraphs.[110])

In sum, *ceteris paribus*, requiring drug purchasers to prove a lack of infringement (or perhaps patent invalidity) by a preponderance of evidence standard should minimize error costs and, to the extent it fails to do so, will likely lead to excessive errors in favor of brand drug manufacturers.

b. Possible Exception: Asymmetric Harms.

Nevertheless, as noted above, the preponderance of evidence rule may not minimize error costs if errors in litigation produce asymmetric harms. In other words, if the harm from enforcing an invalid patent—or from finding infringement when it has not occurred—is greater than the opposite mistake, or *vice-versa*, that asymmetry provides a reason to depart from the preponderance of evidence rule.[111] For several reasons, however, courts should not for this reason place a greater burden on drug purchasers than the preponderance of evidence standard.

First, there is no obvious reason why the harms from premature generic entry are greater than the harms from delayed generic entry. True, patent rights serve an important purpose. They encourage innovation. But so does competition.[112] And competition also drives down the costs for medication, a price reduction that may save lives given the limited health care coverage in this country and the high cost of many drugs. An error to the detriment of a brand manufacturer may tend to discourage innovation, but so may an error in the manufacturer's favor. And each extra dollar a brand manufacturer receives comes from a drug purchaser and inflated prices may deter sales that would have occurred under competitive conditions.[113] For these reasons, an error to the detriment of the brand manufacturer appears unlikely to cause greater harm than an error to its benefit.

The second reason the preponderance of evidence standard is likely to minimize error costs is that the legal system has already addressed the possibility of asymmetric

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[109] *See* Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007).

[110] For an argument that under the current system patents should not be presumed valid see *id*..

[111] *See* Davis, *supra* note 5, at 392-93.

[112] *See*, *e.g.*, Jonathan B. Baker, *Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation*, http://ssrn.com/abstract=962261.

[113] Of note, the harms from purchases that do not occur—so-called allocative inefficiency or deadweight loss—are not recoverable under antitrust law. Robert H. Lande, *Are Antitrust "Treble" Damages Really Single Damages?* 54 OHIO ST. L.J. 115, 152 (1993). This omission may explain in part why successful plaintiffs in antitrust cases are automatically entitled to treble their nominal damages, which may have the deterrent effect of only single the actual harm caused by an antitrust violation. *Id*.

harms in setting up the procedural and substantive rules for a generic manufacturer's challenge to a brand patent. The ordinary litigation rules generally apply in determining the validity or scope of a brand patent. This approach appears to reflect an implicit determination that the harms in patent litigation are not asymmetric. Of course, as noted above, the presumption in favor of validity provides an exception to this point (although out of deference to the supposed expertise of the PTO, not out of concern for asymmetric harms[114]). But that presumption could simply be incorporated in the antitrust litigation. A patent would then be presumed valid in antitrust litigation (although it should not be presumed infringed).

The third reason courts should not be concerned about asymmetric harms is that Congress has made clear the importance of testing the scope and validity of brand patents. As discussed above, the legal regime Congress has put in place under the Hatch-Waxman Act recognizes the significant harms that will result if brand name manufacturers are able to benefit from supra-competitive prices by improperly delaying generic entry.[115] By setting up a system that encourages litigation over this issue, Congress has made the implicit judgment that the harms of errors in favor of brand manufacturers are at least as great as the harms of errors against brand manufacturers.[116]

c. Possible Exception: Errors in Litigation.

Another concern about error costs could arise from the possibility of incorrect results in adjudication. A court may err in applying the preponderance of evidence standard. If such mistakes tend to occur in one direction and to do so with sufficient frequency, minimizing error cost might require imposing a higher (or lower) burden on plaintiffs than the preponderance of evidence standard (or the clear and convincing evidence for claims of invalidity).[117]

Of course, it is quite difficult to detect errors in adjudication. We confront an epistemological problem: how can we gauge the right result in a case other than by the actual outcome of adjudication?

One potentially useful source of information is the success rate of patent challenges. Most relevant in this regard is the high rate at which brand drug manufacturers lose patent litigation under the Hatch-Waxman Act framework. A typical study reflects that generic challenges succeed 73% of the time.[118] Assuming the cases

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[114] *See* Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 47 (2007) ("The theoretical justification [for the presumption of validity]is that patent examiners have expertise when it comes to questions of patent validity, and if patent examiners have decided that a given invention qualifies for protection, judges and juries should not second-guess experts'").

[115] *See supra* notes 62-68 and accompanying text.

[116] *See, e.g.*, H.R. Rep 98-857 pt.1 at 28.

[117] *See* BONE, *supra* note 9, at 128-32.

[118] FTC Generic Drug Study, 2002, pgs. 10, 16, 19-20 (generic won 73% of cases that went to trial; either patent invalid or no infringement). A survey of Federal Circuit decisions from 2002 through 2004 similarly concluded that patentholders were successful in only 30% of cases. See Paul M. Janicke & LiLan Ren,

that go to trial are representative, this high rate of generic success implies that the burden on purchasers should not be increased to protect against errors. Indeed, it is high enough to indicate that a presumption of validity—at least in these kinds of cases—may be inappropriate. If one accepts the overall success of generic challenges as reflecting the merits, when courts rule in ambiguous cases they are more likely to be correct if they risk erring in favor of generic manufacturers rather than in favor of brand manufacturers.[119]

To be sure, this reasoning is somewhat circular. The high success rate of generic manufacturers may itself be the product of systematic errors in their favor. If so, that high rate does not tell us how often generic manufacturers *should* win—as opposed to how often they *do* win. But it is hard to imagine why courts would tend to err in favor of generic manufacturers and, if they do, to err sufficiently often to undermine the inference from the 73% win rate that generic challenges should succeed most of the time.

The possibility that courts tend to err in favor of generic drug manufacturers seems slight. There is no obvious reason why they would do so. And in cases of a dispute about patent validity, generic drug manufacturers have to satisfy a heightened burden of persuasion, proving their case by clear and convincing evidence. For this reason, it is at least as likely that generic manufacturers should have won even more than 73% of the time.

This conclusion would be undermined somewhat if the cases that are adjudicated are not representative. If brand manufacturers have weaker claims in the cases that go to trial than those that settle, some adjustment would be appropriate to the conclusion that generic manufacturers should win patent disputes most of the time. Under those circumstances, we should not read too much into the 73% figure. But the opposite is more likely to occur.

The weaker the brand manufacturer's patent or claim of infringement, the more it will benefit from extending its patent rights through settlement. The brand manufacturer can use this surplus to entice the generic manufacturer to settle through a large reverse payment. And the converse is true as well. The stronger the brand patent, the less it stands to gain from settlement, and the smaller the payment that it should be willing to offer the generic manufacturer to avoid trial. As a result, the weaker the brand position, the more likely that settlement will occur before trial. And brand manufacturers have incentive to bring—and pursue—even weak claims of patent infringement to benefit from the 30 month stay of generic entry under the Hatch-Waxman Act. So the 73% figure is at least as likely to *understate* as to *overstate* how weak brand patents are in disputed cases.[120]

Who Wins Patent Infringement Cases?, 34 AIPLA QUART. J. 1, 20 (2006). This rate of successful challenges appears higher than for patents in general. *See, e.g.*, John R. Allison & Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (finding 46% of patents held invalid in cases reaching final judgment).

[119] *See* BONE, *supra* note 9, at 131-32 (noting importance of base rate at which party should prevail for assessing probability of errors).

[120] It is unclear why brand manufacturers would claim infringement when their claims tend to be so weak. A possibility is that brand manufacturers assert even very weak patent claims, first, to enjoy the benefits

In the end, the high success rate of generic challenges to brand drug patents suggests that applying the Rule of Reason—by requiring drug purchasers to establish non-infringement or invalidity under the same standard a generic drug manufacturer would have to meet—should do a good job of minimizing error costs. And, to the extent it does not, it is likely to lead to errors in favor of brand drug manufacturers.

2. The Rule of Reason Produces High Transaction Costs.

From the perspective of error costs, then, the Rule of Reason fares relatively well. The same is not true regarding transaction costs. Drug manufactures settle in part to avoid the cost of litigation. Courts favor settlement for the same reason. Applying the Rule of Reason would give rise to expensive and prolonged litigation.

Indeed, the transaction costs of litigating antitrust claims could be higher than if the drug manufacturers were forced to resolve their original dispute through trial. After all, drug purchasers may have to do more work—and engage in more extensive discovery—to mount a challenge to a claim of patent infringement than a generic drug manufacturer. The purchasers are likely to have more to learn, and to have access to less of the relevant information and evidence, unless they use formal litigation devices. Those discovery devices can be slow and expensive, and often require judicial oversight and intervention. The largest flaw of applying the Rule of Reason to patent settlements, then, is that doing so would involve high transaction costs.

D. *Per Se* Legality of (Virtually) All Settlements: Manufacturers Win.

The second option is to adopt a rule of *per se* legality, or something close to it. This is the approach the Second and Federal Circuits have taken. They would grant drug manufacturers immunity from liability from a settlement unless the brand manufacturer's claim of patent infringement is a sham or the patent was the result of fraud on the PTO.[121] A rule of *per se* legality performs poorly regarding error costs, although it would give rise to relatively low transaction costs.

1. Error Costs

Under a rule of *per se* legality, almost every settlement would survive scrutiny under antitrust law. Under the version of this rule adopted by the Second and Federal Circuits, drug purchasers could prevail on antitrust claims only if they show the patent

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from using litigation as a delay tactic and, second, in the hope that they can enter into a mutually beneficial settlement agreement with a generic competitor. And perhaps generic manufacturers challenge brand patents only when there is a strong basis for doing so. The generic manufacturers may be unwilling to incur the expense of litigation unless they believe that they have a strong prospect of prevailing. Whatever the explanation, the high success rate of generic manufacturers at trial suggests that deviating from the preponderance of evidence standard in favor of brand manufacturers would produce high error costs.

[121] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) (holding reverse payments are legal unless the underlying patent dispute involves sham litigation or fraud on the patent office); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) (same).

infringement claim was a sham or the brand manufacturer perpetrated a fraud on the patent office.[122] It is hard to say how weak a claim of infringement has to be to qualify as a sham. But it is safe to say that under this rule drug manufacturers could settle—including through use of reverse payments—without liability in the vast majority of cases.

a. *Per Se* Legality Produces High Error Costs.

For antitrust purposes, such an approach is equivalent to a rule that a brand manufacturer virtually always prevails in litigation against generic manufacturers. After all, no matter how weak a brand manufacturer's claim of infringement, the generic manufacturer has incentive to settle. This is so because the brand's monopoly profits far exceed the profits of the brand and generic combined after generic entry.[123] The generic manufacturer, then, can accept a payment as a way to share in the brand manufacturer's monopoly profits from the generic drug. And drug purchasers will be deprived of the benefits of competition, even if the generic drug manufacturer likely would have prevailed in litigation. Indeed, the weaker the brand manufacturer's patent infringement claim is, the greater the likely payment to the generic drug manufacturer would be, and the greater the odds that the most efficient result would have followed from generic competition.

In adopting a rule of *per se* legality, some courts have suggested that settlements involving reverse payments should not result in any significant delay in generic entry. After all, they claim, a weak patent will attract other generic drug manufacturers to enter the market promptly.[124] If this were correct, the harm from the settlement would not be that great.

But it is not correct. It can take a while for a second drug manufacturer to develop a generic drug and mount a challenge. And a brand name drug manufacturer can pay off generic manufacturers successively.[125] Indeed, the market itself confirms that brand manufacturers obtain substantial delays to generic competition through settlement. If they did not, they would not make reverse payments, payments that at times total hundreds of millions of dollars.[126] Brand manufacturers must receive something for their money. The costs of litigation are not nearly high enough to explain these expenditures. The main benefit of settlement to brand manufacturers is the extension of their patent monopoly beyond the average result at trial.[127] It is hard to believe that they are simply

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[122] *Id.*
[123] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECONOMICS 391, 392-93 (2003).
[124] *See, e.g.*, *Tamoxifen*, 466 F.3d at 211-12; *Cipro*, 544 F.3d at 1332.
[125] *F.T.C. v. Cephalon, Inc.*, 551 F.Supp.2d 21, 23-24 (D.D.C. 2008) (noting brand manufacturer ellegedly entered settlements paying off four different generic drug manufacturers to delay generic entry); *see also* C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey*, at 15 (2007),
[126] The payment in *Cipro*, for example, was just shy of $400 million. *See Cipro*, 544 F.3d at 1329, n. 5 (noting total reverse payment was $398.1).
[127] As discuss below, the benefit of certainty can also explain reverse payments, although it is not clear why brand manufacturers would gain more from certainty than would generic drug manufacturers.

(and repeatedly) erring when they pay vast sums of money in settlement of patent disputes.

b. Possible Exceptions: Asymmetric Harms or Adjudicative Errors.

To be sure, as discussed above, a rule of *per se* legality might fare reasonably well under limited conditions: if an error against a brand manufacturer produced a much larger social cost than an error in favor of the brand manufacturer or if brand manufacturers generally bring claims only if they should win. But, also as discussed above, neither condition seems to be met.

Indeed, deference to settlements between manufacturers may encourage brand manufacturers to bring weak claims. After all, by doing so, they can provide a basis for a settlement that preserves a patent monopoly that otherwise would cease to exist. That may explain in part why brand manufacturers currently lose three out of four generic challenges that go to trial.[128]

In contrast, if patent settlements are subject to scrutiny under the antitrust laws, brand manufacturers may just be wasting their money in attempting to protect weak patents. They will have to pay the cost of litigation with a generic drug manufacturer and, if they settle using a reverse payment, they may be subject to treble damages under the antitrust laws. So a rule of *per se* legality is likely to result in high error costs.

2. Transaction Costs.

The greatest virtue of a rule of *per se* legality is that it would produce low transaction costs. Settlements would occur in patent litigation at a high rate, given that they offer likely antitrust immunity. The resulting settlement dividend would be particularly large. Not only would the drug manufacturers save the cost of litigation, through reverse payments brand manufacturers could share the benefits of guaranteed monopoly profits that they might otherwise lose.[129]

A countervailing phenomenon is that brand manufacturers might bring some weak patent infringement claims that they would forego in the absence of a rule of *per se* legality. These claims might be worth the cost of litigation only if settlement through a reverse payment is possible. Without a reverse payment, the brand manufacturer might not be able to obtain a sufficient delay in generic entry to warrant litigation.[130]

On the other hand, the savings in transaction costs should be far greater from the antitrust litigation that does not occur. Under a rule of *per se* legality, drug purchasers

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[128] *See supra* note 118 and accompanying text.
[129] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECONOMICS 391, 392-93 (2003).
[130] Note the litigation might pay for itself in terms of the delay it could effect in generic entry. The litigation costs might be lower than the benefits of delayed competition. That delay could readily last the 30 months granted by the statute, or it might last longer if a generic manufacturer awaits a final ruling or settlement before coming to the market for fear of incurring damages.

will likely bring few antitrust challenges to patent settlements. Proving patent litigation was a sham or that the brand committed fraud on the PTO will not be possible in most cases. So, in the end, the rule of *per se* legality will likely produce low transaction costs.

E. A Ban on Reverse Payments: Compromise Only Through Date of Generic Entry.

A third option is to ban reverse payments. Settlement between drug manufacturers would then occur only through a compromise over the date of generic entry.

The ban on reverse payments captures many of the most attractive features of the Rule of Reason and *per se* legality. If the parties settle for a generic entry date that approximates the expected value of litigation, the error costs should be the same as under the Rule of Reason. Indeed, they will be lower if the manufacturers are averse to risk. Moreover, the manufacturers should generally be able to settle, so transaction costs will also be relatively low.

The one advantage of *per se* legality over the ban on reverse payments is that it may produce a somewhat higher settlement rate. Of course, given the high rate of settlement, the vast majority of cases would likely settle under either rule.[131] But the settlement rate might be a bit higher under a rule of *per se* legality because reverse payments may be necessary at times for drug manufacturers to avoid trial on a patent dispute. This may be so, for example, if a brand manufacturer will benefit sufficiently from the delay occasioned by awaiting a judgment on the merits or if one or both of the manufacturers is overly optimistic about its prospects at trial. Particularly if the brand's patent is weak, the large settlement dividend from extending the brand patent may allow the drug manufacturers to overcome even a great disparity in their predictions about the outcome at trial. But these are apt to be the very situations in which reverse payments are most anticompetitive. So any advantage *per se* legality has in terms of lowering transaction costs is likely to come at a greater sacrifice in error costs.

1. Error Costs.

The ban on reverse payments fares particularly well in terms of error costs. Two propositions establish this point. First, settlement for the expected value of litigation produces the same error costs on average as a trial on the merits, and lower error costs taking into account risk aversion. Second, if drug manufacturers can settle only by adjusting the date of generic entry, they are likely to do so in a way that approximates the expected value of trial.

a. Settlement for Expected Value Has Low Error Costs.

The first key point is that settlement for expected value and trial produce on average the same error costs. To see this, consider an example. A brand manufacturer's

[131] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 392 (2003) (noting 95% of patent lawsuits settle before a court judgment).

patent on a drug, "Phlogiston," has expired. The brand firm accuses a generic firm of infringement. If the brand manufacturer prevails, the generic firm will owe $100 million in damages. Assume that there is a 70% chance that the brand firm should prevail, and a 90% chance that the court will decide in the brand manufacturer's favor. This information suffices to calculate the expected error costs of trial. If the brand should win (70%), there is a 90% chance the court will rule correctly and produce no error costs and 10% the court will rule incorrectly and produce $100 million in error costs. If the brand should lose (30%), there is a 90% chance the court will rule incorrectly and produce $100 million in error costs and a 10% chance the court will rule correctly and produce no error costs. This analysis is summarized in the following formula: .70((.90 x $0) + (.10 x $100,000,000)) + .30((.90 x $100,000,000) + (.10 x $0)) = $34,000,000.

Now consider the expected error costs under an expected value result. The expected value of litigation is 90% of $100 million or $90 million. If the brand should win (70%), this result will produce an error cost of $10 million. If the brand should lose (30%), the result will produce an error cost of $90 million, reflected in the following formula: .70 x ($10,000,000) + .30 x ($90,000,000) = $34,000,000. The error cost is the same for trial and a settlement for the expected value of trial.[132]

The proposition that trial and an expected value settlement produce the same error costs is true in general, whether a court requires a plaintiff to prevail by a preponderance of the evidence, by clear and convincing evidence, or under a different legal standard.[133] Moreover, the errors tend to be smaller in an expected value outcome than in the sort of winner-take-all outcome that occurs through trial.[134] For litigants averse to risk, an expected value outcome should therefore be attractive.[135]

b. The Parties Would Likely Settle for Generic Entry No Earlier than the Expected Value Date.

i. Trend Toward Expected Value.

Parties are apt to settle for an outcome approximating the expected value of litigation. This is true because the expected value is a natural starting point in assessing the benefits of settlement.[136] The expected value of litigation reflects how well the parties will do on average if they do not settle. A settlement that is as good as or better than that expected value should be relatively attractive. A litigant could conclude, for example, that she might as well settle for the expected value, if offered by her adversary, since she will fare as well on average by doing so as she would at trial, without the costs

[132] For a similar example see *id*. at 86-87.
[133] For a proof of this proposition see Davis, *supra* note 80 at 85-94, 122-23. The error costs of trial and the expected value of trial remain the same whether one assumes that the outcome at trial is correct or one recognizes the possibility of adjudicative errors. *Id*. at 87 n. 154, 91 n. 170, 92 n. 172, 122-23.
[134] *Id*. at 89-90, esp. n. 159, 124.
[135] *Id*.
[136] For a germinal article making this claim see Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950 (1979).

and risks of litigation. One might call these benefits a "settlement dividend." That dividend has been traditionally used to explain why the vast majority of cases settle.[137]

So, for example, imagine a brand manufacturer whose patent on a drug, "Phlogiston," has expired. The brand manufacturer has accused a generic manufacturer of infringement. The corporate representatives believe the company has a fifty percent chance of recovering $100 million in damages and a fifty percent chance of recovering nothing.[138] Further assume there would be no additional harms if the company loses the dispute about its patent rights. Because the patent has expired, for example, it would not lose future profits. The corporation might well accept $50 million to settle the claim. That outcome would be as good as litigation on average, without the costs and risks.

The analysis is somewhat more complicated for a compromise involving the date of generic entry rather than the payment of money. The gain to the generic manufacturer from earlier generic entry may not correlate perfectly with the loss to the brand manufacturer. In contrast, a payment of a dollar by one party generally correlates with receipt of a dollar by the other.[139] Still, on the whole earlier generic entry should increase the profits of the generic manufacturer and decrease the profits of the brand manufacturer. Without some reason for believing otherwise, we might reasonably assume the gains and losses would be roughly proportionate over time.

Under this assumption, if drug manufacturers settle only by compromising on the date of generic entry, a natural result would be for them to adopt what one might call the "expected value generic entry date" or the "expected value entry date." This date represents the expected value of litigation. So, for instance, assume an equal likelihood of the brand and generic manufacturer prevailing. Further assume that if the brand manufacturer prevails, it will possess a patent monopoly for five years. Otherwise, the generic should be able to come on the market immediately. We can estimate the expected value entry date as two and a half years from when the dispute arises.[140]

ii. Deviations from Expected Value.

While the expected value date is a natural average amount for which parties might settle, there are many reasons why they would deviate from it. In general, the settlement dividend creates a range of possible resolutions that all parties should prefer to continued

[137] See, e.g., Davis, *supra* note 28, at 106-07.

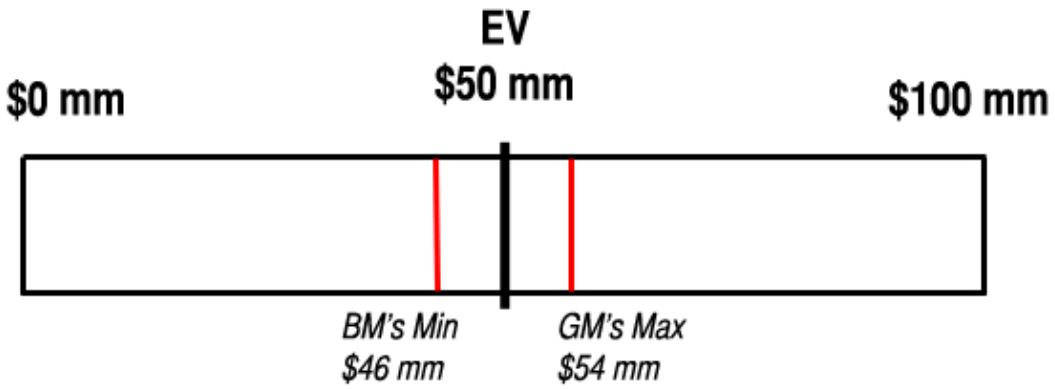
[138] This scenario would be somewhat unusual—although not unheard of—in the context of the Hatch-Waxman Act. Under the Act, a generic manufacturer does not have to bring its drug to market, and risk damages, to trigger a claim of patent infringement. Merely filing an ANDA under Paragraph IV suffices. *See* Carrier, *supra* note 3, at 47; Hemphill, *supra* note 3, at 1592. This procedure reflects and embodies Congress' overall effort to encourage generic challenges to brand patents. *See supra* 62-68 and accompanying text.

[139] Of course, the value of money may not be the same for both parties. Davis, *supra* note 5, at 394-97.

[140] This is, of course, an oversimplification. Various complications would arise in practice. The date should be earlier, for example, to reflect the present value of future dollars. On the other hand, it should be later if drug prices increase at a faster rate than inflation. In addition, an expected increase or decrease in the volume of a sale of a drug over time would result in an adjustment in the expected value entry date.

litigation. Various factors—including strategic behavior—will determine where in that range settlement ultimately occurs.[141]

To see this, consider again the example of the dispute over the patent rights to Phlogiston. If litigation would cost each side $2 million—a plausible sum depending on the complexity of the lawsuit—then both sides might be willing to vary from the expected value by that amount. The brand manufacturer will break even by accepting a settlement of $48 million or more and the generic manufacturer by agreeing to pay $52 million or less. Add the inconvenience of litigation and risk aversion to the mix and the spectrum of possible settlements expands, perhaps doubling the range of mutually acceptable compromises. A diagram of that range might look something like the following:



Any payment between the plaintiff brand manufacturer's minimum and the defendant generic manufacturer's maximum would improve the prospects of both parties on average as compared to trial. This analysis provides a plausible range of possible settlements.

Additional reasons exist why the terms of settlement may vary from the expected value of litigation. One is that either or both parties may be inaccurate in assessing the likely results at trial.[142] A source of this kind of error can be imperfect information, including about the underlying dispute, the evidence that will come to light, or the relevant legal standard. Another source of error could be a misreading of how persuasive the available evidence or legal authorities are. Excessive optimism or pessimism could lead a party to settle, respectively, on better or worse terms than it would if its view of the case were more accurate. (Of course, excessive optimism by one or both parties could also preclude settlement.)

Yet another crucial determinant of the outcome of settlement is strategic behavior.[143] One side may have a strategic advantage over the other. If, for example, the generic manufacturer is on the verge of being acquired by another company, it may have

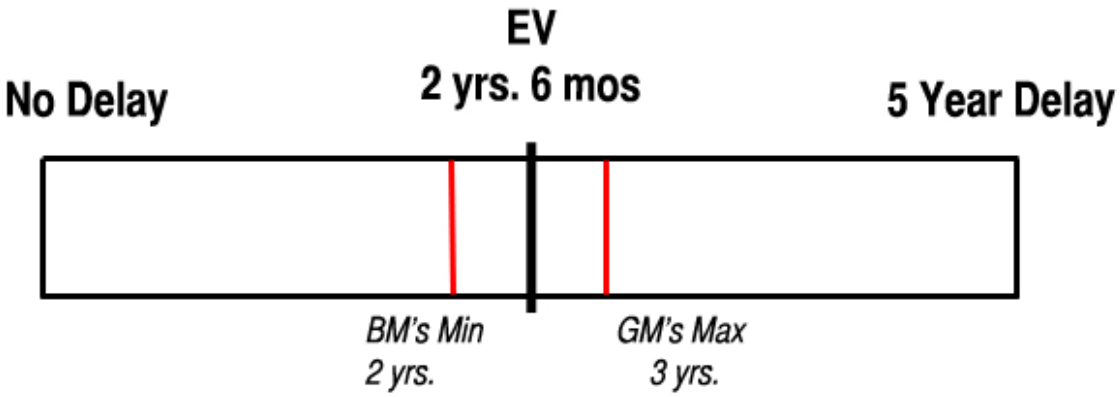
[141] *See* Davis, *supra* note 28, at 127.
[142] *Id*. at 128-32.
[143] *Id*. at 128.

reason to accelerate settlement. Simply dragging out the litigation may hurt the generic company. The generic firm may for this reason pay more for a prompt settlement than it otherwise would.

More generally, strategic behavior during settlement negotiations can explain why parties may not settle for expected value. One side may represent (perhaps falsely) that it is risk neutral or risk prone. Or it may pretend to have an unrealistically optimistic view of the case. The negotiation dynamics can land the parties at any point along the continuum of mutually acceptable results.[144]

This analysis of the dynamics of settlement is most easily envisioned with respect to a payment of a sum of money. But it applies equally well to settlement by other means. So drug manufacturers can reach a settlement that approximates the expected value of litigation by compromising on the date of generic entry.

Consider again the patent dispute over Phlogiston in which the brand claims it has five years remaining on a patent that precludes generic competition.[145] The generic manufacturer claims a right to place a generic version of Phlogiston on the market immediately. The brand manufacturer sues the generic manufacturer, claiming that doing so would involve patent infringement—that the patent prevents generic entry for another five years. If each manufacturer has an equal chance of winning the litigation—and if the harms and benefits to each manufacturer are proportionate over time—we might see a possible range of settlements along the following lines:[146]



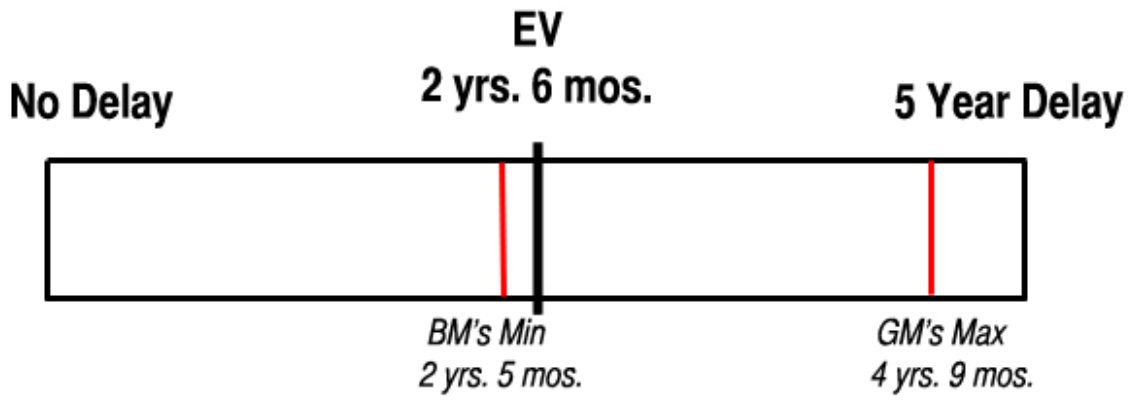
A settlement that permits generic entry between the minimum delay required by the brand manufacturer and the maximum delay acceptable to the generic manufacturer

[144] The psychology of the negotiators may also play a role. *See, e.g.*, *id*. at 127, n. 129 (citing Russell Korobkin & Chris Guthrie, *Psychological Barriers to Litigation Settlement: An Experimental Approach*, 93 MICH. L. REV. 107 (1994)). Psychological considerations may play a lesser role with sophisticated actors in a business dispute. But perhaps not.
[145] *See supra* note 140 and accompanying text.
[146] Of course, any analysis of expected value should correct, for example, for present values. But the diagram is meant only as an instructive illustration.

would improve the prospects of both parties on average as compared to trial. Much like the dispute over money, this analysis suggests a plausible range of settlements.

All else being equal, we might expect that if drug manufacturers were restricted to settling patent disputes by compromising on the date of generic entry, their settlements would cluster around the expected value entry date. Settlements should fall on either side of the expected value, likely forming a bell curve, unless there is some systematic advantage that brand manufacturers hold over generic manufacturers or *vice-versa*. (We will discuss below reasons to believe that brand manufacturers have systematic advantages in negotiation that would push the agreed date well beyond the expected value.[147]) As noted above, if the manufacturers do settle by agreeing to an expected value generic entry date, that settlement would produce the same error costs as resolution through litigation.[148]

Now consider the effect of a reverse payment on the range of likely settlement amounts. The reverse payment allows the brand manufacturer to purchase a delay in generic entry from the generic manufacturer. That increases the total benefit to the manufacturers from settlement. This would have two predictable effects on negotiations. First, the settlement dividend would increase and, with it, so would the range of possible settlement outcomes. Second, the brand manufacturer would receive a delay in exchange for the payment. In terms of the date of generic entry, the resulting diagram of a likely settlement range might look as follows:



Again, the brand manufacturer would fare better by settling for any entry date that is greater than the minimum delay and the generic manufacturer for any entry date that is less than the maximum delay. Of course, this diagram is somewhat arbitrary. In light of the reverse payment, the minimum delay acceptable to the brand manufacturer may remain before or end up being well after the expected value entry date. And the maximum delay that the generic manufacturer would tolerate may fall before or after the expiration of the patent if the brand manufacturer were to prevail. But the key point is that the range of possible entry dates will shift significantly in the brand manufacturer's favor.

[147] See infra part III.E.4.a.
[148] *See supra* note 133 and accompanying text.

To be clear, this diagram represents the result from the perspective of drug *purchasers*. To capture the expected value for the drug *manufacturers*, the payment would have to be taken into account, shifting the parameters back toward a neutral position. But the drug purchasers' perspective is the one that matters for present purposes. The point is that a reverse payment skews the results to the purchasers' detriment, tending to increase the error costs of a negotiated settlement from their perspective.

2. Transaction Costs.

a. A Ban on Reverse Payments Should Not Preclude Settlements.

In theory, drug manufacturers should be able to settle without reverse payments. After all, the vast majority of cases settle, and they do so without the extra incentive of supra-competitive profits.[149] The traditional "settlement dividend" is enough. That settlement dividend consists of whatever time and money each side would expend during litigation, as well as any benefits the parties enjoy from avoiding risk. As a result of the settlement dividend, a negotiated resolution is preferable from the perspective of expected value to pursuing litigation through trial.

This theoretical proposition finds confirmation in practice. For several years beginning in 2000, the Federal Trade Commission had a policy in place hostile to reverse payments.[150] Moreover, during this period, private purchaser cases had succeeded in obtaining rulings from courts declaring certain reverse payment agreements *per se* illegal.[151] Ultimately, the Eleventh Circuit reversed this trend, ruling adversely to the private plaintiffs in 2003 in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[152] and adversely to the FTC in 2005 in *Schering-Plough Corp. v. FTC*.[153] These events created a kind of natural experiment. For several years, drug manufacturers were apparently unwilling to risk a reverse payment as part of a settlement of a patent dispute. Government records reflect that during this period, settlements between drug manufacturers increased in frequency, even though they did not involve reverse payments.

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[149] *See supra* note 28 and accompanying text.
[150] *See In re Abbott Lab. and Geneva Pharm. Inc.*, No. C-3945, at </os/2000/05/c3945complaint.htm> (filed May 22, 2000); *In re Hoechst Marion Roussel, Inc. and Andrx Corp.*, No. 9293, at </os/2000/03/hoechstandrxcomplaint.htm> (filed Mar. 16, 2000) (subsequently settled in April, 2001).
[151] *See, e.g.*, *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 899-903 (6th Cir. 2003) (holding reverse payment *per se* illegal).
[152] 344 F.3d 1294 (11th Cir. 2003).
[153] 402 F.3d 1056 (2005). Other courts followed the Eleventh Circuit's lead, including the Second Circuit in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006) in 2006 and the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) in 2008.

Government reports reflect fourteen relevant settlements occurred between 1992 and 1999, eight of which—slightly more than half—involved reverse payments.[154] In 2000 and 2001 there were a total of six additional settlements, none of which involved reverse payments.[155] Thus, with an FTC policy in place that deterred reverse payments, the rate of settlement increased from about two per year to three per year. Unfortunately, a gap in government information leaves 2002 and 2003 shrouded in mystery.[156]

In 2003 legislation, Congress mandated that companies inform the government about all settlements of disputes of drug patents.[157] Based on this mandate, the government reports that fourteen such settlements occurred in fiscal year 2004 and eleven in fiscal year 2005.[158] None of the fiscal year 2004 settlements involved reverse payments, and only three of the fiscal year 2005 settlements did[159] (presumably, all of them after the Eleventh Circuit in *Schering-Plough* overruled the FTC regarding the legality of reverse payments).

These data are too limited to assess whether reverse payments increase the rate of settlement. But they do establish that settlement is possible in many instances without reverse payments, a result that makes theoretical sense.

b. Any Settlements That Require Reverse Payments Are Likely Anticompetitive.

Moreover, even if settlement is possible in some cases only with the assistance of a reverse payment, trial may be the preferable result. After all, those settlements that require a reverse payment are the most likely ones to be anticompetitive.[160]

As noted above, the weaker the claim of a brand manufacturer, the greater the benefit of extending the life of a patent through settlement.[161] The greater that benefit, the larger the payment the brand firm should be willing to make to the generic firm, and the more likely the payment can facilitate a settlement that otherwise would not occur. But these are the cases in which settlement through a reverse payment is most likely to be

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[154] "*Generic Drug Entry Prior to Patent Expiration: An FTC Study*," at 26-31 (Federal Trade Commission, July 2002) (h*ereinafter* "*The Generic Drug Study*").
[155] *Id. See also* Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* (April 2006) at 4.
[156] The "Generic Drug Study" includes all settlements in which the generic filed its paragraph IV certification before January 1, 2001, and the settlement occurred before June 1, 2002. The study does not include any settlements that may have occurred in or after 2001 as a result of generic filings during 2001.
[157] Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA").
[158] Bureau of Competition Report, Federal Trade Comission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* (April 2006) at 3-4.
[159] *Id.*
[160] *See* Carrier, *supra* note 3, at 78 & n. 264 (noting that Leffler and Leffler determined that "92 percent of cases in which reverse were necessary to reach settlement were likely to reduce consumer welfare") (citing Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should be* Per Se *Illegal*, 21 RES. L. & ECON. 475, 484 (2004)).
[161] *See supra* note 120 and accompanying text.

harmful, allowing a brand manufacturer to protect patents rights that would have poor prospects of surviving scrutiny at trial.

3. Encouraging Challenges to Brand Patents.

A possible concern about banning reverse payments is that doing so may deprive generic manufacturers of an incentive to develop generic drugs. But sufficient incentives likely remain in place. The Hatch-Waxman Act, for example, grants the first generic to file an ANDA 180 days of exclusivity.[162] During this period, and afterwards, generic manufacturers stand to make many millions of dollars, especially in competing with blockbuster drugs. Those profits should suffice to encourage generic competition.

Moreover, more attractive alternatives exist to allowing brand manufacturers to coöpt generic manufacturer by sharing the spoils of supra-competitive profits. If Congress, for example, were to become dissatisfied with the incentives it has created for generic manufacturers, it could extend the exclusivity period beyond 180 days.

4. Reverse Payments Are Unlikely To Correct Deviations from Expected Value.

To minimize expected error costs for both the drug manufacturers and purchasers, then, the date of entry should reflect the expected outcome at trial. In other words, the date of entry should provide the brand manufacturer, the generic manufacturer and purchasers the same financial consequences as would a final adjudication on the merits on average.[163] But, as noted above, the ideal trial would be an instantaneous, cost-free affair. We should want to encourage a settlement for the expected value entry date based on this idealized form of adjudication.

The possibility exists that a payment from one manufacturer to the other—from the brand manufacturer to the generic manufacturer or *vice-versa*—would be necessary to achieve this result. For various reasons, one manufacturer may agree to settle for a date of entry that varies from the expected value date. One manufacturer or the other may: negotiate based on errors about the expected value of litigation, perhaps as a result of limited resources, a lack of sophistication, or inadequate information; use poor negotiation strategy; be averse to risk; or settle to avoid the cost of litigation.

Some commentators have suggested courts should take into account the need for a corrective along these lines in assessing reverse payments.[164] However, various problems would impede any effort to correct for this potential source of error costs: courts are unlikely to be able and willing to determine the expected value date in any case; the

[162] FTC Generic Drug Study at 7.
[163] As noted above, the ideal date would reflect the expected outcome if trial were to occur immediately. *See supra* part II.C and accompanying text. The delay occasioned by the process of litigation lacks any justification based on the merits of the claim of infringement.
[164] *See, e.g.*, Carrier, *supra* note 3, at 76 (suggesting a reverse payment for the amount of anticipated litigation costs should be legal); Hovenkamp, *et al*., *supra* note 30, at 1758 (same).

dynamics of settlement that might cause a deviation from that date are extraordinarily difficult to assess and disentangle; and the cost of the inquiry would likely be quite high.

Moreover, the pattern of reverse payments suggests that they do not generally correct for deviations from the expected value entry dates. If they did, they would likely flow in both directions—sometimes from the brand to generic manufacturer and sometimes the other way around.[165] But they do not. Rather the payments seem to flow uniformly from the brand to generic manufacturer.

The reason is obvious: reverse payments serve as a means for the brand manufacturer to buy and the generic manufacturer to sell as large a delay in generic entry as the law allows. Any permitted payment is likely to serve that end rather than to allow the date of generic entry to approximate the expected value entry date.

a. Brand Manufacturers Will Generally Do at Least as Well in Settlement as the Expected Value of Trial.

For various reasons, brand manufacturers are likely to do better in settlement than the expected value of patent litigation. That is, even without a reverse payment, the agreed date of generic entry is likely to be later than the expected value entry date. For this reason, the effect of allowing reverse payments would be to increase error costs.

A first reason that the compromise date of generic entry may vary from the expected value of trial is that one of the parties may miscalculate.[166] The party may be willing to accept a result less favorable to it then the expected value because it is unduly pessimistic about its prospects. This error may occur for various reasons. The party may have limited resources, and thus be unable to pay sufficiently for an assessment of the expected outcome at trial. It may be unsophisticated and therefore unable to gauge its prospects at trial. It may lack key information relevant to the strength of its position, whether about the facts of the case or the operative law.

Brand firms are unlikely to suffer systematically from these disadvantages as compared to generic firms. In general, they should have the resources, sophistication and information to protect their interests in negotiations. Indeed, brand manufacturers will likely have superior information in many instances, particularly regarding the background circumstances relevant to the strength of their own patents.[167] And brand manufacturers

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[165] *See generally* Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1 (discussing the pattern of payments—often disguised—from brand to generic drug manufacturers).

[166] *See* Davis, *supra* note 28, at 128-30.

[167] Carrier hypothesizes that a brand manufacturer may have better information than a generic manufacturer, causing the two to be unable to settle. Carrier, *supra* note 3, at 77. He suggests that a reverse payment may be able to bridge the gap. *Id.* But if the information helps the brand manufacturer, revealing the information also should lead to settlement without the risk of a deviation from the expected value entry date. And if the information hurts the position of the brand manufacturer, that is a reason why a settlement would result in generic entry *after* the expected value entry date, even without a reverse payment. In neither case is a reverse payment necessary to better approximate the expected value of litigation.

tend to be much larger enterprises with far greater resources than generic manufacturers. Of course, in any given case a brand name manufacturer may blunder to its detriment. But this is unlikely to occur in any systematic manner.

The same is true in regard to negotiation strategy, a second sourced of deviation from the expected value of litigation.[168] Generic drug manufacturers may in some instances out-maneuver brand name manufacturers. But brand manufacturers generally should have the resources and sophistication to hold their own, and to best the generic manufacturers at least as often as they are bested.

Moreover, brand manufacturers are at a strategic advantage because they can use patent litigation to stall. A brand manufacturer can bring and protract patent litigation as a way to delay generic entry. Under the Hatch-Waxman Act, the brand manufacturer qualifies for an automatic 30 month stay on generic entry simply by filing a lawsuit alleging infringement. The stay eliminates any meaningful risk that the generic manufacturer can come to the market immediately, even if a court were to rule eventually that the generic drug does not infringe the patent or that the brand patent is invalid. Indeed, a generic manufacturer may hold off marketing a generic drug even beyond the 30 months for fear of incurring damages.

If the profits from extending the patent are greater than the costs of litigation—a real possibility—the brand manufacturer may benefit from resisting settlement for an extended period of time. Meanwhile, the generic manufacturer will suffer double losses, both from the cost of litigation and from the sales that do not occur while it awaits a final judgment or the lapse of the 30 months. As a result, even if the brand firm loses money from litigation, as long as it does so at a slower rate than the generic firm, the brand manufacturer may be able to employ a credible threat of delay to its strategic advantage in negotiations.

The strategic advantage from delay should allow the brand manufacturer to fare far better in negotiations than it would under an instantaneous decision by a court, if that were possible. Generally, it will postpone generic entry beyond the date that reflects the expected value of a case based purely on the likelihood of the brand manufacturer winning on the merits. Assuming, as we have, that an instantaneous adjudication of the patent dispute on the merits would minimize error costs, the ability of the brand manufacturer to delay should skew any settlement in its favor.

Risk aversion is another matter.[169] A single patent may sometimes be of immense value to a brand manufacturer. The brand firm may be willing to accept less than the expected value of litigation to avoid the risk of losing its patent rights. Of course, the risk a generic manufacturer faces is also considerable. It may have to wait years to bring a generic drug to market. And given the more modest size of generic manufacturers, a smaller loss may prove just as devastating. To be sure, generic manufacturers may be undercapitalized and thus their downside risk (bankruptcy) may not be that great

[168] *See* Davis, *supra* note 28, at 128.
[169] *See* Davis, *supra* note 80, at 71-73 (discussing the effect of risk aversion on settlement).

compared to their upside benefit (early entry of a generic equivalent to a blockbuster drug). But bankruptcy still would not be cost free.

In addition, as Hemphill and Carrier have recognized, a generic manufacturer is likely to care less about the timing of its market entry than its right to be the exclusive generic drug manufacturer when it enters the market.[170] Rather than risk the right to exclusivity if it loses the patent litigation against the brand firm, a generic firm is apt to agree to postpone the date of generic entry beyond the expected value entry date.[171] As a result, risk aversion is far more likely to produce delayed—rather than accelerated—generic entry.

In sum, there is no reason to believe that brand manufacturers would generally cede most of the settlement dividend to generic manufacturers. The opposite seems far more likely to be true. There is scant basis, then, to believe that reverse payments would generally cause the date of generic entry to better approximate the expected value of litigation.

b. Allowing Reverse Payments If They Are Reasonable Would Substantially Increase Error and Transactions Costs.

The above analysis is useful in evaluating the proposal to allow reverse payments if they are reasonable. Different sources have framed a suggestion along these lines in different ways. Carrier, for example, suggests that reverse payments should be legal when they are "reasonable payments."[172] Similarly, the Department of Justice recently suggested in a brief submitted to the Second Circuit that a reverse payment should be legal only if "the agreed upon entry date and other terms of entry reasonably reflected [the brand and generic drug manufacturers'] contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration."[173] The DOJ continued, "However high the parties thought the likelihood the patent would be upheld, a reverse payment settlement permitting significantly less generic competition than would be consistent with that likelihood would be an unreasonable restraint on competition."[174]

These standards are vague. The most sympathetic interpretation from a law and economics perspective would be that reverse payments are legal only if they allow generic competition to occur at approximately the expected value entry date. In other words, reverse payments should be allowed if they serve as a corrective, causing generic entry to occur closer to—rather than further from—the expected value for the date of generic entry if the dispute were litigated perfectly efficiently to a final judgment. This

[170] Hemphill, *supra* note 3, at 1593; Carrier, *supra* note 3, at 74.
[171] Hemphill, *supra* note 3, at 1593.
[172] Carrier, *supra* note 3, at 76; *see also id*. at 77. The Senate has taken a similar approach in the marked up version of S. 369, which places a burden on parties to agreements containing reverse payments to show by clear and convincing evidence that their procompetitive benefits outweigh their anticompetitive effects.
[173] *Arkansas Carpenters Health and Welfare Fund*, et al. *v. Bayer, AG*, et al., 05-2851-cv(L) (2d Cir. filed July 6, 2009) at 30-31.
[174] *Id*. at 31.

Article contends that such a final judgment should be based on what would occur through an instantaneous trial, not a delayed trial that gives the brand firm a strategic advantage in negotiations. Within this framework, the proposal to allow "reasonable" reverse payments is a bad idea because it would likely produce greater error costs and transaction costs than a *per se* ban.

As to error costs, as a general matter reverse payments are more likely to skew the compromise date of generic entry away from—rather than toward—the expected value entry date. Brand manufacturers have incentive to use reverse payments to buy a greater delay than would occur on average if the case were litigated on the merits. And generic drug manufacturers have incentive to sell them that right. That way the drug manufacturers can share the profits from supra-competitive prices.[175]

Worse yet, courts will be in a terrible position to assess whether any reverse payment is necessary to shift the compromise date in the right direction and, if so, how large that payment should be. Determining deviations from the expected value date is likely to be a difficult and expensive task.

Courts would have essentially two options in undertaking that task. First, a court could assess deviations from the expected value directly, gauging the merits of the patent dispute and assigning an expected value to the litigation between the manufacturers. The court could then reject any payment (or other term) that caused the settlement to vary from the expected value entry date. Even if this undertaking were to yield reasonably accurate results, it would come at a high cost. The drug manufacturers would likely hold the key information and evidence. Drug purchasers or the court would be forced to fight a united front to determine the strength of the claim of infringement.[176] If the inquiry is going to be meaningful, it would involve transaction costs comparable to those that would have occurred in litigation of the underlying claim between the drug manufacturers. Alternatively, if the court instead were to defer to the manufacturers, they would have a significant opportunity to delay the generic entry beyond the expected value date and share the resulting supra-competitive profits.

A second approach would be for the court to assess deviations from the expected value indirectly, looking for the sorts of settlement dynamics that would skew the outcome of settlement from an expected value result: risk aversion, strategic behavior, psychological dynamics, and the like.[177] But judges are in an even worse position to do that than they are in comparing the outcome of settlement to the expected value of trial. The drug manufacturers are the only ones with any real insight into what motivated the outcome in settlement. A judge trying to assess settlement dynamics would face all sorts of practical difficulties, not the least of which are evidentiary obstacles our legal system

[175] *See supra* note 123 and accompanying text.
[176] *See Schering-Plough Corp. v. American Home Products Corp*., 136 F.T.C. at 997 (noting difficulty of assessing underlying merits of patent dispute, particularly without true adversarial proceeding between drug manufacturers)
[177] *See* Davis, *supra* note 80, at 73-76; Davis, *supra* note 28, at 128-32.

puts in place that limit what judges can learn about the contents of a negotiation.[178] A judge would be at the mercy of the manufacturers, forced to take at face value whatever justifications they might offer for why a reverse payment served as a corrective, allowing the date of generic entry to approximate the expected value of trial. No meaningful judicial review would be possible. We would end up in effect applying a rule of *per se* legality or something close to it. But with a price tag attached in the form of a costly empty exercise, a charade of judicial oversight.

c. Allowing Payment of the Cost of Litigation Would Increase Error and Transaction Costs, Although by Less Than a General Inquiry into Reasonableness.

A more modest suggestion is that a brand manufacturer should be allowed to pay its anticipated costs of litigation to the generic manufacturer as part of a settlement. Even numerous commentators who are skeptical of reverse payments—including Carrier;[179] Hovenkamp, Janis and Lemley;[180] the FTC;[181] and the Department of Justice[182]—recommend allowing reverse payments for this reason.[183] Perhaps the best that can be said of this proposal is that it would do less harm than allowing a larger payment. But it is likely to produce higher error costs and transaction costs than a ban on reverse payments.

At first blush, allowing payment of litigation cost may not appear to increase error costs. After all, a brand manufacturer might be willing to pay the cost of litigation in addition to settling for the expected value entry date. In theory, doing so would place the brand manufacturer in the same position as litigating the case to a resolution. But the same holds true for the generic manufacturer. Why wouldn't the generic manufacturer be willing to settle for the expected value entry date and in addition pay the brand manufacturer an amount up to its anticipated litigation costs?

Moreover, a host of considerations will inform the amount for which the parties will settle: their attitudes toward risk, their strategic behavior in negotiations, the accuracy of their predictions about litigation, their resources, sophistication and access to information, among others. Separating out one consideration—the anticipated litigation costs of one party—is unlikely to be in any way enlightening. Indeed, as discussed above, a couple of key considerations will place the brand manufacturer at a strategic

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[178] *See, e.g.*, Fed. R. Evid. 408 (limiting admissibility of settlement communications); *Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 332 F.3d 976, 983 (6th Cir. 2003) (recognizing settlement communication privilege).
[179] *See* Carrier, *supra* note 3, at 76-77.
[180] Hovenkamp *et al.*, *supra* note 30, at 1758-59, 1760 n. 177.
[181] *See In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, Part II (F.T.C. Dec. 8, 2003).
[182] *See* Brief for the United States in Response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund v. Bayer, AG*, 05-2852-cv (2d Cir.filed July 6, 2009) at 28-29.
[183] Note that Hemphill expresses reservations about reverse payments approximating a brand manufacturer's litigation costs, recognizing that the claimed payment of litigation costs may actually cause allocative inefficiency, as I argue in the text. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1594-95 (2006).

advantage in negotiations: first, all else equal, the delay caused by litigation will increase the brand manufacturer's profits and eat away at the generic manufacturer's profits; and, second, a generic firm is likely to agree to a delay in generic entry beyond the expected value date in return for the certainty of receiving its 180 day exclusivity period. As a result, payment of litigation costs will likely just postpone belated generic entry further beyond the expected value entry date.

In sum, a reverse payment up to the brand manufacturer's anticipated litigation costs is arbitrary, even though it appears otherwise, and is more likely to skew the compromise date of generic entry away from the expected value entry date than toward it.

And the inquiry into anticipated litigation costs will not be free. To be sure, that inquiry would be much less expensive than full-blown litigation. It will be easier for the court to estimate the likely expense of litigation than, say, the expected value entry date. But some litigation is likely to arise regarding this issue. After all, the drug manufacturers have incentive to push for as large a payment as possible. That will allow them to share the spoils of extending the brand patent beyond the average date of generic entry through trial. Even if a court shows deference to the brand manufacturer, that will just encourage even more aggressive reverse payments, ultimately requiring some judgment by the court.[184]

In the end, then, about the best one can say about allowing a reverse payment of litigation costs is that it is not as bad as permitting payment of some larger sum.

d. Cash-Strapped Generics Do Not Provide a Reason to Allow Reverse Payments.

Some commentators have suggested that reverse payments may be appropriate for patent disputes involving generic manufacturers with limited resources.[185] A "cash-strapped" generic, they reason, may demand an entry date earlier than the expected value date of entry, a brand manufacturer may be unwilling to meet this demand, and only a reverse payment may allow for a settlement.[186]

But this reasoning is exactly backwards. The limited resources of some generic manufacturers may well cause them to want—even desperately—an entry date earlier than the expected value of adjudication, but that very desperation would be apt to place them at a strategic disadvantage. Litigants in desperate need for immediate money tend in negotiations to be particularly vulnerable, not particularly strong. If a generic manufacturer is truly strapped for cash, then it creates no meaningful risk to a brand manufacturer. By assumption, the generic manufacturer cannot withstand delay, much less pay for expensive litigation. A brand manufacturer has little incentive to settle with

[184] *See* Hemphill, *for Delay*, *supra* note 3, at 1595 n. 157 (noting brand manufacturer could use inflated estimate of litigation costs to mask reverse payment designed to delay generic entry).
[185] *See, e.g.*, Carrier, *Unsettling Settlements*, *supra* note 3, at 76, 77; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L. J. 1033, 1059 (2004).
[186] Carrier, *supra* note 3, at 77.

such a generic manufacturer. It should not pay money to avoid a trial that will never occur. So a reverse payment would not benefit the brand manufacturer.

If, on the other hand, the generic manufacturer at least has the resources to make litigation a credible threat, it would still likely be at a significant disadvantage in negotiations. It probably would have to skimp in terms of the resources it could pay attorneys, experts and for the other ingredients of successful litigation. Its economic vulnerability would place it in a poor bargaining position. As a result, it would be likely to agree to a date of entry well after the expected value date, not insist on a date well before it.

A reverse payment thus would compound the resulting error costs, leading to a generic entry date that is even later than would occur in its absence. It would be better from the perspective of error costs to permit settlement only on the basis of a compromise regarding the date of generic entry. The generic drug manufacturer would then either be forced to pursue trial or to demand a date of generic entry that approximates the expected value entry date as closely as the brand manufacturer is willing to allow.

IV. Conclusion

Allowing reverse payments as part of settlements of patent disputes under the Hatch-Waxman Act is a bad idea. Their general tendency will be to delay generic entry beyond the expected value entry date, resulting in unnecessary error costs. Moreover, judicial attempts to scrutinize reverse payments will be unlikely to succeed and will entail substantial transaction costs. Even allowing payment of litigation costs would be arbitrary and tend to exacerbate rather than ameliorate the potential anticompetitive effects of settlement. Unless and until brand name manufacturers are able to show that they tend to fare worse on average in settlement negotiations than their generic counterparts—an unlikely possibility—a ban on reverse payments is likely to produce the most efficient resolution of patent disputes.